Training & Resources for Clinical Research Professionals

In-Person and Web-Based Training Courses, Customized Training, eLearning and Publications for Clinical Research Professionals Including:

- Auditing
- Clinical Operations
- Clinical Research Sites
- Data Management
- Medical Devices
- Monitoring
- Project Management
- Quality Assurance
- Regulatory Affairs
- Safety
- Statistics
- Training

Course & Publications Catalog
January – July 2020
Leverage Barnett’s Resources for Your In-house Training Needs!

**Comprehensive Training Programs:**
- Over 150 pre-developed courses that can be customized to meet your learning objectives
- Content reflects best practices, real-world examples, interactive exercises, and case study simulations
- Materials are designed to be directly applied on the job
- Cost-effective for groups of five or more

**Annual Training Program Development:**
- Curriculum and content development tailored to your needs
- Gap analysis, needs assessment, and “hot spot” identification
- Mock audits with follow-up remediation training

**Curriculum/Train-the-Trainer:**
- Pre-developed curriculum for Coordinators/Investigative Sites and CRA/Monitoring training
- Instructor manuals, power point materials, and train-the-trainer courses
- Materials updated annually at low cost

**Accredited Content:**
- Professional development and nursing CEUs are available from ACPE, PMI, and NJSNA

**Experienced Instructors:**
- Courses are taught by industry subject matter experts with hands-on experience in their topic areas
- Barnett’s instructors can be brought to your site to deliver customized programs that address your exact training needs

**Personalized Service:**
- Contact Naila Ganatra at +1 215.413.2471 or nganatra@barnettinternational.com for more information about how to leverage Barnett’s resources to meet your in-house training goals
November 2019

Dear Colleagues,

It is with great pleasure that we present our January – July 2020 catalog. Included are details about all of Barnett’s offerings, including our in-person courses, interactive web-based training, eLearning and consulting offerings. New for 2020 is the launch of our Clinical Research Training Weeks, which will take place twice between January and July on both the East and West Coasts of the U.S. We hope you will find that our flexible training programs and our performance-based consulting offerings are all designed with practical, on-the-job focused content and the needs of our learners in mind.

Specific new offerings include:

• Building Quality by Design (QbD) and Risk-Based Quality Management (RBQM) Systems into Clinical Operations
• Clinical Trial Registration: Requirements, Record Maintenance and Reporting of Results
• Effective Use of Tools, Job Aids, Process Maps, and Checklists for Project Managers and Clinical Research Teams
• Inspection Readiness: Understanding BIMO Inspection Requirements for Sponsors, CROs, Monitors and Investigators
• Key Considerations in Medical Writing: The Clinical Study Protocol, Investigator’s Brochure, Informed Consent Form, and Adverse Events Narratives
• Managing Phase I Clinical Trials
• Risk-Based Quality and Compliance Management in Combination Product Trials
• A Systematic Approach to Study Start-Up: Improving Site Activation
• Working with Clinical Research Sites: Strategic Planning and Operations for Sponsors and CROs

Finally, please be reminded that Barnett also provides a complete and up-to-date library of numerous publications, regulatory reference guides and job aids, and we regularly assist clients with in-house training needs in numerous content areas. These services include courses delivered at your location, customized content development, role-based training assessments, competency mapping, gap and needs analysis, content focused on the development of critical/executive thinking skills, as well as other types of training support. For more information about these offerings, please feel free to contact Naila Ganatra at +1 215.413.2471.

Thank you again for the continued opportunity to serve you. We look forward to welcoming you to an upcoming course and hope to see you in person at one of our Clinical Research Training Weeks!

Kind regards

Naila Ganatra, M.Ed.
General Manager
Barnett International

Phillips Kuhl
President
Cambridge Healthtech Institute
## Table of Contents

Content By Subject.......................................................................................................................... 2
Barnett’s Blended Curriculum Path: Clinical Research Associate................................................................................. 21
Barnett’s Blended Curriculum Path: Clinical Research Coordinator................................................................................. 22
Barnett’s Blended Curriculum Path: Project Manager......................................................................................................... 23
“Hands-On” In-Person and Web Seminar Workshop Series ............................................................................................... 25
Core Curriculum Courses.................................................................................................................................................... 29
Interactive Web Seminars .................................................................................................................................................. 111
Web Seminar Archives ........................................................................................................................................................ 205
Seminar Accreditation, Policies and Procedures ................................................................................................................ 206
Hotel Information ............................................................................................................................................................... 206
Instructor Biographies .......................................................................................................................................................... 207
Courses Listed by Location and Month ................................................................................................................................. 213
Courses Listed By City .......................................................................................................................................................... 218
Publications........................................................................................................................................................................ 219
Barnett International Publication Order Form ..................................................................................................................... 226
Consulting and Support Services ......................................................................................................................................... 227
eLearning Courses ............................................................................................................................................................. 233
Barnett International Seminar Registration Form ................................................................................................................ 239
Barnet International Publication Order Form ..................................................................................................................... 240

### Content By Subject

#### 21 CFR Part 11

Data Management: Key Regulations Impacting the Role of the Clinical Data Manager (On-Site, Archived Recording) .......................................................... 138, 205
Electronic Source Data in Clinical Investigations: Navigating the Final FDA Guidance (Web, Archived Recording) .......................................................................................................................... 144, 205

#### 510(k) Submissions

Drug and Device Regulatory Submissions: A Comparison (On-Site) .......................................................................................... 141
FDA Medical Device Approval Process (Web, Archived Recording) .......................................................................................... 150, 205

### Adverse Events

Adverse Event Monitoring for CRAs (Web, Archived Recording) .......................................................................................... 123, 205
Adverse Events: Managing and Reporting for Medical Devices (On-Site) .................................................................................. 33
Adverse Events: Managing and Reporting for Pharmaceuticals (On-Site) .................................................................................. 34
Case Narrative Writing for Reporting Adverse Events (On-Site, Archived Recording) .................................................................. 129, 205
Drugs and Pharmacovigilence: Effective Drug Safety Reporting and Surveillance (Core Curriculum) .................................................. 59
Final AE Regulatory Guidance: Reporting/Communication of Safety Information from Clinical Trials to IRBs (Web, Archived Recording) .......................................................................................................................... 152, 205
NEW! Key Considerations in Medical Writing: The Clinical Study Protocol, Investigator’s Brochure, Informed Consent Form, and Adverse Events Narratives (Web) .......................................................... 167
Quality Risk Management in Clinical Trials and Pharmacovigilance (Archived Recording) ......................................................... 205
The Self-Instructional Study Site Training Series (Volume 5), Your Role in Reporting Adverse Experiences (Publication) ........................................................................................................................................................................... 222
The Self-Study CRA Training Series (Volume 6), The CRA’s Reference for Adverse Events (Publication) ........................................... 222

### Adverse Events Narratives

Case Narrative Writing for Reporting Adverse Events (On-Site, Archived Recording) .................................................................. 129, 205
NEW! Key Considerations in Medical Writing: The Clinical Study Protocol, Investigator’s Brochure, Informed Consent Form, and Adverse Events Narratives (Web) .......................................................... 167

### Auditing

30-Hour Clinical Research Auditing Certification Program (Web) .......................................................................................... 121
Advanced Post-Marketing Pharmacovigilance Auditing (On-Site) .......................................................................................... 32
Auditing Clinical Research Studies: An Overview for Assessing GCP Compliance (Web, Archived Recording) ......................... 124, 205
Auditing Sponsors and CROs: Deconstruction and Application of the FDA’s Compliance Program Guidance Manual (Web, Archived Recording) ............................................................................. 125, 205
Auditing Techniques: A Problem-Solving Practicum (Web) .......................................................................................... 125
Auditing Techniques for Clinical Research Professionals (Core Curriculum) ........................................................................ 35
Auditor Emotional Intelligence (On-Site, Archived Recording) .......................................................................................... 126, 205
Basics of Post-Marketing Pharmacovigilance and the Beginner PV Auditor (On-Site) .................................................. 36
Best Practices for Hosting a Client Audit (On-Site) ........................................................................................................ 126
Establishing a Vendor Management Program (Archived Recording) ........................................................................ 205
European Pharmacovigilance Modules: What Are They and Why They Are Important (On-Site) ......................... 148
HIPAA Compliance Monitoring and Auditing (On-Site) ................................................................................................. 159
Preparation, Management, and Response to Inspections and Audits (Web, Archived Recording) ...................... 175, 205
Preparing for SOP Inspection: An Auditor’s Perspective (Archived Recording) ......................................................... 205
Risk-Based Auditing: Effective Compliance Strategies (Web, Archived Recording) .................................................. 181, 205
“Risk-Based Thinking”: How Monitors Can Develop an Auditor’s Perspective (Web, Archived Recording) ........ 184, 205
Strategies for Conducting Vendor Audits (On-Site, Archived Recording) ................................................................. 190, 205

Billing Compliance

10-Week Clinical Research Financial Certification Program: Setting Up Compliant Financial Operations and Budgets (Web) .......................................................................................................................... 115
The Clinical Research Finance Roadmap Companion Reference Guide: Tools, Templates and Resources (Publication) .............................................................................................................................. 225
Incorporating Denials Management into Clinical Research Billing (Web) ................................................................. 161

BIMO

CRA Current Practice Update: Impact of the FDA Bioresearch Monitoring (BIMO) Program (Archived Recording) ................................................................................................................................. 205
FDA’s Bioresearch Monitoring (BIMO) Program: Inspection of Sponsors, CROs, and Monitors (Web, Archived Recording) ...................................................................................................................... 151, 205
NEW! Inspection Readiness: Understanding BIMO Inspection Requirements for Sponsors, CROs, Monitors and Investigators (Web) ...................................................................................................... 163

Biologics

Biologics Development and Regulations (On-Site) ......................................................................................................... 39
Biologics Development: A Regulatory Overview (Publication) ...................................................................................... 224
Expediting Drug and Biologics Development: A Strategic Approach (Publication) ................................................... 224

Budgets and Contracts

10-Week Clinical Research Financial Certification Program: Setting Up Compliant Financial Operations and Budgets (Web) .................................................................................................................. 115
The Clinical Research Finance Roadmap Companion Reference Guide: Tools, Templates and Resources (Publication) .......................................................................................................................... 225
Clinical Research Financial Management for Investigative Sites (Web) ................................................................. 132
Developing and Negotiating Research Site Clinical Study Budgets and Contracts (Web, Archived Recording) ....... 140, 205
Developing Clinical Study Budgets (On-Site) .................................................................................................................. 53
Developing Clinical Study Budgets for Sponsors (Web, Archived Recording) ............................................................. 141, 205
Introduction to Medicare Coverage Analysis: Impact on Site Revenue Cycles (Web) .............................................. 165
Minimizing Risk in Negotiating Clinical Trial Contracts and Budgets (Web) .......................................................... 170
Optimizing Protocol Design and Strategies to Achieve Efficient, Lower Cost Trial Execution (On-Site) ............... 91
Research Billing Processing: Appropriate Segregation of Charges and Medical Documentation (Web) ................ 180
Strategic Clinical Research Operational Planning: Applied Techniques for Cost Estimation, Risk Management, and Quality Assurance (On-Site) ................................................................. 106

CAP and CLIA

CAP and CLIA Requirements for Clinical Research Laboratories (Web, Archived Recording) ......................... 128, 205

Case Report Forms

Case Report Form Design, Strategy, and Standards (Web, Archived Recording) ..................................................... 129, 205
Case Report Form Design, Strategy, and Standards Workshop (Web) ........................................................................ 26
Data Management: Key Regulations Impacting the Role of the Clinical Data Manager (On-Site, Archived Recording) ........................................................................................................................... 138, 205
Data Management in the Electronic Data Capture Arena (Archived Recording) .................................................... 205
Data Management in the Electronic Data Capture Arena: Regulatory Considerations and Practical Applications for eCDM (On-Site) ........................................................................................................ 50
Data Management Plan Creation: Content and Rationale (Web, Archived Recording) ........................................ 138, 205
Medical Writing Fundamentals: How to Write Regulatory Documents (On-Site) ..................................................... 85
Medical Writing Fundamentals: How to Write Regulatory Documents (Web, Archived Recording) ..................... 170, 205
Writing Clinical Study Reports for Diagnostic Studies (On-Site, Archived Recording) ........................................... 201, 205

CDISC and CDASH

Case Report Form Design, Strategy, and Standards (Web, Archived Recording) ..................................................... 129, 205
Case Report Form Design, Strategy, and Standards Workshop (Web) ........................................................................ 26
Data Management in the Electronic Data Capture Arena: Regulatory Considerations and Practical Applications for eCDM (On-Site) ........................................................................................................ 50
Introduction to Clinical Data Management (On-Site) ................................................................................................... 76
SDTM and CDASH: What’s the Connection? ( Archived Recording) ......................................................................... 205
Understanding Clinical Data Management for the Non-CDM Professional (On-Site) ................................................ 108
### Content by Subject

#### Clinical Evaluation Reports

- Writing Clinical Evaluation Reports (On-Site) .......................................................... 110

#### Clinical Laboratories

- CAP and CLIA Requirements for Clinical Research Laboratories (Web, Archived Recording) ............................................................................................................... 128, 205
- cGMP for the Quality Control Laboratory (On-Site) ................................................... 131
- Good Clinical Practice for the Laboratory Scientist (On-Site) .................................. 70
- Understanding Clinical Laboratory Regulatory Requirements (On-Site) ................. 197

#### Clinical Research Organizations (CROs)

- Approaches to Address Challenges in Vendor Management (Web, Archived Recording) ............................................................................................................. 124, 205
- Auditing Sponsors and CROs: Deconstruction and Application of the FDA’s Compliance Program Guidance Manual (Web, Archived Recording) .............. 125, 205
- Best Practices for Hosting a Client Audit (On-Site) .................................................. 126
- CRO Partnership Management (Web, Archived Recording) ..................................... 137, 205
- CRO Selection Criteria, Evaluation, and Establishing the Relationship (Archived Recording) .............................................................................................. 205
- Establishing a Vendor Management Program (Archived Recording) ..................... 205
- FDA’s Bioresearch Monitoring (BIMO) Program: Inspection of Sponsors, CROs, and Monitors (Web, Archived Recording) ........................................... 151, 205
- Managing Risks in Outsourced Clinical Trials: Practical Approaches and Tools (Web, Archived Recording) ................................................................. 169, 205
- Re-Engineering the RFP and Bid Defense Meeting to Effectively Manage Risk and Quality (Archived Recording) ............................................................... 205
- Strategies for Conducting Vendor Audits (On-Site, Archived Recording) .............. 190, 205
- Working with CROs: Building a Partnership for Project Success (On-Site) .............. 109

#### Clinical Research Overview

- 10-Week Fundamentals of Clinical Research Series: Getting Started in Clinical Research (Web) ................................................................. 117
- Introduction to Clinical Research (Core Curriculum) ............................................. 77
- Introduction to Clinical Research (Web, Archived Recording) ......................... 164, 205

#### Clinical Trial Assistant

- ABCs of GCP and the 13 Principles of ICH GCP E6 (Web, Archived Recording) ...... 122, 205
- Clinical Trial Assistant Fundamentals (Core Curriculum) .................................... 42

#### Clinical Trial Authorization (CTA)

- Writing and Maintaining the EU Clinical Trial Authorization (On-Site, Archived Recording) .......................................................... 200, 205

#### Clinical Trial Design

- Clinical Trials for Medical Devices: Design and Development (On-Site) ................. 44
- Design and Conduct of Clinical Trials: Design Requirements, Statistical Issues, and Clinical Protocols (On-Site) ................................................................. 51
- Optimizing Protocol Design and Strategies to Achieve Efficient, Lower Cost Trial Execution (On-Site) ................................................................. 91

#### Clinical Trial Registration

- NEW! Clinical Trial Registration: Requirements, Record Maintenance and Reporting of Results (Web) ................................................................. 133
- ClinicalTrials.gov Requirements: Clinical Trial Registration and Trial Results Reporting, Expanded Registry and Results Data Bank (Web, Archived Recording) .......... 134, 205

#### Combination Products

- NEW! Risk-Based Quality and Compliance Management in Combination Product Trials (Web) ................................................................. 183

#### Common Rule

- The Revised HHS Common Rule: What You Need to Know Now (Web, Archived Recording) ................................................................. 181, 205

#### Communication Skills

- See Soft Skills ........................................................................................................... 18

#### Compliance and Noncompliance

- 30-Hour Clinical Research Auditing Certification Program (Web) ......................... 121
- Auditing Clinical Research Studies: An Overview for Assessing GCP Compliance (Web, Archived Recording) ................................................................. 124, 205
- Auditing Sponsors and CROs: Deconstruction and Application of the FDA’s Compliance Program Guidance Manual (Web, Archived Recording) .......... 125, 205
- Current FDA and EMA Inspection Findings: Lessons Learned (Web, Archived Recording) ..................................................................................................... 137, 205
- EU Clinical Trial Regulation 536/2014: Are You Ready? (On-Site) ...................... 149
- FDA’s Role in Device Safety Inspections (On-Site) ................................................ 151
- Final ICH GCP E6 R2 Addendum: Overview of Changes Impacting Sponsors, CROs, Clinical Investigators/Sites (Web, Archived Recording) .......... 155, 205
- The Future of Good Clinical Practice Demands a Quality System Approach: Will You be Ready? (On-Site) ................................................................. 158, 205
- Informed Consent Procedure: Lessons Learned from Inspection Findings (Web, Archived Recording) ................................................................. 162, 205
- Preparation, Management, and Response to Inspections and Audits (Web, Archived Recording) ................................................................. 175, 205
- Quality by Design in Clinical Research: Is This Only for the Protocol? (On-Site, Archived Recording) ................................................................. 177, 205
- Quality Systems: A Controlled Approach to GCP Compliance (Web, Archived Recording) ................................................................. 178, 205
- Recent Trends in Noncompliance: Critical Review and Analysis of Recent Regulatory Letters and Communications from the FDA, EMA, and Health Canada (Web, Archived Recording) .......... 179, 205
- Risk-Based Auditing: Effective Compliance Strategies (Web, Archived Recording) .............................................................................................. 181, 205
### Content by Subject

<table>
<thead>
<tr>
<th>Topic</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Root Cause Analysis: Applying the Concept for Better Study Compliance Management (Web, Archived Recording)</td>
<td>185, 205</td>
</tr>
<tr>
<td>Sponsor Management of Investigator Non-Compliance (Web, Archived Recording)</td>
<td>187, 205</td>
</tr>
<tr>
<td>Warning Letters: Applying Lessons Learned from Misbranding and Adulteration Noncompliance Findings (On-Site)</td>
<td>199</td>
</tr>
</tbody>
</table>

**Cost Estimation and Management**

- Clinical Project Management: Advanced Concepts in Project Management (Core Curriculum) .......................................................... 41
- Clinical Project Management: Fundamentals of Project Management (Core Curriculum) ................................................................. 40
- Optimizing Protocol Design and Strategies to Achieve Efficient, Lower Cost Trial Execution (On-Site) .................................................. 91

**CRA Management and Development**

- The CRA Manager Course (On-Site) .......................................................................................... 49
- Developing CRAs as Site Study Managers (On-Site) ................................................................. 54
- Leading Teams in a Changing Clinical Research Environment (Web, Archived Recording) .................................................................... 167, 205
- Managing CRAs to Improve Performance and Study Outcomes (Web, Archived Recording) .................................................................... 168, 205

**CRA Training**

- 10-Week Clinical Research Associate (CRA) On-Boarding Program (Web) .......................................................................................... 113
- 10-Week CRA & CRC Beginner Program (Web) ........................................................................... 112
- 30-Hour Monitoring Oncology Clinical Trials Program (On-Demand eLearning) .......................... 236
- ABCs of GCP and the 13 Principles of ICH GCP E6 (Web, Archived Recording) ......................... 122, 205
- Applied Clinical Statistics in Risk-Based Monitoring (On-Site) ................................................ 123
- CFR/ICH GCP Reference Guide for Drugs (Publication) .............................................................. 223
- CFR/ICH GCP Reference Guide for Medical Devices (Publication) ........................................... 223
- Comprehensive Monitoring for Medical Devices (Core Curriculum) ........................................ 46
- CRA & CRC: Beginner Program (Core Curriculum) ................................................................. 48
- CRA Current Practice Update: Impact of the FDA Bioresearch Monitoring (BIMO) Program (Archived Recording) .................................... 205
- The CRA Role in Risk-Based Monitoring: Strategies for Effective Remote Monitoring (Web, Archived Recording) ..................................... 136, 205
- Detecting Risk Signals in Protocols, Data, and Monitoring (On-Site) ........................................ 52
- Detecting Risk Signals in Protocols, Data, and Monitoring (On-Site, Archived Recording) .......... 140, 205
- Developing Effective Training and Facilitation Skills in Clinical Research: An Application-Based Course (On-Site) ................................. 55
- Ensuring Success Through Smarter Site Selection and Study Feasibility (Web, Archived Recording) ................................................................ 145, 205
- The Form FDA 1572: A Reference Guide for Clinical Researchers, Sponsors, and Monitors (Publication) .................................................. 223
- Global GCP Monitoring: Domestic and International Compliance (On-Site) ............................ 69
- Good Clinical Practice: A Question & Answer Reference Guide (Publication) ............................ 223
- Good Clinical Practice for Sponsors and CROs (On-Demand eLearning) .................................... 234
- The Highly Effective CRA: Soft Skills for Taking Your Work to the Next Level (On-Site) .......... 72
- How to Write Effective Monitoring Reports and Communications Workshop (On-Site) ............... 27
- NEW! Inspection Readiness: Understanding BIMO Inspection Requirements for Sponsors, CROs, Monitors and Investigators (Web) ............. 163
- Introduction to Clinical Research (Core Curriculum) ................................................................ 77
- Introduction to Clinical Research (Web, Archived Recording) .................................................. 164, 205
- Investigational Product Accountability Best Practices (Web, Archived Recording) ..................... 166, 205
- Leading Teams in a Changing Clinical Research Environment (Web, Archived Recording) ................................................................ 167, 205
- Monitoring Clinical Drug Studies: Advanced (Core Curriculum) ........................................... 89
- Monitoring Clinical Drug Studies: Beginner (Core Curriculum) ............................................. 87
- Monitoring Clinical Drug Studies: Intermediate (Core Curriculum) ......................................... 88
- Monitoring Oncology Clinical Trials (Web, Archived Recording) ............................................. 171, 205
- Monitoring Phase I Clinical Trials (On-Site, Archived Recording) ............................................. 172, 205
- Monitoring Reports: 10 Rules of Effective Report Writing (Web, Archived Recording) ............... 173, 205
- Monitoring Visit Reports for Medical Device Studies (Web, Archived Recording) ..................... 173, 205
- Presentation Skills Training for Clinical Research Professionals (Archived Recording) ............... 205
- Real-World Monitoring: Tips for Success and Sanity (On-Site, Archived Recording) ............... 178, 205
- Report Writing for CRAs (On-Site) ............................................................................................ 99
- The Self-Study CRA Training Series (7 Volume Set) (Publication) ............................................ 222
- The Self-Study CRA Training Series (Volume 1), An Overview of Drug Development (Publication) ................................................................ 222
- The Self-Study CRA Training Series (Volume 2), Identifying and Screening Investigators (Publication) ................................................................ 222
- The Self-Study CRA Training Series (Volume 3), Conducting Prestudy Visits (Publication) .......... 222
- The Self-Study CRA Training Series (Volume 4), Conducting Study Initiation Visits (Publication) ................................................................ 222
- The Self-Study CRA Training Series (Volume 5), Conducting Routine Monitoring Visits (Publication) ................................................................ 222
- The Self-Study CRA Training Series (Volume 6), The CRA’s Reference for Adverse Events (Publication) ................................................................ 222
- The Self-Study CRA Training Series (Volume 7), Test Your CRA Knowledge (Publication) .......... 222
- Sponsor Responsibilities for Global Drug Studies (Web, Archived Recording) ............................. 188, 205
- State-by-State Clinical Trial Requirements Reference Guide (Publication) ................................ 221
- State Laws Governing Clinical Trial Regulatory Compliance (Web, Archived Recording) ............. 188, 205
- Strategies for Developing Effective Training and Facilitation Skills in Clinical Research (Web, Archived Recording) ............................. 190, 205
- Study Initiation Strategies for Sponsors: Study and Site Start-Up (On-Site, Archived Recording) ................................................................ 193, 205
### Content by Subject

| Subject Enrollment: Creating Effective Enrollment Models (Archived Recording) | 205 |
| Transitioning Pharmaceutical Professionals to Medical Device Professionals (Archived Recording) | 205 |
| Using Data to Identify Risk Indicators in Risk-Based Monitoring (Archived Recording) | 205 |

### CRC Training

| 10-Week Clinical Research Coordinator (CRC) On-Boarding Program (Web) | 114 |
| 10-Week CRA & CRC Beginner Program (Web) | 112 |
| 30-Hour Clinical Research Coordinator On-Boarding Program (On-Demand eLearning) | 236 |
| ABCs of GCP and the 13 Principles of ICH GCP E6 (Web, Archived Recording) | 122, 205 |
| Advanced Clinical Research Coordinator (CRC) Training (On-Site) | 30 |
| Applied Clinical Statistics in Risk-Based Monitoring (On-Site) | 123 |
| Best Practices to Become a Preferred Site (On-Site) | 38 |
| CFR/ICH GCP Reference Guide for Drugs (Publication) | 223 |
| CFR/ICH GCP Reference Guide for Medical Devices (Publication) | 223 |
| Comprehensive CRC Training (On-Site) | 45 |
| CRA & CRC: Beginner Program (Core Curriculum) | 48 |
| CRC Role/Responsibilities Training (On-Site, Archived Recording) | 136, 205 |
| Developing Effective Training and Facilitation Skills in Clinical Research: An Application-Based Course (On-Site) | 55 |
| Electronic Informed Consent Guidance: Regulatory Updates (Web) | 143 |
| Ensuring Success Through Smarter Site Selection and Study Feasibility (Web, Archived Recording) | 145, 205 |
| The Form FDA 1572: A Reference Guide for Clinical Researchers, Sponsors, and Monitors (Publication) | 223 |
| Good Clinical Practice: A Question & Answer Reference Guide (Publication) | 223 |
| Good Clinical Practice for Study Coordinators (On-Demand eLearning) | 235 |
| Informed Consent: Beyond the Basics (On-Site) | 74 |
| Informed Consent Procedure: Lessons Learned from Inspection Findings (Web, Archived Recording) | 162, 205 |
| Introduction to Clinical Research (Core Curriculum) | 77 |
| Introduction to Clinical Research (Web, Archived Recording) | 164, 205 |
| Investigational Product Accountability Best Practices (Web, Archived Recording) | 166, 205 |
| Risk-Based Monitoring for Sites: Prepare Your Site for Success (On-Site, Archived Recording) | 182, 205 |
| The Self-Instructional Study Site Training Series (6 Volume Set) (Publication) | 222 |
| The Self-Instructional Study Site Training Series (Volume 1), The Clinical Study Site Team: Roles and Responsibilities (Publication) | 222 |
| The Self-Instructional Study Site Training Series (Volume 2), FDA Clinical Research Regulations and CGPs: The Essentials (Publication) | 222 |
| The Self-Instructional Study Site Training Series (Volume 3), IRBs/IECs and Informed Consent: Protecting the Rights of Human Subjects (Publication) | 222 |
| The Self-Instructional Study Site Training Series (Volume 4), Sponsor Visits and Regulatory Audits: What You Need to Know (Publication) | 222 |
| The Self-Instructional Study Site Training Series (Volume 5), Your Role in Reporting Adverse Experiences (Publication) | 222 |
| The Self-Instructional Study Site Training Series (Volume 6), Understanding, Evaluating, and Implementing Clinical Protocols (Publication) | 222 |
| Strategies for Developing Effective Training and Facilitation Skills in Clinical Research (On-Site, Archived Recording) | 190, 205 |
| Subject Enrollment: Creating Effective Enrollment Models (Archived Recording) | 205 |

### CTD/eCTD

| The IND in a CTD/eCTD Format (Web, Archived Recording) | 162, 205 |

### Data Management

| 30-Hour Clinical Data Management On-Boarding Program (Web) | 119 |
| The CRA Role in Risk-Based Monitoring: Strategies for Effective Remote Monitoring (Web, Archived Recording) | 136, 205 |
| Data Management in the Electronic Data Capture Arena (Archived Recording) | 205 |
| Data Management in the Electronic Data Capture Arena: Regulatory Considerations and Practical Applications for eCDM (On-Site) | 50 |
| Data Management: Key Regulations Impacting the Role of the Clinical Data Manager (On-Site, Archived Recording) | 138, 205 |
| Data Management Plan Creation: Content and Rationale (Web, Archived Recording) | 138, 205 |
| Detecting Risk Signals in Protocols, Data, and Monitoring (On-Site) | 52 |
| Detecting Risk Signals in Protocols, Data, and Monitoring (On-Site, Archived Recording) | 140, 205 |
| eSource and Mobile Technology Initiatives: Data Management Considerations (Web) | 145 |
| Final ICH GCP E6 R2: Impact on Clinical Data Management (Web, Archived Recording) | 154, 205 |
| Introduction to Clinical Data Management (On-Site) | 76 |
| Introduction to Data Management (Web, Archived Recording) | 164, 205 |
| Risk-Based Monitoring: The Data Management Connection (Web, Archived Recording) | 182, 205 |
| SDTM and CDASH: What’s the Connection? (Archived Recording) | 205 |
| Understanding Clinical Data Management for the Non-CDM Professional (On-Site) | 108 |
| Using Data to Identify Risk Indicators in Risk-Based Monitoring (Archived Recording) | 205 |

### Documentation

<p>| Corrective Action Plans: Essential Documentation of a Site’s Response to GCP Deficiencies (Web, Archived Recording) | 135, 205 |
| Essential Documentation in Clinical Trials at Research Sites (Web, Archived Recording) | 146, 205 |
| The GCPs of Essential Documents (Web, Archived Recording) | 157, 205 |
| Strategies for Ensuring Good Documentation Practices (GDP) (On-Site, Archived Recording) | 191, 205 |</p>
<table>
<thead>
<tr>
<th>Subject</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug Discovery, Development, and Approval</strong></td>
<td></td>
</tr>
<tr>
<td>Biologics Development: A Regulatory Overview (Publication)</td>
<td>224</td>
</tr>
<tr>
<td>Drug Approval Process: Preparation and Processing of INDs and NDAs (On-Site)</td>
<td>56</td>
</tr>
<tr>
<td>Drug Development and FDA Regulations (On-Site)</td>
<td>57</td>
</tr>
<tr>
<td>Drug Development and FDA Regulations (Web, Archived Recording)</td>
<td>142, 205</td>
</tr>
<tr>
<td>Drug Discovery: The Path from Development to Marketing Approval (On-Site)</td>
<td>58</td>
</tr>
<tr>
<td>Expediting Drug and Biologics Development: A Strategic Approach (Publication)</td>
<td>224</td>
</tr>
<tr>
<td>FDA Drug Approval Process (Web, Archived Recording)</td>
<td>150, 205</td>
</tr>
<tr>
<td>Fundamentals of Drug Development and the Conduct of Clinical Trials (On-Site)</td>
<td>67</td>
</tr>
<tr>
<td>Introduction to Clinical Research (Core Curriculum)</td>
<td>77</td>
</tr>
<tr>
<td>Introduction to Clinical Research (Web, Archived Recording)</td>
<td>164, 205</td>
</tr>
<tr>
<td>New Drug Development: A Regulatory Overview (Publication)</td>
<td>220</td>
</tr>
<tr>
<td>PAREXEL Biopharmaceutical R&amp;D Statistical Sourcebook (Publication)</td>
<td>Inside back cover</td>
</tr>
<tr>
<td>The Self-Instructional Study Site Training Series (Volume 2), FDA Clinical Research Regulations and GCPs: The Essentials (Publication)</td>
<td>222</td>
</tr>
<tr>
<td>The Self-Study CRA Training Series (Volume 1), An Overview of Drug Development (Publication)</td>
<td>222</td>
</tr>
<tr>
<td><strong>Electronic Health Records (EHRs) and Electronic Medical Records (EMRs)</strong></td>
<td></td>
</tr>
<tr>
<td>SDTM and CDASH: What's the Connection? (Archived Recording)</td>
<td>205</td>
</tr>
<tr>
<td>Use of Electronic Health Record Data in Clinical Investigations (Web, Archived Recording)</td>
<td>198, 205</td>
</tr>
<tr>
<td><strong>Essential Documents</strong></td>
<td></td>
</tr>
<tr>
<td>Corrective Action Plans: Essential Documentation of a Site’s Response to GCP Deficiencies (Web, Archived Recording)</td>
<td>135, 205</td>
</tr>
<tr>
<td>Essential Documentation in Clinical Trials at Research Sites (Web, Archived Recording)</td>
<td>146, 205</td>
</tr>
<tr>
<td>The GCPs of Essential Documents (Web, Archived Recording)</td>
<td>157, 205</td>
</tr>
<tr>
<td>Strategies for Ensuring Good Documentation Practices (GDP) (On-Site, Archived Recording)</td>
<td>191, 205</td>
</tr>
<tr>
<td>Trial Master Files: Why They Are Important and How to Organize Them Workshop (In-Person and Web)</td>
<td>28</td>
</tr>
<tr>
<td>Trial Master File (TMF) for Research Sites: Set Up and Maintenance (Archived Recording)</td>
<td>205</td>
</tr>
<tr>
<td>Trial Master File (TMF) for Sponsors: Set-Up and Maintenance (Web, Archived Recording)</td>
<td>196, 205</td>
</tr>
<tr>
<td>Use of Notes to File in Clinical Trial Essential Documentation (Web, Archived Recording)</td>
<td>198, 205</td>
</tr>
<tr>
<td><strong>EU Clinical Trial Regulation</strong></td>
<td></td>
</tr>
<tr>
<td>EU Clinical Trial Regulation 536/2014: Are You Ready? (On-Site)</td>
<td>149</td>
</tr>
<tr>
<td><strong>European Medicines Agency (EMA)</strong></td>
<td></td>
</tr>
<tr>
<td>Advanced Post-Marketing Pharmacovigilance Auditing (On-Site)</td>
<td>32</td>
</tr>
<tr>
<td>Basics of Post-Marketing Pharmacovigilance and the Beginner PV Auditor (On-Site)</td>
<td>36</td>
</tr>
<tr>
<td>Current FDA and EMA Inspection Findings: Lessons Learned (Web, Archived Recording)</td>
<td>137, 205</td>
</tr>
<tr>
<td>FDA and EMAinspections: Key Differences and Similarities (Archived Recording)</td>
<td>205</td>
</tr>
<tr>
<td>EMA and MHRA Inspections: Successful Planning and Execution Tips and Techniques (Web, Archived Recording)</td>
<td>144, 205</td>
</tr>
<tr>
<td>European Pharmacovigilance Modules: What Are They and Why They Are Important (On-Site)</td>
<td>148</td>
</tr>
<tr>
<td>Global GCP Monitoring: Domestic and International Compliance (On-Site)</td>
<td>69</td>
</tr>
<tr>
<td>Recent Trends in Noncompliance: Critical Review and Analysis of Recent Regulatory Letters and Communications from the FDA, EMA, and Health Canada (Web, Archived Recording)</td>
<td>179, 205</td>
</tr>
<tr>
<td>Writing and Maintaining the EU Clinical Trial Authorization (On-Site, Archived Recording)</td>
<td>200, 205</td>
</tr>
<tr>
<td><strong>Facilitation Skills</strong></td>
<td></td>
</tr>
<tr>
<td>Developing Effective Training and Facilitation Skills in Clinical Research: An Application-Based Course (On-Site)</td>
<td>55</td>
</tr>
<tr>
<td>Facilitation Skills for Clinical Research Team Leaders (On-Site)</td>
<td>62</td>
</tr>
<tr>
<td>Strategies for Developing Effective Training and Facilitation Skills in Clinical Research (On-Site, Archived Recording)</td>
<td>190, 205</td>
</tr>
<tr>
<td><strong>FDA</strong></td>
<td></td>
</tr>
<tr>
<td>EMA and FDA Inspections: Key Differences and Similarities (Archived Recording)</td>
<td>205</td>
</tr>
<tr>
<td>FDA Meetings 101: How to Hold a Successful Meeting with Regulatory Agencies (On-Site)</td>
<td>63</td>
</tr>
<tr>
<td>FDA’s Role in Device Safety Inspections (On-Site)</td>
<td>151</td>
</tr>
<tr>
<td>Introduction to the FDA (On-Site)</td>
<td>78</td>
</tr>
<tr>
<td>Introduction to the FDA (Archived Recording)</td>
<td>205</td>
</tr>
</tbody>
</table>
Content by Subject

FDA Regulatory and Guidance Updates
Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank: Draft Guidance (Web) .......................................................... 131
Clinical Trials and the “Sunshine Act”: The Effect on the Clinical Research Industry (Web, Archived Recording) ...................... 134, 205
CRA Current Practice Update: Impact of the FDA Bioresearch Monitoring (BiM0) Program (Archived Recording) .......................... 205
Electronic Informed Consent Guidance: Regulatory Updates (Web) ....................................................................................... 143
NEW! Inspection Readiness: Understanding BiM0 Inspection Requirements for Sponsors, CROs, Monitors and Investigators (Web) .......................... 163
Scientific and Ethical Considerations for Inclusion of Pregnant Women in Clinical Trials (Web) .............................................. 185

Financial Management
10-Week Clinical Research Financial Certification Program: Setting Up Compliant Financial Operations and Budgets (Web) .......................................................... 115
The Clinical Research Finance Roadmap Companion Reference Guide: Tools, Templates and Resources (Publication) .......................... 225
Clinical Research Financial Management for Investigative Sites (Web) .................................................................................. 132
Developing and Negotiating Research Site Clinical Study Budgets and Contracts (Web, Archived Recording) .............................. 140, 205
Developing Clinical Study Budgets (On-Site) ......................................................................................................................... 53
Developing Clinical Study Budgets for Sponsors (Web, Archived Recording) ...................................................................................... 141, 205
Incorporating Denials Management into Clinical Research Billing (Web) ....................................................................................... 161
Introduction to Medicare Coverage Analysis: Impact on Site Revenue Cycles (Web) .............................................................. 165
Minimizing Risk in Negotiating Clinical Trial Contracts and Budgets (Web) .................................................................................. 170
Optimizing Protocol Design and Strategies to Achieve Efficient, Lower Cost Trial Execution (On-Site) ............................................ 91
Research Billing Processing: Appropriate Segregation of Charges and Medical Documentation (Web) ............................................. 180

Form FDA 1572
Final FDA Guidance: How to Complete the Form FDA 1572, Adequately and Accurately (Web, Archived Recording) ............... 152, 205
The Form FDA 1572: A Reference Guide for Clinical Researchers, Sponsors, and Monitors (Publication) ............................................. 223

Fraud
Fraud in Clinical Research: An Overview (On-Site, Archived Recording) .................................................................................. 156, 205
Fraud in Clinical Research: Detection and Deterrence (On-Site) ....................................................................................... 66

Global Clinical Trials
Global GCP Monitoring: Domestic and International Compliance (On-Site) .................................................................................. 69
Planning and Conducting Global Clinical Trials (On-Site) ............................................................................................................... 93
Recent Trends in Noncompliance: Critical Review and Analysis of Recent Regulatory Letters and Communications from the FDA, EMA, and Health Canada (Web, Archived Recording) .................................................. 179, 205
Sponsor Responsibilities for Global Drug Studies (Web, Archived Recording) .................................................................................. 188, 205
Writing and Maintaining the EU Clinical Trial Authorization (On-Site, Archived Recording) ......................................................... 200, 205

Good Clinical Practice (including ICH GCP E6 R2)
10-Week Final ICH GCP E6 R2: Risk-Based Monitoring Plan Development Series (Web) .......................................................... 116
ABCs of GCP and the 13 Principles of ICH GCP E6 (Web, Archived Recording) .................................................................................. 122, 205
Advanced Good Clinical Practice: Practical Application and Implementation (On-Site) ........................................................................... 31
Annual GCP Training Update: MHRA Inspection Findings for 2015 (Archived Recording) .............................................................. 205
Cases in Advanced GCP: A Problem-Solving Practicum (Web, Archived Recording) .................................................................................. 130, 205
CFR/ICH GCP Reference Guide for Drugs (Publication) .................................................................................................................. 223
CFR/ICH GCP Reference Guide for Medical Devices (Publication) .............................................................................................. 223
Clinical Trial Assistant Fundamentals (Core Curriculum) .................................................................................................................. 42
Conducting Clinical Trials Under ICH GCP E6 (Core Curriculum) .............................................................................................. 47
Design Considerations for GCP Training Programs (On-Site, Archived Recording) .............................................................. 139, 205
EU Clinical Trial Regulation 536/2014: Are You Ready? (On-Site) ....................................................................................... 149
FDA and MHRA: Annual GCP Inspection Findings (On-Site) ......................................................................................................... 149
FDA Pre-Approval Inspection Readiness: Clinical Investigators (On-Site) .................................................................................. 64
FDA Pre-Approval Inspection Readiness: Sponsors and CROs (On-Site) .................................................................................. 65
Final ICH GCP E6 R2: Changes Impacting Clinical Investigators, Sites, and IND Holders (Sponsors-Investigators and Institutions) (Web, Archived Recording) .................................................. 153, 205
Final ICH GCP E6 R2: Changes Impacting Sponsors/CROs (Web, Archived Recording) .................................................................................. 153, 205
Final ICH GCP E6 R2: Impact on Clinical Data Management (Web, Archived Recording) .................................................................................. 154, 205
Final ICH GCP E6 R2: Implementing Risk Management Approaches for Compliance (Web, Archived Recording) .......................... 154, 205
Final ICH GCP E6 R2: Sponsor Quality Management Risk-Based/Risk Management Requirements and Approaches for Compliance (Web, Archived Recording) .................................................. 155, 205
Final ICH GCP E6 R2 Addendum: Overview of Changes Impacting Sponsors, CROs, Clinical Investigators/Sites (Web, Archived Recording) .................................................. 155, 205
Fundamentals of Good Clinical Practice (On-Demand eLearning) .............................................................................................. 235
The Future of Good Clinical Practice Demands a Quality System Approach: Will You be Ready? (On-Site) ............................................. 68
GCP Training for Investigators (On-Site, Archived Recording) ........................................................................................................... 157, 205
The GCPs of Essential Documents (Web, Archived Recording) ..................................................................................................... 157, 205
Global GCP Monitoring: Domestic and International Compliance (On-Site) .................................................................................. 69
## Content by Subject

**Good Clinical Practice**

- Drug Development and FDA Regulations (On-Site) ......................................................... 57
- Drug Development and FDA Regulations (Web, Archived Recording) .......................... 142, 205
- Good Clinical Practice for the Laboratory Scientist (On-Site) ........................................ 70
- Good Laboratory Practice for Non-Clinical Studies (Web) .............................................. 159
- Introduction to the FDA (On-Site) .................................................................................... 78

**Good Manufacturing Practice**

- cGMP for the Quality Control Laboratory (On-Site) ....................................................... 131
- Drug Development and FDA Regulations (On-Site) ....................................................... 57
- Drug Development and FDA Regulations (Web, Archived Recording) ......................... 142, 205
- Introduction to the FDA (On-Site) .................................................................................... 78
- Warning Letters: Applying Lessons Learned from Misbranding and Adulteration Noncompliance Findings (On-Site) ................................................................. 199

**HIPAA**

- HIPAA Compliance Monitoring and Auditing (On-Site) .............................................. 159
- HIPAA Team Training: Fundamental Training Specifically for Clinical Research Settings (Web, Archived Recording) ................................................................. 160, 205

**Human Subject Protection**

- Electronic Informed Consent Guidance: Regulatory Updates (Web) .............................. 143
- Informed Consent: Beyond the Basics (On-Site) .............................................................. 74
- Informed Consent Content & Process Requirements (Archived Recording) ................... 205
- Informed Consent Procedure: Lessons Learned from Inspection Findings (Web, Archived Recording) ................................................................. 162, 205
- The Self-Instructional Study Site Training Series (Volume 3), IRBs/IECs and Informed Consent: Protecting the Rights of Human Subjects (Publication) .............. 222
- State-by-State Clinical Trial Requirements Reference Guide (Publication) ..................... 221
- State Laws Governing Clinical Trial Regulatory Compliance (Web, Archived Recording) ................................................................. 188, 205

**IND Submissions**

- Drug and Device Regulatory Submissions: A Comparison (On-Site) ............................ 141
- The IND in a CTD/eCTD Format (Web, Archived Recording) ........................................ 162, 205
- IND Submissions: A Primer (Publication) ........................................................................ 220
- New Drug Development: A Regulatory Overview (Publication) ...................................... 220
- Preparing IND Submissions: How to Organize, Write, Submit, and Track Submissions (On-Site) ......................................................................................................... 95

**Informed Consent**

- Electronic Informed Consent Guidance: Regulatory Updates (Web) .............................. 143
- Informed Consent: Beyond the Basics (On-Site) .............................................................. 74
- Informed Consent Content & Process Requirements (Archived Recording) ................... 205
- Informed Consent Procedure: Lessons Learned from Inspection Findings (Web, Archived Recording) ................................................................. 162, 205
- NEW! Key Considerations in Medical Writing: The Clinical Study Protocol, Investigator’s Brochure, Informed Consent Form, and Adverse Events Narratives (Web) .................. 167
- The Self-Instructional Study Site Training Series (Volume 3), IRBs/IECs and Informed Consent: Protecting the Rights of Human Subjects (Publication) .............. 222
- State-by-State Clinical Trial Requirements Reference Guide (Publication) ..................... 221
- State Laws Governing Clinical Trial Regulatory Compliance (Web, Archived Recording) ................................................................. 188, 205

**Inspections and Inspection Readiness**

- 30-Hour Clinical Research Auditing Certification Program (Web) ................................. 121
- Adequate Sponsor Monitoring Systems in Anticipation of FDA Sponsor GCP Inspections (Archived Recording) ................................................................. 205
Content by Subject

Annual GCP Training Update: MHRA Inspection Findings for 2015 (Archived Recording) .................................................. 205
Best Practices to Become a Preferred Site (On-Site) .................................................................................................................. 38
Current FDA and EMA Inspection Findings: Lessons Learned (Web, Archived Recording) .................................................. 137, 205
EMA and FDA Inspections: Key Differences and Similarities (Archived Recording) ..................................................... 144, 205
EMA and MHRA Inspections: Successful Planning and Execution Tips and Techniques (Web, Archived Recording) ........... 144, 205
FDA and MHRA: Annual GCP Inspection Findings (On-Site) ........................................................................................................ 149
FDA Pre-Approval Inspection Readiness: Clinical Investigators (On-Site) ........................................................................ 64
FDA Pre-Approval Inspection Readiness: Sponsors and CROs (On-Site) .............................................................................. 65
FDA’s Bioresearch Monitoring (BIMO) Program: Inspection of Sponsors, CROs, and Monitors (Web, Archived Recording) .... 151, 205
FDA’s Role in Device Safety Inspections (On-Site) .......................................................................................................................... 151
Informed Consent Procedure: Lessons Learned from Inspection Findings (Web, Archived Recording) ................................. 162, 205
NEW! Inspection Readiness: Understanding BIMO Inspection Requirements for Sponsors, CROs, Monitors and Investigators (Web) .................................................................................................................................................................................. 163
Preparation, Management, and Response to Inspections and Audits (Web, Archived Recording) .............................................. 176, 205
Preparing Clinical Research Sites for FDA Inspections (Web, Archived Recording) ................................................................. 176, 205
Preparing for SOP Inspection: An Auditor’s Perspective (Archived Recording) ................................................................. 205
Risk-Based Auditing: Effective Compliance Strategies (Web, Archived Recording) .............................................................. 181, 205
The Self-Instructional Study Site Training Series (Volume 4), Sponsor Visits and Regulatory Audits: What You Need to Know (Publication) ......................................................................................................................... 222

Investigator Initiated Trials
Investigator Initiated Trials: Roles and Responsibilities (Web, Archived Recording) ................................................................. 166, 205
Investigator-Initiated Trials (IITs) and the Role and Responsibilities of the Investigator (On-Site) ...................................................... 80
Investigator Selection Criteria and Strategies for Investigator Qualification (Archived Recording) ........................................ 205

Investigator Training
ABCs of GCP and the 13 Principles of ICH GCP E6 (Web, Archived Recording) ........................................................................ 122, 205
Becoming a Clinical Research Investigator: Expectations and Responsibilities (On-Site) ................................................................. 37
Best Practices to Become a Preferred Site (On-Site) .......................................................................................................................... 38
Electronic Informed Consent Guidance: Regulatory Updates (Web) ............................................................................................. 143
Ensuring Success Through Smarter Site Selection and Study Feasibility (Web, Archived Recording) ......................................... 145, 205
The Form FDA 1572: A Reference Guide for Clinical Researchers, Sponsors, and Monitors (Publication) .............................. 223
GCP Training for Investigators (On-Site, Archived Recording) ....................................................................................................... 157, 205
Good Clinical Practice for Investigators (On-Demand eLearning) ............................................................................................... 234
Informed Consent: Beyond the Basics (On-Site) .............................................................................................................................. 74
Informed Consent Procedure: Lessons Learned from Inspection Findings (Web, Archived Recording) ......................................... 162, 205
Introduction to Clinical Research (Core Curriculum) ...................................................................................................................... 77
Introduction to Clinical Research (Web, Archived Recording) ........................................................................................................... 164, 205
Investigational Product Accountability Best Practices (Web, Archived Recording) ................................................................. 166, 205
Principal Investigator Oversight and the Appropriate Delegation of Tasks (Web, Archived Recording) .............................................. 176, 205
Principal Investigator/Site GCP Compliance and Performance: What It Really Takes to Be GCP Compliant (Archived Recording) .... 205
Principal Investigator Training: Roles and Responsibilities (Archived Recording) ........................................................................ 205
The Self-Instructional Study Site Training Series (6 Volume Set) (Publication) ............................................................................. 222
The Self-Instructional Study Site Training Series (Volume 1), The Clinical Study Site Team: Roles and Responsibilities (Publication) .................................................................................................................................................. 222
The Self-Instructional Study Site Training Series (Volume 2), FDA Clinical Research Regulations and GCPs: The Essentials (Publication) .................................................................................................................................................. 222
The Self-Instructional Study Site Training Series (Volume 3), IRBs/IECs and Informed Consent: Protecting the Rights of Human Subjects (Publication) .................................................................................................................................................. 222
The Self-Instructional Study Site Training Series (Volume 4), Sponsor Visits and Regulatory Audits: What You Need to Know (Publication) .................................................................................................................................................. 222
The Self-Instructional Study Site Training Series (Volume 5), Your Role in Reporting Adverse Experiences (Publication) ................. 222
The Self-Instructional Study Site Training Series (Volume 6), Understanding, Evaluating, and Implementing Clinical Protocols (Publication) .................................................................................................................................................. 222
Subject Enrollment: Creating Effective Enrollment Models (Archived Recording) ........................................................................ 205

Investigator’s Brochure
Medical Writing Fundamentals: How to Write Regulatory Documents (On-Site) ........................................................................... 85
Medical Writing Fundamentals: How to Write Regulatory Documents (Web, Archived Recording) .................................................. 170, 205
Writing and Updating the Investigator’s Brochure (Web, Archived Recording) ............................................................................. 200, 205

In Vitro Diagnostics
In Vitro Diagnostics: Study Design, Conduct, Regulatory Requirements and Submissions for Approval (On-Site) ....................... 81

IRBs/IECs
Final AE Regulatory Guidance: Reporting/Communications of Safety Information from Clinical Trials to IRBs (Web, Archived Recording) .................................................................................................................................................. 152, 205
Institutional Review Board (IRB) Written Procedures: Final Guidance for Institutions and IRBs (Web) ............................................. 163
Institutional Review Boards (IRBs): The Changing Landscape and the Effect on the Conduct of Clinical Research (On-Site) ........... 75
The Revised HHS Common Rule: What You Need to Know (Web, Archived Recording) ............................................................... 181, 205
The Self-Instructional Study Site Training Series (Volume 3), IRBs/IECs and Informed Consent: Protecting the Rights of Human Subjects (Publication) .................................................................................................................................................. 222
State Laws Governing Clinical Trial Regulatory Compliance (Web, Archived Recording) ......................................................... 188, 205
Understanding the FDA/CHRP Joint Guidance on Minutes of IRB Meetings (Web) ........................................................................ 197
## Medical Devices

Adverse Events: Managing and Reporting for Medical Devices (On-Site) ................................................................. 33
Bringing the Clinical Perspective into ISO 14971 Risk Management Discussions (On-Site) ............................................ 127
CFR/ICH GCP Reference Guide for Medical Devices (Publication) ............................................................................. 223
Clinical Evidence Writing for Medical Device Regulatory Submissions (On-Site) ..................................................... 132
Clinical Trials for Medical Devices: Design and Development (On-Site) ................................................................. 44
Comprehensive Monitoring for Medical Devices (Core Curriculum) ................................................................. 46
Drug and Device Regulatory Submissions: A Comparison (On-Site) ........................................................................ 141
FDA Medical Device Approval Process (Web, Archived Recording) ...................................................................... 150, 205
FDA’s Role in Device Safety Inspections (On-Site) ........................................................................................................ 151
Good Clinical Practice (GCP) for Medical Devices: ICH GCP E6 and ISO 14155 (Web, Archived Recording) ........ 158, 205
Introduction to Clinical Research (Core Curriculum) ............................................................................................. 77
Introduction to Clinical Research (Web, Archived Recording) .................................................................................. 164, 205
In Vitro Diagnostic Devices: Study Design, Conduct, Regulatory Requirements and Submissions for Approval (On-Site) ..... 81
Medical Device Approval Process: Preparation and Processing of 510(k)s, IDEs, and PMAs (On-Site) ......................... 82
Medical Device Development: Preparation and Processing of 510(k)s, IDEs, and PMAs (On-Site) ......................... 21, 221
Medical Device GCP Overview (On-Site) .................................................................................................................. 221
Medical Device GCP Overview (Web, Archived Recording) .................................................................................... 221
Medical Device Tracking (Archived Recording) ....................................................................................................... 205
Monitoring Medical Device Trials: An Introduction (Web, Archived Recording) .................................................... 171, 205
Monitoring Visit Reports for Medical Device Studies (Web, Archived Recording) ............................................. 173, 205
Software as a Medical Device: Clinical Considerations (On-Site) ....................................................................... 186
Sponsor Responsibilities for Global Drug Studies (Web, Archived Recording) ....................................................... 188, 205
Transitioning Pharmaceutical Professionals to Medical Device Professionals (Archived Recording) ................ 205
Writing Clinical Evaluation Reports (On-Site) ............................................................................................................ 110
Writing Clinical Study Reports for Diagnostic Studies (On-Site, Archived Recording) ...................................... 201, 205
Writing Protocols for Diagnostic Studies (On-Site, Archived Recording) ............................................................. 202, 205

## Medical Terminology

Medical Terminology for Clinical Research Professionals (On-Site) ........................................................................ 84

## Medical Writing

NEW! Key Considerations in Medical Writing: The Clinical Study Protocol, Investigator’s Brochure, Informed Consent Form, and Adverse Events Narratives (Web) ................................................................. 167
Medical Writing Fundamentals: How to Write Regulatory Documents (On-Site) ..................................................... 85
Medical Writing Fundamentals: How to Write Regulatory Documents (Web, Archived Recording) ........................ 170, 205

## Medicare Billing Compliance

10-Week Clinical Research Financial Certification Program: Setting Up Compliant Financial Operations and Budgets (Web) .................................................................................................................................................. 115
The Clinical Research Finance Roadmap Companion Reference Guide: Tools, Templates and Resources (Publication) .................................................................................................................................................. 225
Incorporating Denials Management into Clinical Research Billing (Web) ................................................................ 161
Introduction to Medicare Coverage Analysis: Impact on Site Revenue Cycles (Web) ............................................. 165
Research Billing Processing: Appropriate Segregation of Charges and Medical Documentation (Web) ................. 180

## MHRA Inspections

Annual GCP Training Update: MHRA Inspection Findings for 2015 (Archived Recording) ........................................ 205
EMA and MHRA Inspections: Successful Planning and Execution Tips and Techniques (Web, Archived Recording) .................................................................................................................................................. 144, 205
FDA and MHRA: Annual GCP Inspection Findings (On-Site) ................................................................................. 149
TMF/eTMF Regulatory Agency Expectations, Inspections, and Findings (Web, Archived Recording) ................. 196, 205

## Monitoring

10-Week Clinical Research Associate (CRA) On-Boarding Program (Web) ............................................................. 113
10-Week CRA & CRC Beginner Program (Web) ........................................................................................................ 112
10-Week Final ICH GCP E6 R2: Risk-Based Monitoring Plan Development Series (Web) ........................................... 116
30-Hour Monitoring Oncology Clinical Trials Program (On-Demand eLearning) ............................................... 236
Adequate Sponsor Monitoring Systems In Anticipation of FDA Sponsor GCP Inspections (Archived Recording) .... 205
Applied Clinical Statistics in Risk-Based Monitoring (On-Site) ................................................................................ 123
Current FDA and EMA Inspection Findings: Lessons Learned (Web, Archived Recording) .................................. 137, 205
Data Management: Key Regulations Impacting the Role of the Clinical Data Manager (On-Site, Archived Recording) .................................................................................................................................................. 138, 205
Detecting Risk Signals in Protocols, Data, and Monitoring (On-Site) ................................................................... 52
Detecting Risk Signals in Protocols, Data, and Monitoring (On-Site, Archived Recording) .................................. 140, 205
Developing CRAs as Site Study Managers (On-Site) .............................................................................................. 54
Ensuring Success Through Smarter Site Selection and Study Feasibility (Web, Archived Recording) .................. 145, 205
The Form FDA 1572: A Reference Guide for Clinical Researchers, Sponsors, and Monitors (Publication) ........ 223
The Highly Effective CRA: Soft Skills for Taking Your Work to the Next Level (On-Site) ....................................... 72
## Content by Subject

<table>
<thead>
<tr>
<th>Subject</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitoring Plans</td>
<td></td>
</tr>
<tr>
<td>10-Week Final ICH GCP E6 R2: Risk-Based Monitoring Plan Development Series (Web)</td>
<td>116</td>
</tr>
<tr>
<td>Detecting Risk Signals in Protocols, Data, and Monitoring (On-Site)</td>
<td>52</td>
</tr>
<tr>
<td>Monitoring Plans</td>
<td></td>
</tr>
<tr>
<td>Detecting Risk Signals in Protocols, Data, and Monitoring (On-Site, Archived Recording)</td>
<td>140, 205</td>
</tr>
<tr>
<td>Monitoring Plan Development (Web, Archived Recording)</td>
<td>172, 205</td>
</tr>
<tr>
<td>Using Data to Identify Risk Indicators in Risk-Based Monitoring (Archived Recording)</td>
<td>205</td>
</tr>
<tr>
<td>NDA Submissions</td>
<td></td>
</tr>
<tr>
<td>Drug and Device Regulatory Submissions: A Comparison (On-Site)</td>
<td>141</td>
</tr>
<tr>
<td>Drug Approval Process: Preparation and Processing of INDs and NDAs (On-Site)</td>
<td>56</td>
</tr>
<tr>
<td>Drug Development and FDA Regulations (Web, Archived Recording)</td>
<td>142, 205</td>
</tr>
<tr>
<td>FDA Drug Approval Process (Web, Archived Recording)</td>
<td>150, 205</td>
</tr>
<tr>
<td>New Drug Development: A Regulatory Overview (Publication)</td>
<td>220</td>
</tr>
<tr>
<td>Negotiation Skills</td>
<td></td>
</tr>
<tr>
<td>Negotiation Skills for Clinical Research Professionals (Web)</td>
<td>174</td>
</tr>
<tr>
<td>Notes to File</td>
<td></td>
</tr>
<tr>
<td>Strategies for Ensuring Good Documentation Practices (GDP) (On-Site, Archived Recording)</td>
<td>191, 205</td>
</tr>
<tr>
<td>Use of Notes to File in Clinical Trial Essential Documentation (Web, Archived Recording)</td>
<td>198, 205</td>
</tr>
<tr>
<td>Observational Studies</td>
<td></td>
</tr>
<tr>
<td>Managing Observational Studies (On-Site, Archived Recording)</td>
<td>168, 205</td>
</tr>
<tr>
<td>On-Boarding/New Hire Training</td>
<td></td>
</tr>
<tr>
<td>10-Week CRA &amp; CRC Beginner Program (Web)</td>
<td>112</td>
</tr>
<tr>
<td>10-Week Clinical Research Associate (CRA) On-Boarding Program (Web)</td>
<td>113</td>
</tr>
<tr>
<td>10-Week Clinical Research Coordinator (CRC) On-Boarding Program (Web)</td>
<td>114</td>
</tr>
<tr>
<td>10-Week Fundamentals of Clinical Research Series: Getting Started in Clinical Research (Web)</td>
<td>117</td>
</tr>
<tr>
<td>30-Hour Clinical Data Management On-Boarding Program (Web)</td>
<td>119</td>
</tr>
<tr>
<td>30-Hour Clinical Project Management Fundamentals Certification Program (Web)</td>
<td>120</td>
</tr>
<tr>
<td>30-Hour Clinical Research Auditing Certification Program (Web)</td>
<td>121</td>
</tr>
<tr>
<td>30-Hour Clinical Research Coordinator On-Boarding Program (On-Demand eLearning)</td>
<td>236</td>
</tr>
<tr>
<td>Oncology Trials</td>
<td></td>
</tr>
<tr>
<td>30-Hour Monitoring Oncology Clinical Trials Program (On-Demand eLearning)</td>
<td>236</td>
</tr>
<tr>
<td>Monitoring Oncology Clinical Trials (On-Site)</td>
<td>90</td>
</tr>
</tbody>
</table>

---

**Notes:**
- Pages are listed for each subject for reference purposes. The actual content may vary.
Patient Recruitment and Retention
Best Practices to Become a Preferred Site (On-Site) .......................................................... 38
Effective Recruitment Planning and Management for Sponsors and CROs (On-Site) ................. 60
Ensuring Success Through Smarter Site Selection and Study Feasibility (Web, Archived Recording) ................................................................. 145, 205
Scientific and Ethical Considerations for Inclusion of Pregnant Women in Clinical Trials (Web) ................................................................. 185
Social Media in Clinical Research: Effective, Innovative, and Compliant Applications (On-Site, Archived Recording) ........................................................................... 186, 205
Study Feasibility: Eliminating Low and Late Enrollment (On-Site, Archived Recording) ............ 193, 205
Subject Enrollment: Creating Effective Enrollment Models (Archived Recording) ..................... 205
Subject Recruitment: Proactive Project Plans and Issues Management (Web, Archived Recording) ................................................................. 194, 205

Patient Registries
Critical Decision Points in Design and Conduct of Patient Registries (Archived Recording) ........................................................................... 205

Pharmacokinetics
Pharmacokinetics: A Comprehensive Overview of Principles and Applications (On-Site) ........... 92

Pharmacology
Introductory Pharmacology for Non-Clinical Professionals (On-Site) ........................................... 79

Pharmacovigilance
Advanced Post-Marketing Pharmacovigilance Auditing (On-Site) ................................................... 32
Adverse Event Monitoring for CRAs (Web, Archived Recording) .................................................... 123, 205
Adverse Events: Managing and Reporting for Medical Devices (On-Site) ........................................ 33
Adverse Events: Managing and Reporting for Pharmaceuticals (On-Site) ........................................ 34
Basics of Post-Marketing Pharmacovigilance and the Beginner PV Auditor (On-Site) ..................... 36
Case Narrative Writing for Reporting Adverse Events (On-Site, Archived Recording) ................. 129, 205
Drug Safety and Pharmacovigilance: Effective Drug Safety Reporting and Surveillance (Core Curriculum) ........................................................................... 59
European Pharmacovigilance Modules: What Are They and Why They Are Important (On-Site) ........................................................................... 148
Final AE Regulatory Guidance: Reporting/Communication of Safety Information from Clinical Trials to IRBs (Web, Archived Recording) ................................................. 152, 205
Quality Risk Management in Clinical Trials and Pharmacovigilance (Archived Recording) ............ 205
Writing and Updating the Investigator’s Brochure (Web, Archived Recording) ................................ 200, 205

Phase I Trials
NEW! Managing Phase I Clinical Trials (Web, Archived Recording) ............................................ 169, 205
Monitoring Phase I Clinical Trials (On-Site, Archived Recording) .................................................. 172, 205
Phase I Study Management (On-Site, Archived Recording) ............................................................. 175, 205

Post-Marketing
Advanced Post-Marketing Pharmacovigilance Auditing (On-Site) ................................................... 32
Adverse Events: Managing and Reporting for Medical Devices (On-Site) ........................................ 33
Adverse Events: Managing and Reporting for Pharmaceuticals (On-Site) ........................................ 34
Basics of Post-Marketing Pharmacovigilance and the Beginner PV Auditor (On-Site) ..................... 36
Case Narrative Writing for Reporting Adverse Events (On-Site, Archived Recording) ................. 129, 205
European Pharmacovigilance Modules: What Are They and Why They Are Important (On-Site) ........................................................................... 148

Project Management
30-Hour Clinical Project Management Fundamentals Certification Program (Web) ........................... 120
Clinical Project Management: Advanced Concepts in Project Management (Core Curriculum) ........................................................................... 41
Clinical Project Management: Fundamentals of Project Management (Core Curriculum) .............. 40
Clinical Trial Start-Up: Effective Planning for Sponsors, CROs, and Sponsor-Investigators (On-Site) ........................................................................... 43
Clinical Trial Start-Up: Using a Work Breakdown Structure (WBS) for Effective Planning (Web, Archived Recording) ......................................................... 133, 205
NEW! Effective Use of Tools, Job Aids, Process Maps, and Checklists for Project Managers and Clinical Research Teams (Web) .......................................................... 142
The Fundamentals of Clinical Research Project Management (Web) ............................................. 156
Optimizing Protocol Design and Strategies to Achieve Efficient, Lower Cost Trial Execution (On-Site) ........................................................................... 91
Overseeing Teams and Projects (Web) .......................................................................................... 174
Strategic Clinical Research Operational Planning: Applied Techniques for Cost Estimation, Risk Management, and Quality Assurance (On-Site) ......................... 106
Study Initiation Strategies for Sponsors: Study and Site Start-Up (On-Site, Archived Recording) ........................................................................... 193, 205
NEW! A Systematic Approach to Study Start-Up: Improving Site Activation (Web, Archived Recording) ........................................................................... 195, 205

Protocol Deviations
Protocol Deviations: Documenting, Managing, and Reporting (Web, Archived Recording) .......... 177, 205
Content by Subject

Protocols
Design and Conduct of Clinical Trials: Design Requirements, Statistical Issues, and Clinical Protocols (On-Site) ................................................................. 51
Effectively Writing Clinical Trial Protocols (On-Site) ................................................................................................................................. 61
NEW! Key Considerations in Medical Writing: The Clinical Study Protocol, Investigator’s Brochure, Informed Consent Form, and Adverse Events Narratives (Web) ......................................................... 167
Medical Writing Fundamentals: How to Write Regulatory Documents (On-Site) ............................................................................................ 85
Medical Writing Fundamentals: How to Write Regulatory Documents (Web, Archived Recording) ................................................................. 170, 205
Optimizing Protocol Design and Strategies to Achieve Efficient, Lower Cost Trial Execution (On-Site) ........................................................................... 91
The Self-Instructional Study Site Training Series (Volume 6), Understanding, Evaluating, and Implementing Clinical Protocols (Publication) ............. 222
Strategies for Protocol Operationalization and Adherence (On-Site, Archived Recording) ..................................................................................... 192, 205
Writing Clinical Study Protocols (Web, Archived Recording) ...................................................................................................................... 201, 205
Writing Protocols for Diagnostic Studies (On-Site, Archived Recording) .................................................................................................... 202, 205

Quality
30-Hour Clinical Research Auditing Certification Program (Web) ........................................................................................................... 121
Auditing Techniques: A Problem-Solving Practicum (Web) ......................................................................................................................... 125
Best Practices for Hosting a Client Audit (On-Site) ............................................................................................................................... 126
Cases in Advanced GCP: A Problem-Solving Practicum (Web, Archived Recording) ................................................................. 130, 205
Data Quality in Clinical Trials: Rationale and Impact (Web, Archived Recording) .................................................................................... 139, 205
Establishing a Vendor Management Program (Archived Recording) ........................................................................................................ 205
Establishing Quality Tolerance Limits (Web, Archived Recording) .............................................................................................................. 147, 205
Final ICH GCP E6 R2: Implementing Risk Management Approaches for Compliance (Web, Archived Recording) ........................................... 154, 205
Final ICH GCP E6 R2: Sponsor Quality Management — Risk-Based/Risk Management Requirements and Approaches for Compliance (Web, Archived Recording) ...................................................... 155, 205
The Future of Good Clinical Practice Demands a Quality System Approach: Will You be Ready? (On-Site) ................................................................. 68
Implementing Quality Agreements (Web, Archived Recording) ................................................................................................................... 160, 205
Quality by Design in Clinical Research: Is This Only for the Protocol? (On-Site, Archived Recording) .............................................................. 177, 205
Quality Risk Management in Clinical Trials and Pharmacovigilance (Archived Recording) ............................................................................ 205
Quality Systems: A Controlled Approach to GCP Compliance (Web, Archived Recording) ................................................................. 178, 205
Strategic Clinical Research Operational Planning: Applied Techniques for Cost Estimation, Risk Management, and Quality Assurance (On-Site) .................................................................................. 106
Strategies for Conducting Vendor Audits (On-Site, Archived Recording) ............................................................................................... 190, 205
Warning Letters: Applying Lessons Learned from Misbranding and Adulteration Noncompliance Findings (On-Site) ....................................................... 199

Quality by Design/Lean Six Sigma
NEW! Building Quality by Design (QbD) and Risk-Based Quality Management (RBQM) Systems into Clinical Operations (Web, Archived Recording) ........... 127, 205
Establishing a Risk Management Framework for Clinical Trial Conduct and Oversight (On-Site, Archived Recording) ........................................ 146, 205
Optimizing Protocol Design and Strategies to Achieve Efficient, Lower Cost Trial Execution (On-Site) ........................................................................ 91
Quality by Design: A Lean Six Sigma Approach to Risk-Based Monitoring (Archived Recording) ........................................................................ 205
Quality by Design in Clinical Research: Is This Only for the Protocol? (On-Site, Archived Recording) .............................................................. 177, 205
Quality Risk Management in Clinical Trials and Pharmacovigilance (Archived Recording) ............................................................................ 205

Quality Control
cGMP for the Quality Control Laboratory (On-Site) ............................................................................................................................... 131

Quality Risk Management
10-Week Risk Management/Risk-Based Quality Management for Clinical Trials Certification Program (Web) ........................................................................ 118
NEW! Building Quality by Design (QbD) and Risk-Based Quality Management (RBQM) Systems into Clinical Operations (Web, Archived Recording) ........... 127, 205
Detecting Risk Signals in Protocols, Data, and Monitoring (On-Site) ..................................................................................................................... 52
Detecting Risk Signals in Protocols, Data, and Monitoring (On-Site, Archived Recording) ............................................................................ 140, 205
Establishing Quality Tolerance Limits (Web, Archived Recording) .............................................................................................................. 147, 205
Final ICH GCP E6 R2: Sponsor Quality Management — Risk-Based/Risk Management Requirements and Approaches for Compliance (Web, Archived Recording) ...................................................... 155, 205
The Future of Good Clinical Practice Demands a Quality System Approach: Will You be Ready? (On-Site) ................................................................. 68
Implementing Quality Agreements (Web, Archived Recording) ................................................................................................................... 160, 205
Optimizing Protocol Design and Strategies to Achieve Efficient, Lower Cost Trial Execution (On-Site) ........................................................................ 91
Quality by Design: A Lean Six Sigma Approach to Risk-Based Monitoring (Archived Recording) ........................................................................ 205
Quality by Design in Clinical Research: Is This Only for the Protocol? (On-Site, Archived Recording) .............................................................. 177, 205
Quality Risk Management in Clinical Trials and Pharmacovigilance (Archived Recording) ............................................................................ 205
NEW! Risk-Based Quality and Compliance Management in Combination Product Trials (Web) ........................................................................... 183
Risk Management/Risk-Based Quality Management for Clinical Trials Certification Program (On-Site) .............................................................. 101

Queries
Query Creation and Processing: Assessing Data Discrepancies and the Communications for Corrections (On-Site) ............................................................ 96
Content by Subject

R

RECISt
RECISt 1.0 and 1.1: Overview and Data Challenges in Oncology Clinical Trials (Web, Archived Recording) ................................................................................................................. 179, 205

Regulatory Affairs
Case Narrative Writing for Reporting Adverse Events (On-Site, Archived Recording) ................................................................................................................................. 129, 205
Clinical Evidence Writing for Medical Device Regulatory Submissions (On-Site) ................................................................................................................................. 132
ClinicalTrials.Gov Requirements: Clinical Trial Registration and Trial Results Reporting, Expanded Registry and Results Data Bank (Web, Archived Recording) ............ 134, 205
Critical Decision Points in Design and Conduct of Patient Registries (Archived Recording) ...................................................................................................................... 205
Drug and Device Regulatory Submissions: A Comparison (On-Site) ......................................................................................................................................................... 141
Drug Development and FDA Regulations (On-Site) ............................................................................................................................................................................................ 57
EU Clinical Trial Regulation 536/2014: Are You Ready? (On-Site) ........................................................................................................................................................ 149
FDA Medical Device Approval Process (Web, Archived Recording) ........................................................................................................................................... 150, 205
Final ICH GCP E6 R2 Addendum: Overview of Changes Impacting Sponsors, CROs, Clinical Investigators/Sites (Web, Archived Recording) ................................................. 155, 205
Good Clinical Practice Regulatory Changes, Trends, and Best Practices Implementation (Core Curriculum) ............................................................................................................. 71
The IND in a CTD/eCTD Format (Web, Archived Recording) ............................................................................................................................................................................. 162, 205
IND Submissions: A Primer (Publication) ................................................................................................................................................................................................. 220
Introduction to Clinical Research (Core Curriculum) ...................................................................................................................................................................................... 77
Introduction to Clinical Research (Web, Archived Recording) ................................................................................................................................................................. 164, 205
Medical Device Approval Process: Preparation and Processing of 510(k)s, IDEs, and PMAs (On-Site) ........................................................................................................... 82
Medical Device Development: Regulation and Law (Publication) ......................................................................................................................................................... 221
Medical Writing Fundamentals: How to Write Regulatory Documents (On-Site) ............................................................................................................................................ 85
Medical Writing Fundamentals: How to Write Regulatory Documents (Web, Archived Recording) ...................................................................................................... 170, 205
New Drug Development: A Regulatory Overview (Publication) ................................................................................................................................................. 220
Preparing IND Submissions: How to Organize, Write, Submit, and Track Submissions (On-Site) ............................................................................................................. 95
Regulatory Intelligence (Web, Archived Recording) .................................................................................................................................................................................. 180, 205
Regulatory Intelligence 101 (On-Site) ................................................................................................................................................................................................. 97
Regulatory Strategy 101 (On-Site) ........................................................................................................................................................................................................... 98
Understanding the FDA/OHRP Joint Guidance on Minutes of IRB Meetings (Web) ............................................................................................................................................. 197
Use of Electronic Health Record Data in Clinical Investigations (Web, Archived Recording) .................................................................................................................. 198, 205
Writing and Maintaining the EU Clinical Trial Authorization (On-Site, Archived Recording) .................................................................................................................. 200, 205
Writing Clinical Study Reports for Diagnostic Studies (On-Site, Archived Recording) ........................................................................................................................................ 201, 205
Writing Protocols for Diagnostic Studies (On-Site, Archived Recording) ...................................................................................................................................................... 202, 205
Writing the Clinical Study Report (Web, Archived Recording) ................................................................................................................................................................. 203, 205

Remote Monitoring
Applied Clinical Statistics in Risk-Based Monitoring (On-Site) .......................................................................................................................................................... 123

The CRA Role in Risk-Based Monitoring: Strategies for Effective Remote Monitoring (Web, Archived Recording) ................................................................................. 136, 205

Report Writing
How to Write Effective Monitoring Reports and Communications Workshop (On-Site) ............................................................................................................................................. 27
Medical Writing Fundamentals: How to Write Regulatory Documents (On-Site) ........................................................................................................................................ 85
Medical Writing Fundamentals: How to Write Regulatory Documents (Web, Archived Recording) ...................................................................................................... 170, 205
Monitoring Reports: 10 Rules of Effective Report Writing (Web, Archived Recording) ......................................................................................................................... 173, 205
Monitoring Visit Reports for Medical Device Studies (Web, Archived Recording) ......................................................................................................................................... 173, 205
Report Writing for CRAs (On-Site) ........................................................................................................................................................................................................... 99

Risk-Based Monitoring
10-Week Final ICH GCP E6 R2: Risk-Based Monitoring Plan Development Series (Web) ......................................................................................................................... 116
Applied Clinical Statistics in Risk-Based Monitoring (On-Site) .......................................................................................................................................................... 123

NEW! Building Quality by Design (QbD) and Risk-Based Quality Management (RBQM) Systems into Clinical Operations (Web, Archived Recording) ................. 127, 205
The CRA Role in Risk-Based Monitoring: Strategies for Effective Remote Monitoring (Web, Archived Recording) ................................................................................. 136, 205
Data Management: Key Regulations Impacting the Role of the Clinical Data Manager (On-Site, Archived Recording) ............................................................................... 138, 205
Detecting Risk Signals in Protocols, Data, and Monitoring (On-Site) ......................................................................................................................................................... 52
Detecting Risk Signals in Protocols, Data, and Monitoring (On-Site, Archived Recording) .................................................................................................................. 140, 205
Implications of the FDA Guidance for a Risk-Based Approach to Monitoring and the EMA Reflection Paper on Risk-Based Quality Management in Clinical Trials (Web, Archived Recording) ......................................................................................................................... 161, 205
Monitoring Medical Device Trials: An Introduction (Web, Archived Recording) ........................................................................................................................................ 171, 205
Quality by Design: A Lean Six Sigma Approach to Risk-Based Monitoring (Archived Recording) ........................................................................................................... 205
Risk-Based Monitoring for Sites: Prepare Your Site for Success (On-Site, Archived Recording) ................................................................................................................ 182, 205
Risk-Based Monitoring: Successful Planning and Implementation (On-Site) ..................................................................................................................................................... 100
Risk-Based Monitoring: The Data Management Connection (Web, Archived Recording) ...................................................................................................................... 182, 205
Risk-Based Site Monitoring (Web, Archived Recording) ......................................................................................................................................................... 183, 205
“Risk-Based Thinking”: How Monitors Can Develop an Auditor’s Perspective (Web, Archived Recording) ...................................................................................... 184, 205
Risk-Proof Your Sites: Monitoring Strategies for Managing Risks (On-Site) ............................................................................................................................................. 184, 205
Content by Subject

Using Data to Identify Risk Indicators in Risk-Based Monitoring (Archived Recording) .......................................................... 205

Risk-Based Quality Management

Final ICH GCP E6 R2: Changes Impacting Clinical Investigators, Sites, and IND Holders (Sponsors-Investigators and Institutions) (Web, Archived Recording) .............. 153, 205
Final ICH GCP E6 R2: Implementing Risk Management Approaches for Compliance (Web, Archived Recording) ................................. 154, 205
Final ICH GCP E6 R2: Sponsor Quality Management – Risk-Based/Risk Management Requirements and Approaches for Compliance (Web, Archived Recording) ... 155, 205

Risk Management

10-Week Risk Management/Risk-Based Quality Management for Clinical Trials Certification Program (Web) .......................................................... 118
Applied Clinical Statistics in Risk-Based Monitoring (On-Site) .................................................................................................................. 123
Bringing the Clinical Perspective into ISO 14971 Risk Management Discussions (On-Site) ........................................................................... 127
Establishing a Risk Management Framework for Clinical Trial Conduct and Oversight (On-Site, Archived Recording) ................................. 146, 205
Final ICH GCP E6 R2: Implementing Risk Management Approaches for Compliance (Web, Archived Recording) ................................. 154, 205
Final ICH GCP E6 R2: Sponsor Quality Management – Risk-Based/Risk Management Requirements and Approaches for Compliance (Web, Archived Recording) ... 155, 205
The Future of Good Clinical Practice Demands a Quality System Approach: Will You be Ready? (On-Site) .......................................................... 68
Managing Risks in Outsourced Clinical Trials: Practical Approaches and Tools (Web, Archived Recording) ........................................... 169, 205
Quality by Design in Clinical Research: Is This Only for the Protocol? (On-Site, Archived Recording) .......................................................... 177, 205
Quality Risk Management in Clinical Trials and Pharmacovigilance (Archived Recording) ........................................................................... 205
Re-Engineering the RFP and Bid Defense Meeting to Effectively Manage Risk and Quality (Archived Recording) ........................................... 205
“Risk-Based Thinking”: How Monitors Can Develop an Auditor’s Perspective (Web, Archived Recording) .................................................. 184, 205
Risk Management/Risk-Based Quality Management for Clinical Trials Certification Program (On-Site) .......................................................... 101
Strategic Clinical Research Operational Planning: Applied Techniques for Cost Estimation, Risk Management, and Quality Assurance (On-Site) ............................................. 106

Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA)

Cases in Advanced GCP: A Problem-Solving Practicum (Web, Archived Recording) .......................................................... 130, 205
Corrective Action Plans: Essential Documentation of a Site’s Response to GCP Deficiencies (Web, Archived Recording) ................................. 135, 205
Current FDA and EMA Inspection Findings: Lessons Learned (Web, Archived Recording) .......................................................... 137, 205
The Future of Good Clinical Practice Demands a Quality System Approach: Will You be Ready? (On-Site) .......................................................... 68
Root Cause Analysis: Applying the Concept for Better Study Compliance Management (Web, Archived Recording) ........................................... 185, 205
Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) in Site Management (Core Curriculum) ........................................ 102

Safety

Advanced Post-Marketing Pharmacovigilance Auditing (On-Site) .................................................................................................................. 32
Adverse Event Monitoring for CRAs (Web, Archived Recording) .................................................................................................................. 123, 205
Adverse Events: Managing and Reporting for Medical Devices (On-Site) .................................................................................................. 33
Adverse Events: Managing and Reporting for Pharmaceuticals (On-Site) ................................................................................................. 34
Basics of Post-Marketing Pharmacovigilance and the Beginner PV Auditor (On-Site) .................................................................................. 36
Case Narrative Writing for Reporting Adverse Events (On-Site, Archived Recording) .................................................................................. 129, 205
Drug Safety and Pharmacovigilance: Effective Drug Safety Reporting and Surveillance (Core Curriculum) .................................................. 59
European Pharmacovigilance Modules: What Are They and Why They Are Important (On-Site) .......................................................... 148
FDA’s Role in Device Safety Inspections (On-Site) .......................................................................................................................... 151
Final AE Regulatory Guidance: Reporting/Communication of Safety Information from Clinical Trials to IRBs (Web, Archived Recording) ................................. 152, 205
Quality Risk Management in Clinical Trials and Pharmacovigilance (Archived Recording) .......................................................... 205
The Self-Instructional Study Site Training Series (Volume 5), Your Role in Reporting Adverse Experiences (Publication) .......................................................... 222
Writing and Updating the Investigator’s Brochure (Web, Archived Recording) .......................................................................................... 200, 205

Signal Detection

Detecting Risk Signals in Protocols, Data, and Monitoring (On-Site) ........................................................................................................ 52
Detecting Risk Signals in Protocols, Data, and Monitoring (On-Site, Archived Recording) .......................................................... 140, 205

Site Relationship Management

Building Relationships with Clinical Research Sites (Web, Archived Recording) .......................................................................................... 128, 205
Current FDA and EMA Inspection Findings: Lessons Learned (Web, Archived Recording) .......................................................... 137, 205
Ensuring Success Through Smarter Site Selection and Study Feasibility (Web, Archived Recording) .......................................................... 145, 205
Site Management and the Art of Assertiveness (Archived Recording) ......................................................................................................... 205
Strategies for Managing Difficult Clinical Research Sites (Web, Archived Recording) .................................................................................. 192, 205
NEW! Working with Clinical Research Sites: Strategic Planning and Operations for Sponsors and CROs (Web, Archived Recording) .......................................................... 199, 205

Site Selection, Initiation, and Oversight

Building Relationships with Clinical Research Sites (Web, Archived Recording) .......................................................................................... 128, 205
Corrective Action Plans: Essential Documentation of a Site’s Response to GCP Deficiencies (Web, Archived Recording) ................................. 135, 205
Current FDA and EMA Inspection Findings: Lessons Learned (Web, Archived Recording) .......................................................... 137, 205
Developing Effective Training and Facilitation Skills in Clinical Research: An Application-Based Course (On-Site) .......................................................... 55
Ensuring Success Through Smarter Site Selection and Study Feasibility (Web, Archived Recording) .......................................................... 145, 205
Facilitation Skills for Clinical Research Team Leaders (On-Site) ................................................................. 62
Investigator Selection Criteria and Strategies for Investigator Qualification (Archived Recording) ......................... 205
Preparing Clinical Research Sites for FDA Inspections (Web, Archived Recording) .............................................. 176, 205
Preparing for SOP Inspection: An Auditor’s Perspective (Archived Recording) ....................................................... 205
Principal Investigator/Site GCP Compliance and Performance: What it Really Takes to Be GCP Compliant (Archived Recording) 205
Risk-Based Monitoring: Successful Planning and Implementation (On-Site) ......................................................... 100
Risk-Based Site Monitoring (Web, Archived Recording) ....................................................................................... 183, 205
Risk-Proof Your Sites: Monitoring Strategies for Managing Risks (On-Site) ........................................................ 184
Root Cause Analysis: Applying the Concept for Better Study Compliance Management (Web, Archived Recording) ...... 185, 205
Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) in Site Management (Core Curriculum) .... 102
The Self-Study CRA Training Series (Volume 2), Identifying and Screening Investigators (Publication) ..................... 222
The Self-Study CRA Training Series (Volume 3), Conducting Prestudy Visits (Publication) ...................................... 222
The Self-Study CRA Training Series (Volume 4), Conducting Study Initiation Visits (Publication) ......................... 222
The Self-Study CRA Training Series (Volume 5), Conducting Routine Monitoring Visits (Publication) .................... 222
The Self-Study CRA Training Series (Volume 6), The CRA’s Reference for Adverse Events (Publication) .................. 222
Site Management and the Art of Assertiveness (Archived Recording) .................................................................. 205
Strategies for Developing Effective Training and Facilitation Skills in Clinical Research (On-Site, Archived Recording) 190, 205
Strategies for Managing Difficult Clinical Research Sites (Web, Archived Recording) ........................................... 192, 205
Study Initiation Strategies for Sponsors: Study and Site Start-Up (On-Site, Archived Recording) ............................ 193, 205
Study Site Start-Up: Opening and Managing a Successful Clinical Research Site (On-Site) ........................................ 107
Study Site Start-Up: Organization and Management Tips for the Novice Clinical Research Site (On-Site, Archived Recording) 194, 205
Using Data to Identify Risk Indicators in Risk-Based Monitoring (Archived Recording) ........................................ 205
NEW! Working with Clinical Research Sites: Strategic Planning and Operations for Sponsors and CROs (Web, Archived Recording) 199, 205

Site Training

10-Week Clinical Research Coordinator (CRC) On-Boarding Program (Web) ......................................................... 114
30-Hour Clinical Research Coordinator On-Boarding Program (On-Demand eLearning) .......................................... 236
ABCs of Clinical Research for Clinical Administrative Support Staff (Web, Archived Recording) ............................ 122, 205
ABCs of GCP and the 13 Principles of ICH GCP E6 (Web, Archived Recording) ..................................................... 122, 205
Applied Clinical Statistics in Risk-Based Monitoring (On-Site) .................................................................................. 123
Best Practices to Become a Preferred Site (On-Site) .................................................................................................. 38
CFR/ICH GCP Reference Guide for Drugs (Publication) ............................................................................................ 223
CFR/ICH GCP Reference Guide for Medical Devices (Publication) .......................................................................... 223
Clinical Trial Start-Up: Effective Planning for Sponsors, CROs, and Sponsor-Investigators (On-Site) ......................... 43
Design Considerations for GCP Training Programs (On-Site, Archived Recording) .................................................. 139, 205
Developing Effective Training and Facilitation Skills in Clinical Research: An Application-Based Course (On-Site) .... 55
NEW! Effective Use of Tools, Job Aids, Process Maps, and Checklists for Project Managers and Clinical Research Teams (Web) 142
Electronic Informed Consent Guidance: Regulatory Updates (Web) ........................................................................... 143
Ensuring Success Through Smarter Site Selection and Study Feasibility (Web, Archived Recording) ........................ 145, 205
The Form FDA 1572: A Reference Guide for Clinical Researchers, Sponsors, and Monitors (Publication) ................. 223
GCP Training for Investigators (On-Site, Archived Recording) ................................................................................. 157, 205
Good Clinical Practice: A Question & Answer Reference Guide (Publication) ......................................................... 223
Good Clinical Practice for Investigators (On-Demand eLearning) ............................................................................ 234
Good Clinical Practice for Study Coordinators (On-Demand eLearning) .............................................................. 235
Informed Consent: Beyond the Basics (On-Site) ......................................................................................................... 74
Informed Consent Procedure: Lessons Learned from Inspection Findings (Web, Archived Recording) ......................... 162, 205
Introduction to Clinical Research (Core Curriculum) ............................................................................................... 77
Introduction to Clinical Research (Web, Archived Recording) ..................................................................................... 164, 205
Investigational Product Accountability Best Practices (Web, Archived Recording) .................................................... 166, 205
Investigator-Initiated Trials (IITs) and the Role and Responsibilities of the Investigator (On-Site) ................................. 80
Principal Investigator Oversight and the Appropriate Delegation of Tasks (Web, Archived Recording) ....................... 176, 205
Principal Investigator/Site GCP Compliance and Performance: What it Really Takes to Be GCP Compliant (Archived Recording) 205
Principal Investigator Training: Roles and Responsibilities (Archived Recording) ...................................................... 205
Risk-Based Monitoring for Sites: Prepare Your Site for Success (On-Site, Archived Recording) ....................... 182, 205
The Self-Instructional Study Site Training Series (6 Volume Set) (Publication) .......................................................... 222
The Self-Instructional Study Site Training Series (Volume 1), The Clinical Study Site Team: Roles and Responsibilities (Publication) 222
The Self-Instructional Study Site Training Series (Volume 2), FDA Clinical Research Regulations and GCPs: The Essentials (Publication) 222
The Self-Instructional Study Site Training Series (Volume 3), IRBs/IECs and Informed Consent: Protecting the Rights of Human Subjects (Publication) 222
The Self-Instructional Study Site Training Series (Volume 4), Sponsor Visits and Regulatory Audits: What You Need to Know (Publication) 222
The Self-Instructional Study Site Training Series (Volume 5), Your Role in Reporting Adverse Experiences (Publication) 222
The Self-Instructional Study Site Training Series (Volume 6), Understanding, Evaluating, and Implementing Clinical Protocols (Publication) 222
State-by-State Clinical Trial Requirements Reference Guide (Publication) .............................................................. 221
State Laws Governing Clinical Trial Regulatory Compliance (Web, Archived Recording) ........................................ 188, 205
Strategies for Developing Effective Training and Facilitation Skills in Clinical Research (On-Site, Archived Recording) 190, 205
Strategies for Protocol Operationalization and Adherence (On-Site, Archived Recording) .......................................... 192, 205
Subject Enrollment: Creating Effective Enrollment Models (Archived Recording) .................................................. 205
Social Media

- Social Media in Clinical Research: Effective, Innovative, and Compliant Applications (On-Site, Archived Recording) | Page 186
- Subject Recruitment: Proactive Project Plans and Issues Management (Web, Archived Recording) | Page 194

Soft Skills

- Auditor Emotional Intelligence (On-Site, Archived Recording) | Page 126
- Building Relationships with Clinical Research Sites (Web, Archived Recording) | Page 128
- Coaching Skills for Leaders (Web, Archived Recording) | Page 135
- CRO Partnership Management (Web, Archived Recording) | Page 137
- Facilitation Skills for Clinical Research Team Leaders (On-Site) | Page 62
- The Highly Effective CRA: Soft Skills for Taking Your Work to the Next Level (On-Site) | Page 72
- Making Good Teams Better: Taking Your Cross-Functional Global Team to the Next Level ( Archived Recording) | Page 205
- Mindfulness for the Clinical Research Professional (On-Site) | Page 86
- Negotiation Skills for Clinical Research Professionals (Web) | Page 174
- Overseeing Teams and Projects (Web) | Page 174
- Practical Problem Solving for Clinical Research Professionals (On-Site) | Page 94
- Presentation Skills Training for Clinical Research Professionals (Archived Recording) | Page 205
- Real-World Monitoring: Tips for Success and Sanity (On-Site, Archived Recording) | Page 178
- Site Management and the Art of Assertiveness ( Archived Recording) | Page 205
- Soft Skills Development for Clinical Research Professionals (Core Curriculum) | Page 103
- Strategies for Active Listening (Web) | Page 189
- Strategies for Building High-Performing Clinical Research Teams (Web) | Page 189
- Strategies for Having Difficult Conversations (Web, Archived Recording) | Page 191

SOPs

- Five Key Strategic Steps for Developing Global SOPs (Archived Recording) | Page 205
- How to Write Great SOPs and Work Instructions (On-Site) | Page 73
- Implementation of Procedural Documents (Archived Recording) | Page 205
- Improving Readability of SOPs and Other Procedural Documents (Archived Recording) | Page 205
- Medical Writing Fundamentals: How to Write Regulatory Documents (On-Site) | Page 85
- Medical Writing Fundamentals: How to Write Regulatory Documents (Web, Archived Recording) | Page 170
- Preparing for SOP Inspection: An Auditor’s Perspective (Archived Recording) | Page 105
- SOP on SOPs and Procedural Document Templates (Archived Recording) | Page 205
- Writing Quality SOPs: Guidelines, Tools, and Templates for Easy SOP Creation (On-Site, Archived Recording) | Page 202
- Writing SOPs and Procedural Documents: Strategies for Creating Readable Documents (Archived Recording) | Page 205

Source Documentation

- Best Practices to Become a Preferred Site (On-Site) | Page 38
- Electronic Source Data in Clinical Investigations: Navigating the Final FDA Guidance (Web, Archived Recording) | Page 144
- eSource and Mobile Technology Initiatives: Data Management Considerations (Web) | Page 145
- Source Documentation Best Practices (On-Site) | Page 104
- Strategies for Ensuring Good Documentation Practices (GDP) (On-Site, Archived Recording) | Page 191

Statistics

- Applied Clinical Statistics in Risk-Based Monitoring (On-Site) | Page 123
- Design and Conduct of Clinical Trials: Design Requirements, Statistical Issues, and Clinical Protocols (On-Site) | Page 51
- Introduction to Statistics for Non-Statisticians (Web, Archived Recording) | Page 165
- Statistical Concepts for Non-Statisticians (Core Curriculum) | Page 105

Study Feasibility

- Study Feasibility: Eliminating Low and Late Enrollment (On-Site, Archived Recording) | Page 193

Study Site Start-Up

- Clinical Trial Start-Up: Effective Planning for Sponsors, CROs, and Sponsor-Investigators (On-Site) | Page 43
- Clinical Trial Start-Up: Using a Work Breakdown Structure (WBS) for Effective Planning (Web, Archived Recording) | Page 133
- Study Site Start-Up: Opening and Managing a Successful Clinical Research Site (On-Site) | Page 107
- Study Site Start-Up: Organization and Management Tips for the Novice Clinical Research Site (On-Site, Archived Recording) | Page 194
- NEW! A Systematic Approach to Study Start-Up: Improving Site Activation (Web, Archived Recording) | Page 195
<table>
<thead>
<tr>
<th><strong>Content by Subject</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sunshine Act</strong></td>
</tr>
<tr>
<td>Clinical Trials and the “Sunshine Act”: The Effect on the Clinical Research Industry (Web, Archived Recording)</td>
</tr>
<tr>
<td><strong>Team Building</strong></td>
</tr>
<tr>
<td>Making Good Teams Better: Taking Your Cross-Functional Global Team to the Next Level (Archived Recording)</td>
</tr>
<tr>
<td>Strategies for Building High-Performing Clinical Research Teams (Web)</td>
</tr>
<tr>
<td><strong>Training Skills</strong></td>
</tr>
<tr>
<td>Design Considerations for GCP Training Programs (On-Site, Archived Recording)</td>
</tr>
<tr>
<td>Developing Effective Training and Facilitation Skills in Clinical Research: An Application-Based Course (On-Site)</td>
</tr>
<tr>
<td>NEW! Effective Use of Tools, Job Aids, Process Maps, and Checklists for Project Managers and Clinical Research Teams (Web)</td>
</tr>
<tr>
<td>Strategies for Developing Effective Training and Facilitation Skills in Clinical Research (On-Site, Archived Recording)</td>
</tr>
<tr>
<td>Tools for Trainers: Clinical Research Job-Aids and Checklists (Archived Recording)</td>
</tr>
<tr>
<td><strong>Trial Master Files</strong></td>
</tr>
<tr>
<td>Centralized TMF Management: The CRO Sponsor Partnership (Web, Archived Recording)</td>
</tr>
<tr>
<td>eTMF Implementation Strategies (Web, Archived Recording)</td>
</tr>
<tr>
<td>eTMF Quality Oversight: A Risk-Based Approach (Web, Archived Recording)</td>
</tr>
<tr>
<td>TMF/eTMF Audit Strategies (Web, Archived Recording)</td>
</tr>
<tr>
<td>TMF/eTMF Regulatory Agency Expectations, Inspections, and Findings (Web, Archived Recording)</td>
</tr>
<tr>
<td>Trial Master Files: Why They Are Important and How to Organize Them Workshop (In-Person and Web)</td>
</tr>
<tr>
<td>Trial Master File (TMF) for Research Sites: Set Up and Maintenance (Archived Recording)</td>
</tr>
<tr>
<td>Trial Master File (TMF) for Sponsors: Set-Up and Maintenance (Web, Archived Recording)</td>
</tr>
<tr>
<td>Use of Notes to File in Clinical Trial Essential Documentation (Web, Archived Recording)</td>
</tr>
<tr>
<td><strong>Vendor Management</strong></td>
</tr>
<tr>
<td>Approaches to Address Challenges in Vendor Management (Web, Archived Recording)</td>
</tr>
<tr>
<td>Auditing Sponsors and CROs: Deconstruction and Application of the FDA’s Compliance Program Guidance Manual (Web, Archived Recording)</td>
</tr>
<tr>
<td>Best Practices for Hosting a Client Audit (On-Site)</td>
</tr>
<tr>
<td>CRO Partnership Management (Web, Archived Recording)</td>
</tr>
<tr>
<td>CRO Selection Criteria, Evaluation, and Establishing the Relationship (Archived Recording)</td>
</tr>
<tr>
<td>Establishing a Vendor Management Program (Archived Recording)</td>
</tr>
<tr>
<td>Managing Risks in Outsourced Clinical Trials: Practical Approaches and Tools (Web, Archived Recording)</td>
</tr>
<tr>
<td>Re-Engineering the RFP and Bid Defense Meeting to Effectively Manage Risk and Quality (Archived Recording)</td>
</tr>
<tr>
<td>Strategies for Conducting Vendor Audits (On-Site, Archived Recording)</td>
</tr>
<tr>
<td>Working with CROs: Building a Partnership for Project Success (On-Site)</td>
</tr>
<tr>
<td><strong>Writing</strong></td>
</tr>
<tr>
<td>Case Narrative Writing for Reporting Adverse Events (On-Site, Archived Recording)</td>
</tr>
<tr>
<td>Clinical Evidence Writing for Medical Device Regulatory Submissions (On-Site)</td>
</tr>
<tr>
<td>Effectively Writing Clinical Trial Protocols (On-Site)</td>
</tr>
<tr>
<td>How to Write Effective Monitoring Reports and Communications Workshop (On-Site)</td>
</tr>
<tr>
<td>Medical Writing Fundamentals: How to Write Regulatory Documents (On-Site)</td>
</tr>
<tr>
<td>Medical Writing Fundamentals: How to Write Regulatory Documents (Web, Archived Recording)</td>
</tr>
<tr>
<td>Monitoring Reports: 10 Rules of Effective Report Writing (Web, Archived Recording)</td>
</tr>
<tr>
<td>Monitoring Visit Reports for Medical Device Studies (Web, Archived Recording)</td>
</tr>
<tr>
<td>Report Writing for CRAs (On-Site)</td>
</tr>
<tr>
<td>Strategies for Ensuring Good Documentation Practices (GDP) (On-Site, Archived Recording)</td>
</tr>
<tr>
<td>Writing and Maintaining the EU Clinical Trial Authorization (On-Site, Archived Recording)</td>
</tr>
<tr>
<td>Writing and Updating the Investigator’s Brochure (Web, Archived Recording)</td>
</tr>
<tr>
<td>Writing Clinical Evaluation Reports (On-Site)</td>
</tr>
<tr>
<td>Writing Clinical Study Protocols (Web, Archived Recording)</td>
</tr>
<tr>
<td>Writing Clinical Study Reports for Diagnostic Studies (On-Site, Archived Recording)</td>
</tr>
<tr>
<td>Writing Protocols for Diagnostic Studies (On-Site, Archived Recording)</td>
</tr>
<tr>
<td>Writing Quality SOPs: Guidelines, Tools, and Templates for Easy SOP Creation (On-Site, Archived Recording)</td>
</tr>
<tr>
<td>Writing SOPs and Procedural Documents: Strategies for Creating Readable Documents (Archived Recording)</td>
</tr>
<tr>
<td>Writing the Clinical Study Report (Web, Archived Recording)</td>
</tr>
</tbody>
</table>
## Barnett’s Blended Curriculum Path: Clinical Research Associate

### Background:
Barnett’s CRA curriculum sets the highest standards for rigorous, focused and engaging study, developing learners’ innovative, collaborative, critical-thinking and problem-solving skills. Our courses are designed to appeal to all participants and help them make the critical connections between key principles and solving real challenges in their job settings.

### How it Works:
Barnett recommends the following three-level competency map for CRA training. For one low price per level, CRAs have two years to complete the curriculum, which can be tailored to each participant by mixing and matching the appropriate courses for your organization. All courses are accredited by Barnett and ACPE and combined include over 50 credit hours!

### Level 1: Minimal Experience (0-2 Years)

#### Core Curriculum Training
- Conducting Clinical Trials Under ICH GCP E6

#### Web Seminars (Choose 4)
- 10-Week Clinical Research Associate (CRA) On-Boarding Program*
- Adverse Event Monitoring for CRAs
- Building Relationships with Clinical Research Sites
- Essential Documentation in Clinical Trials at Research Sites
- Good Clinical Practice: Practical Application and Implementation
- Monitoring Clinical Drug Studies: Beginner

### Level 2: Moderate Experience (2-4 Years)

#### Core Curriculum Training
- Auditing Techniques for Clinical Research Professionals

#### Web Seminars (Choose 4)
- Corrective Action Plans: Essential Documentation of a Site’s Response to GCP Deficiencies
- FDA’s Bioresearch Monitoring (BIMO) Program: Inspection of Sponsors, CROs, and Monitors
- Good Clinical Practice: Practical Application and Implementation
- Implications of the FDA Guidance for a Risk-Based Approach to Monitoring and the EMA Reflection Paper on Risk-Based Quality Management in Clinical Trials
- Monitoring Visit Reports for Medical Device Studies
- Monitoring Clinical Drug Studies: Intermediate

### Level 3: Extended Experience (4+ Years)

#### Core Curriculum Training
- Clinical Project Management: Fundamentals of Project Management

#### Web Seminars (Choose 4)
- 10-Week Final ICH GCP E6 R2: Risk-Based Monitoring Plan Development Series*
- Cases in Advanced GCP: A Problem-Solving Practicum
- Corrective Action Plans: Essential Documentation of a Site’s Response to GCP Deficiencies
- Current FDA and EMA Inspection Findings: Lessons Learned
- Electronic Informed Consent Guidance: Regulatory Updates
- Final ICH GCP E6 R2: Implementing Risk Management Approaches for Compliance
- Inspection Readiness: Understanding BIMO Inspection Requirements for Sponsors, CROs, Monitors and Investigators
- Leading Teams in a Changing Clinical Research Environment
- Managing CRAs to Improve Performance and Study Outcomes
- Monitoring Plan Development
- Overseeing Teams and Projects
- Protocol Deviations: Documenting, Managing, and Reporting
- “Risk-Based Thinking”: How Monitors Can Develop an Auditor’s Perspective
- Root Cause Analysis: Applying the Concept for Better Study Compliance Management
- Strategies for Active Listening
- Strategies for Building High-Performing Clinical Research Teams
- Strategies for Having Difficult Conversations
- A Systematic Approach to Study Start-Up: Improving Site Activation

### Included with All Levels:
- **eLearning:** Barnett’s On-Demand GCP for Sponsors and CROs

### Recommended Reading:
- 2018 Good Clinical Practice: A Question & Answer Reference Guide
- 2019 CFR Regulations, ICH, and EU Directives Reference Book

### Cost: $5,000
*For the 10-Week Clinical Research Associate (CRA) On-Boarding Program or the 10-Week Final ICH GCP E6 R2: Risk-Based Monitoring Plan Development Series Web Seminars, please add $500

### To Register:
Simply select your courses and contact Barnett at +1 781.972.5400 or toll-free in the U.S. at 800.856.2556. Course schedules can be viewed on our website at: barnettinternational.com.
## Barnett's Blended Curriculum Path: Clinical Research Coordinator

### Background:
Barnett's CRC curriculum sets the highest standards for rigorous, focused and engaging study, developing learners' innovative, collaborative, critical-thinking and problem-solving skills. Our courses are designed to appeal to all participants and help them make the critical connections between key principles and solving real challenges in their job settings, and in particular, those encountered at clinical research sites.

### How it Works:
Barnett recommends the following three-level competency map for CRC training. For one low price per level, CRCS have two years to complete the curriculum, which can be tailored to each participant by mixing and matching the appropriate courses for your organization. All courses are accredited by Barnett and ACPE and combined include over 50 credit hours!

### Level 1: Minimal Experience (0-2 Years)
#### Core Curriculum Training
- Conducting Clinical Trials Under ICH GCP E6

#### Web Seminars (Choose 4)
- 10-Week CRA & CRC Beginner Program*
- 10-Week Clinical Research Coordinator (CRC) On-Boarding Program*
- Drug Development and FDA Regulations
- Essential Documentation in Clinical Trials at Research Sites
- Final AE Regulatory Guidance: Reporting/Communication of Safety Information from Clinical Trials to IRBs
- Final FDA Guidance: How to Complete the Form FDA 1572, Adequately and Accurately

**Included with All Levels:**
- Web Seminars (Choose 4)
- Core Curriculum Training

**Recommended Reading:**
- 2018 Good Clinical Practice: A Question & Answer Reference Guide
- 2019 CFR Regulations, ICH, and EU Directives Reference Book

**Cost:** $5,000

**To Register:**
Simply select your courses and contact Barnett at +1 781.972.5400 or toll-free in the U.S. at 800.856.2556. Course schedules can be viewed on our website at: barnettinternational.com.

*For the 10-Week CRA & CRC Beginner Program, 10-Week Clinical Research Coordinator On-Boarding Program or the 10-Week Clinical Research Financial Certification Program Web Seminars, please add $500

### Level 2: Moderate Experience (2-4 Years)
#### Core Curriculum Training
- Auditing Techniques for Clinical Research Professionals

#### Clinical Project Management: Fundamentals of Project Management

#### Web Seminars (Choose 4)
- Corrective Action Plans: Essential Documentation of a Site’s Response to GCP Deficiencies
- Developing and Negotiating Research Site Clinical Study Budgets and Contracts
- Ensuring Success Through Smarter Site Selection and Study Feasibility
- The GCPs of Essential Documents
- Good Clinical Practice: Practical Application and Implementation

### Level 3: Extended Experience (4+ Years)
#### Core Curriculum Training
- Clinical Project Management: Advanced Concepts in Project Management

#### Web Seminars (Choose 4)
- 10-Week Clinical Research Financial Certification Program: Setting Up Compliant Financial Operations and Budgets*
- Clinical Research Financial Management for Investigative Sites
- Correcive Action Plans: Essential Documentation of a Site’s Response to GCP Deficiencies
- Developing and Negotiating Research Site Clinical Study Budgets and Contracts
- Electronic Source Data in Clinical Investigations: Navigating the Final FDA Guidance
- Final AE Regulatory Guidance: Reporting/Communication of Safety Information from Clinical Trials to IRBs
- Final ICH GCP E6 R2: Implementing Risk Management Approaches for Compliance
- Incorporating Denials Management into Clinical Research Billing

**Recommended Reading:**
- Investigator Initiated Trials: Roles and Responsibilities
- Minimizing Risk in Negotiating Clinical Trial Contracts and Budgets
- Negotiation Skills for Clinical Research Professionals
- Preparing Clinical Research Sites for FDA Inspections
- Recent Trends in Noncompliance: Critical Review and Analysis of Recent Regulatory Letters and Communications from the FDA, EMA, and Health Canada
- Root Cause Analysis: Applying the Concept for Better Study Compliance Management
- Strategies for Active Listening
- Strategies for Having Difficult Conversations
- Subject Recruitment: Proactive Project Plans and Issues Management
- Use of Notes to File in Clinical Trial Essential Documentation

**Cost:** $5,000

**To Register:**
Simply select your courses and contact Barnett at +1 781.972.5400 or toll-free in the U.S. at 800.856.2556. Course schedules can be viewed on our website at: barnettinternational.com.
# Barnett’s Blended Curriculum Path: Project Manager

## Background:
Barnett’s Project Management curriculum sets the highest standards for rigorous, focused and engaging study, developing learners’ innovative, collaborative, critical-thinking and problem-solving skills. Our courses are designed to appeal to all participants and help them make the critical connections between key principles and solving real challenges in their job settings.

## How it Works:
Barnett recommends the following three-level competency map for Project Management training. For one low price per level, Project Managers have two years to complete the curriculum, which can be tailored to each participant by mixing and matching the appropriate courses for your organization. All courses are accredited by Barnett and ACPE and combined include over 50 credit hours!

## Level 1: Minimal Experience (0-2 Years)

### Core Curriculum Training
- Clinical Project Management: Fundamentals of Project Management

### Web Seminars (Choose 4)
- 30-Hour Clinical Project Management Fundamentals Certification Program®
- Auditing Sponsors and CROs: Deconstruction and Application of the FDA’s Compliance Program Guidance Manual
- Building Relationships with Clinical Research Sites
- CRO Partnership Management
- Drug Development and FDA Regulations
- Final FDA Guidance: How to Complete the Form FDA 1572, Adequately and Accurately

### Level 2: Moderate Experience (2-4 Years)

### Core Curriculum Training
- Auditing Techniques for Clinical Research Professionals

### Web Seminars (Choose 4)
- Clinical Trial Start-Up: Using a Work Breakdown Structure (WBS) for Effective Planning
- Corrective Action Plans: Essential Documentation of a Site’s Response to GCP Deficiencies
- CRO Partnership Management
- Developing Clinical Study Budgets for Sponsors
- Effective Use of Tools, Job Aids, Process Maps, and Checklists for Project Managers and Clinical Research Teams
- FDA’s Bioresearch Monitoring (BIMO) Program: Inspection of Sponsors, CROs, and Monitors
- Good Clinical Practice: Practical Application and Implementation

### Level 3: Extended Experience (4+ Years)

### Core Curriculum Training
- Clinical Project Management: Advanced Concepts in Project Management

### Web Seminars (Choose 4)
- Approaches to Address Challenges in Vendor Management
- Cases in Advanced GCP: A Problem-Solving Practicum
- Clinical Trial Start-Up: Using a Work Breakdown Structure (WBS) for Effective Planning
- Corrective Action Plans: Essential Documentation of a Site’s Response to GCP Deficiencies
- Current FDA and EMA Inspection Findings: Lessons Learned
- Effective Use of Tools, Job Aids, Process Maps, and Checklists for Project Managers and Clinical Research Teams
- Final ICH GCP E6 R2: Implementing Risk Management Approaches for Compliance
- Inspection Readiness: Understanding BIMO Inspection Requirements for Sponsors, CROs, Monitors and Investigators
- Managing Risks in Outsourced Clinical Trials: Practical Approaches and Tools

### Included with All Levels:
**eLearning:**
- Barnett’s On-Demand GCP for Sponsors and CROs

### Recommended Reading:
- *2018 Good Clinical Practice: A Question & Answer Reference Guide*
- *2019 CFR Regulations, ICH, and EU Directives Reference Book*

### Cost: $5,000
- For the 30-Hour Clinical Project Management Fundamentals Certification Program Web Seminar, please add $500

### To Register:
Simply select your courses and contact Barnett at +1 781.972.5400 or toll-free in the U.S. at 800.856.2556. Course schedules can be viewed on our website at: barnettinternational.com.
What is a “Hands-On” Workshop?

Barnett “Hands-On” Workshops are designed to provide intensive, hands-on training in a highly targeted clinical research topic area in a very interactive and engaging learning environment. Whether attending in-person or on the web, learners will gain an in-depth knowledge of the topic area and practice in applying the content on-the-job through this highly effective training approach.

By inter-mixing instructor-led presentations with facilitated group and individual activities, learners will be able to share experiences, discuss emerging trends, and problem-solve with other participants.

Learners will also have the opportunity to reinforce concepts presented by applying newly-learned skills and knowledge to case studies or to a current work project, document or challenge. Each workshop includes take-away tools and products for application and reference as learners return to their work environments.

Workshops are 6 contact hours in length and available in-person or on the web. To focus on the customized application of the exercises, **registration for both the in-person and web-based workshops are for individual registrants only.** Workshop size will be limited to 12 individual participants in order to facilitate the numerous activities and ensure maximum interaction among learners.

**Adult Learning Principles in Action**

Adult learners have the following unique needs which Barnett’s workshop-type learning experience can help address:

- **Experience** – adults have considerable life experience which leads them to look for opportunities to speak, participate, and contribute during learning experiences.
  Barnett’s workshop design minimizes lecture time, clearing the schedule for more participatory learning activities.

- **Self-Esteem** – adults have a strong need to maintain their self-esteem.
  Barnett’s workshop activities allow adult learners the chance to increase their competency with skills and behaviors, enhancing self-esteem.

- **Relevance** – adults want courses that focus on real-life tasks with a strong how-to focus.
  The unique workshop learning experience provides learning objectives that are hands-on and practice-oriented.

- **Benefit** – adult learners need to know why the learning is important and see progress being made.
  Barnett’s workshops provide a structured approach to learning about a focused problem and practicing skills to solve the problem.

- **Time Orientation** – adults wish to focus on current issues and materials that are immediately important.
  Barnett’s workshops are designed around our most popular curriculum content and provide take-home tools and skills for immediate application on the job.

- **Participation** – adults are accustomed to being active and need opportunities to actively participate in the learning process.
  The workshop format is structured such that the majority of “classroom” time is spent on applying skills and knowledge and receiving feedback.

- **Self-Direction** – adults are accustomed to making their own decisions and being consulted on how best to accomplish their tasks.
  Workshop participants are encouraged to bring real-life work examples or current projects to the workshop for direct application of workshop topics and skills.

**System Requirements For Web-Based Workshops:**

WebEx offers cross-platform, unmatched support across a wide range of devices. Supported computer operating systems include Windows, Mac, Linux, and Solaris. Browser support includes Internet Explorer, Microsoft Edge, Google Chrome, Mozilla Firefox, and Safari. You can also download the free WebEx Meetings app to your Apple, Android, or Amazon smartphone or tablet. You can always test your system at: BarnettWebSeminars.webex.com. In the panel on the left side, select Setup – Training Manager and follow the on-screen prompts.

**Registration:**

Registration is limited to individual registration only. Registration can be accessed online at: barnettinternational.com. Or by calling +1 781.972.5400 or toll-free in the U.S. 800.856.2556.

After registering, you will receive an invoice receipt. For web-based workshops, you will also receive an email confirmation that provides you with the Web Seminar link and audio connection information. For in-person workshops, registration includes a Networking Lunch. Prior to the start of the course, participants will receive comprehensive course materials. Upon completion, Barnett International attendance certificates will be provided.

**Accreditation:**

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education (ACPE). Workshop participants will receive continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

**Custom Versions For “Hands-On” Workshops Are Available:**

Have multiple team members who need training? Want to tailor course material to your organization’s processes and SOPs? Barnett Workshops can be customized to fit your needs. For more information, please contact Naiila Ganatra at +1 215.413.2471 or nganatra@barnettinternational.com.
In-Person and Web Seminar Workshops

In-Person and Web Seminar Workshops
Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.

Case Report Form Design, Strategy, and Standards

Course Description
According to the Society for Clinical Data Management (SCDM) Good Clinical Data Management Practices (GCDMP): “…no document in a clinical trial (other than the study protocol) is more important than the instrument designed and used to acquire data. The quality of the data collected relies first and foremost on the quality of this instrument. Regardless of the time and effort spent conducting the trial, the correct data points must be collected; otherwise, a meaningful analysis of the study’s outcome may not be possible. Therefore, it follows that the design, development, and quality assurance of such an instrument must receive the utmost attention.”

Other regulations, such as the ICH Good Clinical Practice E6 Guideline, identify the Case Report Form (CRF) as one of the essential documents for a clinical trial. Therefore, it is imperative to understand and implement the best practices of the CRF design process. That includes making sure all the protocol-required data are collected, ensuring the design of the CRF minimizes errors, and keeping the study coordinator in their normal workflow.

It is also important to consider the future compilation of data from multiple clinical trials for agency submission and the assurance that data collection is consistent, concise, and compatible, hence, the need for standards. CDISC and CDASH are instrumental in the establishment of these standards.

This workshop will discuss the principles of good CRF design, the timing of CRF design in relation to clinical trial start-up, and the team that will contribute to the data collection recommendations. Participants will review a sample protocol and determine which CRFs will be required to collect the appropriate data. We will discuss design philosophies and rationales and apply these principles in reviewing CRFs to critique design. We will also discuss the resources that are utilized in data collection recommendations. Participants will review a sample protocol and determine which CRFs will be required to collect the appropriate data. We will discuss design philosophies and rationales and apply these principles in reviewing CRFs to critique design. We will also discuss the resources that are utilized in data collection recommendations.

The module based on best practices for CRF design as documented in the SCDM GCDMP will provide the understanding of the expectations for purposeful CRF design.

Note: This workshop will deal with the principles and fundamentals relating to data elements for good CRF design. It is not intended as a training in a software application to create the CRF.

Learning Objectives
- Identify data requirements/CRFs based on protocol review
- Evaluate the rationale for consistency in data collection
- Discuss CDASH standards for data collection in CRFs
- Identify data compatibility issues and solutions to ensure appropriate data integration
- List the “best practices” for CRF design

Course Outline
Day One: 9:00 a.m. – 4:00 p.m. Eastern
- CRF Definition, Purpose, Considerations
- Best Practices in CRF Design
- External Data Integration
- CDISC/CDASH

Interactive Activities
- Learners should bring a case study to describe the CRF design process in their environment, and be prepared to discuss pitfalls or success stories based on their experiences
- Review the ICH GCP E6 Guideline and two sample CRFs (provided). Based on what they have read, learners will make the necessary amendments to the CRF to ensure compliance with this guideline
- Review the sample protocol and schedule of events, and prepare a list of the CRFs which will be required for this study
- Take the Sample Standard CRF Specifications document and amend according to the sample protocol provided
- Utilize the sample protocol and schedule of events to “design” Efficacy CRFs required by the protocol (Spirometry Testing, ABECB Symptom Assessment, or Evaluation of Clinical Response), and then add this form to the CRF Specification that was completed in the previous exercise
- Students will review the CDASH document and prepare a rationale document that they can use to “influence” management on the benefits using CDASH initiative

Who Should Attend
- Case Report Form Designers
- Clinical Data Managers
- Clinical Research Associates
- Project Managers

Instructor
Denise G. Redkar-Brown, MT

Course Dates and Locations
May 26, 2020
Online via WebEx
Course #: BI13906
$850 by April 24
$1,050 after April 24
ACRP Members: Receive 10% off!
NOTE: This course is for individual registrants only.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Participants will receive 6 hours (0.6 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
How to Write Effective Monitoring Reports and Communications

Course Description
Clinical Monitors (CRAs) must document many details of the happenings at investigational sites, including Confirmation Letters to sites, Monitoring Visit Reports, Follow-Up Letters to sites, Telephone Contact Reports, Email/Faxes to sites, and Queries and Notes to File (NTF). All of these become essential documents as they demonstrate the compliance of the monitor and, thus, the sponsor in the conduct of the clinical trial. These are all eligible for inspection by the regulatory authorities at any time both during and after the study is completed and submitted for product approval. This is the same regulation for drugs, biologics, and devices. Effective writing skills are, therefore, extremely important so that we show the diligence and detail involved in effective monitoring. Increasingly, we notice that the Confirmation Letters, Monitoring Visit Reports, and Follow-Up Letters have discrepancies. This may be simple date inconsistencies, or critical data credibility issues. It is important that the monitor be aware of the importance of these issues in the review of study documentation. This course will provide some practical solutions to addressing document deficiencies as well as provide a practical understanding of how these documents provide evidence for the regulated activities of the investigator and the sponsor.

The monitor visit starts with a well-written Confirmation Letter informing the investigator and investigator’s staff of the expectations of the upcoming visit. An accurate and complete Monitoring Visit Report details all of the activities of the monitor in meeting the sponsor’s obligation during the actual monitor visit, including action items and demonstrable management of the site by the monitor. Queries must be well-written if they are to be understood by the study coordinator or Principal Investigator at the site. The Follow-Up Letter, which must detail the progress made on this visit and highlight any deficiencies for which the monitor expects resolution must agree with the action items listed in the Monitoring Visit Report. Written documentation of Telephone Contacts must be direct, accurate, and timely; other communications between monitor visits need to be associated with the proper events as well. This course will provide an understanding of the information required, importance of timely and well-documented discussions, and proper methods of filing this key documentation.

Learning Objectives
• Describe the requirements of documenting monitoring activities
• Implement strategies for effective writing outside of the monitor visit
• Effectively manage site and sponsor activities and document appropriately
• Recognize the importance of a well written Monitoring Visit Report
• Evaluate well-written and poorly written material from actual studies
• Identify the appropriate use of Notes to File in both patient-related and study-related situations
• Write effective documents for various types of monitor visits

Who Should Attend
• Clinical Research Associates/Monitors
• Lead Clinical Research Associates
• Contract Clinical Research Associates
• Clinical Research Associate Managers
• Project and/or Study Managers
• Project and/or Clinical Trial Assistants
• Quality Assurance Personnel

Instructor
Nikki Christison, B.S., C.C.R.A., T.I.A.C.R.

Course Outline
(Lunch Break will run from approximately 12:00 - 1:00 p.m.)
Day One: 9:00 a.m. – 4:00 p.m. Eastern
• Confirmation Letters, Follow-Up Letters
• Queries, Monitoring Visit Report
• Communication Outside the Monitor Visit (telephone, email, faxes, Notes to File)

Interactive Activities
• Review a Monitoring Visit Report and evaluate examples of well-written and poorly written documentation of issues, deviations, and action items for follow-up
• Write sections of a Monitoring Visit Report based on a scenario provided
• Draft a Follow-up letter given some issues to review in the Monitoring Visit Report
• Critique Confirmation and Follow-up letters
• Discuss the importance of providing consistent information
• Critique a Telephone Contact Report
• Discuss the value of proper filing of documentation related to the visit but conducted outside of the actual visit
• Review several scenarios and associated NTFs and evaluate if the NTF was the most appropriate manner for managing and documenting the issue
• Learners are encouraged to bring specific work-related document samples for evaluation in light of best practices and GCP standards

Accreditation available upon request.
Trial Master Files: Why They Are Important and How to Organize Them

Course Description
The Trial Master File is a collection of the essential documents for a sponsor to record how they have fulfilled their obligations for a clinical trial. The Code of Federal Regulations states in 21 CFR 312.50 that, “Sponsors are responsible for… ensuring that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND.” The European Directive 2005/28/EC states that, “the trial master file shall consist of essential documents, which enable both the conduct of a clinical trial and the quality of the data produced to be evaluated.” ICH GCP E6 Guideline, Section 8.1 defines these essential documents as those that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements. They are all also eligible for inspection by the regulatory authorities at any time during and after the study is completed and submitted for product approval. This is the same regulation for drugs, biologics and devices. It is, therefore, paramount that these documents are filed in a way to make them immediately accessible for use by the study team and for regulatory inspection. This module will provide some practical solutions to meet these challenges.

Participants will review the content that is required of a Trial Master File for drugs and devices for a clinical trial, and will acquire a practical understanding of how these documents provide evidence for the regulated activities of the investigator and the sponsor.

The activities of set-up, maintenance, and quality assurance will be discussed, as well as common deficiencies and challenges. The need for an effective Standard Operating Procedure (SOP) will also be examined.

In today’s regulatory environment, the files must be “audit ready” at all times. Regulatory authorities may contact the sponsor and request a particular document Operating Procedure (SOP) will also be examined.

The activities of set-up, maintenance, and quality assurance will be discussed, as well as common deficiencies and challenges. The need for an effective Standard Operating Procedure (SOP) will also be examined.

In today’s regulatory environment, the files must be “audit ready” at all times. Regulatory authorities may contact the sponsor and request a particular document Operating Procedure (SOP) will also be examined.

Learning Objectives
• Describe the required components of a Trial Master File
• Implement strategies for effective filing of required documents
• Effectively manage the Trial Master File
• Recognize the importance of a well-organized Trial Master File
• Investigate common deficiencies in filing systems
• Participate in filing some key documents and discuss the rationale for the placement of such documents

Course Outline
(Lunch Break will run from approximately 12:00 - 1:00 p.m.)
Day One: 9:00 a.m. – 4:00 p.m. Eastern
• Required Components of a Trial Master File
• Set Up and Maintenance of a Trial Master File
• SOP Review and Critique
• Practical Experience Filing Using a Sample Trial Master File
• Discussion of Common Deficiencies and Review of Challenges Presented by Participants

Interactive Activities
• The pitfalls and challenges encountered in setting up a Trial Master File
• The challenges in maintaining an effective Trial Master File
• Critique a Standard Operating Procedure established as a sample policy
• Participate in actual filing of sample documents using the Drug Information Association Trial Master File Reference Model
• Discuss the value of proper filing of documentation related to the Trial Master File
• Learners are encouraged to bring specific work-related document samples, and will have the opportunity to evaluate these in light of best practices and GCP standards

Who Should Attend
• Lead Clinical Research Associates
• Clinical Research Associate Managers
• Project and/or Study Managers
• Project and/or Clinical Trial Assistants
• Clinical Operations Administrators
• Quality Assurance Personnel
• Sponsor and CRO personnel involved in set up, maintenance, and auditing of the Trial Master File for sponsors

Instructor
Donna W. Dorozinsky, R.N., M.S.N., C.C.R.C.

Course Dates and Locations
March 26, 2020
Philadelphia, PA 19103
Convene Commerce Square
Course #: STMA0320
$850 by February 24
$1,050 after February 24
By May 22
June 25, 2020
San Diego, CA 92101
San Diego Solamar
Course #: STMD0620
$850 by May 22
$1,050 after May 22

May 15, 2020
Online via WebEx
Course #: BI13894
$850 by April 17
$1,050 after April 17

ACRP Members: Receive 10% off!
NOTE: This course is for individual registrants only.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 6 hours (0.6 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-19-063-L01-P. Released: 10/19.
What Are Core Curriculum Courses?

Barnett International’s Core Curriculum courses are provided to you as In-Person 1-, 2-, or 3-day courses at state-of-the-art meeting venues. Courses are offered quarterly at locations on both the East and West Coasts of the U.S. Barnett’s goal is to provide you with a unique combination of strategy development and practical, hands-on content and course materials to enable you to get the most out of your training experience. Our experienced instructors offer application-focused instruction that is based on content that can be immediately applied on the job. The “Barnett Difference” is evident through our high-quality content, instructors who are not only trainers experienced in adult learning but are also subject matter experts working in the field, our deep organizational understanding of the clinical research process, and through the rapid and tangible performance improvements we deliver.

What Are the Benefits?

- Face-to-face interaction with industry experts
- Real-world examples and hands-on learning activities
- Practical, application-based content with job aids and tools to take back to your setting
- The ability to ask questions and learn from others’ experiences and challenges
- Networking opportunities with others in the clinical research field
- Designed for core competency training

Interactive Components:

Barnett’s Core Curriculum includes highly engaging interactive exercises which are based on “on-the-job” situations and issues that are regularly encountered. Exercises include:

- Case Study Reviews
- Mock Audits
- Self-Assessments
- Personal Inventories
- Group Discussions
- Analysis of Scenarios
- Roundtable Discussions
- Question and Answer Sessions
- Document Verification Simulations
- Role-Plays
- Plan Development
- …and many more!

Registration:

Registration for Core Curriculum courses can be accessed online at: barnettinternational.com. By calling +1 781.972.5400 or toll-free in the U.S. 800.856.2556. Or submitting the Registration Form (on page 239) with payment to Barnett Customer Service.

After registering, you will receive an email confirmation that provides you with all of the details you need for the course. Registration includes a Networking Lunch which will be served each training day. Prior to the start of the course, participants will receive comprehensive course materials. Upon completion, Barnett International attendance certificates will be provided.

Accreditation:

Barnett International is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CEUs). Core Curriculum participants will receive continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

Custom Seminars Available:

Have multiple team members who need training? Want to tailor course material to your organization’s processes and SOPs? Barnett’s Core Curriculum courses can be customized to fit your needs and brought to your team.

For more information, contact Naila Ganatra at +1 215.413.2471 or nganatra@barnettinternational.com.
Advanced Clinical Research Coordinator (CRC) Training

Course Description
This refresher course provides additional training for the clinical research coordinator (CRC) with greater than three years of experience. We will start out with a review of the key governing regulations and guidelines in clinical research, and will then discuss trends, management issues and the financial impact of clinical research on the research site. We will also cover inspection preparation, as well as CAPA planning and implementation. This course will also focus on investigator responsibilities and developing processes that will ensure adequate investigator oversight.

Learning Objectives
• Describe the relevant regulations and guidelines
• Discuss trends in clinical research
• List and prioritize study management activities
• Discuss study management issues
• Describe financial impacts and trends
• Prepare for an inspection
• Develop Corrective and Preventive Action Plans (CAPA)
• Ensure adequate training and documentation of training of clinical research staff

Who Should Attend
• This course has been developed for the individual CRC, nurse coordinator, site manager or investigator who has a solid background in the FDA Code of Federal Regulations (CFRs) and the ICH GCP E6 Guideline and is involved in or manages the daily operation of clinical research at a trial site. The course can also be beneficial to the CRA and members of the sponsor/CRO industry.

Interactive Activities
• Case scenarios, case study, and site priorities exercises are among the scheduled activities in this interactive class

Instructors
This course will be taught by one of the following instructors:
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.
Lily Romero, P.A., C.C.R.C.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

What Participants Say About Barnett Seminars:
“Very informative, I will find what I learned to be very useful in my job.”
Advanced Good Clinical Practice: Practical Application and Implementation

Course Description
This course provides an advanced, in-depth review of the structural elements of Good Clinical Practice (GCP). Participants will learn practical application of GCP regulations and guidelines for critical components of the clinical research process. Incorporating the updates in ICH E6 R2, we will discuss how clinical research team members can implement systems to manage quality throughout the trial process.

Specific attention will be given to how quality systems, or a lack thereof, impact overall data quality and regulatory risk.

This program is designed for professionals with at least two years of experience in the clinical research industry.

Learning Objectives
• Describe the elements of functional Quality Systems for Sponsors, Institutional Review Boards (IRBs), and Clinical Investigators
• Identify the universal and local components of GCP
• Explain the differences between the legal and procedural elements of GCP
• Describe the overlap between GCP and Good Manufacturing Practice (GMP)
• Recognize key differences in pharmaceutical, device, and biologics GCP
• Examine recent trends in non-compliance
• Develop and implement site-specific approaches for corrective action of non-compliance

Who Should Attend
• This course is recommended for experienced Clinical Quality Assurance Professionals, Clinical Research Associates, Project Managers, Investigators, Study Coordinators, and GCP-Focused Regulatory Affairs Professionals.

Interactive Activities
• Document Reviews
• Mock Audit/Inspection Exercise
• Case Study Scenario Problem Solving
• Group Discussions of Best Practices

Instructors
This course will be taught by one of the following instructors:
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.
Elizabeth Ronk Nelson, M.P.H.
Lily Romero, P.A., C.C.R.C.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• Principles of GCP: Different Perspectives: Examination; application; implementation
• New Developments and Emerging Trends in GCP
• The “Forgotten” Elements of GCP: Regulations; laws; guidelines
• Quality Systems: The Roadmap to GCP: Quality control; quality assurance; quality improvement

Day Two: 8:30 a.m. – 5:00 p.m.
• Quality Risk Management (QRM) in Clinical Trials: Application of risk assessment in the review of protocols
• The Role of Standard Operating Procedures in GCP: Rationale; development; training; implementation; maintenance
• GCP Across Investigational Products: Drugs; devices; biologics
• Are We There Yet? Recent non-compliance issues with discussion of Corrective and Preventive Action planning
Advanced Post-Marketing Pharmacovigilance Auditing

Course Description
The European Medicines Agency’s (EMA) post-marketing Pharmacovigilance (PV) regulations known as the EMA PV Modules are designed with the expectation that companies adhere to this new global “gold” standard regarding the receipt, processing, managing, maintenance, and submissions of Adverse Event (AE) data to the relevant health authorities. Not only are these standards applicable to EU-based companies, but any company marketing products (drugs or devices) on a global level. We will review the FDA and EMA expectations and apply them to the various PV audits.

This course is designed for those that already have some post-marketing PV experience (either experienced auditors or practical hands-on PV staff). Learners will receive training on how to audit PV at the local level, but to do it with a global perspective. The course will focus on understanding PV agreements, and reporting to health authorities and the relevant auditing mechanisms, including the generation of the annual audit plan based on a risk assessment; generating audit agendas once the plans are put into play; understanding Safety Data Exchange Agreements (SDEA); understanding Periodic Safety Update Reports (PSURs); requesting pre-audit information of PV departments in-house, at a license/marketing partner, vendor, or distributor; and generating the correct categorization of findings for the audit reports.

Learning Objectives
• Determine whether Safety Data Exchange Agreements are adequate
• Determine whether PSURs are covering the correct information and timeframes
• Prepare annual PV audit plans
• Prepare relevant PV audit agendas based on the type of PV audit required
• Request relevant PV data as part of the audit preparation activities
• Conduct PV audits with a focus on different PV topics
• Prepare audit findings and categorizations

Who Should Attend
• Heads of Pharmacovigilance Quality Assurance Departments
• Pharmacovigilance Auditors
• Heads of Pharmacovigilance Departments
• Relevant Pharmacovigilance Staff
• PV Safety Scientists
• Quality Assurance Staff responsible for pharmacovigilance self-inspections

Instructors
This course will be taught by one of the following instructors:
Sharon Donatucci
Vaska Tone

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Who Should Attend
• Heads of Pharmacovigilance Quality Assurance Departments
• Pharmacovigilance Auditors
• Heads of Pharmacovigilance Departments
• Relevant Pharmacovigilance Staff
• PV Safety Scientists
• Quality Assurance Staff responsible for pharmacovigilance self-inspections

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• EMA & FDA Safety Reporting: When and How?
• Who to Audit: Internal Systems, Affiliates, License Partners, Vendors, and Distributors
• PV Audit Plans, Scope and Agendas
• Understanding Different Contracts/Agreements
• Hands-on Exercise:
  • Designing an annual audit plan – risk based
  • Preparing the correct scope for the various PV audits
  • Preparing the correct audit agenda (2, 3, or 4 day audits)

Day Two: 8:30 a.m. – 5:00 p.m.
• Auditor Preparation: PV Audit Questionnaires & Checklists
• PV Audit Conduct
• Hands-on Exercise:
  • Use of the pre-audit questionnaire – review of several examples
  • Use of PV Audit Checklists
  • Follow the AE: Review of PV tracker, source document(s), cases (MedWatch/CIOMS), submissions
  • Role Playing
Adverse Events: Managing and Reporting for Medical Devices

Course Description
This course provides a detailed and thorough introduction of FDA regulations for newcomers in the field of medical device safety: a comprehensive overview of the requirements, current approaches for professionals in the research and post-marketing areas, an overview of the emerging field of devices that deliver drugs or biologics, and an opportunity to discuss the challenges facing those reporting and managing adverse events in the medical device industry.

Learning Objectives
- Discuss the history, need, purpose of adverse event reporting in medical devices (device/safety vigilance)
- Define the terms related to reporting adverse events in clinical trials: seriousness, expectedness, and causality
- Describe current considerations in reporting adverse events in clinical trials: timing, terminology, consent, blinding, device-related versus procedural complication, and follow-up
- Describe the reporting requirements for adverse events observed in clinical trials involving devices
- Evaluate and express the safety issues and information sources for marketed products
- Explain the rationale underlying the reporting requirements of adverse events in marketed products
- Discuss why and how coding terminologies (including MedDRA) are used
- Summarize the considerations required when the device delivers a drug/biologic
- Critique the past and evolving roles of the FDA in device safety

Who Should Attend
- Clinical Trial Personnel (Monitors, Managers, Support staff, Data Entry) responsible for: 1) collecting, reviewing, and reporting adverse events occurring in clinical trials of new and marketed products; and 2) ensuring adverse event reporting compliance at the investigator site
- Quality Control Personnel involved in the investigation of adverse event reports
- Regulatory Affairs Personnel responsible for submitting safety reports to FDA and other health authorities
- Safety Surveillance Personnel responsible for the acquisition, classification, entry, analysis, and reporting of clinical trial and marketed products adverse events
- Medical Affairs Personnel responsible for safety-related decisions regarding product labeling, regulatory interactions, or customer communication.

Interactive Activities
- Adverse Event Reporting in Clinical Trials
- Analyzing the Key Concepts: Expectedness, Labeling, and Seriousness
- Case Studies
- Review and Evaluation of FDA Warning Letters

Instructors
This course will be taught by one of the following instructors:
Lee Truax-Bellows, M.S., FNP, C.C.R.A., RQAP-GCP
Glenda Guest, RQAP-GCP, C.C.R.A.

Course Outline

**Day One: 8:30 a.m. – 5:00 p.m.**
- Overview of Safety: History; need for safety surveillance and what it can accomplish; FDA regulations; Good Clinical Practices; CIOMS recommendations; ICH considerations
- Adverse Event Reporting in Clinical Trials: Review of FDA regulations, definitions, and concepts; Good Clinical Practices; IDE safety reporting
- Coding: Narrative descriptions; electronic records; coding principles, standardized dictionaries: COSTART, WHO-ART, and MedDRA

**Day Two: 8:30 a.m. – 5:00 p.m.**
- Adverse Event Reporting for Marketed Products: Managing domestic spontaneous reports: maximizing information, minimum requirements for a valid report; managing events from other sources: foreign, literature, and FDA; reporting requirements to the FDA and other authorities
- Considerations When a Device Delivers a Drug/Biologic: Overview of drug/biologic adverse event definitions and concepts; overview of reporting requirements in clinical trials and post-marketing
- FDA’s Role in Device Safety: FDA audit procedures; post-inspection reports and findings

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Adverse Events: Managing and Reporting for Pharmaceuticals

Course Description
This course provides an excellent introduction for newcomers to the field of drug and biologic product AE reporting, a comprehensive overview of current approaches and regulations for professionals in the field, and challenging questions and ideas for the experienced clinical research professional. This course contains medical device content related only to use in combination products.

Learning Objectives
- Explain the purpose and capability of AE reporting
- Review and apply the concepts of seriousness, expectedness, and causality
- Review how to describe, characterize, and document adverse events
- Discuss safety issues and reporting obligations associated with clinical trials and marketed products, including combination products
- Identify key concepts related to electronic records
- Discuss the use of various coding systems
- Describe the evolving role of the FDA in drug and biologics development

Who Should Attend
- Clinical Trial Personnel responsible for collecting, reviewing, and reporting investigational adverse events
- Safety Surveillance Personnel responsible for the acquisition, classification, entry, analysis, and reporting of adverse events in marketed products
- Regulatory Affairs Personnel responsible for submitting safety reports to FDA and international regulatory authorities
- Quality Control Personnel involved in the investigation of adverse event reports

Interactive Activities
- Routine Reporting in Clinical Trials
- Using MedWatch for 15-Day Alerts
- Practice Using Coding Terminology
- Review of FDA Warning Letters in the Clinical Trial Setting
- Review and Evaluation of FDA Warning Letters in the Post-Marketing Setting
- Analysis of AE Reports on Combination Products

Instructors
This course will be taught by one of the following instructors:
Glenda Guest, RQAP-GCP, C.C.R.A.
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Auditing Techniques for Clinical Research Professionals

Course Description
This workshop teaches practical, immediately usable techniques that top-notch Good Clinical Practice (GCP) auditors and FDA investigators employ. They include techniques that are useful when auditing clinical trials that employ Electronic Medical Records (EMR) and/or Electronic Data Capture (EDC). When monitors and auditors apply these techniques, they can better detect, correct, and prevent clinical study performance deficiencies at clinical sites and within their organizations. Significant updates to the seminar focus on the development and utilization of Quality Systems (QS) at clinical sites to improve their performance. The workshop will emphasize Simple Efficient & Effective QS processes that clinical site personnel can utilize and how monitors and auditors can help them develop and implement them.

Learning Objectives
- Apply auditing standards based in current law, regulations, and guidelines
- Utilize electronic systems to enhance your auditing techniques, allowing more efficiency in your daily monitoring or auditing activities
- Understand the role of quality systems in GCP, including techniques for detecting root causes of performance deficiencies and developing and implementing effective Corrective and Preventive Action (CAPA)
- Select investigators and records for auditing or special monitoring emphasis
- Conduct clinical investigator audits
- Detect, prove, and prevent scientific fraud and misconduct
- Learn techniques for writing audit plans and reports

Who Should Attend
- Clinical Quality Assurance Professionals who audit the quality of clinical trials
- Clinical Research Associates and Managers, Project Leaders, and Medical Monitors who want to enhance their effectiveness
- Regulatory Affairs Professionals responsible for GCP regulatory compliance
- Investigators, Study Coordinators and Trial Center Managers who want to learn how to prepare for FDA and sponsor audits and to improve the quality of their research activities

Interactive Activities
- Perform Data Trend Analysis
- Accomplish an Audit of Source Documents and CRFs
- Work on an Audit Team to Discuss and Present Findings

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Dates and Locations

<table>
<thead>
<tr>
<th>Date</th>
<th>Locations</th>
<th>Course #:</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 20-21</td>
<td>Boston, MA 02108</td>
<td>SFCB0120</td>
<td>$1,675 by Dec</td>
</tr>
<tr>
<td>March 30-31</td>
<td>Philadelphia, PA 19103</td>
<td>SFCO320</td>
<td>$1,675 by Feb</td>
</tr>
<tr>
<td>June 22-23, 2020</td>
<td>San Diego, CA 92101</td>
<td>SFC00620</td>
<td>$1,675 by May</td>
</tr>
</tbody>
</table>

ACRP Members: Receive 10% off!

Academic Discount
A $400 academic discount is available to those who qualify.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 15 hours (1.5 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-001-L01-P. Released: 1/19.

Day One: 8:30 a.m. – 5:00 p.m.
- The Standards: Important aspects of GCP-related law and regulations; Food, Drug, and Cosmetic Act, Title 18 Criminal Statutes, HIPAA, 21CFR 11, 50, 54, 56, 312, and 812; Corporate standards
- Trial Center Auditing Methods: Selecting centers to audit, auditing and inspection procedures and methodology, including special procedures for “e-trials”; differences between auditing and monitoring; Defining and determining the adequacy of source documentation; developing and implementing Simple, Effective, and Efficient Quality Systems to improve clinical site performance
- Fraud and Misconduct: Motives; discovering, reporting, and preventing fraud and misconduct, including special techniques for e-trials

Day Two: 8:30 a.m. – 5:00 p.m.
- Data Trend Analysis: Definition and description of this special auditing technique; multiple examples; how to practically use this technique; Special subsection on detecting the signs and symptoms of impeding failure at a trial center
- Auditing Techniques Exercise: Perform data trend analysis; audit to determine document validity and data accuracy; perform root cause analysis; build a CAPA; work individually and within a group of your peers
- Essential Documents: Define and prioritize; auditing the essential document binder or files; the legal and regulatory basis behind the EDs
- Enforcers and Enforcement: The compliance organizations in CDER, CBER and CDRH; FDA inspection results and consequences of adverse findings; how to manage a regulatory authority inspection; FDA’s Application Integrity Policy
- Summary of Auditing and QS Processes: Audit Planning, Notifications, Conduct, Reporting: Root Cause Analysis; developing and implementing CAPAs

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Basics of Post-Marketing Pharmacovigilance and the Beginner PV Auditor

Course Description
As of 2012, the “gold” standard of pharmacovigilance (PV) and adverse event (AE) reporting on a global level is based on the European Medicines Agency (EMA) PV Modules, which require that Quality Assurance (QA) be part of the quality management system (QMS), and that PV audits be performed at various levels and at varying sites. Although most Good Clinical Practice (GCP) experts are familiar with pre-marketing drug safety, there is a difference to post-marketing PV and the associated activities.

This is an introductory course for those unfamiliar with the EMA PV Modules or global reporting requirements. The basics of EMA (and FDA) expectations on the receipt, processing, reporting, and management of AEs for marketed products (drug and device), and how to prepare for auditing these systems will be presented. Learners will be shown the basic concepts of reportable events, timelines of reporting, what the global PV department is responsible for, and the audit process to be applied for both systematic internal audits as well as at affiliated offices and PV vendors. The course will include presentations, discussions, and problem-solving techniques using case studies applicable to both drug. Exercises are designed to help you understand what the PV process actually is and how to apply an auditing perspective.

Learning Objectives
- Recognize post-marketing PV expectations and compliance on a global level
- Review the EMA PV Modules at the basic level
- Determine PV reporting responsibilities applicable to global PV submissions
- Apply basic auditing concepts to assess PV compliance

Who Should Attend
- Heads of Pharmacovigilance Quality Assurance Departments (with limited PV Audit experience)
- Auditors transitioning into pharmacovigilance auditing
- Drug Safety Staff
- Quality Assurance Staff responsible for pharmacovigilance self-inspections
- Medical Information Staff
- Safety Physicians

Instructors
This course will be taught by one of the following instructors:
Sharon Donatucci
Vaska Tone

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- EMA PV Modules and FDA Safety Reporting Basics
- Systems Used in PV Data Gathering and Individual Safety Case Reporting (ICSRs)
- Understanding Requirement to Periodic Safety Update Reports (PSURs)
- Eudravigilance & Signal Detection
- Hands-on Exercise: Reviewing “AE Source Documents” & Resulting ICSRs

Day Two: 8:30 a.m. – 5:00 p.m.
- PV Audit Plans, Scope, and Agendas
- PV Audit Questionnaires and Checklists
- Current EMA/FDA PV inspection findings
- Hands-on Exercise: Drafting the audit agendas and checklists for:
  - System Audit
  - Affiliate Audit
  - Vendor Audit

What Participants Say About Barnett Seminars:
“"You will not leave class uninformed.""
Becoming a Clinical Research Investigator: Expectations and Responsibilities

Course Description
Industry trends indicate that the majority of physicians who participate in a research study do not return to do another. This costs the industry time, money and frustration in trying to identify new investigators, ensure adequate training, and support compliance at inexperienced sites. Additionally, the cost to the physicians acting as an investigator for the first time are possible loss of income, more time spent than anticipated, frustration, and possible inspection findings that are publicly posted. In this course, the core requirements, regulatory expectations, and practical approaches to becoming an industry research investigator are covered. Included are the expectations for setting up a research site and staff, what questions investigators should ask before taking on a study, and ongoing regulatory requirements for investigator oversight and Good Clinical Practices (GCPs). FDA regulations and applicable guidance documents will be explored as well as ICH GCP E6 for application to international trials.

Learning Objectives
- Review industry clinical research and regulatory requirements
- Describe investigator responsibilities in the context of study protocol oversight and GCP compliance
- Discuss basic requirements for setting up a research site including staffing and essential budget considerations
- Discuss questions to ask a sponsor before taking on a research study
- Recognize critical elements of human subject protection
- Discuss the requirements for investigational product management and maintenance of adequate and accurate records for research trials
- Recognize key requirements for patient safety management and regulatory reporting
- Discuss mandatory critical interactions with Institutional Review Boards (IRBs) or Ethics Committees (ECs)
- Explain the concepts of root cause analysis (RCA) and corrective and preventive action (CAPA) to improve compliance
- Examine recent trends in non-compliance

Who Should Attend
- Investigators
- Study Coordinators
- Site Managers
- Project Managers
- General Managers
- Project and Department Leads
- Clinical Research Associates
- Personnel that want to learn more about the regulatory expectations for a Clinical Research Investigator, site selection, Investigator training, or site set-up

Interactive Activities
- Practical Applications of FDA Guidance Documents
- Identification of Audit Preparation Best Practices
- Informed Consent Process and Signature Group Discussion
- Source Document to Case Report Form Issue Identification

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
Best Practices to Become a Preferred Site

Course Description
Mirror, Mirror, on the wall, who’s the fairest site of all? It could be you! What is a preferred site? How can you increase your site’s visibility? How does one assess feasibility to determine if a study is a good fit for your site/sponsor? What can a site do to ensure a clinical trial is operational? This workshop will explore best practices for FDA-compliant source and regulatory documentation and the tools that can help to get you there. Most non-compliance noted through monitor visits, regulatory inspections, and audits stem from inadequate and inconsistent documentation at sites. Learn how to best prepare for a monitoring visit or site audit/inspection. Learn techniques to better manage your regulatory files and prepare to answer sponsors, auditors, and inspectors regarding screening/enrollment numbers, subject withdrawal, informed consent, recruitment efforts, delegation of authority, protocol violations, and adverse events. Identify what is adequate source. What do I really need to file in my site master file, what are “extras” that will make my site preferred by sponsors? Evaluate how to best document PI oversight. Determine when to use a note-to-file and what constitutes an effective CAPA. Tips and tricks for managing the regulatory file will be provided through tools/worksheets/templates and interactive activities. Over 200 pages of templates and tools will be provided.

Learning Objectives
• Recognize the importance of quality in clinical trials by identifying key areas for improved documentation and communication
• Identify key factors in site selection
• Discuss the steps in evaluating a site from both the sponsor and site perspectives
• Implement best practices that will ensure successful completion of trials and preferred site status with sponsors
• Manage documentation of recruitment efforts effectively
• Manage potential document management inconsistencies proactively

Instructor

Who Should Attend
• Clinical Research Coordinators
• Site Managers
• Investigators
• Site Selection Personnel
• Clinical Research Associates who wish to help develop sites
• Quality Personnel

Interactive Activities
• Site Assessment/Study Feasibility Exercise
• Create a site recruitment plan
• Review of Warning Letters and creation of appropriate CAPAs
• Review of tools and templates

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• Quality in Clinical Trials: Key factors determining quality of sites
• Site/Study Selection: Questions to ask and tools to impress
• Study Documentation: Best practices for maintaining and archiving
• FDA Monitoring/Audits/Inspections: Best practices to be inspection ready
• Tips on Promoting Your Site
Biologics Development and Regulations

Course Description
This course offers extensive examination of the FDA’s regulations for biological products from preclinical testing to post-marketing regulatory requirements. Specific ethical and regulatory considerations are discussed for various biological therapeutics such as gene therapy, vaccines, protein, antibodies and stem cells. FDA’s regulation and policy updates for regenerative medicine including stem cell treatments, tissue engineering, and gene therapies are reviewed as well as updates on policies regarding regenerative combination products and devices.

Learning Objectives
- Review preclinical and clinical development phases for biological products
- Review FDA’s regulatory approvals process for biologics
- Discuss FDA guidance documents and most recent policy updates for regenerative medicine and stem cell technologies
- Review applicable Good Manufacturing and Good Laboratory Practices
- Discuss product labeling, marketing, and advertising
- Discuss post-licensure requirements

Who Should Attend
- Project Managers and Team Leaders
- Staff from Pharmaceutical Companies or Contract Research Organizations (CROs) involved in biologics trials
- New Clinical, Regulatory, and Department Staff who will design biologics clinical trial programs

Interactive Activities
- Biologics Quality by Design (QBD) Case Study: Application of Quality Risk Management (QRM) perspectives to develop baseline quality metrics and Key Risk Indicators (KRIs)

Instructor
Marina Malikova, Ph.D., MSci, M.A., C.C.R.A., RAC

Course Outline

Day One: 8:30 a.m. – 5:00 p.m.
- What is biologic?
- Preclinical safety assessment of therapeutic proteins and monoclonal antibodies
- The Biological IND review process in CBER and CDER
- Clinical testing of biologically derived therapeutics
- The clinical evaluations of preventive vaccines for infectious disease indications
- FDA regulatory approvals for regenerative treatments and stem cell-based therapies
- FDA guidance documents for stem cell technologies
- Global approval of stem cell technologies

Day Two: 8:30 a.m. – 5:00 p.m.
- How to design appropriate clinical trials for biologics
- The Biological License Application (BLA) and review process
- Regulations for regenerative products as medical devices, combination products
- Applicable Good Manufacturing and Good Laboratory Practices
- Product labeling, marketing, and advertising
- Post-licensure requirements
- Bioresearch Monitoring Program for biologics

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
Clinical Project Management: Fundamentals of Project Management

Course Description
Theoretical concepts from the Project Management Institute, PMBOK® are introduced in this introductory project management course for the clinical research professional working in the pharmaceutical or medical device industry. Whether you are looking to become a clinical research project manager, are already in an entry-level project manager role, or a project manager without formal project training, this two-day interactive course hands-on program will provide you with project management skills, tools and processes required to successfully manage projects in clinical research settings. Case studies, discussion, and interactive activities are utilized to aid the learner in application of clinical project management concepts and principles.

Learning Objectives
- Describe project management as it applies to clinical research and in the management of clinical trials
- Identify how project managers develop high performance project teams
- Develop a project plan and work breakdown structure
- Identify process mapping tools used in clinical research
- Recognize the importance of effective project schedules
- Identify clinical trial project budgetary needs
- Identify performance metrics and utilize effectively to monitor project
- Management of vendors within a clinical trial for optimal oversight and outcomes
- Implement successful project closure and lessons learned

Who Should Attend
- Project Managers from pharmaceutical, medical device, or CRO industry with less than two years in the role of Clinical Project Manager or experienced Clinical Projects Managers without formal clinical project management training
- Newly Hired Clinical or Project Team Leaders who will be managing projects (either at the sponsor, CRO, or investigational site)
- Clinical Research Associates, Data Managers, or other members interested in transitioning into the Clinical Project Management role or Clinical Trial Management

Interactive Activities
- Case Study: Creation of a Work Breakdown Structure (WBS)
- Case Study: Project Management Plan in Study Start Up
- Case Study: Projection of Budget for Clinical Trial
- Case Study: Vendor Management Effectively Addressing Performance Issues
- Review of Project Management Lifecycle: Team Members Roles, Responsibilities, Schedules

Course Dates and Locations

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>Course #</th>
<th>Fee Information</th>
<th>ACRP Members Discount</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 30-31, 2020</td>
<td>San Diego Solamar</td>
<td>SPMD0320</td>
<td>$1,675 by February 28, $1,875 after February 28</td>
<td>10% off</td>
</tr>
</tbody>
</table>

June 15-16, 2020
Boston, MA 02110
Metro Meeting Centers
Course #: SPMB0620
$1,675 by May 14, $1,875 after May 14

ACRP Members: Receive 10% off!

Academic Discount
A $400 academic discount is available to those who qualify.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 15 hours (1.5 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-18-023-L01-P. Released: 3/18.

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold This Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Blended Curriculum Course

Clinical Project Management: Advanced Concepts in Project Management

Course Description
This course provides the experienced Clinical Project Manager (with a minimum of three years in either the pharmaceutical, biotech, biologics or medical device industries) the advanced clinical project management and leadership skills to effectively lead project teams to their optimal performance. This two-day course builds upon advanced clinical research project management skills benchmarking, to Project Management Institute, PMBOK® concepts as they apply to clinical project management, including effective use of the project manager’s communication and leadership skills to overcome difficult issues a project manager may encounter. Advanced concepts will be presented to explore how project managers can effectively: Prioritize project needs, influence, lead project teams and stakeholders, and utilize best practices for documentation of project and team decisions. Operational challenges will also be explored including vendor lifecycle management, assessment of risk (project, quality), issue management with the use of root cause analysis, and corrective and preventive action (CAPA) plans for effective management. All concepts are presented in a dynamic, interactive manner to facilitate learning and retention.

Learning Objectives
• Explain project management tools and principles used in clinical trials
• Formulate project priorities and approach to effectively manage project needs
• Appraise effective use of communication and leadership skills for the project needs
• Manage projects and quality risks
• Appraise effective stakeholder and vendor management in clinical trials
• Describe effective leadership skills in leading project teams

Who Should Attend
• Project Managers
• Clinical Research Coordinators, Associates, Monitors, and Managers
• Regulatory, Medical, and Clinical Affairs Professionals

Interactive Activities
• Case Study: Prioritization management
• Case Study: Effective leadership skills, per the topic or situation encountered
• Practice: Effective negotiation skills and stakeholder management
• Case Study: Identify risks in vendor management
• Case Study: Stakeholder and vendor management

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Dates and Locations
April 6-7, 2020
Philadelphia, PA 19103
Convene Commerce Square
Course #: SMYA0420
$1,675 by March 5
$1,875 after March 5

ACRP Members: Receive 10% off!

June 25-26, 2020
San Diego, CA 92101
San Diego Solamar
Course #: SMYD0620
$1,675 by May 22
$1,875 after May 22

ACRP Members: Receive 10% off!

Academic Discount
A $400 academic discount is available to those who qualify.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 15 hours (1.5 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.


Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Clinical Trial Assistant Fundamentals

Course Description
This course focuses on the responsibilities of the Clinical Trial Assistant or Associate (CTA), a key administrative member of a project team at the sponsor or CRO. The course provides foundational knowledge on how investigational new drugs and medical devices are approved. The importance of ICH GCP and FDA regulations in the conduct of clinical trials will be reviewed, and the various roles and responsibilities of the clinical research team members are discussed, including the importance of the CTA role in daily administrative operations of clinical trials. Responsibilities the CTA may have in their role is reviewed including: Clinical trial start-up, maintenance, and closure, essential documentation tracking and management using the Trial Master File, distribution and management of adequate studies supplies (e.g., investigational product, laboratory kits, and other items used by the investigative site), reconciliation of documentation, coordination of team meetings, management and updating of study trackers, and the creation of documentation used in clinical trials (e.g., regulatory binder, newsletters).

Learning Objectives
• Review FDA regulations and the ICH GCP E6 Guideline for Good Clinical Practice (GCP)
• Describe the role of the Clinical Trial Assistant and other team members in clinical research
• Describe the investigational product development process: Drug and device
• List essential documentation required in the conduct of clinical research
• Describe the Trial Master File
• Develop tracking tools used in clinical research
• Define investigational product management and accountability in clinical research

Who Should Attend
• Clinical Trial Associate
• Clinical Trial Assistant
• Clinical Coordinator at the sponsor or CRO

Interactive Activities
• Define Roles and Responsibilities of the Clinical Research Team
• List Clinical Trial Assistant Duties and Responsibilities
• Identification of Type of Investigational Drug or Device
• Trial Master File Set Up Requirements (using the DIA Reference Model User Guide)
• Simulation Exercise: Review of Essential Documentation for Completion and Acceptance: Form FDA 1572, Financial Disclosure Form, Curriculum Vitae, Medical Licensure, IRB Correspondence

Instructors
This course will be taught by one of the following instructors:
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Dates and Locations
April 2-3, 2020
Philadelphia, PA 19103
Convene CityView
Course #: STFA0420
$1,675 by February 28
$1,875 after February 28
ACRP Members: Receive 10% off!

June 22-23, 2020
San Diego, CA 92101
San Diego Solamar
Course #: STFD0620
$1,675 by May 21
$1,875 after May 21

ACRP Members: Receive 10% off!

Academic Discount
A $400 academic discount is available to those who qualify.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 15 hours (1.5 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-020-L01-P. Released: 3/19.

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
HOLD THIS COURSE AT YOUR COMPANY: In-person or On the Web! Call +1 215.413.2471 for more information.
Clinical Trial Start-Up: Effective Planning for Sponsors, CROs, and Sponsor-Investigators

Course Description
Successful projects require planning, and often, start-up processes are not planned or defined, and risks are not considered. This lack of effective planning often leaves sponsors, CROs, and investigative sites behind schedule, which leads to delays in site selection, approval of IRB/IEC and clinical trial agreements (CTAs), and ultimately enrollment of subjects. Project management principles are introduced in this course to address clinical trial start-up challenges. Whether you are working for a sponsor, CRO, or as a Sponsor-Investigator (SI), this course will identify successful project planning techniques that can be used to effectively address the issues surrounding clinical trial start-up challenges. This course focuses on building a collaborative working relationship at the sponsor (CRO or SI) and the investigative site to help improve turnaround times with upfront planning, communication, and the use of a Work Breakdown Structure (WBS) in your project planning. Case studies, schematics, handouts, and tools will be provided for immediate implementation to address your start-up needs.

Learning Objectives
• Identify project requirements and risks
• Create tools and templates for clinical trial start-up planning
• Identify three benefits of a communication plan
• Examine a WBS in clinical trial start-up
• Identify situations where a WBS would have a positive impact on clinical trial start-up planning

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Who Should Attend
• Clinical Project Managers
• Clinical Trial Managers
• Clinical Research Associates
• Clinical Trial Assistants
• Other team members from the sponsor/CRO working in start-up of clinical trials with investigative sites
• Clinical Research Coordinators
• Clinical Research Team Leaders/Managers
• Other team members at the investigative site responsible for investigative site start-up activities

Interactive Activities
• Case Study: Mapping Out Protocol Start-Up Plan: Assessment, Needs, and Risk — Identification, Planning, Mitigation
• Case Study: Create a Communication Plan for Successful Site Start-Up
• Create Tools: FIO, SQV Questions, and Site Submission of IRB/IEC and CTA Questionnaire
• Case Study: Develop a WBS

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
Clinical Trials for Medical Devices: Design and Development

Course Description
This course addresses the practical issues in the design of medical device trials and protocol development, as well as broader issues related to clinical trial design and interaction between FDA and sponsors to provide clear direction to support marketing of the medical device.

Learning Objectives
- Manage the ethical considerations involved in conducting clinical trials
- Develop a strategic plan for successful clinical trials
- Develop trial objectives and hypothesis testing
- Evaluate basic statistical issues relating to sample size
- Distinguish and utilize assessment instruments

Who Should Attend
- Staff from medical device manufacturers or Contract Research Organizations (CROs) who will be involved in the design of clinical trials and have responsibility for protocol development
- Project Managers who have little or no clinical trial experience
- Project Team Leaders who will be designing clinical trials
- Clinical, Regulatory, and Development Staff who would like to learn how to design a clinical trial program
- Investigators who would like to learn how to conduct a clinical trial and about protocol development

Interactive Activities
- Case Studies
- Group Assignments
- Protocol Modifications
- Control Types
- Study Objectives

Course Outline

Day One: 8:30 a.m. – 5:00 p.m.
- Historical Overview: Overview of the regulatory process and general ethical considerations
- Device Regulations Pertaining to Device Trial Design and Development: “Least Burdensome” approach in the USA; Europe; Japan; “Rest of World”
- Impact of ICH on Device Trials and Development: Principles of the ICH GCP E6 Guideline
- Investigational Plan: Strategic planning; risk analysis; clinical operations; regulatory planning; marketing considerations
- Trial Design Considerations: Definitions; types; randomizing; blinding or masking; outcomes

Day Two: 8:30 a.m. – 5:00 p.m.
- Trial Design Considerations, continued: Investigator selection
- Protocol Structure and Format: Sections and sub-divisions
- Populations: Inclusion/exclusion criteria; cultural considerations
- Determining Sample Size; Statistical Power: Qualitative and quantitative endpoints, equivalence, rare events; single group
- Objectives and Hypothesis Testing: Null vs. alternative hypotheses; Type I and Type II errors; single vs. multiple objectives; statistical concepts for non-diagnostic devices and diagnostic tests (IVD)

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
Comprehensive CRC Training

Course Description
This course provides an in-depth survey of the roles and responsibilities of the investigator site Clinical Research Coordinator (CRC). The course begins with an overview of the investigational product development process and regulatory environment in which the CRC operates. From there, critical CRC responsibilities will be discussed, including patient recruitment and retention, informed consent, adverse event reporting, and investigational product accountability. The CRC’s role at the site will be explored, from study start-up through site close-out visits, including documentation that occurs along the way. Finally, the role the CRC plays in both sponsor audits and FDA inspections will be reviewed, along with how to effectively prepare for an audit or inspection.

Learning Objectives
- Describe the investigational product development process (drug and medical device)
- Prepare for all sponsor site visits
- Develop strategies for recruiting and retaining study subjects
- Define the informed consent process and the elements of the informed consent
- Review the reporting requirements of adverse events for both drug and medical devices
- Employ study documentation requirements and standards for collecting and reporting clinical trials data and investigational product
- Develop strategies for preparing, implementing, and managing clinical studies, including budget considerations
- Prepare your site for sponsor audits and FDA inspection
- Identify strategies for issues management include root cause analysis and corrective and preventive action plans

Who Should Attend
- Clinical Research Coordinators with limited experience in managing industry-sponsored investigational drug studies
- Experienced Coordinators seeking to enhance their skills to more efficiently and effectively manage their studies
- Clinical Research Associates who are interested in gaining a better understanding of the CRC and Investigator roles

Interactive Activities
- Review of Select Essential/Study Documents
- Review of a Protocol
- Adverse Events/Serious Adverse Events Exercise

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Overview of the Investigational Product Development: Terminology; phases of drug development classification of medical devices, and introduction to GCP
- The Clinical Research Team: Roles and responsibilities; appropriate delegation of investigator responsibilities
- The Site Selection Process: Criteria for site selection; planning and preparing for the site qualification visit
- IRBs and the Protocol Approval Process: IRB membership and operational requirements; sponsor-site-IRB relationships
- Study Start-up and Study Initiation Visits: Preparations and activities
- Subject Recruitment and the Informed Consent Process: Advertising guidelines, strategies for successful recruitment, documentation requirements; execution considerations

Day Two: 8:30 a.m. – 5:00 p.m.
- Study Implementation and Study Documents: Regulatory files, source documents and case report forms; records retention
- Monitoring Visits: Preparation and activities; simulation exercise
- Managing and Reporting Adverse Events: Definitions and reporting requirements; differences in various sponsor policies
- Investigational Product Accountability: Documentation, storage requirements and CRC responsibilities
- Close-Out Visits: Preparation and activities
- Sponsor Audits and FDA Inspections: Mechanics of a Sponsor Audit and FDA inspection; common FDA inspection findings
- Budgets: Development of study budgets
- Time Management and Prioritization: Simulation exercise

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Core Curriculum

Comprehensive Monitoring for Medical Devices

Course Description
This course provides an in-depth overview of the medical device development process and the role of the Clinical Research Associate (CRA) in managing and monitoring medical device studies. This course is ideal for CRAs new to the device industry, as well as experienced CRAs who are transitioning from monitoring drug studies to monitoring device studies.

Learning Objectives
- Discuss the FDA regulations pertaining to clinical research and describe the ICH structure and function.
- Define the common terms used in the field of device clinical research and identify the three ways devices are characterized.
- Prepare and conduct a pre-investigation visit, an investigator’s meeting, an initiation visit, a periodic visit, and a closeout visit.
- List the types of regulatory and study documents required for the sponsor and for the investigator.
- List both the sponsor’s and investigator’s responsibilities as they relate to device accountability.
- Describe the differences between adverse events, adverse device effects, and unanticipated adverse device effects.
- Discuss the “dos and don’ts” in the event of an FDA inspection.

Who Should Attend
- CRAs with one to two years of experience, and Engineers and other Device Industry Professionals responsible for the placement and monitoring of clinical trials, who want a practical, hands-on introduction to monitoring medical device studies according to Good Clinical Practice.

Interactive Activities
- Monitoring Skills – Hands-On Simulation
- The Device Approval Process – Classifying Devices and Determining Pathways to Marketing
- Selecting Study Sites
- Coaching Tips for an FDA Inspection

Instructor
Shana Zink, B.S.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Introduction to the FDA and the Medical Device Approval Process: Introduction to the FDA; ICH overview; definitions; medical device regulatory processes.
- IRB Approval & Informed Consent Process: IRB application for approval; approval process – initial and ongoing; informed consent process and documentation; HIPAA authorization.
- Pre-Study Processes: Determining the sponsor’s investigator/site needs; pre-investigation and confidentiality agreement; investigator/site selection; contracts/agreements; investigator’s meeting; initiation visit; recruitment and advertising.

Day Two: 8:30 a.m. – 5:00 p.m.
- Study Documentation: Sponsor files; investigator files; source documentation; case report forms; communication.
- Monitoring: Roles and responsibilities of the monitor during periodic visits; source document verification; case report form review and correction onsite; data retrieval and correction; document retrieval; protocol, investigational plan and GCP deviations; monitoring documentation.

Day Three: 8:30 a.m. – 5:00 p.m.
- Device Accountability: Sponsor responsibilities as they relate to device accountability; investigator responsibilities as they relate to device accountability.
- Close-out Visits: Reasons for a closeout visit; roles and responsibilities of the monitor during a closeout visit; investigator responsibilities after closeout.
- Managing and Reporting Adverse Events: Adverse event terminology; variations in adverse event reporting and documentation; sponsor obligations relating to adverse event reporting; investigator obligations relating to adverse event reporting.
- FDA Inspections: Purpose, types and mechanics of FDA inspections; common audit findings; FDA actions following an inspection; the ‘dos’ and ‘don’ts’ in the event of a FDA inspection.

Course Dates and Locations

<table>
<thead>
<tr>
<th>Month</th>
<th>Location</th>
<th>Course #</th>
<th>Start Date</th>
<th>End Date</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 31-April 2, 2020</td>
<td>San Diego, CA 92101</td>
<td>SD00320</td>
<td>$1,795 by March 28</td>
<td>$1,995 after March 28</td>
<td>ACRP Members: Receive 10% off!</td>
</tr>
</tbody>
</table>

ACPE#: 0778-0000-20-005-L01-P. Released: 3/20.

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Conducting Clinical Trials Under ICH GCP E6

Course Description
This course provides a comprehensive review of Good Clinical Practice (GCP) and FDA regulations and requirements. Participants receive a foundation of knowledge about GCP, practical examples, and the underlying scientific and regulatory principles involved. Guidelines for each aspect of research are provided, as well as information on the structuring and preparation of protocols, consent forms, and investigator brochure. Information on maintaining an ongoing relationship with the FDA will also be discussed. This course enables clinical professionals to prepare concise documents and provide their company and the FDA with necessary information for their clinical studies. The R2 changes are covered in this course.

Learning Objectives
• Summarize Good Clinical Practice (GCP) Clinical Research Team Roles and Responsibilities
• Recognize how GCP impacts the clinical research process through review of key documents and necessary information for clinical trials
• Apply concepts of root cause analysis and corrective and preventive actions for quality management
• Discuss key elements for monitoring reports and written documentation in GCP
• Review regulatory compliance, audit preparation and inspections

Who Should Attend
• This course is intended for Clinical, Regulatory, and Quality Personnel who require an understanding of the GCP regulations and requirements. This course will also benefit other personnel who must be familiar with the essentials of the clinical process and requirements.

Instructors
This course will be taught by one of the following instructors:
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.
Angie Maurer, R.N., B.S.N., M.B.A., C.C.R.A.
Lily Romero, P.A. C.C.R.C.

Course Dates and Locations
March 26-27, 2020
Philadelphia, PA 19103
Convene CityView
Course #: SGCA0320
$1,675 by February 25
$1,875 after February 25
ACRP Members: Receive 10% off!

June 25-26, 2020
San Diego, CA 92101
San Diego Solamar
Course #: SGCD0620
$1,675 by May 22
$1,875 after May 22

Academic Discount
A $400 academic discount is available to those who qualify.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 15 hours (1.5 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-19-036-L01-P. Released: 9/19.

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
CRA & CRC: Beginner Program

Course Description
This beginner course provides an excellent introduction to clinical research and the job responsibilities of Clinical Research Associates (CRAs) and Clinical Research Coordinators (CRCs). It explores topics relevant to those considering a career as an entry-level CRA or CRC.

Learning Objectives
- Describe the investigational product development process
- Review FDA regulations and the ICH GCP E6 Guideline for Good Clinical Practices (GCPs)
- Describe the roles and responsibilities of the Clinical Research Associate and the Clinical Research Coordinator before, during, and after a clinical trial
- Identify the requirements of the Investigator in supervising clinical research
- Discuss the role of an Institutional Review Board, its composition, and responsibilities in the clinical trial process
- Define the informed consent process, the elements of the informed consent document
- Describe an overview of the different types of Monitoring Visits, including preparation, activities, and monitoring visit follow-up
- Define source documents and Case Report Forms (CRFs) in relation to CRF completion and source document verification
- Describe definitions related to safety management, identification of adverse events, and reporting requirements
- Describe the difference between a sponsor audit and an FDA inspection and preparation

Who Should Attend
- Aspiring Clinical Research Coordinators and Nurses
- Aspiring Clinical Research Associates – In-house or Field-based
- College Students and New Graduates in a Scientific Field
- NOTE: This course is also appropriate for CRAs or CRCs with less than six months experience

Interactive Activities
- Case Study Reviews – Adverse Events, Protocol Modifications, Study Feasibility, Informed Consent and Monitoring Visit Scenarios
- Site Selection, IP Accountability, Source Document Verification and Case Report Form Exercises

Instructors
This course will be taught by one of the following instructors:
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.
Lily Romero, P.A., C.C.R.C.

Course Dates and Locations

<table>
<thead>
<tr>
<th>Course Dates and Locations</th>
<th>Philadelphia, PA 19103</th>
<th>San Diego, CA 92101</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 31-April 2, 2020</td>
<td>Convene CityView</td>
<td>San Diego Solamar</td>
</tr>
<tr>
<td></td>
<td>Course #: SC0A0320</td>
<td>Course #: SC0D0620</td>
</tr>
<tr>
<td></td>
<td>$1,795 by February 28</td>
<td>$1,795 by May 15</td>
</tr>
<tr>
<td></td>
<td>$1,995 after February 28</td>
<td>$1,995 after May 15</td>
</tr>
</tbody>
</table>

ACRP Members: Receive 10% off!

Academic Discount
A $400 academic discount is available to those who qualify.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 22.5 hours (2.25 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

The CRA Manager Course

Course Description
The focus of this course is to strengthen the skills required of the CRA Manager to effectively hire, manage, motivate, and optimize the performance of CRA teams. In this course, you will sharpen your people skills and develop an understanding of the key components of successful team and performance management. This course is a must for new and aspiring managers. Several document templates will be provided for you to customize and use during your daily activities as a Manager. Examples and interactive exercises will pertain specifically to managing Clinical Research Associates (CRAs).

Learning Objectives
- Describe a CRA management philosophy based on competencies, performance objectives and metrics
- Identify effective interviewing techniques to hire CRAs
- Demonstrate effective communication skills
- Identify motivational needs of CRA employees
- Develop strategies for “Win-Win” conflict resolution
- Analyze performance problems and understand the goals and limitations of performance appraisals
- Recognize effective use of feedback, coaching, and praise as a CRA Manager
- Describe the principles of effective delegation
- Develop a more engaged team which contributes to quality performance
- Describe methods for managing clinical research projects more effectively

Who Should Attend
- Managers, Clinical Project Coordinators, or newly promoted Project Team Leaders who are responsible for managing clinical personnel
- Experienced Clinical Research Associates who are becoming involved, or hope to become involved, in teams and/or people
- Technically trained staff with little or no management experience

Interactive Activities
- Developing a CRA Performance Model Based on Performance Competencies
- Developing Interviewing Questions and Choosing Candidates
- Active Listening
- Analyzing Motivational Needs
- Case Study: Win-Win Conflict Resolution Discussion
- Conflict Management Style Survey
- Case Study in Feedback and Praise
- Case Study: Analyzing Performance Problems
- Delegation: A Self-Test
- Delegation Personal Action Plan
- A Good Team Leader Checklist
- Teambuilding Personal Action Plan

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Introduction: Defining the role of the CRA Manager
- Establishing Competencies, Setting Performance Objectives, and CRA Performance Metrics
- Interviewing and Hiring CRA Candidates
- Communication and Listening Skills
- Motivation
- Conflict Resolution: Conflict Management Styles, Initiating Win-Win Discussions

Day Two: 8:30 a.m. – 5:00 p.m.
- Effective Feedback, Praise and Coaching
- Analyzing Performance Problems
- Constructive Criticism and Counseling
- Performance Appraisals and Counseling
- Effective Delegation
- Team Building and Project Management Introduction

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
## Course Description

This program will explore the evolution of Clinical Data Management from a paper case report form (CRF) process to the “real time” data review capable world of electronic data capture (EDC). We will review the specific regulations that govern the electronic data capture and electronic signature requirements, and examine the changing role of the Data Manager in an environment where the technology drives the process. Although the basic data management principles remain the same, for example good CRF design and ensuring the integrity of the data, the timelines and tasks surrounding today’s EDC are not interpreted exactly as the paper CRF process has previously dictated. The understanding of how the technology has changed the process will enable today’s Data Managers to move forward in the discipline and ensure their place as viable members of the clinical study team. As electronic data capture utilized as patient e-source or eCRF becomes more the routine, it is important that the CDM be fully aware of the capabilities of the EDC application in order to ensure a comprehensive data management component in the clinical trial conduct.

### Learning Objectives

- Assess the impact of the regulations on Data Management
- Discuss the rationale and enhancements regarding the utilization of EDC
- Discuss in-depth the changing role of the Clinical Data Manager
- Outline the CDM focus on protocol review and CRF design
- Employ “best practices” for eCRF design
- Describe the Data Management documentation required in clinical trial conduct
- Identify EDC system enhancements for the industry

### Interactive Activities

- Review a simple protocol synopsis and plan to design a simple eCRF
- Utilize a “training” database in an EDC application to review navigation and discuss site training issues

### Who Should Attend

- Clinical Operations and Project Management Personnel who need to familiarize themselves with the process of EDC set-up requirements and the role that utilizing EDC plays in the conduct of clinical trials
- Clinical Data Managers (CDMs) who are involved in the transition of paper CRF process to EDC
- CDMs new to the EDC process
- EDC developers who require a better understanding of the CDM process and role

### Course Outline

#### Day One: 8:30 a.m. – 5:00 p.m.

- **The Regulatory Environment for the Utilization/Consideration of EDC:** Overall review of the 21 CFR Part 11 regulations; e-signature requirements for FDA, EU, and Japan
- **Transitioning from Paper CRF to EDC:** Examine the considerations surrounding the adoption of EDC while still working in a paper environment
- **The Changing Role of the CDM:** The CDM was process driven, whereas the EDC environment has moved the focus from process to Project Management
- **Study Start-up, Protocol Synopsis Review, eCRF Development:** Examine the activities associated with the study start-up in an EDC environment; discuss eCRF development and also the impact that CDISC/CDASH may have on future CDM endeavors
- **Best Practices in eCRF Development:** Review the best practices as they relate to EDC activities and the issues surrounding eCRF creation/testing

#### Day Two: 8:30 a.m. – 5:00 p.m.

- **User Acceptance Testing (UAT):** How does the application work? How do we test it or try to “break” it?
- **Creating the Data Management Plan:** The documentation required for a robust DMP when utilizing an EDC application; reviewing the components of the DMP as described by the Society of Clinical Data Management Good Clinical Data Management Practices (SCDM GCDMP)
- **Ancillary Documentation for EDC:** What do we need for training the users in the application? Navigation documentation, query resolution hints, report generation
- **External Electronic Data:** Lab data, ECG data – can the application accept data uploads?
- **Outsourcing EDC DM Issues:** Vendor outsourcing, discussion surrounding evaluation of vendors for total CDM projects or vendor development of eCRFs
Design and Conduct of Clinical Trials: Design Requirements, Statistical Issues, and Clinical Protocols

Course Description
Clinical trials play a pivotal role in evidence-based medicine. This course will provide an introduction to the scientific, statistical, and ethical aspects of clinical research. Topics will include basic principles and current methodologies used in the design, implementation, and analysis of clinical trials, including first-in-human studies (dose-finding, safety, proof of concept, and Phase I), Phase II, Phase III, and Phase IV studies. All aspects of the development of a study protocol will be addressed, including criteria for the selection of participants, assignment of study treatments, endpoints, randomization procedures, sample size determination, data analysis, adverse event reporting, and protocol compliance monitoring. The ethical issues that arise at each phase of new biomedical product development will also be explored.

Learning Objectives
- Describe study designs and their limitations
- Identify scientific and practical issues associated with the planning of a clinical research study
- Manage protocol structure, outline, timeline, and amendments
- Discuss requirements for protection of human research subjects
- Review statistical issues in design and analysis of clinical research studies
- Develop a basic statistical understanding (e.g., qualitative and quantitative data, sample size determination, and interim analysis)

Who Should Attend
- New or Novice Project Managers
- New Clinical, Regulatory, Research and Development, and Department Staff who will design clinical trial programs
- Clinical Research Associates
- Data Managers
- Staff interested in transitioning into clinical trial management
- Grant Administrators
- Medical Directors
- Medical Writers

Instructor
Marina Malikova, Ph.D., MSci, M.A., C.C.R.A., RAC

Interactive Activities
- Review and identification of elements of Informed Consent
- Develop a preliminary Quality by Design (QbD) strategy and apply Quality Risk Management (QRM) perspective to develop baseline quality metrics and key risk indicators based on specific study protocol

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
Detecting Risk Signals in Protocols, Data, and Monitoring

Course Description
In an environment where remote monitoring and management techniques are becoming the daily practice, preventative measures need to be implemented to identify risks. You need to be able to identify protocol data thresholds and parameters for risks to establish management and escalation triggers. As data becomes available in real time, you should not be waiting until deviations become a “trend” before intervention is implemented; we need to know how to look for outliers and “red flags” on a daily basis. With increasing use of CROs and vendors, it is essential that best practices are established for identifying risk signals in management and monitoring practices. This course will discuss how to detect risk signals in protocols, data, and monitoring based on risk-based quality management, industry guidances, and practical application. This one day course will include hands-on activities centered around identifying and implementing preventative measures in a sample protocol, communication and management techniques, and plan development.

Learning Objectives
- Describe quality risk management and regulatory expectations based on industry and international guidance
- Apply proactive quality management techniques through signal detection and training for operational and scientific management of clinical trials
- Identify key risk factors, thresholds, and issues in protocols, reports, and data listings
- Apply signal detection techniques and preventative measures through hands-on application

Who Should Attend
- Clinical Research Associates
- Project Managers

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Introductions
- Regulatory Environment and Risk Management
- Review regulatory trends and risk analysis applications
- Detection of signals and categories
- Proactive Management
- Identify operational and scientific risks through metrics, data, and reports
- Analyze and apply management techniques to source of risk at site, CRA, manager, and CRO level
- Facilitation of instructional methods and training practices to ensure transference and application of knowledge
- Root Cause Analysis and CAPA in signal detection
- Apply techniques for identifying the cause of risk signals
- Manage risk through practical application of correction and prevention
- Evaluate “agile theory” as a preventative method of management
- Workshop: Hands-on Analysis and Application
- Review sample protocol to identify potential risks, thresholds for management of data, strategic interventions, and escalation requirements

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Developing Clinical Study Budgets

Course Description
This course provides the practical skills needed to construct and negotiate study budgets that appropriately compensate investigative sites for resources needed in the conduct of clinical research.

Learning Objectives
- Analyze protocols to assess resource needs
- Develop study budgets that adequately reimburse sites for their time and effort
- Use various approaches for structuring study budgets
- Identify the options available for developing budgets and tracking study costs and payments
- Identify important aspects of negotiating study budgets

Who Should Attend
- Clinical Trial Personnel (Clinical Research Coordinators, Investigators) responsible for preparing and implementing study budgets
- Sponsor Representatives in the pharmaceutical or medical device industry
- Contract Research Organization and Consultant Representatives whose function is to design and/or apply study budgets for sites

Interactive Activities
- Core Concepts
- Case Study

Instructors
This course will be taught by one of the following instructors:
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Protocol Dissection Techniques: Assessing protocol feasibility; determining resource needs
- Negotiation Considerations: Identifying negotiable items; performance-based contracts; payment schedules
- Developing the Study Budget: Identifying line items; accounting for the site’s time; fee for service, fixed and fixed-unit pricing structures; case study
- Technology to Enhance the Budget Development Process
- Protocol Dissection Techniques: Using spreadsheets; clinical study software programs
- Tracking Payments and Financial Reports: Accounting systems; tracking and managing payments; financial reports
Developing CRAs as Site Study Managers

Course Description
The person that has the most contact with the site is the Clinical Research Associate (CRA); they are the “face” of the sponsor, the purveyor of information, and the person that most influences the site’s performance on a study. In a sense, CRAs are the sponsor’s On-Site Study Managers. It is critical that this individual be in a position to positively reflect the sponsor and ensure the site performs to their full potential through training, knowledge, and support. CRAs must understand the data review process, but they must also have the skills to train, mentor, and communicate with new and experienced site staff, and to navigate the path through challenging situations. In addition, the CRA needs to be equipped and prepared to communicate with the Principal Investigator (PI) and be able to support the site in recruitment efforts and the documentation process. A better understanding of adult learning techniques, unique and thorough approaches to recruitment and retention strategies, carefully developed and implemented communication plans, and an understanding of project management techniques can make the difference between a site meeting enrollment with minimal deviations, and a site lacking in enrollment with multiple protocol violations. This course will focus on a variety of techniques and training to help CRAs move from monitors to on-site study managers in their skills.

Learning Objectives
- Evaluate the role of the CRA as the first point of contact and expert on a study
- Explain the importance of live conversations with the site
- Demonstrate advanced monitoring and communication techniques for the challenging site
- Discuss techniques used in adult learning and how to best apply them to clinical research
- Facilitate techniques for preparing for and having conversations with Principal Investigators
- Describe advanced recruitment and retention activities to ensure the CRA is equipped to support the sites in recruitment efforts
- Explain how to develop a solid and reasonable recruitment action plan and how to support the evolution of this document throughout the trial
- Discuss information and support for an on-site study manager
- Evaluate various project management and tracking techniques to provide the CRA with a wealth of tools for managing multiple sites

Who Should Attend
- Managers of CRAs
- Senior, lead, or advanced CRAs
- Study Managers
- New CRAs looking to develop their skills

Interactive Activities
- Hands on development of a recruitment action plan
- Prioritization activity for workload and activity balance
- Conversation development and techniques practice and discussion

Instructor
Beth Harper, B.S., M.B.A.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
Developing Effective Training and Facilitation Skills in Clinical Research: An Application-Based Course

Course Description
In clinical research, there is an ongoing need to conduct training whether it is at the onset of a study, due to a change in staff or new staff, as a result of an amendment, or because of an identified noncompliance during a study. How we approach and deliver training is important. Delivering hours’ worth of PowerPoint presentations does not facilitate learning or identify where the knowledge gaps may lie in order to make the best use of time and resources. If our goal in training is to pass on knowledge and to ask learners to apply that information, we need to consider our approach in how to make this happen. It is important to consider how essential every teleconference, meeting, and conversation is within research; the information shared can have a huge impact on study timelines, data integrity, and compliance. If information is not internalized by the learner, then the time spent discussing it is a waste and the consequences may be significant.

In this course, training and facilitation methodology, skills, and fundamentals will be applied in a highly interactive and engaging day of activities. Learning styles and approaches will be explored with a focus on how we can apply this to our daily tasks in clinical research. This course focuses on the practical application and tools needed to ensure that an audience is able to remember and apply the information shared. Learners will have time to work in groups in developing activities, creating course plans, and practicing skills. An emphasis of the course will be to change the way we approach instruction in order to best facilitate learning and the transfer and ownership of the information.

Learning Objectives
• Review the application of training and good facilitation skills in clinical research
• Discuss adult learning principles and styles
• Identify successful training techniques applied to a clinical research setting
• Apply skills that facilitate training
• Identify the optimal learning environment
• Describe methods to manage the learning environment and challenging situations
• Apply facilitation skills to different types of activities in clinical research including initiation visits, investigator meetings, and on-going study training activities for sponsors and site staff

Who Should Attend
• Clinical Research Managers and Leads
• Clinical Research Associates
• Clinical Research Coordinators
• Research Professionals interested in building additional training and facilitation skills to apply to daily transference of knowledge

Interactive Activities
• Develop a course outline and define key objectives
• Build a toolkit of activities to engage learners
• Practice presentation and facilitation skills

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

What Participants Say About Barnett Seminars:
“"The trainer is an exceptional instructor. He made training items practical and easy to learn and apply in real-life situations.""
Drug Approval Process: Preparation and Processing of INDs and NDAs

Course Description
This course provides a comprehensive approach to the preparation and submission of documents to the FDA for approval of drug products. Participants receive a foundation of knowledge about the drug approval process, submission preparation, and the underlying scientific and regulatory principles involved. Guidelines for each aspect of research are provided, as well as information on the structuring and assembly of INDs, NDAs, and post-approval documents. Information on maintaining on-going relationships with the FDA is also discussed. The course enables regulatory affairs professionals to prepare concise documents, provide the FDA with necessary information, and obtain rapid product approval.

Learning Objectives
• Navigate the FDA drug approval system
• Prepare an IND
• Prepare an NDA
• Navigate the FDA review process

Who Should Attend
• This course is intended for Regulatory, Clinical, Manufacturing, Technical, and Quality Personnel who require an in-depth understanding of the drug approval system. The course will also benefit management, legal, and other personnel who must be familiar with the essentials of the drug approval system and the preparation and submission of related documents.

Instructor
Caroline Ritchie, Ph.D., M.B.A.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1.215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• General Perspective: History; law; definitions; overview of FDA; establishment registration; product listing; regulatory strategy
• IND Process: FDA IND Form 1571; cover letter; table of contents; introduction; investigational plan; chemistry, manufacturing, and control; nonclinical studies (pharmacology and toxicology); clinical studies; investigator brochure; labeling; USAN procedures; compiling IND; IND filing; IND review process; amendments to IND; safety reports; annual reports; IND withdrawal; IND termination

Day Two: 8:30 a.m. – 5:00 p.m.
• NDA Process: FDA NDA Form 356(h); cover letter; index; labeling; summary; chemistry section (chemistry, manufacturing, and controls information; samples; methods validation package); nonclinical pharmacology and toxicology section; human pharmacokinetics and bioavailability section; clinical data section; safety update report; statistical section; case report tabulations; case report forms; patent information on any patent which claims the drug; patent certification; establishment description; debarment certification; field copy certification; user fee cover sheet; compiling NDA; NDA amendments; NDA review process; post-approval requirements
• Exploratory IND: Clinical information; CMC information; safety program designs; GLP compliance
• Clinical Trials: Phase 0 studies; Phase 1 studies; Phase 2 studies; Phase 3 studies; Phase 4 studies

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Drug Development and FDA Regulations

Course Description
This course provides an overview of the drug development process including Good Laboratory Practice (GLP), Good Clinical Practice (GCP), and Good Manufacturing Practice (GMP) processes. It is ideal for early stage investigators from varied disciplines and new industry professionals with a need to develop an understanding of the drug development process. The course will review the steps that lead up to the clinical trial process. It will discuss the phases of clinical development that are part of the IND (the actual human trials that are conducted to demonstrate safety and efficacy to allow the regulatory authorities reason to approve the investigational drug for marketing). The NDA process will then be reviewed with insight into possible post-NDA activities that may be requested. The included workbook is a great tool for reference purposes.

Learning Objectives
• Discuss the FDA’s role in drug development
• Explain the logic of the drug development process
• Cite the basics of non-clinical drug testing
• Discuss briefly the requirements for an IND
• Cite the basics of clinical trial structure and design, including Phase 1, 2, and 3 clinical trials
• Discuss briefly the requirements for an NDA
• Explain briefly the post approval responsibilities of sponsors, including Phase 4 clinical trials
• Describe the fundamentals of GLP, GCP, and GMP

Who Should Attend
• Investigators
• Site Study Team Members
• Clinical Research Associates
• Regulatory Affairs Associates
• Project Managers
• New industry professionals with a need to understand the drug development process

Instructor
Nikki Christison, B.S., C.C.R.A., T.I.A.C.R.

Interactive Activities
• Drug Development Process
• Review of Form FDA 1571 for an IND application
• Review of Form FDA 1572 for conducting a clinical trial
• Review of Form FDA 356h for an NDA application

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• Introduction
• FDA’s Role in Drug Development
• Logic of Drug Development
• Basics of non-clinical drug testing
• Requirements for an IND
• Basics of clinical trial structure and design (Phase 1, 2, 3 clinical trials)
• Requirements for an NDA
• Post approval responsibilities of sponsor (Phase 4 clinical trial)
• Fundamentals of GLP, GCP and GMP

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Drug Discovery: The Path from Development to Marketing Approval

Course Description
This course will introduce the concept of translational approach in clinical research and examine its application. An overview of state-of-the-art translational technologies will be provided. Topics will include review of molecular and pathophysiological aspects of several diseases, and the exploration basis for drug design, pre-clinical, and clinical testing. Additional topics will include clinical evaluation, regulatory approval of biological drugs, and frontiers in translational research. We will review requirements for transitions from the pre-clinical phase of drug development to the clinical trial process and subsequently to marketing of a new drug. In addition, the phases of clinical drug development that are part of the Investigational New Drug (IND) application will be discussed. The New Drug Application (NDA) pre-market application process and regulatory requirements will then be reviewed with insight into possible post-NDA activities that may be required.

Learning Objectives
• Apply an in-depth understanding about pre-clinical research and the steps necessary for transition to clinical phases of the drug development process
• Identify translational approach in clinical research
• Describe current considerations in reporting adverse events in clinical trials: timing, terminology, consent, blinding, device-related versus procedural complication, and follow-up
• Describe the concept of molecular targeted therapeutics
• Identify the information required in an IND and IND amendments, NDA, or a Biologic License Application (BLA)
• Describe how to write an Investigational NDA

Who Should Attend
• Industry Professionals with a need to understand the drug development process
• Investigators and Site Study Team Members
• Clinical Research Associates, Regulatory Affairs Personnel and Project Managers

Interactive Activities
• Exercises involving Forms FDA 1571 and 1572 and 356h

Instructor
Marina Malikova, Ph.D., MSc, M.A., C.C.R.A., RAC

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• An Overview of Modern Drug Discovery and Development Research
• Pharmacogenetics and Pharmacogenomics Types of High Throughput (HTP) Assays
• Small Drug Molecules
• Large Drug Molecules and Protein-Based Therapies (Vaccines, Gene Therapy, Growth Factor, etc.)
• Drug/Discovery — Targets and Receptors
• Pre-Clinical Studies in Drug Development

Day Two: 8:30 a.m. – 5:00 p.m.
• Overview of Main Pharmacology and Toxicology Parameters as Applicable to Drug Development
• Overview of GLPs, GMPs, and QSRs at Pre-Clinical Stages
• Clinical Trial Regulatory Requirements for Drugs and Biologics
• Investigational New Drug Application
• Transition from Clinical Research to Clinical Practice
• Post Approval (Phase IV Clinical) Responsibilities of the Sponsor

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

What Participants Say About Barnett Seminars:
“This seminar is a ‘must’ for anybody working in clinical development.”
Drug Safety and Pharmacovigilance: Effective Drug Safety Reporting and Surveillance

Course Description
This course covers the fundamentals of drug safety and pharmacovigilance, including regulatory requirements, adverse event reporting, signaling and risk management. The course addresses the regulatory issues across U.S. and EU agencies that improve safety. Keeping products on the market without interruption becomes more essential with the reduced pipeline of drugs in development. Successful navigation of drug safety and pharmacovigilance are keys to product longevity, consumer confidence, and regulatory compliance. This course will provide learners with regulatory references, processes, best practices, and analysis and investigation techniques to minimize risk, avoid product recall, and meet U.S. and EU safety reporting standards.

Learning Objectives
- Describe regulatory requirements for product safety
- Perform signaling analysis and risk assessment and management functions
- Define how to collect, assess, report, and analyze adverse events
- Demonstrate the importance of good adverse event data collection in identifying signals
- Create signaling analyses based on FDA Good Pharmacovigilance Practices
- Introduce FDA Good Pharmacovigilance Practices and EMA Good Pharmacovigilance (GVP) Modules and their relevance to Aggregate Reporting, Risk Management, and Signal Detection

Who Should Attend
- Drug Safety and Pharmacovigilance Professionals
- Regulatory Affairs Professionals
- Senior Level Executives
- Clinical Development Staff

Interactive Activities
- Case Study Reviews
- Exercises in Drug Safety and Signaling Reviews

Instructor
Sharon Donatucci

Course Dates and Locations
March 31- April 1, 2020
San Diego, CA 92101
San Diego Solamar
Course #: SSVD0320
$1,675 by February 28
$1,875 after February 28
ACRP Members: Receive 10% off!

June 16-17, 2020
Boston, MA 02110
Metro Meeting Centers
Course #: SSVB0620
$1,675 by May 15
$1,875 after May 15

Academic Discount
A $400 academic discount is available to those who qualify.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 15 hours (1.5 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-18-033-L01-P. Released: 10/18.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- What is Pharmacovigilance?: Definition and history; corporate pharmacovigilance; ADR system; critical elements
- What is an Adverse Event Drug Reaction?: Adverse Drug Reaction definition; sources of SADRs; types of ADRs; ADR reports to FDA/EMEA; serious ADR; unlabeled or unexpected ADR; expectedness "listed" vs. "unlisted"; severity/intensity; lack of efficacy; pharmacovigilance
- Global Regulatory References and Expectations: Global regulations addressing safety (ICH, CIOMS, FDA and EU)
- Regulatory Reporting: Expedited reporting timelines; aggregate reports and timelines

Day Two: 8:30 a.m. – 5:00 p.m.
- PV Audits and Audit Issues: Regulatory inspections; preparation, problems and issues; checklists; ADR; inspection principles; inspection results; potential regulatory actions
- Signaling: What is safety signal; safety signal generation; definition; pharmacovigilance process; risk/benefit; situations for signal detection; sources of signals; analysis and investigation of a signal; understanding safety signals; suspected signals, risk assessment
- Characteristics of a Good Case Report: How to do a narrative evaluation for follow-up or active query
- Risk Management: Understanding Risk Evaluation and Mitigation Strategy (REMS) and Risk Management Plans (RMP)

Registration
Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Effective Recruitment Planning and Management for Sponsors and CROs

Course Description
With some 80-90% of clinical trials failing to meet their enrollment timelines, developing a proactive and effective patient recruitment plan is an essential requirement for any clinical trial. This course is targeted for sponsor and CRO personnel who are eager to learn more about how to establish and manage a patient recruitment plan that can ensure on-time enrollment performance. This course will focus on proven recruitment planning, management, and troubleshooting techniques. This intensive one-day interactive course is not about recruitment tactics (although we will discuss how to determine if and when study awareness activities are needed to help drive patients to the sites from external sources), but how to think strategically about all of the factors contributing to successful recruitment.

Learning Objectives
- List the core root causes of why most studies fail to meet their enrollment timelines
- Discuss the factors that contribute to a successful recruitment effort
- Describe the components of a patient recruitment plan
- Explain when, where, and how to best monitoring enrollment performance

Who Should Attend
- Personnel responsible for study level recruitment planning at sponsors and CROs (e.g., Study Directors, Project Managers, Feasibility and Recruitment Specialists)
- Personnel responsible for recruitment performance management at sponsors and CROs (e.g., Site Relationship Liaisons, CRAs)

Instructor
Beth D. Harper, B.S., M.B.A.

Interactive Activities
- Identify and map out poor enrollment root causes
- Conduct a recruitment funnel analysis calculation
- Critique sample recruitment plan
- Brainstorm sources of patients and tactics for fictitious study

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Welcome and Introductions
- Study “Rescue” Root Causes
- Recruitment is more than advertising and tactics: Uncovering all of the CSFs (Critical Success Factors)
- Recruitment Planning: What it is, what it’s not, why it’s needed, and what’s involved
- Components of a patient recruitment plan (document)
- Assessing how many patients need to be reached and identified
- Determining where the patients will come from
- Determining tactics, materials and messaging, and site support needed to address all of the CSFs
- Critique and Evaluation of a sample plan; recommendations for creating your own plans
- Evaluating recruitment performance metrics to ensure performance
- Q&A/Discussion/Wrap-Up
Effectively Writing Clinical Trial Protocols

Course Description
The basis and success of any clinical development program is the study protocol. Clinical trials conducted under an IND or IDE cannot begin without a protocol. However, there is considerable variability between companies and individuals regarding the approach to writing this critical document, even with a good understanding of ICH guidelines. Clinical trials and entire programs have failed because the protocol was not scientifically sound, and knowing how to effectively research and write a clinical trial protocol is essential to achieving IRB and ultimately market approval. Moreover, amendments, however unwelcome, are a necessary part of the development process and must be managed efficiently to avoid costly implementation or delays to the ongoing trial.

Learning Objectives
• Improve basic writing skills, and learn the use and importance of style guides and templates
• Differentiate between the phases of investigation for drugs and devices
• Manage the timeline for protocols and their amendments, including internal and external review, key opinion leader input, collation, revisions, QC process, sign-off, and meetings
• Navigate the protocol concept sheet and synopsis; using these as an outline for the protocol
• Describe the requirements for and elements of a protocol including the hypothesis, clear and concise objectives, primary and secondary endpoints, inclusion/exclusion criteria, and the Schedule of Assessments
• Describe adverse events and serious adverse events and their reporting, depending on type of study and type of intervention
• Develop a basic statistical understanding (e.g., qualitative and quantitative data, sample size determination, and interim analysis)
• Develop protocol amendments: how and when to do it and documentation needed

Who Should Attend
• New or Intermediate Medical Writers
• Personnel who review protocols — Medical Directors, Statisticians, Clinical Pharmacologists, Regulatory Affairs Professionals
• Clinical Research Associates, Coordinators and Investigators
• Non-Clinical Personnel
• Marketing Personnel

Interactive Activities
• Development of the objectives, review of the synopsis process, and generation of a Schedule of Assessments

Instructor
Caroline Ritchie, Ph.D., M.B.A.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• Writing Basics
• Overview of the Protocol Requirements
• Building the Protocol
Day Two: 8:30 a.m. – 5:00 p.m.
• Building the Protocol, cont.
• Past precedence and approved labels
• Constructing protocol based on research
• Informed Consent Form
• Case Report Forms
• Protocol Amendments

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
Facilitation Skills for Clinical Research Team Leaders

Course Description
Today’s clinical research teams spend so much time in meetings, but is it time well-spent? In this course, participants will be provided with a best practices approach to facilitating interactions and meetings that are both quick and contribute to progress towards goals. Clinical research team leaders are expected to be strong facilitators, yet few clinical research professionals ever receive training on this critical skill set. This course presents participants with 24 easy-to-use tools and best practices techniques that can be immediately applied on the job. The training is in a workshop format, providing application of facilitation tools presented.

Learning Objectives
• Describe the role of facilitation in clinical research
• Define facilitation and explain why it is an essential skill for managing clinical research today
• Implement facilitation processes and best practices, including:
  • Best practices facilitation techniques (e.g., ground rules, prioritization strategies, handling objections)
  • Methods for engaging participants
  • Techniques to assess if participants comprehend meeting content and can articulate next steps/results of the meeting
• Apply facilitation techniques in clinical trials

Who Should Attend
• Sponsor/CRO Team Leaders
• Clinical Research Associate Managers
• Project Managers

Interactive Activities
• Outcomes-Based Planning
• Applying What You Learned: The Facilitation Process
• Applying What You Learned: Managing Participants
• Knowledge Sharing: Story Share Roundtable

Instructors
This course will be taught by one of the following instructors:
Holly J. Deiaco-Smith, M.S.Ed.
Kirsten Morasco

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1.215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• Introduction to Facilitation
  • The facilitative mindset
  • The role of the facilitator
  • Facilitator responsibilities
• The Facilitative Process
  • Story Share: Pain points and facilitation war stories
  • Plan the Meeting: Best practices techniques and tools
  • Open the Meeting: Best practices techniques and tools
• Conduct the Meeting Using the Facilitation Framework: Best practices techniques and tools, managing the process, managing the participants
• Close the Meeting: Best practices techniques and tools

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
FDA Meetings 101: How to Hold a Successful Meeting with Regulatory Agencies

Course Description
An integral part of any successful regulatory strategy is meeting with a regulatory agency, early and often, to reach concurrence on certain development plans. To ensure that your strategy is well communicated and that a successful meeting occurs, the process must be seamless. You need to know not only all the components of the FDA’s meeting requirements, but the elements that are not requirements but make the process smoother. This course applies to products currently in Phases 1-3, and does not provide the basics of an Advisory Committee Meeting, negotiating labeling, or postmarketing meetings. While some of the concepts are the same, the regulations and meeting content are different. What a company needs to discuss with the agency during a Pre-IND (or IDE) meeting is quite different than an End of Phase 1 or 2 meeting, and the needs for the Pre-NDA meeting are vastly different from the earlier meetings. All Phase 1-3 meeting types will be discussed, specific requirements will be reviewed, and a meeting request template will be provided. The basics reviewed in this seminar can be applied to both drugs and devices alike.

Learning Objectives
- Discuss types of FDA meetings
- Apply the regulations and guidance for meeting with the agency
- Develop questions and issues for the meeting request and package
- Determine the timing for the meeting request
- Determine the timing for the meeting package
- Construct the meeting package (using the traditional or Target Product Profile format)
- Manage meeting logistics (including who should attend)
- Manage meeting decorum
- Perform meeting rehearsals
- Compose meeting minutes and submit them to the agency
- Determine the agency meeting minute receipt
- Express clarification if the agency’s meeting minutes do not reflect important discussion points
- Examples of mock meeting packages will be provided for discussion and to illustrate how the types of meetings differ at each stage of development

Who Should Attend
- Any member of the device or drug development team who wishes to know more about FDA meeting logistics. Regulatory, Quality Assurance, Manufacturing, Clinical, Project Management, and Pre-Clinical personnel will all benefit from this course.

Interactive Activities
- Participants will create a meeting request for their own product or a mock one (a template will be provided electronically)
- Participants will hold a mock FDA meeting

Instructor
Joy Frestedt, Ph.D., C.P.I., R.A.C., F.R.A.P.S.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline

Day One: 8:30 a.m. – 5:00 p.m.
- Introduction to the ABCs and 123s of FDA meetings
- How to develop and track questions and issues for a meeting request and package
- The basic components of a meeting request and timing for submission (this will be a class activity for a mock product or real one if provided by participant)
- Timing of the meeting request and coordination of the team’s schedule
- Scheduling the meeting with the FDA
- Meeting package contents and organization
- Managing the timeline
- Drafting, reviewing, and finalizing the meeting package
- Meeting package submission logistics
- Meeting logistics (where to stay, travel schedule arrangement)
- Meeting decorum
- Meeting rehearsals
- How to take meeting minutes and when to submit them to the agency
- How to ask for clarification if the agency’s meeting minutes do not reflect all important discussion points
- Mock Meeting: A mock meeting package will be provided to the participants for reading ahead of the course along with “Rules of Engagement” for the mock meeting. One half of the class will represent a specific discipline from the Sponsor and defend the package while the other half of the participants will represent a specific discipline from the FDA.

What Participants Say About Barnett Seminars:

“The trainer was well-equipped, knowledgeable and open to Q&A’s. She provided excellent course material and spoke with great details from her current and past experience. This has been the best learning I have received as a CRA. I look forward to more courses!”

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
FDA Pre-Approval Inspection Readiness: Clinical Investigators

Course Description
This course will prepare participants for FDA pre-approval inspections, for pharmaceuticals, biologics, or medical devices. Clinical Investigator inspections will be addressed. Not only will we review the documents Investigators need to provide for a GCP inspection, but also the FDA’s rationale for different lines of questioning. Data shows a prepared Investigator is more likely to have a successful inspection.

The course will focus on a detailed review of the FDA Compliance Programs. For each topic in the Compliance Program, the questions the Investigator should expect, different ways questioning will be completed, and the types of documentation to be provided to readily satisfy FDA requests will be outlined. The information covered can be used to prepare Inspection Management teams and Subject Matter Experts.

Learning Objectives
- Understand what to prepare/FDA inspection logistics
- Identify what you can do on site to prepare for an FDA inspection
- Learn what to expect and provide during an FDA inspection
- Apply learning to real-life situations by inspecting records using FDA techniques

Who Should Attend
- Clinical Research Coordinators
- Principal Investigators
- Project Managers
- Personnel responsible for inspection preparation, representation

Interactive Activities
- Inspect sample records from the Clinical Investigator site using the same techniques as the FDA

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Regulatory Inspections of Clinical Investigators
  - The standards
  - Logistics and pre-inspection activities
  - Clinical Investigator inspections
  - Post inspection
  - Case study
FDA Pre-Approval Inspection Readiness: Sponsors and CROs

Course Description
This course will prepare participants for FDA pre-approval inspections, for pharmaceuticals, biologics, or medical devices. Sponsor/CRO inspections will be addressed. Not only will we review the documents sponsors and CROs need to provide for a GCP inspection, but also the FDA’s rationale for different lines of questioning. Data shows prepared sponsors and CROs are more likely to have a successful inspection.

The course will focus on a detailed review of the FDA Compliance Programs. For each topic in the Compliance Program, the questions the sponsor should expect, different ways questioning will be completed, and the types of documentation to be provided to readily satisfy FDA requests will be outlined. The information covered can be used to prepare Inspection Management teams and Subject Matter Experts.

Learning Objectives
• Understand what to prepare/FDA inspection logistics
• Identify what you can do on site to prepare for an FDA inspection
• Learn what to expect and provide during an FDA inspection
• Apply learning to real-life situations by inspecting records using FDA techniques

Who Should Attend
• Directors and Managers, Clinical Operations
• Quality Assurance Professionals
• Regulatory Affairs Professionals
• Clinical Research Associates
• Project Managers
• Personnel responsible for inspection preparation, representation

Interactive Activities
• Inspect sample records from the sponsor/CRO using the same techniques as the FDA

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
Fraud in Clinical Research: Detection and Deterrence

Course Description
Developing and incorporating systems for detecting and preventing fraud should be a standard part of any compliance plan. This course provides a critical examination of fraud in clinical research and seeks to support the clinical research professional in developing proficiency in detecting and preventing fraud. Attendees will learn the regulatory background of fraud and the criteria for characterizing misconduct as fraud. Using interactive case studies, the class will explore who commits fraudulent acts and how fraud is presented in clinical trials. Particular focus will be placed on recent cases of fraud in clinical research and how regulatory agencies and the clinical research industry are responding to discover and contain fraud. Methods for detecting and reporting suspect clinical data will be of special interest to monitors and auditors, while techniques for preventing fraud will be relevant for all attendees.

Learning Objectives
- Define, and differentiate between, fraud and misconduct/noncompliance
- Develop an understanding of why and how fraud occurs
- Examine methods for detecting and preventing fraud and misconduct
- Explain the Sponsor/CRO, IRB, Clinical Investigator, and Study Staff role in detection and prevention
- Review regulatory and industry documents from recent fraud cases and assess the impact and consequences
- Employ proactive risk analysis and internal controls for investigating and containing suspect clinical data

Who Should Attend
- This course is recommended for experienced Clinical Quality Assurance Professionals, Clinical Research Associates, Project Managers, Clinical Investigators, Study Coordinators, IRB Professionals, Institutional Officials involved in oversight of clinical research, Data Management Professionals, and Regulatory Affairs Professionals

Interactive Activities
- Critical Review of Regulatory and Industry Documents
- Assessment of Corrective and Preventive Action Plans and Responses
- Case Studies
- Problem Solving Scenarios
- Group Discussions of Best Practices

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
Learning Objectives
- Discuss the role of regulatory bodies in drug development
- Explain the logistics of the drug development process
- Provide an overview of regulations and guidance documents for drugs and biologics submissions
- Discuss content and requirements for the Investigational New Drug (IND) Application
- Review fundamentals of clinical trial structure and design, including Phases I-IV clinical studies
- Identify scientific and practical issues associated with the planning of a clinical research study

Instructor
Marina Malikova, Ph.D., MSci, M.A., C.C.R.A., RAC

Who Should Attend
- Clinical or Project Team Leaders who will be managing projects
- New Clinical, Regulatory, and Department Staff who will design clinical trial programs
- Clinical Research Associates, Data Managers or others interested in transitioning into clinical trial management
- Grant Administrators
- Medical Directors
- Medical Writers
- Regulatory Affairs Professionals
- Research and Development Personnel

Interactive Activities
- Review of Informed Consent: Identification of required and optional elements of the consent form according to current FDA and GCP ICH regulations
- Review of Form FDA 1571 for an IND application: create checklists that encompass timelines and sections needed from different parties involved

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
The Future of Good Clinical Practice Demands a Quality System Approach: Will You be Ready?

Course Description
The future of Good Clinical Practice (GCP) for the conduct of clinical trials demands a Quality System approach. With the advent of ICH E6 R2 and its subsequent adoption by several countries and many sponsors and clinical investigators, a quality system approach is necessary for the design, development, and execution of clinical studies.

FDA guidances speak on the need to conduct clinical trials using such an approach, but provide little in the way of direction on how to accomplish this. Risk management along with the application of corrective and preventive actions (CAPA) when issues arise, has become an integral component of GCP quality system approach. Many researchers do not have the knowledge or experience to conduct clinical trial risk management and adequately execute CAPA. This course will apply practical approaches and demonstrate associated tools and skills to assist the participant in using a quality system approach within the clinical trial arena from both the site and sponsor perspective.

Learning Objectives
• Identify regulatory body/authority recommendations for a GCP quality system
• Describe a quality system approach as it pertains to trial conduct
• Apply the concepts of a risk management approach to GCP and how they relate to a quality system approach
• Describe how corrective and preventive action (CAPA) and root cause analysis (RCA) pertain to a GCP quality system approach
• Define and demonstrate the application of GCP quality system approach tools to study conduct

Who Should Attend
• GCP Clinical Quality Assurance Professionals
• Sponsor and Vendor Clinical Operations Personnel
• Investigators and Sub-Investigators
• Study Coordinators
• Study Monitors
• Project Managers

Interactive Activities
• Group Breakout Exercises
• Q&A

Instructor
Lee Truax-Bellows, M.S., FNP, C.C.R.A., RQAP-GCP

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
Global GCP Monitoring: Domestic and International Compliance

Course Description
This course examines global Good Clinical Practice (GCP) compliance issues and GCP monitoring responsibilities. Participants explore GCP issues relevant to studies conducted within the US and internationally. There is a special focus on the culture issues impacting clinical research.

Learning Objectives
- Describe FDA Good Clinical Practice
- Define ICH Good Clinical Practice E6 Guideline
- Discuss the European Union Clinical Trial Regulations and associated documents (guidelines, reflection papers) and GCP
- Review other select countries’ monitoring bodies and responsibilities
- Assess the cultural impacts on monitoring responsibilities OUS

Who Should Attend
- Clinical Research Coordinators
- Clinical Research Associates
- Principal and Sub-Investigators
- Clinical Research Assistants
- Quality Assurance and other Regulatory Professionals

Instructors
This course will be taught by one of the following instructors:
Elizabeth Ronk Nelson, M.P.H.
Lily Romero, P.A., C.C.R.C.

Interactive Exercises
- Shared Participants’ Good Monitoring Practices
- Examination of Real Life Scenarios
- Review of FDA Q&A Information Sheet
- Review of the EMA regulatory agency document framework and select requirements

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
Good Clinical Practice for the Laboratory Scientist

Course Description
This course is designed particularly for the laboratory scientist to provide an appreciation of the regulated environment in which clinical studies are conducted and its relevance when collecting and analyzing biological specimens during a study. The drug development process (discovery through post-market) will be reviewed with particular attention to the fundamentals of Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), and where/how they apply. Examples and the impact of non-compliance will be discussed. Review and reinforcement of important concepts, such as laboratory accreditation, will be achieved through discussion and examples. The role of quality management in GCP Laboratories will be evaluated along with the standards to have in place that will ensure compliance, including outsourcing clinical laboratory activities. The challenges when conducting global studies related to specimen collection will also be discussed.

Learning Objectives
• Review the drug development process from discovery through post-market
• Describe the regulated environment in which clinical studies are conducted, including the handling/analyzing of biological specimens
• Discuss the fundamentals of GLP, GCP and GMP and where/how they apply
• Examine examples and impact of non-compliance with GLP/GCP
• Describe the role of quality management in GCP laboratories and the standards to have in place that will ensure compliance
• Discuss outsourcing clinical laboratory activities to minimize compliance risks
• Identify the role of laboratory accreditation in clinical studies
• Discuss the additional challenges related to specimen collection when conducting global studies

Who Should Attend
• Laboratory Scientists
• Research Assistants
• Laboratory Supervisors
• Principal Scientists
• Research Personnel that write protocols and/or handle/analyze biological specimens collected during a clinical study (analysis for drug metabolites, biomarkers, investigational products)

Interactive Activities
• Group activities: Situational reviews of practical scenarios
• Critique of current FDA Warning Letters
• Group discussions

Instructor
Suzi Tran, M.B.A., CMQ/OE, CQA, CSQE

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• Overview of the drug development process
• Discovery through post-market
• Working in a regulated environment
• Definitions of GLP, GCP, and GMP
• Global regulatory authorities – mission and responsibilities
• Fundamentals of GLP, GCP and GMP
• Non-clinical testing (GLP) – elements and examples of non-compliance
• Clinical research (GCP) – elements, sponsor responsibilities, examples of non-compliance
• Investigational product manufacture (GMP) – elements and examples of non-compliance
• Quality Management of GCP Laboratories
• Laboratory Quality System identification
• Qualifications
• Outsourcing
• Accreditation
• Challenges with global studies

What Participants Say About Barnett Seminars:
“Up-to-date teaching by an excellent presenter.”
Good Clinical Practice Regulatory Changes, Trends, and Best Practices Implementation

Course Description
This course will review recent FDA guidance documents and general regulatory trends, including revisions to ICH GCP E6 R2 and the repeal of the EU Clinical Trial Directive with replacement with the EU Clinical Trial Regulation 536/2014. With a number of new FDA guidances released over the past several years related to investigator oversight, risk-based monitoring, electronic medical records, and electronic informed consent, the industry must consider the trends and what the regulatory agencies are focusing on. We are seeing revisions in the U.S. and EU related to risk management and oversight that sponsors and sites should be prepared to implement with best practices. With the availability of multiple electronic resources there is an expectation to review information in real time; however, we still need to consider resources, confidentiality, and applications in a global research environment. In this session, we will discuss recent trends, upcoming changes and how to design best practices in an evolving clinical research world.

Learning Objectives
• Review recent FDA guidance documents
• Discuss changes to ICH GCP E6 R2 and the impact on the industry
• Evaluate regulatory trends and applications to best practices
• Review systems and techniques for quality control and proactive risk management
• Apply root cause analysis (RCA) and corrective and preventive actions (CAPA) to issue management
• Apply techniques and tools to manage performance issues and non-compliance

Who Should Attend
• Investigators
• Study Coordinators
• Site Manager
• Project Managers
• General Managers
• Project and Department Leads
• Clinical Research Associates
• Regulatory Managers
• Clinical Trial Assistants

Interactive Activities
• Team review of guidance documents and presentations of practical elements and applications
• GCP advanced case studies
• Risk identification and proactive management
• RCA and CAPA practical applications
• Group development of best practices for audits and inspections

Instructors
This course will be taught by one of the following instructors:
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.
Lily Romero, P.A., C.C.R.C.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
The Highly Effective CRA: Soft Skills for Taking Your Work to the Next Level

Course Description
Good monitoring skills are not the only critical skills a CRA needs to be effective in their role. A highly effective CRA is a great communicator; is able to anticipate potential challenges and barriers to success and takes the steps to remove and/or mitigate them; focuses on building relationships and partnership with their key stakeholders to position their projects/studies for success; resolves conflict with confidence, bravery, and laser-sharp solution focus; and identifies and solves problems for their root causes. This course is for the CRA who wants to build upon their existing communication, problem solving, and conflict resolution skills, and ultimately increase their effectiveness at the study site. Through highly interactive role-play and real-world case study activities, we will address:

• How can I move from reacting to challenges to anticipating and removing barriers to success?
• How do I drive results when I do not have direct authority over the investigator?
• How do I take a proactive approach to my work and work-related issues?
• How do I have the tough conversations with the investigator and her/his staff?
• How do I take my work to the next level of effectiveness?

Learning Objectives
• Describe what it means to be a highly effective CRA
• Describe the CRA/Investigative Team relationship lifecycle during a study
• Identify common pain points in this relationship, their root cause, prevention, and solutions
• Identify three steps to being proactive and deliberate in your everyday activities
• Explain how great communicators think
• Perform active listening behaviors
• Identify five motivators and points of leverage in the Investigator-CRA relationship
• Describe the mindset of a true professional and name 10 tips for increasing your professionalism
• Examine issues in real world situations between the CRA and Investigative sites
• Conduct two root cause analysis techniques with your peers
• State 6 practical tips for assessing and addressing conflict
• Define partnership

Who Should Attend
• This is an intermediate level course for the CRA who has more than 2 years of experience and seeks to build upon their existing communication, problem solving, and conflict resolution skills

Interactive Activities
• Case study review; situational reviews; conflict simulation; active listening simulation; problem identification simulation; problem solving relay

Instructor
Holly J. Deiaco-Smith, M.S.Ed.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• The Highly Effective CRA Defined
• Common Pain Points in the CRA-Investigative team relationship lifecycle
• The Proactive CRA
  • Being Deliberate
  • Proactive Language Activity
  • Outcomes-Based CRA Activity
• The Great Communicator
  • 5 components of communication
  • Active Listening
  • Investigative Site Role Play
  • Self-Awareness and Thinking Win-Win
  • Win-Win Island Activity
  • Points of Leverage in the CRA-Investigative Site Relationship
Day Two: 8:30 a.m. – 5:00 p.m.
• The True Professional
  • Building trust through your actions
  • Professionalism Case Study Activity
• The Problem Solver
  • A problem solving method
  • Root cause analysis techniques
  • Root causes analysis Team Activity
  • Sustainable solutions
  • Problem Solving Activity
• Conflict Resolution Framework
  • Being Brave: Tips for having the difficult discussions
  • Sticky Situations Case Study Activity
  • Conflict Resolution Simulation
• Moving to Partnership

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
How to Write Great SOPs and Work Instructions

Course Description
Standard Operating Procedures (SOPs) and Work Instructions are of high value when they are written properly. Too often authors leave out the right details to make these documents user-friendly and add-in items can cause confusion and lead to misunderstandings and at worse, non-compliance. This course presents a best practice for developing SOPs and Work Instructions starting with the critical technique of process mapping. In this seminar, learners will be taught the various components of each document and tips on how to write effective, user-friendly SOPs and Work Instructions. Participants will have an opportunity to bring a draft SOP and/or Work Instruction to the class and obtain feedback.

This is a highly practical course with real-world tips from persons in the field who create, review, and audit these documents.

Learning Objectives
- Define an SOP, Work Instruction, and a “controlled document”
- Describe the benefits or process mapping and explain how to process map
- Create an SOP from a Process Map
- Explain how an SOP and Work Instruction are different than other procedural documents
- State the key components of an SOP and WI and explain each components purpose
- Identify three situations where the writing in an SOP/WI might expose the department to risk
- Identify three situations where the writing in an SOP/WI would require intensive maintenance and review

Who Should Attend
- Authors and Reviewers of SOPs and Work Instructions

Interactive Activities
- Activity 1: SOPs and Work Instructions
- Activity 2: Name that Controlled Document
- Activity 3: Let's Process Map
- Activity 4: Write the SOP
- Activity 5: SOP, Work Instruction, Both, Neither?
- Activity 6: Write “Fun” Work Instructions
- Activity 7: Document Swap

Instructors
This course will be taught by one of the following instructors:
Holly J. Deiaco-Smith, M.S.Ed.
Kirsten Morasco

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- What is an SOP?
- Methodology for Developing SOPs
- Components of an SOP
- Dos and Don’ts of SOP Writing
- What is a Work Instruction?
- Methodology for Developing Work Instructions
- Components of a Work Instruction
- Dos and Don’ts of Work Instruction Writing

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Informed Consent: Beyond the Basics

Course Description
This intensive course provides a detailed exploration of best practices surrounding the development of informed consent and patient educational materials as well as tools and methodologies for obtaining informed consent. Going beyond the minimum regulatory requirements, this course offers practical as well as theoretical information for enhancing the informed consent process.

Learning Objectives
- Describe tools and techniques for communicating risk and benefits of clinical research trials
- Explain methods for evaluating readability and understandability of informed consent/patient education materials
- List various resources available to aid in developing more patient friendly consent forms
- Discuss how to optimize the informed consent discussion

Interactive Activities
- Evaluate readability of a sample document
- Craft "important messages" using a sample protocol
- Create a comprehension or knowledge validation "quiz"
- Process map the "ideal" patient education flow

Who Should Attend
- Principal Investigators and Sub-Investigators
- Research Nurses and Study Coordinators
- Project Managers/Directors
- Recruitment Specialists

Instructor
Beth D. Harper, B.S., M.B.A.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Welcome and Introductions
- Regulatory Recap – the Letter and Spirit of the Laws and Regulations
- Common Consenting Challenges: Troubleshooting the Issues
- Consent Development Best Practices: Messages and Materials to Ensure Understandability
- Communication Best Practices: Strategy and Flow to Ensure Seamless Consent
- Validating Knowledge Transfer: Ensuring the Message is Received
- The Role of E-Consenting and Additional Resources for “Out-of-the-Box” Consenting
- Wrap-Up / Q & A / Departures

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Institutional Review Boards (IRBs): The Changing Landscape and the Effect on the Conduct of Clinical Research

Course Description
This course examines the evolution of the Institutional Review Board and how current events are shaping its future and that of the conduct of clinical research. Special attention is given to how IRBs can develop internal systems that assist in meeting their regulatory obligations of protecting human research participants in response to new requirements. Primary attention will be given to examination and development of Quality Systems within the Institutional Review Board and their positive impact on meeting the demands for regulatory compliance and the protection of human research subjects. The content is appropriate for any professional working with IRBs that review, approve, and oversee clinical investigations regulated by the FDA.

Learning Objectives
• Explain the regulations, agencies, and guidance that govern IRB composition and function
• Compare and contrast the IRB model of past and present and how IRBs have adapted
• Identify the new and proposed regulations, guidance, and legislation and the impact on IRBs
• Utilize corrective and preventive action plans and other tools to detect and deter noncompliance
• Describe how regulatory authorities inspect and assess IRBs, their current findings, and proper responses
• Define Quality Improvement (QI) and explore how to leverage it to help fulfill IRB responsibilities
• Review the FDA’s updated plan for inspecting local and central IRBs
• Discuss new guidance for continuing review and transfer of study oversight

Who Should Attend
This course is recommended for experienced:
• Clinical Quality Assurance Professionals
• Clinical Research Associates
• Project Managers, or others involved in site and IRB assessment and/or selection
• Clinical Investigators, Study Coordinators
• IRB Members, IRB Professionals, and Institutional Officials

Interactive Activities
• Review of Regulatory and Industry Documents
• Assessment of Corrective and Preventive Action Plans and Responses
• FDA Mock Audit/Inspection Exercise
• Case Studies and Problem Solving Scenarios

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- The Role of IRBs in Clinical Research: Established and Evolving
- New Developments and Emerging Trends in IRB Oversight and Function
- Scandal and Scrutiny: Current Compliance Concerns and the “Ripple Effect”

Day Two: 8:30 a.m. – 5:00 p.m.
- Operational Quality Systems for the IRB: Format for Compliance
- Regulatory Authority Inspections and Assessments: Current Focus and Processes
- Using Risk Management Assessments and Quality Improvement as Tools for Securing Compliance

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
Introduction to Clinical Data Management

Course Description
This course provides an excellent introduction to clinical data management in the pharmaceutical, medical device, biotech and academic research areas. Its focus on processes and their rationale renders it ideal for the new data manager and to other individuals who wish to learn basic clinical data management skills and the function of clinical data management in the medical product development process.

Learning Objectives
- Understand the medical product development and study development process and the regulations that govern the clinical research process
- Identify the roles and responsibilities of the clinical research team
- Discuss the protocol design and development process
- Review the CDM Start-up activities/documentation
- Analyze case report form design, data tracking and collection, data entry and capture
- Discuss data review, validation, and queries
- Comprehend the rationale of the MedDRA dictionary
- Identify the role that CDISC and CDASH play in the standardization of data collection and reporting
- Understand quality control and quality assurance
- Discuss database lock and release
- Understand adverse event reporting and reconciliation
- Identify the changing CDM role towards project management and the issues associated with managing mega-trials and CROs

Who Should Attend
- Academic Research Organization members, Biotech and Device company personnel who will be managing data
- Staff of Pharmaceutical Companies, Contract or Independent Research Organizations whose function is to review, correct, enter, or manage data, with less than one year of experience in that function
- Individuals who desire a basic understanding of the function of clinical data management in the medical product development process

Interactive Activities
- Core Definitions and Concepts
- To “Split” or Not to Split
- Identifying Data Checks

Instructor
Denise Redkar-Brown, MT

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Introduction to Medical Product Development: Good clinical practice – purpose and history; roles and responsibilities of the FDA/ICH; phases of medical product research and development
- Overview of Clinical Data Management: Data management core processes and data flow; roles and responsibilities within clinical data management; interfaces with other disciplines within clinical research and development
- Protocol and Design: Good clinical study; steps in protocol development; designing a clinical trial; protocol elements and modifications
- Study Start-Up – A Clinical Data Management Perspective: Study documentation; data handling manual; annotated case report form and database design; remote data management
- Case Report Form Design and Development: Standard and study specific case report form modules; organization of a case report form; CRF design guidelines; data collection methods; CRF tracking; data capture, flow and entry; remote data capture

Day Two: 8:30 a.m. – 5:00 p.m.
- Data Review and Validation: Data errors; frequently encountered problems; identifying and developing data checks; data queries
- Coding: Purpose of coding; common coding dictionaries; computerized coding (autoencoding); coding philosophies
- Quality Control and Quality Assurance: Roles of quality control and quality assurance; audits and documentation
- Database Release and Lock: Study close-out and database release; lock and unlock
- Adverse Event (AE) Reporting: Definitions; describing and documenting AEs; collecting AE data

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold This Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Introduction to Clinical Research

Course Description
This two-day course will cover topics designed to explain exactly what a clinical trial is and how clinical research is conducted. Since many clinical trials are often conducted in the European Union (EU), we will also include some key EU requirements. We will start by looking at the history of clinical trials to give you a better understanding of how and why current regulations were created to protect and inform clinical trial participants as well as ensure the public that the information obtained from those trials is accurate and reliable. Then we will look at the process of drug and device development from discovery to approval. We will introduce you to the protocol which is the blueprint for any clinical trial and explain what an informed consent is and why it is so important. In addition to these key trial documents, we will also review other important documents that are used in clinical trials. Finally, we will provide you with resources that will enable you to stay informed about topics and regulations regarding clinical trials in the U.S. and in the European Union.

Learning Objectives
- Identify the members of the clinical research team and describe their primary roles and responsibilities
- Describe the difference between drug development and medical device development
- Discuss the historical events and importance of Good Clinical Practice (GCP) in clinical research conducted throughout the world
- Identify key FDA and EU regulations that pertain to clinical research
- Describe what a clinical protocol, informed consent, investigator’s brochure, and essential documents are and their importance in clinical trials
- Identify how safety information is collected and reviewed during clinical trials
- Define and identify adverse events

Who Should Attend
- Clinical Research Associates and Clinical Research Coordinators with less than six months experience
- Nurses
- Individuals interested in the fundamentals of clinical research and clinical trials
- Aspiring Clinical Research Associates and Clinical Research Coordinators
- College Students and New Graduates considering a career in clinical research
- Individuals considering participating in a clinical trial or know of someone who is considering participating in a clinical trial

Interactive Activities
- Discussion: Ethics in Clinical Research
- Protocol and Informed Consent Review
- Recruitment Advertisement Review
- Identifying and Delineating Clinical Research Team Roles and Responsibilities
- Adverse Event Identification Exercise

Instructors
This course will be taught by one of the following instructors:
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Dates and Locations

<table>
<thead>
<tr>
<th>Course Dates</th>
<th>Locations</th>
<th>Course #:</th>
<th>Registration Dates</th>
<th>Course Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2-3, 2020</td>
<td>Philadelphia, PA 19103</td>
<td>SC2A0420</td>
<td>$1,675 by February 28</td>
<td>$1,875 after February 28</td>
</tr>
<tr>
<td>June 18-19, 2020</td>
<td>San Diego, CA 92101</td>
<td>SC2D0620</td>
<td>$1,675 by May 15</td>
<td>$1,875 after May 15</td>
</tr>
</tbody>
</table>

ACRP Members: Receive 10% off!

Academic Discount
A $400 academic discount is available to those who qualify.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 15 hours (1.5 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-18-005-L01-P. Released: 5/18.
Introduction to the FDA

Course Description
This course provides an introduction to the Food and Drug Administration (FDA) to those who need to have an understanding of FDA to perform their jobs. The course provides a background on the agency, FDA history, FDA organization, and how the FDA functions divisionally.

Those attending will learn about the various FDA centers and what the center responsibilities are. The attendee will also learn about the FDA review process, FDA submissions, Advisory Committees, FDA clinical trials, and FDA compliance activities.

Learning Objectives
- Navigate the FDA
- Describe FDA responsibilities
- Describe the FDA centers
- Describe the FDA review process
- Summarize FDA compliance activities
- Describe the FDA submissions process
- Navigate FDA Advisory Committees

Who Should Attend
- Those who need to have an understanding of FDA in research, clinical, regulatory affairs, quality, and administrative positions

Interactive Activities
- Scenario reviews
- Discussion

Instructor
Nikki Christison, B.S., C.C.R.A., T.I.A.C.R.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Introduction To FDA
- FDA History/Background
- FDA Laws/Regulations/Policies/Guidances
- FDA Definitions
- FDA Centers
  - CDER
  - CBER
  - CDRH
- FDA Combination Products
  - FDA Office of Combination Products

Day Two: 8:30 a.m. – 5:00 p.m.
- FDA Activities
  - FDA Relationships
  - FDA Meetings
  - FDA Meeting Preparation
  - FDA Review Process
- FDA Submissions
  - CDER (IND, NDA)
  - CBER (IND, BLA)
  - CDRH (510(k), IDE, PMA)
- FDA Clinical Trials
  - Phase 0
  - Phase 1
  - Phase 2
  - Phase 3
  - Phase 4
- FDA Advisory Committees
  - CDER
  - CBER
  - CDRH
- FDA Inspections
  - GMP
  - GCP
  - GLP
Introductory Pharmacology for Non-Clinical Professionals

Course Description
This course is designed to introduce basic pharmacology concepts which are utilized in drug development and clinical research to non-clinical professionals. Topics will include the basic principles of pharmacology and overview of several major classes of therapeutic agents, with attention to their mechanisms of action. Issues of current and future directions in pharmacology will be addressed, including the sources of information about pharmacologic agents, the ethics of human experimentation, the drug development process, and new biotechnological approaches to drug design.

Learning Objectives
- Become familiar with the concepts of pharmacokinetics and pharmacodynamics
- Develop knowledge regarding several major classes of therapeutic agents and understand their mechanisms of action
- Gain an in-depth understanding about pre-clinical research and steps necessary for transition to clinical phases of the drug development process
- Become familiar with the concept of molecular targeted therapeutics
- Review of Investigator’s Brochure (IB) contents and the Investigational New Drug Application (IND)
- Critique and analyze information obtained from scientific literature and demonstrate an understanding of the pharmacology parameters

Who Should Attend
- Clinical or Project Team Leaders who will be managing projects
- New Clinical, Regulatory, and Department Staff who will design clinical trial programs
- Clinical Research Associates, Data Managers or others interested in transitioning into clinical trial management
- Grant Administrators
- Medical Directors
- Medical Writers
- Regulatory Affairs Professionals
- Research and Development Personnel

Interactive Activities
- Review of Investigator’s Brochure: Create checklists that encompass timelines and sections needed from different parties involved
- Interactive Discussions
- Questions and Answers

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1.215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Instructor
Marina Malikova, Ph.D., MSci, M.A., C.C.R.A., RAC

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Introduction: The Heritage of Pharmacology
- Sources of Information about Drugs
- Drug-Receptor Interactions
- Overview of pharmacology parameters utilized in the drug development process (i.e. half-life of the drug, plasma concentration, therapeutic index, area under the curve (AUC), effective concentration EC50, etc.)
- Principles of Pharmacokinetics (PK studies): Drug Absorption, Distribution, Metabolism and Elimination (ADME parameters overview)
- Pharmacodynamics (PD studies): Dose-Response Relationships; Time-Concentration Relationships
- Drug Interactions: CYP enzymes and their role in drug metabolism and drug-drug interactions and side effects
- Overview of Investigator’s Brochure contents and Investigational New Drug Application (IND)

Day Two: 8:30 a.m. – 5:00 p.m.
- Principles of Endocrine Pharmacology
- Pharmacology of the Autonomic and Peripheral Nervous System
- Central Nervous System Pharmacology
- Pharmacology of Pain and Inflammation
- Principles of Cardiovascular Pharmacology
- Principles of Chemotherapy
- Molecular targeted therapeutics for cancer treatment

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Investigator-Initiated Trials (IITs) and the Role and Responsibilities of the Investigator

Course Description
This course provides an overview of the applicable regulations for Investigator-Initiated Trials (IITs), including the role and responsibilities of the individual investigator who acts as an investigator and a sponsor in conducting the study. The seminar includes a review of the reporting requirements and essential documentation required for these trials, and illustrates the risks involved. Tips on how to avoid the common pitfalls are addressed, including examples from FDA inspections and how to prepare for a possible inspection.

Learning Objectives
- Explain the applicable federal regulations for IITs, including sponsor and investigator responsibilities
- Recognize GCPs and the principles involved in quality research
- State the steps involved in initiating an IIT, and review the regulatory reporting requirement of investigators and sponsors, including safety reporting and investigational product accountability
- Examine protocol development and compliance
- Examine informed consent development and the HIPAA authorization
- Discuss required essential documentation and the need to remain “audit-ready” throughout the study
- Discuss the need for adequate monitoring and a monitoring plan
- Cite ways to minimize risks associated with IITs
- Provide examples of regulatory deficiencies as noted in FDA Warning Letters
- Discuss the principles of ethics and the quality control process, including possible FDA inspections

Who Should Attend
- Investigators/Site Study Team Members
- Sponsor Study Team Members
- Ethics Committee Members

Interactive Activities
- Investigator Responsibilities
- Sponsor Responsibilities
- Issues with Informed Consent Process
- Differences between industry-sponsored and investigator-initiated studies
- Value of a Monitor
- Avoiding Common Pitfalls

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
In Vitro Diagnostic Devices: Study Design, Conduct, Regulatory Requirements and Submissions for Approval

Course Description
This course reviews the different regulatory pathways for medical devices, including the determination of significant and non-significant risks and how it affects submissions and the review process. A specific focus on in vitro diagnostic devices (IVDs) will be taken as participants learn how the determination is made for the exemption of requirements of the Investigational Device Exemption (IDE) regulations. Study design conduct and Quality Control (QC) requirements for IVDs and laboratory developed tests will be discussed.

Learning Objectives
- Discuss the FDA’s role in device development
- Explain the logistics of the device development process
- Understand regulatory pathways for devices, specifically in vitro diagnostic tests
- Review the “pre-submission” process for IVDs
- Identify scientific and practical issues associated with the planning of a clinical research study for medical devices
- Explain the post approval responsibilities of sponsors and device reporting requirements

Who Should Attend
- New Project Managers
- Project Managers with little or no device development or clinical trial experience
- New Clinical, Regulatory, and Department Staff who will design clinical trial programs for medical devices
- Project Team Leaders with limited direct clinical trial experience who will be managing device development programs and supervising project managers
- Medical Directors involved in the development and conduct of device research
- Medical Writers involved in device trials
- Clinical Research Associates working with organizations that sponsor device research
- Regulatory Affairs Professionals involved in research with IVDs
- Research professionals involved in submitting material for IRB review
- IRB members and support staff involved in review of device research

Interactive Activities
- Review a medical device application. Create a checklist that encompass timelines and sections needed from different parties involved.

Instructor
Marina Malikova, Ph.D., MSci, M.A., C.C.R.A., RAC

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Module 1: Review of the device development process and regulatory requirements for devices
- Module 2: Overview of regulatory requirements to plan, initiate and execute a clinical trial for medical devices; Investigational Device Exemptions (IDEs) and types of IDEs; IDE-exempt studies
- Module 3: Transition from pre-clinical phase of drug development to clinical phases, including feasibility and Pivotal study requirements; sponsor’s responsibilities for significant and non-significant risk devices
- Module 4: Review the “pre-submission” process for IVDs; documentation required for IRB submissions
- Module 5: Classification of in vitro diagnostic products (IVDs) and regulatory requirements for IVDs
- Module 6: Investigational IVDs used in clinical investigations of therapeutic products, including differences between IVDs and companion diagnostic trials and classifications

Day Two: 8:30 a.m. – 5:00 p.m.
- Module 7: Emergency use of IVDs outside of study protocol
- Module 8: De Novo classification for IVD devices
- Module 9: Labelling and pre-market approval requirements for IVDs
- Module 10: Laboratory developed tests and applicable FDA regulations
- Module 11: FDA requirements for Quality Control (QC) and safety reporting for medical devices and IVDs
- Module 12: Current Good Manufacturing Practices (CGMPs) and Quality System Regulation (QSR) requirements for medical devices

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Medical Device Approval Process: Preparation and Processing of 510(k)s, IDEs, and PMAs

Course Description
This course highlights new changes to medical device regulations and provides an overview to the submission of documents to the FDA for approval of medical device products. Participants gain a better understanding of the medical device approval process and the underlying scientific and regulatory principles involved. Guidelines for each aspect of research are provided, as well as information on the structuring of submissions and post-approval documents. Information on maintaining on-going relationships with the FDA is also discussed. The course enables regulatory affairs professionals to provide the FDA with necessary information and obtain product approval.

Learning Objectives
- Navigate the FDA medical device approval system
- Prepare contents of a 510(k)
- Prepare contents of an IDE
- Prepare contents of a PMA

Who Should Attend
- This course is intended for Regulatory, Technical, and Quality Personnel who require an understanding of the medical device approval system. The course also benefits management, legal, and other personnel who must be familiar with the essentials of the medical device approval process system and submission of related documents.

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Introduction to the FDA: History; law; definitions; overview of FDA; establishment registration; product listing
- 510(k) Process: Substantial equivalence; letter of notification; truthful and accurate statements; cover page; table of contents; checklist for filing; executive summary; intended use; device description; table of comparison; similarities and differences; environmental testing; comparative performance; clinical performance; software; biocompatibility; voluntary standards; sterility; reusable or single use device control; labeling; kit information; 510(k) summary; FDA 510(k) review

Day Two: 8:30 a.m. – 5:00 p.m.
- Investigational Device Exemption (IDE): Significant risk versus nonsignificant risk; prior investigations; investigational plan; methods, facilities, and controls; investigator agreement; IRB; institutions; sale of device; environmental assessment; labeling; informed consent; others; GCP; FDA actions on applications
- Premarket Approval (PMA): Applicant; table of contents; summary; device description; standards; non-clinical studies; clinical studies; one investigator; bibliography; samples; labeling; environmental assessment; other; PMA amendments; PMA supplements; FDA action on PMA; post-approval requirements
Medical Device GCP Overview

Course Description
This course provides information across the full range of medical device clinical trial activities; and applicable Good Clinical Practices (FDA 21 CFR 812 Investigational Device Exemption, ISO 14155 Clinical Investigations of Medical Devices, and principles of ICH Good Clinical Practices E6 Guideline). It is an ideal source of information for those new to clinical research and those requiring information specifically relating to regulatory and practical aspects of medical device clinical research.

Learning Objectives
- Recognize the regulatory pathways for medical devices
- Explore practical aspects of investigator and site selection
- Discuss how to comply with the fundamentals of Good Clinical Practice (GCP)
- Examine practical aspects of conducting international clinical trials under GCP

Instructor
Elizabeth Ronk Nelson, M.P.H.

Who Should Attend
- Clinical Research Associates who want a greater understanding of the medical device clinical trial process and their role in it
- Clinical Project Managers who are taking on a wider range of responsibilities and need to gain a greater understanding of the regulatory and practical issues involved in medical device clinical trials
- Regulatory Affairs Professionals who may be new to the device industry or new to the clinical trials process
- Clinical Investigators and Clinical Research Coordinators interested in gaining a broader understanding of their role and responsibilities and how these tasks relate to the overall research process

Interactive Exercises
- Clinical and Data Management Discussions
- Review of Regulatory Documents

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline

<table>
<thead>
<tr>
<th>Course Outline</th>
<th>Day One: 8:30 a.m. – 5:00 p.m.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Medical Device and Good Clinical Practices</td>
</tr>
<tr>
<td></td>
<td>Medical Device and Regulatory Requirements</td>
</tr>
<tr>
<td></td>
<td>Clinical Research Team: Roles and Responsibilities</td>
</tr>
<tr>
<td>Day Two: 8:30 a.m. – 5:00 p.m.</td>
<td>Clinical Study Protocol Elements and Device Accountability</td>
</tr>
<tr>
<td></td>
<td>Role of the Institutional Review Board (IRB) and Informed Consent</td>
</tr>
<tr>
<td></td>
<td>Principles of Ethics and Quality Control</td>
</tr>
</tbody>
</table>

Day One: 8:30 a.m. – 5:00 p.m.
- Medical Device and Good Clinical Practices
- Medical Device and Regulatory Requirements
- Clinical Research Team: Roles and Responsibilities

Day Two: 8:30 a.m. – 5:00 p.m.
- Clinical Study Protocol Elements and Device Accountability
- Role of the Institutional Review Board (IRB) and Informed Consent
- Principles of Ethics and Quality Control
Medical Terminology for Clinical Research Professionals

Course Description
This course provides an excellent introduction to and review of medical terminology for newcomers and seasoned professionals responsible for reviewing clinical charts, reviewing CRFs, and entering CRF data. Participants will receive a comprehensive overview and body system approach to understanding the root of medical terms, normal body system functions, and abnormal or disease states. Students will investigate the structure of medical terms and analyze written health care communication.

Learning Objectives
- Identify word roots
- Identify and define prefixes and suffixes in the construction of medical terms
- Identify and use medical terms correctly for body systems and disease conditions
- Describe normal human anatomy and body systems related to medical terminology
- Apply medical terminology knowledge to the analysis of subject records in clinical research

Who Should Attend
- Clinical Trial Personnel: Monitors, Managers, Support Staff, Data Entry, and Study Coordinators responsible for documenting, collecting, and reviewing medical history and adverse events occurring in clinical trials of new and marketed products

Interactive Activities
- Flash Cards
- Sample Patient Progress Notes, Procedure Reports, and Hospitalization Records
- Crossword Puzzles
- Interactive CD
A copy of the book "Medical Terminology in a Flash!: An Interactive Flash-Card Approach" will be provided for all participants.

Instructors
This course will be taught by one of the following instructors:
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.
Lily Romero, P.A., C.C.R.C.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Overview of medical terminology from a body system approach
- Break down medical terms into the core elements: prefix, suffix, and root words
- Combining forms: Learn to take a root word and a prefix or suffix with a combining vowel to form a medical term
- Discussion of body systems, basic anatomy, and disease states

Day Two: 8:30 a.m. – 5:00 p.m.
- Continue the discussion of body systems, basic anatomy, and disease states
- Simulation: review of sample patient records to determine subject eligibility for a trial, and identify adverse events and serious adverse events
Medical Writing Fundamentals: How to Write Regulatory Documents

Course Description
Medical writing has its own standard practices and idiosyncrasies. Knowing what to write, how to format, and how to navigate corporate processes can require a big learning curve. This seminar will give learners a broad understanding of writing practices, formatting, working with tables and figures, and communicating effectively. Practical applications of these skills will be described as they apply to writing all types of documents for submission to global regulatory authorities, including protocols, clinical study reports, investigator’s brochures, data management plans, statistical analysis plans, documents for modules in the Common Technical Document (CTD) format, and briefing books. In addition, real-life examples of strategies for generating a great document each time by understanding the what and why of the different documents will be presented.

Learning Objectives
- Use basic medical writing skills, including correct abbreviation practices, consistent captioning, and table generation
- Utilize styles and templates
- Describe style guides and their importance
- Navigate the communication process necessary for document review and completion
- Conduct a literature search
- Apply these skills to all regulatory documents

Who Should Attend
- New Medical Writers
- Clinical Research Professionals (i.e., Clinical Research Associates, Data Managers)
- Statisticians
- Study Coordinators
- Document Signatories (i.e., Chief Medical Officers, Clinical Pharmacologists)
- Personnel who review regulatory documents
- Personnel involved with investigator-sponsored studies

Instructor
Caroline Ritchie, Ph.D., M.B.A.

Interactive Activities
During the course, participants will:
- Create a standard table applying correct medical writing practices
- Perform an active literature search
- Practice tips and shortcuts that medical writers use every day
- Participate in a short exercise regarding application of the course materials to different types of documents or different types of development (i.e., drugs, biologics, devices, diagnostics)

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

What Participants Say About Barnett Seminars:
“I would highly recommend Barnett; the class was informative, interesting and the instructor was very engaging.”

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Mindfulness for the Clinical Research Professional

Course Description
Simply put, mindfulness is paying attention in the moment to thoughts and actions. Mindfulness increases productivity, enhances leadership effectiveness and supports happiness. It also helps leaders to meet adaptive challenges resulting from constant change. This highly interactive course teaches clinical research professionals how to employ mindfulness in their day-to-day work, how to make the connection between mindfulness and emotional intelligence, and tips on reducing stress and improving performance for themselves and their teams in high stress clinical research environments.

Learning Objectives
• Describe mindfulness and emotional intelligence and explain their applicability to the clinical research professional
• Explain how the practice of mindfulness contributes to increased productivity, enhanced creativity, and compassionate leadership
• Describe the benefits of mindfulness in clinical research situations
• Identify five tips and techniques to integrate mindfulness practice into daily life

Who Should Attend
• Leaders and Managers from Sites, Sponsors and CROs
• Project Management Professionals

Interactive Activities
• Dyads
• Attention and Focus Exercise
• Self-Awareness-Emotional Regulation Practice
• Mindful Listening (Informal and Formal)
• Mindful Conversation (Informal and Formal)

Instructor
Kelli J. Deiaco, Ph.D.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• Module 1: Mindfulness and Emotional Intelligence
  • What is mindfulness and emotional intelligence?
  • Development of emotional intelligence
  • How regular practice can lead to better decision making
  • Improving communication skills through mindfulness
Day Two: 8:30 a.m. – 5:00 p.m.
• Module 2: Application of Skills
  • Benefits of emotional intelligence: Increasing productivity, enhancing leadership effectiveness, promoting happiness
  • Continuing to reap the rewards: Sustaining practice

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Monitoring Clinical Drug Studies: Beginner

Course Description
This fundamental “how to” and “why” workshop focuses on current regulatory requirements to promote successful monitoring of studies. Participants will learn about the role and responsibilities of the monitor, the investigator, and the IRB from pre-study through post study. Best practice techniques for site management will be provided, and activities such as case scenarios and simulation exercises reviewing an informed consent document, investigator study file, subject case report forms, and source documents will reinforce learning concepts. This is a practical, hands-on introduction to the job and how clinical monitoring tasks are performed.

Learning Objectives
• Discuss the role the CRA plays in the drug development process
• State the “letter” and “spirit” of FDA regulations as well as ethical considerations pertinent to conducting clinical trials
• Identify and select qualified investigators and the investigative site
• Prepare for and conduct Site Selection/Qualification, Site Initiation, Routine Monitoring, and Study Close-Out Visits
• Manage and report adverse events (AEs)
• List study documentation requirements and standards for collecting and reporting clinical trial data

Instructors
This course will be taught by one of the following instructors:
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.
Lily Romero, PA, C.C.R.C.
Elizabeth Ronk Nelson, M.P.H.

Who Should Attend
• This course is beneficial if you have been monitoring for less than one year, or if you are an in-house CRA or project assistant who supports CRA monitoring activities

Interactive Activities
• Basic Monitoring Skills – Hands-on Simulation Exercise
• Informed Consent Critique and Selecting Clinical Sites
• Identifying, Classifying, and Reporting Adverse Events
• Drug Accountability Case Studies and Calculating IP Compliance
• Case Scenarios: Site Selection, Study Initiation Visits, and Routine Monitoring Visits
• Monitoring Visit Priorities Activity

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• Overview of Drug Development and ICH GCP: Terminology; the drug approval process
• The Clinical Research Team: Roles and responsibilities
• The Site Selection Process and Site Qualification Visits: Locating, screening, and evaluating prospective investigators; selection criteria

Day Two: 8:30 a.m. – 5:00 p.m.
• IRBs/IECs and the Protocol Approval Process: Membership requirements; documents and activities
• Study Subject Recruitment, and the Informed Consent Document and Process: FDA and ICH requirements; the role of the monitor in assuring appropriate consent
• Investigator’s Meetings and Study Initiation Visits: Purpose, preparation, and documentation
• Managing and Reporting Adverse Events: Terminology and examples; investigator and sponsor reporting requirements
• Investigational Product Accountability and Essential Documents: Regulatory and subject Documents; drug storage, documentation, and accountability requirements

Day Three: 8:30 a.m. – 5:00 p.m.
• Routine Monitoring Visits and Source Data Verification: Preparing for, during the visit, and post visit activities; process for reviewing source documents and identifying discrepancies
• Clinical Data Management Overview, Trip Reports, and Study Close-out Visits: Paper-based and electronic case report forms, queries, and conducting close-out visits
• Monitoring Simulation Exercise: Regulatory Binder and Source Data Verification

Course Dates and Locations
March 25-27, 2020
San Diego, CA 92101
San Diego Solamar
Course #: SSB00320
$1,795 by February 24
$1,995 after February 24
ACRP Members: Receive 10% off!

June 10-12, 2020
Boston, MA 02110
Metro Meeting Centers
Course #: SSB00620
$1,795 by May 8
$1,995 after May 8

A $400 academic discount is available to those who qualify.


Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Monitoring Clinical Drug Studies: Intermediate

Course Description
This course reflects current industry trends and challenges for the more experienced monitor/clinical research associate – with a focus on developing tools and identifying challenges for effective monitoring. Industry standards and best practices will be discussed with an emphasis on the relationship between the Sponsor/CRO and the Investigator/site personnel. References and resources (including those available online) will be provided. Topics include site management, developing tools for effective monitoring, co-monitoring assessments, challenges in our global environment, and successful time management. Discussion will include how sponsors/CROs interpret and implement various aspects of clinical trials and GCP principles.

Learning Objectives
- Describe various sponsor interpretations of FDA regulations and practical application of the ICH GCP E6 Guideline
- Discuss current trends in clinical research
- Evaluate and develop more efficient study tracking and management tools
- Identify more effective mentoring and CRA assessments
- Manage your sites more effectively and ensure their optimum performance
- Identify strategies for managing issues including root cause analysis and corrective and preventive action plans
- Prepare for monitoring challenges in a global clinical trial
- Prepare sites for an FDA/Regulatory Authority inspection

Who Should Attend
- Experienced Clinical Research Associates and Medical Research Associates with more than two years of experience seeking to update their knowledge of the GCP regulations and guidelines and fine tune their site management and monitoring skills
- Clinical Research Professionals involved in the management of Clinical Research Associates, and/or study/project management
- Identify more effective mentoring and CRA assessments
- Manage your sites more effectively and ensure their optimum performance
- Identify strategies for managing issues including root cause analysis and corrective and preventive action plans
- Prepare for monitoring challenges in a global clinical trial
- Prepare sites for an FDA/Regulatory Authority inspection

Interactive Exercises
- The experienced Monitor’s simulation exercise
- Case studies in motivation and site management
- CAPA documentation critique

Instructors
This course will be taught by one of the following instructors:
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.
Lily Romero, P.A., C.C.R.C.
Elizabeth Ronk Nelson, M.P.H.

Course Dates and Locations

<table>
<thead>
<tr>
<th>Month</th>
<th>Date(s)</th>
<th>Location</th>
<th>Course #:</th>
<th>Fee(s) by Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>April</td>
<td>8-9, 2020</td>
<td>Philadelphia, PA 19103</td>
<td>SSA0420</td>
<td>$1,675 by March 6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$1,875 after March 6</td>
</tr>
<tr>
<td>ACRP Members: Receive 10% off!</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>June 22-23, 2020</td>
<td>San Diego, CA 92101</td>
<td>SSSID0620</td>
<td>$1,675 by May 21</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$1,875 after May 21</td>
</tr>
</tbody>
</table>

ACRP Members: Receive 10% off!

Academic Discount
A $400 academic discount is available to those who qualify.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 15 hours (1.5 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.


Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Monitoring Clinical Drug Studies: Advanced

Course Description
This course will focus on more complex and challenging issues affecting the Clinical Research Associate with management/leadership responsibilities. Current hot topics and trends will be discussed. Participants will analyze case studies to identify how monitors/study leaders could have identified, managed, and followed up on under performance or non-compliance issues. Corrective and preventive action plans (CAPA) will be developed as part of the course activities. Training and mentoring techniques will be included to assist training/mentoring sponsor/CRO and site staff.

Learning Objectives
• Explain the most recent regulations and guidance documents that govern clinical research
• Discuss current issues that affect clinical monitoring
• Describe effective mentoring techniques
• Discuss ways of assessing monitor skills
• Develop techniques to manage stakeholders
• Define techniques to promote successful site management
• Identify, manage, and report study-related issues
• Describe how to manage situations involving fraudulent data
• Discuss FDA’s BIMO program for sponsor and investigator inspections

Who Should Attend
• CRAs with management responsibilities that include mentoring and assessing monitoring skills and complex issues involving site management, study management, sponsor/ CRO challenges

Interactive Exercises
• Reviewing Reports and Study Documentation
• Case Studies/Scenarios: Assessing Monitoring Skills, Site Issues, Stakeholder Relations
• Detecting Fraudulent Data

Instructors
This course will be taught by one of the following instructors:

Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.
Lily Romero, P.A., C.C.R.C.

Course Dates and Locations

<table>
<thead>
<tr>
<th>Course Dates</th>
<th>Course Location</th>
<th>Course #:</th>
<th>Price Before</th>
<th>Price After</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2-3, 2020</td>
<td>San Diego, CA 92101</td>
<td>SSAD0420</td>
<td>$1,875 by February 28</td>
<td>$1,875 after February 28</td>
</tr>
<tr>
<td>June 18-19, 2020</td>
<td>Boston, MA 02110</td>
<td>SSAB0620</td>
<td>$1,675 by May 15</td>
<td>$1,875 after May 15</td>
</tr>
</tbody>
</table>

ACRP Members: Receive 10% off!

Academic Discount
A $400 academic discount is available to those who qualify.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 15 hours (1.5 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-18-007-L01-P. Released: 1/18.
Monitoring Oncology Clinical Trials

Course Description
This course is designed for Clinical Research Associates (CRAs) currently working in the industry who are interested in gaining knowledge about monitoring in the oncology therapeutic area. As the demand for CRAs in the oncology arena continues to grow, this course offers practical, hands-on training covering oncology-specific logistical, clinical, and ethical considerations. The application of clinical monitoring skills to oncology trials is reinforced through interactive discussions, case studies, and practice-based activities. The course content is also valuable to Project Managers and CRA Managers working in the oncology field as they seek to design feasible protocols, clinical monitoring plans, and monitoring tools adaptable to the unique requirements of these study sites and trials.

Learning Objectives
- Manage challenges with infrastructure and delegation of authority at oncology sites
- Describe common characteristics of Institutional Review Board (IRB) review and communications in oncology trials
- Examine approaches to facilitate decision-making at sites for dosing toxicities and dose modifications in oncology trials
- Apply standardized grading criteria to adverse events in oncology studies
- Utilize appropriate oncology disease progression algorithms
- Determine approaches to address common challenges in managing laboratory and biomarker samples in oncology studies
- Establish strategies to identify and obtain appropriate source documentation at oncology sites
- Develop plans for thorough and efficient oncology monitoring visits

Who Should Attend
- Clinical Research Associates
- Clinical Research Associate Managers
- Clinical Operations and Trial Management Personnel
- Project Managers

Interactive Activities
- Scenario: Managing the Complexity of Oncology Site Infrastructure
- Case Studies in Oncology Dosing Toxicity Management
- Activity: Identification and Toxicity Grading of Adverse Events
- Simulation: Tumor/Disease Progression
- Critique: Adequate and Complete Source Documentation
- Scenario: Planning the Monitoring Visit

Instructor
Karen L. Gilbert, B.S., C.C.R.A.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556. Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Optimizing Protocol Design and Strategies to Achieve Efficient, Lower Cost Trial Execution

Course Description
This course will explore the challenges clinical teams face in developing protocols to ensure that the right patients are enrolled and that the right data are collected to demonstrate a drug is safe and efficacious, while at the same time managing study costs and study complexity, especially in trials that involve imaging and interventional procedures. Key factors to consider when developing protocols and techniques to minimize complexity, while at the same time ensuring trial success, will be discussed. This course will also identify pre-award processes and institutional approaches to increasing fiscal return and mitigating fiscal compliance risk for clinical trials. The ability to develop comprehensive budgets and ensure billing compliance for clinical trials is challenging for many clinical sites. Poor financial planning/forecasting and undefined billing compliance practices are associated with increased risk leading to deficits and Office of Inspector General (OIG) investigations. Strategies for covering true costs related to protocol design and multi-disciplinary approaches will be discussed.

Learning Objectives
• Assess study protocol for complexity and identify potential risks
• Describe the processes for fiscal oversight of clinical trials
• Recognize key performance indicators for managing fiscal/regulatory activities
• Apply leading practices to coverage analysis and financial oversight
• Perform cost estimation for a project and develop a schedule for completion of milestones
• Establish systems for quality control and monitoring of clinical trials
• Identify resources needed to complete projects and assign roles and responsibilities
• Perform cause-effect analysis for identified risks and develop mitigation strategies

Who Should Attend
• Personnel involved in the development of clinical trial protocols
• Project Managers and Project Team Leaders
• Clinical Research Associates
• New Clinical, Regulatory, and Department Staff who will design clinical trial programs
• Grant Administrators
• Medical Writers

Interactive Exercises
• Identify project issues/risks
• Perform cause-effect analysis and develop risk management strategies
• Develop a preliminary Quality by Design (QbD) strategy and apply a Quality Risk Management (QRM) perspective to develop baseline quality metrics and key risk indicators
• Perform cost estimation and establish clinical research study schedules

Instructor
Marina Malikova, Ph.D., MSci, M.A., C.C.R.A., RAC

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• Introduction to the Project Life Cycle
• Study Protocol Design, Risk Analysis, and Templating
• Process Mapping as a Planning and Management Tool
• Scope, Timeline Management, Monitoring, Milestones

Day Two: 8:30 a.m. – 5:00 p.m.
• Development of Project Budgets and Cost Estimation Techniques
• Tracking Expenditures, Aggregate Spend, and Transparency Reporting in Clinical Trials
• Risk Management and Implementation of Strategic Project Management Concepts in Clinical Trials
• Quality by Design (QbD) Principles, Risk-Based Monitoring, and Developing Key Performance and Quality Indicators (KP-QIs)
• Communication and Team Building
• Contractors: Managing Outsourcing
Pharmacokinetics: A Comprehensive Overview of Principles and Applications

Course Description
The course will provide participants with a comprehensive overview of pharmacokinetics by integrating concepts in physiology and mathematics. At the end of this seminar, attendees will understand fundamental pharmacokinetic concepts and be able to use them to design pharmacokinetic studies, compute pharmacokinetic parameters, and predict the effect of physiological and formulation changes on the pharmacokinetics of drugs. The instructor will provide an overview of the anatomy and physiology of organ systems relevant to drug absorption, distribution, metabolism, and excretion, explain pharmacokinetic concepts, demonstrate computation of pharmacokinetic parameters after intravenous and/or oral doses, and highlight concepts in bioavailability, bioequivalence, and biopharmaceutics. Understanding of theoretical principles will be facilitated by numerous practical examples from the literature, and through case studies. Periodic review and reinforcement of important concepts will be achieved through discussions, and completion of a series of in-class assignments.

Learning Objectives
- Describe the anatomy and physiology of systems involved in drug absorption, distribution, and elimination
- Compute pharmacokinetic parameters after intravenous and/or oral drug administration
- Design pharmacokinetic studies
- Analyze and interpret data from pharmacokinetic studies
- Evaluate bioequivalence data
- Predict the effect of physiological and formulation changes on the pharmacokinetics of drugs

Who Should Attend
- This course is designed for individuals working in the pharmaceutical industry with degrees in biology, chemistry, or chemical engineering who desire an understanding of the fundamental principles and concepts in pharmacokinetics

Instructor
Anil D'Mello, Ph.D.

Interactive Exercises
- Classroom discussions customized to participants’ backgrounds and questions
- A series of in-class assignments
- Group examination of case studies

Course Outline
Day One: 8:30 a.m. – 4:30 p.m.
- Anatomy and Physiology: Anatomy and physiology of systems responsible for drug absorption, distribution, metabolism, and excretion
- Intravenous Dose: Conceptual description and computation of half-life, volume of distribution, area under the plasma concentration – time curve, and clearance
- Oral Absorption: Description of the phases in drug absorption, computation of half-life, volume of distribution, area under the plasma concentration – time curve, clearance, Cmax, and tmax; effect of alterations in pharmacokinetic parameters on the area under the plasma concentration – time curve, Cmax, and tmax of the drug

Day Two: 8:30 a.m. – 4:30 p.m.
- Bioavailability and Bioequivalence: Definition of terms and computation of bioavailability and bioequivalence; design of bioavailability studies; historical perspective of statistical techniques used to evaluate bioequivalence data
- Physiological and Formulation Factors Affecting Drug Absorption: Effect of food, drug solubility, permeability, and surface area on the rate and extent of drug absorption
- Clearance Concepts: Physiological model for organ clearance and the effect of alterations in organ blood flow, intrinsic clearance, and plasma protein binding on drug pharmacokinetics

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
Planning and Conducting Global Clinical Trials

Course Description
Increased competition for clinical trial subjects and resources has spread investigational sites and vendors all over the world. This globalization of clinical trials has helped sponsors to control drug development costs and timelines, but at the same time has generated new challenges for sponsors. This course provides a comprehensive overview of the considerations for planning and conducting trials outside the United States. Expectations of the FDA, EMA, and MHLW for trials conducted outside their regions are reviewed. Strategies for meeting these expectations in the context of differences in clinical research experience, patient populations, medical practice, language, culture, legal and regulatory requirements, logistics, and technological capacity are discussed. The course includes specific operational strategies for clinical trial implementation in both developed and developing countries.

Learning Objectives
• Summarize the trends in globalization of clinical trials
• Explain the impetus for globalization of clinical trials
• Identify the factors supporting globalization of clinical trials
• Understand the impact of the FDA’s, EMA’s, and MHLW’s expectations on global clinical trials
• Describe the issues critical to planning a global clinical trial
• Identify key variables for understanding local clinical research environments
• Recognize the differences among countries that may be advantageous or challenging to clinical trial sponsors
• Develop capacity for working in a multi-cultural environment
• Predict the challenges involved in global clinical trials
• Formulate strategies for meeting the challenges

Who Should Attend
• Experienced clinical research professionals who want to develop skills in planning and conducting international clinical trials

Interactive Activities
• Brainstorming group discussions
• 12 Golden Rules development
• Small group assignments
• Cross-cultural simulation
• Change planning exercise

Instructor

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• Globalization of Clinical Trials: Where are clinical trials being conducted? Why are clinical trial sites and services moving around the world?
• FDA Rule on Foreign Clinical Trials/EMA Reflection Papers/MHLW Basic Principles on Global Clinical Trials: What are the impacts of these documents on the planning and conduct of global clinical trials?
• Considerations for Planning Global Trials: What are the ethical, scientific, and practical considerations for global clinical trial design and country selection?
• Understanding the Local Environments: What do we already know? What else do we need to find out? How do we get this information? How can we perform successfully in a multi-cultural environment?

Day Two: 8:30 a.m. – 5:00 p.m.
• Regulation: How can we ensure compliance with the local clinical trial regulations?
• Legal: What other kinds of laws affect clinical trials? How do we manage contracts and insurance?
• Language: What needs translation or interpretation? How do we do it?
• Communication: How do we communicate and train in many languages, to people of many cultures, in countries all over the globe, in time zones around the clock?
• Logistics: How do we manage international differences in shipping, technology, and currency?
• Clinical Trial Procedures: What are the considerations for investigational products, study supplies and equipment, informed consent, data collection, monitoring, pharmacovigilance, record retention?
Practical Problem Solving for Clinical Research Professionals

Course Description
Twenty-first century leaders are problem solvers. But how do successful leaders get from point A: Identifying a problem exists to point B: The problem is solved? The answer is: Very carefully, especially when they don’t have authority over budget. This highly interactive, practical course presents participants with best practice methodologies and key tools and techniques to help them take a problem from root cause analysis, to creating a cost-benefit analysis, to crafting a compelling story in an effort to obtain funding. Participants will have the opportunity to work on their own work-related problem during several activities. Participants will leave with a partially completed business case for their solution as well as the benefit of hearing first-hand accounts of practical solutions from other participants.

Learning Objectives
- Create a clear problem statement
- Articulate the effects of this problem
- Identify the root cause(s)
- Identify the stakeholders and decision makers for funding the solution
- Create a cost-benefit analysis
- Craft a value proposition
- Create a compelling story communicating the vision and business case to secure funding

Who Should Attend
- Site Managers
- Sponsor Managers
- Project Managers
- Project Leads
- Senior Clinical Research Associates

Interactive Activities
- Activity 1: Writing Good Problem Statements
- Activity 2: Root Cause Analysis: Five Whys
- Activity 3: Root Cause Analysis: Cause and Effect Diagram
- Activity 4: Your Problem’s Root Cause Analysis
- Activity 5: Your Problem’s Solutions
- Activity 6: Your Solution’s Stakeholder Analysis
- Activity 7: Your Solution’s Cost-Benefit Analysis
- Activity 8: Your Solution’s Value Proposition
- Activity 9: Telling Your Story

Instructor
Holly J. Deiaco-Smith, M.S.Ed.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Module 1: Problem Solving: Developing clear problem statements, analyzing root cause, defining quality solutions – corrective actions

Day Two: 8:30 a.m. – 5:00 p.m.
- Module 1: Problem Solving, continued: Defining quality solutions – preventative actions
- Module 2: Building the Business Case: Identifying and analyzing stakeholders, when you need funding – developing a cost-benefit analysis
- Module 3: Obtaining Buy-In: Crafting the value proposition, telling your story
Preparation INP Submissions: How to Organize, Write, Submit, and Track Submissions

Course Description
The Regulatory Department is the key contact with regulatory agencies. Regulatory must prepare documents that inform the Agency about the proposed development plan, keep the Agency up-to-date and answer any questions the Agency has about an ongoing investigation, request and prepare for meetings with the Agency to discuss development plans, and construct and write the marketing application and submit any updates to the marketing application in a concise and informative manner.

Submissions to a regulatory agency involve more than just writing. They also encompass strategy, editing, publishing and systematic tracking of key information. Through lectures, case studies, and hands-on exercises, new and experienced regulatory professionals learn how to work with the regulations, guidance documents and style guides to produce submissions that comply with the requirements and are clear to the reviewers.

In this practical course, approved drug labels and summary basis of approvals are used to help students acquire the knowledge and insight needed to understand and begin to construct core U.S. drug and biologics submissions, including pre-marketing (IND), and marketing (NDA/CTD) applications. Participants also gain experience with tools that help manage timelines and sections needed from contributors.

Learning Objectives
- Identify the required regulations and guidance documents for drug and biologic submissions
- Use regulations and guidance documents to outline and construct a variety of drug and biologic submissions
- Formulate a working knowledge of regulatory submissions, publishing, and style guides
- Create checklists that encompass timelines and sections needed from contributors

Who Should Attend
- Any part of the drug development team who wishes to know more about the IND submission and amendment process such as: regulatory associates, quality assurance, manufacturing, clinical, project management, and pre-clinical personnel will benefit from this course

Instructor
Joy Frestedt, Ph.D., C.P.I., R.A.C., F.R.A.P.S.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.

FDA Division Information
- Submission Basics
  - Outlining the submission, creating the Table of Contents, timing of submission/timelines, contributions from other departments, editing, style guides, templates, supportive documents, QAing the submission

Publishing the Submission
- Submission publishing basics
- Copies (how many to make and keep)
- Introduction to electronic publishing requirements

Tracking the Submissions
- Creating the index history
- Creating an issues log

Day Two: 8:30 a.m. – 5:00 p.m.

- Common Technical Document Format
- Pre-Market
  - FDA Meetings (Type A, B and C): Pre-IND, Phase I, Phase II, End of Phase II, requesting the meeting, preparing the meeting package, meeting minutes
  - The IND Submission
  - Routine IND Submissions: Clinical, Non-Clinical, CMC, Annual Reports, Investigator Brochure updates, protocol/protocol amendments, Investigators
  - Additional IND submissions: Fast track, orphan drug, special protocol assessment

Marketing Application
- NDA in a CTD Format

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Core Curriculum

Query Creation and Processing: Assessing Data Discrepancies and the Communications for Corrections

Course Description
This course is designed to build the foundational understanding of the identification of discrepancies in the data that are collected for a clinical trial protocol. Query processing begins with a functional understanding of the study and study documents. There will be a sample protocol to review along with the case report forms (CRFs) which will allow you to understand the study as well as the data collection instruments. Supplemental information and the Data Management Plan (DMP) will provide the data quality checks (or “edit checks”) that will describe the data logic and information that is expected on the CRFs. Query creation involves the identification of the data anomaly as per protocol requirements, creating a question to be sent to the investigative site for data clarification or data amendment/update. Managing query follow-up is vital to developing reliable data. Once queries have been written it is necessary to ensure appropriate responses are made and to identify when database updates are necessary.

Learning Objectives
• Examine the role of query processing in data management
• Analyze the relationship between the Schedule of Events and case report forms
• Identify necessary edit checks and analyze edit check content
• Describe the key elements for a good query
• Identify multiple results of query resolution
• Describe options for inappropriate query responses
• Integrate/update data amendments as a result of query resolution

Who Should Attend
• Clinical Data Managers who are beginning their careers and desire to grasp a better understanding of the query process

Interactive Activities
Pre-class:
• Read protocol and DMP and review CRFs
• Identify Study Phase
• Identify Study design
• Review schedule of events vs. protocol text vs. CRFs to ensure all data points are accounted for
• Examine the edit check list in the sample protocol and compare that to the case report forms

Instructor
Denise G. Redkar-Brown, MT

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• Protocol review, CRFs. and the DMP
• Activity Discussion: Queries Gone Wrong
• Examine the DMP for the edit checks and output messages.
• Activity
• Examine whether there is a CRF for each item listed on the Schedule of Events (purposely some will be missing)
• Identify any items you consider missing. How do the CRFs for this study differ from those used in your company?
• Queries to definition, elements of a good query, examples of queries.
• Discussion
• Using self-evident corrections is not always self evident. Does your company use self-evident corrections? What are some examples of self-evident corrections? How do you manage self-evident corrections with the investigator?
• Query Resolution and Database Updates
• Part 1: From previous activity, for each discrepancy not matched to the edit check appendices, create a query based on the elements of a “good query.”
• Part 2: Review your partner’s queries as if you are at the study site. Are these queries easy to understand? Identify whether each is clear, ambiguous, or impossible? Describe the data you would send based on each query. Propose rewording ambiguous or impossible queries.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556. Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Regulatory Intelligence 101

Course Description
The regulatory environment is constantly shifting and changing. This dynamism necessitates keeping abreast of current information from a variety of sources. Regulatory Intelligence (RI) is the act of gathering and analyzing regulatory information for impact or changes in laws, regulations, directives, guidance documents, etc. There is more to regulatory intelligence than keeping up with the latest regulations and guidelines. Regulatory precedence, industry practices, regulatory agency opinions, and competitor information are just a few of the valuable sources of information that can help regulatory affairs professionals to develop successful regulatory strategies.

The monitoring and gathering of RI will ultimately culminate in developing a regulatory strategy which can result in decreased time to approval; potentially decreased cost of product development through strategizing risk based on current information; and maximization of target market(s). As more companies are conducting trials and filing marketing applications worldwide, the need to keep abreast of worldwide regulatory information is crucial as a change in the global landscape can affect the global regulatory strategy. RI allows a regulatory professional to determine requirements for conducting global clinical trials, meet manufacturing requirements, advise personnel, answer strategic regulatory questions, and write or construct a global marketing application.

This class examines the scope of regulatory intelligence which encompasses: identifying information sources; monitoring the regulatory landscape (periodic versus ongoing); using an RI database and other sources to research the regulatory question; summarizing, analyzing, integrating, and presenting RI; and discussing implementation choices – with in-house staff, consultants, information services, or a mixture thereof – and the advantages/disadvantages of each choice. Hands-on class exercises help participants gain experience using a regulatory intelligence database to search and summarize regulatory intelligence information.

Learning Objectives
- Discuss what Regulatory Intelligence is and why it is important to companies
- Identify multiple sources of Regulatory Intelligence
- Evaluate the constantly changing regulatory landscape
- Evaluate a regulatory research question in to researchable units, and conduct the research using a Regulatory Intelligence Database
- Summarize and present Regulatory Intelligence findings back to a team
- Describe how to archive and store RI
- Apply and integrate Regulatory Intelligence to current company practices and global regulatory strategy

Who Should Attend
- This course is designed for seasoned regulatory affairs professionals looking to develop their skill set, as well as other research and development professionals who are interested in learning a new skill

Interactive Activities
- Use regulatory intelligence databases to answer a series of RI questions
- Learn to fill out RI overview form for effective presentation of information to team

Instructor
Joy Frestedt, Ph.D., C.P.I., R.A.C., F.R.A.P.S.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- What is Regulatory Intelligence (RI), regulatory information and sources of RI
- How RI is conducted at large, medium, and small drug, biologic, and medical device companies
- How RI differs at each stage of product development
- Using Regulatory consultants to conduct RI and what to expect
- How to break down regulatory research questions down into researchable components
- How to conduct regulatory research using the internet and an RI database
- How to compile, analyze, and summarize regulatory information
- Storage and archiving RI

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Regulatory Strategy 101

Course Description
Drug development is getting more expensive by the year and a sound regulatory strategy can make or break a drug or biologic’s ability to initiate and support clinical trials or obtain marketing approval. Knowing what to research, review, negotiate and include in the regulatory strategy differs by company; however, basic requirements include:

- Target product profile/draft package insert
- Past precedence review
- Clinical endpoints
- Competitor label analysis
- FDA interactions planning

As a regulatory professional develops their skill set, knowing how to create and implement a regulatory strategy is critical to career advancement. This session will walk participants through a case study for a hypothetical Type 2 Diabetes drug that has just been developed and the process of creating a regulatory strategy. The session will:

- Define regulatory strategy
- Provide an overview of regulatory strategy elements, by phase of development and discipline
- Illustrate how to research and pull together a strategy
- Planning regulatory strategy in Phase 1, Phase 2 and Phase 3
- How to adapt and update a strategy as information changes

Participants will walk away with a strategy toolbox they can immediately apply to their jobs.

Learning Objectives
- Identify the elements of regulatory strategy
- Understand the questions that need to be addressed when developing a regulatory strategy, by phase and discipline
- Locate and use available tools that can aid in developing regulatory strategy
- Summarize the data and perform strategic analysis once the data is identified
- Determine the output and format of strategic information after analysis into a “playbook”

Who Should Attend
- Mid-level regulatory professionals who have 3-5 years of regulatory experience and are looking to learn the “next level” of regulatory, beyond submission preparation
- Any other drug development team member that would like to learn more about regulatory strategy

Interactive Activities
- Using a mock indication and regulatory intelligence tools, research sections of the regulatory strategy
- How to use templates to summarize components of the strategy
- How to formalize regulatory’s portion of the strategy into a “playbook”

Instructor
Joy Frestedt, Ph.D., C.P.I., R.A.C., F.R.A.P.S.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.

- What is regulatory strategy?
- What makes good strategic qualities?
- How to perform strategic analysis
- Component of strategic analysis
  - Questions to be answered by discipline and phase
  - The tools to answer questions (free and for fee)
  - History of indication
  - Clinical endpoints
  - Past precedence
  - Planning FDA interactions
  - Summarizing the information
  - Analysis
  - Format and output examples
  - Presentation to the team (let format follow information)
- Land mines (how to plan for them or mitigate as much risk as possible)
- Updates and monitoring the regulatory landscape
- Performing strategy at different phases of investigation and how it differs

What Participants Say About Barnett Seminars:

“The trainer was an excellent presenter, very knowledgeable and timed the training in a great way with fun activities and questions to keep us engaged.”
Report Writing for CRAs

Course Description
This course is designed so that the participants walk away with usable skills and invaluable knowledge in clinical trial site visit report writing and review. The course combines lecture with real life scenarios, practicum exercises involving writing, editing and mapping of findings. Both beginners and those with experience will benefit from the content.

Learning Objectives
- Identify and become familiar with industry regulations and guidelines relating to report writing
- List the rules for writing an effective report
- Identify the steps in effective report writing
- List the essential content of the four major types of monitoring visit reports
- Define the report mapping process relating to action item identification, documentation & resolution monitoring
- Identify the difference between efficient and inefficient report writing tools
- Demonstrate the ability to write a protocol deviation, onsite data query, action items, and more

Who Should Attend
- Clinical Research Monitors
- In-house and field CRAs, CRCs transitioning to CRA role
- Contract CRAs
- Anybody responsible for reviewing clinical reports including Project Managers, Quality Assurance Auditors, CRA Managers, Lead CRAs

Interactive Exercises
- The Mapping Process: Documenting and Critiquing
- Writing Critic: Review of “the Good, the Bad and the Ugly” — Documentation of findings, use of bullet points, documenting deviations from the protocol & other discrepancies, writing action items, writing on-site data queries, phone contact reports
- Group Discussions of Best Practices

Instructor
Lily Romero, P.A., C.C.R.C.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Report Writing Roots and Mandates: FDA requirements regarding monitoring, record and report keeping; ICH GCP E6 Guideline for monitoring visit reports and non-compliance
- 10 Rules of Effective Report Writing: Application of good report writing practices; steps in report writing; before, during, after
- Approaches to Report Writing: Objective vs. subjective, choice of tense & voice, use of abbreviations, fragments vs. full sentences, proper use of bullets, etc.
- Remember Who Your Audience Is: Who reviews and has access to monitoring reports
- Always Be Ready if Abducted by Aliens: Designing reports to be independent of author to smoothly handle staffing changes and/or temporary stand-ins
- The Mapping and Flow of Reports: Each report depends on one another; reports and follow-up letters correlation; contact reports; mapping to action item resolution
- The Major Types of Monitoring Reports: Evaluation, initiation, interim, closeout, combos and abbreviated
- Use of References to Support Report Claims: Documentation of protocol sections and past correspondence, etc.
- Answering the Question Right and Answering the Right Question: Comment when needed; make it mean something; document teaching and re-instruction; document what was accomplished and what was not
- Compliance Plans: Development, agreement, and success!
- Industry Standards: Best practice; goals and content of industry monitoring reports; regulatory authority use of report content
Risk-Based Monitoring: Successful Planning and Implementation

Course Description
A fundamental shift has occurred in the clinical research industry related to how sponsors satisfy their regulatory and GCP requirements for the adequate monitoring of clinical trials. Recent regulatory authority guidance and industry initiatives have promoted a modern approach to clinical trial monitoring based upon program and study-specific risk assessments and mitigation plans. In order for clinical research professionals to embrace this industry shift, it is critical that they understand the rationale, concepts, and actual work practices inherent in risk-based monitoring.

This course is designed for clinical research professionals across the spectrum of research organizations, investigational product types, and experience levels. Participants will acquire a deeper understanding of the philosophy of risk-based monitoring and be able to apply this understanding to operational activities including the following:

- Performing program and study-level risk assessments and managing risks
- Writing a risk-based Monitoring Plan
- Designing reports and metrics for central monitoring activities
- Supporting Clinical Research Associates for success in the new monitoring environment
- Preparing Investigators and site personnel for risk-based monitoring

Learning Objectives
- Compare and contrast risk-based monitoring with a traditional monitoring approach
- Identify program and study-level monitoring risks
- Develop a monitoring plan which focuses on mitigating risks at both the program and study levels
- List the activities, responsibilities, and outputs of Clinical Data Management in risk-based monitoring
- Describe approaches and techniques for central/remote monitoring and data review
- Predict changes for Investigators/sites as a result of wider adoption of risk-based monitoring

Who Should Attend
- Sponsors/CROs Clinical Operations Staff
- Clinical Research Associates and Managers
- Clinical Data Management Staff
- Investigators and Staff
- Clinical Quality Compliance and Quality Assurance Professionals

Interactive Activities
- Risk Assessment Case Study
- Design a Risk-Based Monitoring Plan Table of Contents
- Brainstorming Clinical Data Management Reports for Central Monitoring
- Data Trend Analysis Activity
- Site Transition Planning

Instructors
This course will be taught by one of the following instructors:
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.
Lily Romero, P.A., C.C.R.C.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
Risk Management/Risk-Based Quality Management for Clinical Trials Certification Program

Course Description
Are you prepared for Quality Risk Management (QRM), Risk Management (RM), Risk-Based Quality Management (RBQM)? With ICH GCP E6 R2 now requiring risk-based approaches to managing quality in clinical trials, this course takes you through how to execute the requirements in Section 5.0, and reviewing tools while discussing hands-on experience with various risk management programs.

This course focuses on all the critical elements for clinical trial sponsors and CROs included in the ICH GCP E6 R2 expectations, while highlighting key points from other regulatory bodies such as ISO 31000 Risk Management. Further, this course reviews each step of risk identification, assessment, control, review, reporting, management, and communication. Having an effective Risk Management program not only ensures compliance with the ICH GCP E6 R2 requirements but also ensures continuous improvement strategies for your clinical trials.

Learning Objectives
- Describe the expectations of QRM in relation to the ICH E6 R2 updates
- Discuss how to analyze risks and develop a risk register
- Describe how to use multiple risk analysis tools
- Describe how to formulate risk mitigation strategies

Who Should Attend
- Quality Control/Assurance Professionals
- Regulatory Affairs Professionals
- Clinical Research/Operations Personnel
- Information Technology/Security Personnel
- Data Managers
- Study Managers
- Project Physicians/Medical Monitors
- Pharmacovigilance Professionals
- Biostatisticians

Instructor
Susan M. Leister, M.B.A., Ph.D., CQA, CSSBB

Interactive Activities
- Knowledge Checks
- Group Discussions
- Case Studies
- Group Exercises

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day 1: 8:30 a.m. – 5:00 p.m.
- Quality Risk Management: Describe Quality Risk Management/Risk Management (ICH GCP E6 R2 & ISO 31000); Discuss establishing a Risk Management Policy/Program and Accountability considerations
- Risk Management Plan and Culture: Describe the framework for communicating risk within an organization/program; Discuss communication strategies and challenges for risk stakeholders
- Risk Identification: Describe how to identify risks and when to start; Describe system level risks and project (clinical trial) level risks; Discuss the use of a risk register (risk log) for tracking risks

Day 2: 8:30 a.m. – 5:00 p.m.
- Risk Analysis Tools: SWOT (Strength, Weakness, Opportunities, Threats); Root Cause Analysis and affinity diagrams
- Risk Control: Discuss developing risk mitigation strategies, options and priority rankings; Discuss internal and external stakeholders and their impact; Describe escalation processes and plans
- Risk Communication: Discuss how to document risk mitigation plans in the risk register/log
- Risk Review: Describe the need for periodic review and when a risk is closed or when it needs further mitigation; Discuss how to detect change and emerging risks (what clinical data to look at)
- Risk Reporting: Discuss risks, deviations, and predefined quality tolerance limits; Discuss access, retention and the value of lessons learned/continuous learning

Day 3: 8:30 a.m. – 5:00 p.m.
- Risk Analysis Tools: SWOT (Strength, Weakness, Opportunities, Threats); Root Cause Analysis and affinity diagrams
- Risk Control: Discuss developing risk mitigation strategies, options and priority rankings; Discuss internal and external stakeholders and their impact; Describe escalation processes and plans
- Risk Communication: Discuss how to document risk mitigation plans in the risk register/log
- Risk Review: Describe the need for periodic review and when a risk is closed or when it needs further mitigation; Discuss how to detect change and emerging risks (what clinical data to look at)
- Risk Reporting: Discuss risks, deviations, and predefined quality tolerance limits; Discuss access, retention and the value of lessons learned/continuous learning

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) in Site Management

Course Description
Managing investigator noncompliance in the research industry is critical to successful clinical trials. Regulatory authorities expect that all stakeholders identify noncompliance, correct the noncompliance through intervention, and evaluate the effectiveness of the intervention. Root cause analysis provides a process through which issues can be accurately identified and interventions can be effectively designed. The corrective action process including, when appropriate, preventive action planning, should be implemented when RCA has been completed. An effective CAPA process can lead to improved human subject protections and confidence in the integrity of the data. Lack of effective corrective action management can lead to repeated noncompliance, compromised subject safety, poor data quality, and/or unacceptable inspection findings with subsequent negative impact on the final submission. This course focuses specifically on the management of noncompliance issues occurring at investigative sites.

Learning Objectives
- Define investigator and site noncompliance
- Describe performance management concepts and skills for effective site risk management
- Integrate prevention of performance issues and ensure adequate site issues management
- Implement Gilbert’s Behavioral Engineering Model for a diagnostic root cause analysis process
- Apply performance management concepts in case studies with a focus on prevention and issues management
- Recognize components of effective corrective action planning and documentation
- Identify examples of corrective action planning for different site noncompliance case scenarios
- Discuss successful preventive action planning and implementation

Who Should Attend
- Clinical Research Associates, Project Managers and Clinical Research Associate Managers
- Principal Investigators, Site Research Directors and Coordinators
- Quality Assurance Staff

Interactive Activities
- Individual case studies (based on actual FDA warning letters) are assigned to each participant to practice and apply
- Identification of noncompliance and Questions to ask to determine the root cause
- Identification of necessary corrective and preventive actions
- Identification of necessary preventive actions
- Documenting the issue in monitoring reports and correspondence

Instructors
This course will be taught by one of the following instructors:
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.
Lily Romero, P.A., C.C.R.C.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Defining Investigator Noncompliance: Regulatory definitions and categories
- Performance Management Concepts: Theories of motivation, taking a risk-based approach to monitoring, issues escalation and management
- Root Cause Analysis: Detailed examination of Gilbert’s Behavioral Engineering Model and its application to root cause analysis
- Application of Root Cause Analysis Concepts: Behavioral interviewing, the 5 Why’s, and open-ended questions

Day Two: 8:30 a.m. – 5:00 p.m.
- Application of Performance Management Concepts: 7 Comprehensive compliance management steps
- Corrective and Preventive Action Plans (CAPA) – Concepts and Examples: Problem solving and implementing both short-term corrective and long-term preventive actions
- Documenting Investigator Noncompliance: Linking noncompliance to regulatory requirements; documentation best practices
- Exercises in Concept Application: Review and critique of simulated monitoring reports documenting noncompliance and CAPA
Soft Skills Development for Clinical Research Professionals

Course Description
In an environment that is ever changing with organizational mergers, role revisions, and an emphasis on risk-based oversight approaches, the need for better communication skills and comfort with change is essential. It is during these times of change that leaders emerge. What are the skills that differentiate a leader? The aim of this course is to present the concept of the Highly Effective Clinical Research Professional as a model for transforming the way you work. In this two-day course that is jam-packed with interactive activities, knowledge sharing and practical tips you can start doing right away, you will identify and utilize soft skills techniques which will increase your effectiveness with key stakeholders and advance and develop your skills as Clinical Research Professionals.

This course also includes a Myers-Briggs Type Indicator component, enabling participants to increase their self-awareness and reduce instances where they might take things personally.

Learning Objectives
• Increase self-awareness through discovery of my communication preferences and use that knowledge to increase my interpersonal communication effectiveness
• Identify best practices planning strategies and evaluate my priorities
• Utilize active listening techniques to build relationships and increase my effectiveness at work
• Identify techniques for influencing without authority in a clinical research environment
• Utilize conflict management techniques
• Describe the mindset and behaviors of professionals who demonstrate accountability
• Utilize best practices problem solving skills, including root cause analysis techniques
• Identify why a clinical research team may not be collaborating and employ techniques to foster collaboration and alignment

Who Should Attend
• Investigators
• Study Coordinators
• Site Managers
• Project Managers
• General Managers
• Project and Department Leads
• Clinical Research Associates
• Regulatory Managers
• Clinical Trial Assistants

Interactive Activities
• Introduction
• Putting First Things First
• Fostering Trust & Credibility
• Modeling Leadership Behaviors
• Solving Problems
• Leading Teams through Change

Instructor
Holly J. Deiaco-Smith, MS

Course Dates and Locations

<table>
<thead>
<tr>
<th>Course Location</th>
<th>Date Range</th>
<th>Course #:</th>
<th>Credit</th>
<th>Price</th>
</tr>
</thead>
</table>
| Philadelphia, PA | April 7-8, 2020 | SACAO0420 | 1.5 CEUs | $1,675 by March 6
|                 |            |          |       | $1,875 after March 6 |
| San Diego, CA   | June 23-24, 2020 | SACDD0620 | 1.5 CEUs | $1,675 by May 22
|                 |            |          |       | $1,875 after May 22 |

ACRP Members: Receive 10% off!

Academic Discount
A $400 academic discount is available to those who qualify.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 15 hours (1.5 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.


Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556. Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Source Documentation Best Practices

Course Description
Adequate and accurate source documentation in clinical research is critical to ensuring subject safety, data integrity, and investigators meeting regulatory expectations. Appropriate monitoring of source data is also vital for the sponsor stakeholder performance. Best practices will be presented and applied as participants work through a simulated clinical research study from first subject, first visit, to site-close out - while examining source documentation from the perspective of the CRC, CRA, and the auditor. All of the regulatory required attributes of quality source data will be presented and applied using real-life case studies, simulations, and interactive group exercises. Participants, sponsors/CROs and/or research sites will gain new insights into the role source documentation plays in the clinical research process.

Learning Objectives
• Employ the regulatory required attributes of quality supporting source data to case scenarios
• Describe what is required for electronic data from electronic health records to meet FDA requirements
• Describe the requirements for electronic CRFs to be 21 CFR Part 11 compliant
• Argue for and against the use of source document worksheets
• Identify the process for documenting deviations from the protocol and Good Clinical Practice (e.g., notes-to-file, and creating and documenting corrective and preventive action plans)
• Determine how best practice source documentation can be incorporated into any clinical research environment

Who Should Attend
• Clinical Research Associates
• Clinical Research Coordinators
• Site Managers
• Clinical Research Associate Managers
• Clinical Research Trainers
• Principles Investigators
• Clinical Research Professional looking to move into a quality assurance role

Interactive Activities
• Clinical research scenarios
• Simulations Critique of FDA Warning Letters
• Create a corrective and preventive action (CAPA) plan
• Source documentation best practice discovery session

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• What is Source Documentation and Supporting Source Data? Interactive exercise examining which documents are classified as source data, which documents are classified as source documents, and which documents are neither
• Review Roles and Responsibilities of creation, maintenance and monitoring source
• What are Required Quality Source Document Characteristics? Interactive exercise applying the attributes
• Developing a Source Documentation Verification Plan: Sponsor vs. Site. Collaboration
• Reviewing the Requirements of e-CRFs For Compliance with 21 CFR Part II
• Working with Auditors and Inspectors: Examination of FDA Warning Letters with Findings of Inadequate and Inaccurate Case Histories
• How to Document Deviations from Protocol and GCP: The role of notes-to-file and corrective action and preventative action plans

Register: Online at barnetinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Statistical Concepts for Non-Statisticians

Course Description
Designed for non-statisticians, this basic statistical concepts workshop has direct applicability to clinical research. The choice of statistical method, the application of statistical principles, and the interpretation of statistical results are the foundation of the design and analysis of clinical trials. It is therefore critical that statistical methods are fully understood before they are implemented. This course is beneficial to all clinical research professionals involved in the design, monitoring, interpretation, and reporting of clinical trials. Please note that this is not a course on statistical formulas or computations.

Learning Objectives
- Determine what information the statistician needs to determine the sample size
- Identify the appropriate sample statistical designs for a study
- Employ statistical terms used in clinical research
- Define the role of the statistician in the study design
- Determine the approach to become comfortable talking to statisticians

Who Should Attend
- Monitors who will assist in designing and evaluating studies
- Clinical Research Associates who will be communicating with statisticians
- Clinical Project Leaders who will be designing and evaluating studies
- Regulatory Professionals who utilize statistical concepts in their reports
- Medical Writers who must interpret statistical reports

Instructor
Stella Stergiopoulos, M.S., M.P.H.

Interactive Exercises
- Drawing Random Samples
- Constructing Confidence Intervals
- Creating and Testing with Real Data Individual and Group Hypotheses

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Elements in Choice of Statistical Method
- Descriptive Statistics: Distributions; mean, median, mode, standard deviation
- Methods for Preserving Objectivity: Blinding; randomization; consequences of violations
- Inference, Generalizing to a Population: Standard error; confidence interval; estimation and prediction
- Study Design: Uncontrolled studies; parallel groups; crossover designs (patient as own control); block designs

Day Two: 8:30 a.m. – 5:00 p.m.
- Hypothesis Testing: Creating hypothesis from objectives; level of significance, p-values; one-sided versus two-sided; types of errors
- Power and Sample Size: Accuracy of estimates; confidence intervals; testing (effect size and variability)
- Choice of Statistical Method
- Specialized Topics
- Interpreting the Statistical Report

Course Dates and Locations

MARCH 31-April 1, 2020
San Diego, CA 92101
San Diego Solamar
Course #: SSTD0320
$1,675 by February 28
$1,875 after February 28

ACRP Members: Receive 10% off!

June 16-17, 2020
Boston, MA 02110
Metro Meeting Centers
Course #: SSTB0620
$1,675 by May 15
$1,875 after May 15

ACRP Members: Receive 10% off!

Academic Discount
A $400 academic discount is available to those who qualify.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 15 hours (1.5 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-18-034-L01-P. Released: 12/18.

Course Description
This course is an integrative learning experience, combining a comprehensive review of the Good Clinical Practice core principles and project management strategies applicable to clinical research during the new drug development process. We will examine the concepts and applied techniques for cost estimation (PERT analysis, bottom-up, top-down, etc.), risk management, and quality assurance. We will focus on the principles and methodology of planning, controlling, and coordinating individual and group efforts. Key topics include organization strategy and project selection, developing a project plan, scheduling resources, project risk analysis, work breakdown structures, and project networks. Mastery of key tools and concepts introduced in this course and development of the skills vital to effective management of multidisciplinary tasks will provide clinical research professionals a significant competitive advantage in the marketplace.

Learning Objectives
- Apply a new understanding of infrastructure and clinical operations in industry and clinical sites
- Develop skills for strategic planning of clinical trials
- Perform cost estimation and develop a schedule
- Establish systems for quality control and monitoring of clinical trials
- Identify resources needed to complete projects
- Assign roles and responsibilities for a clinical trial and develop a communication plan
- Identify, manage, and mitigate risks of clinical trials

Who Should Attend
- New Project Managers and Team Leaders with little or no drug development or clinical trial experience who will be managing drug development programs and supervising Project Managers
- New Clinical, Regulatory, and Department Staff who will design clinical trial programs
- Clinical Research Associates
- Data Managers

Interactive Activities
- Identify Project Issues/Risks
- Perform Cause-Effect Analysis and Develop a Risk Management Strategy
- Develop Preliminary Quality by Design (QbD) Strategy and Apply Quality Risk Management (QRM) Perspective to Develop Baseline Quality Metrics and Key Risk Indicators
- Perform Cost Estimation and Establish Clinical Research Study Schedules

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

What Participants Say About Barnett Seminars:
“Lots of good energy and ideas, kept it interesting the whole time.”

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556. Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Study Site Start-Up: Opening and Managing a Successful Clinical Research Site

Course Description
The role of the clinical research site is vital in the success of the clinical trial process. The research site is the key conductor of studies, and quality research sites are in great demand in the current research environment. This course presents the core ingredients with explanation, tools and examples for a successful research site. Case scenarios will be presented throughout the course for study and benchmarking practices that lead to high performance and successful businesses.

Learning Objectives
• Identify components of a successful research site through benchmarking elite performers
• Identify the primary elements of business and marketing planning for a research site
• Review research site GCP responsibilities
• Recognize essential content of clinical research site SOPs
• Describe the staffing needs of a research site and review various models
• Review the process of contract and budget negotiations and content
• Describe the process of conducting project feasibility
• Identify effective approaches to subject recruitment
• Implement quality systems promoting audit readiness

Who Should Attend
• Research Site Managers/Directors
• Clinical Research Coordinators
• Principal Investigators
• Research Consultants
• Entrepreneurs

Interactive Exercises
• Simulations/Scenarios
• Pre- and Post-Tests
• Case Scenario: Used Throughout the Course to Apply the Information to Promote Increased Understanding

Instructor
Lily Romero, P.A., C.C.R.C

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• Demonstrated Keys to Success for Research Sites: Benchmarking successful site practices; case scenario of the successful research site
• Business Planning: Stakeholder buy-in and support; incorporating liability insurance; vision and mission statements; objectives and goals
• Site GCP Responsibilities: ICH GCP E6 Guideline; FDA regulations 21 CFR Parts 11, 50, 54, 56; drug/biologic 21 CFR Part 312; device and combinations 21 CFR Parts 3 & 812; other GCPs, state laws and HIPAA; NIH studies, The Common Rule 45 CFR Part 46 Human Subject Protections Government Funded Research; other best practices
• Content of Clinical Research SOPs: Components; training and implementation; measuring compliance
• Staffing: Design of department: facilities and management models; key players; credentialing; national average salaries
• Marketing a Research Site: How; to whom: customers (sponsors, participants and FDA); when: healing a bruised reputation; PR
• Contracts & Budget: Negotiating; contract language; budget components; essentials to include; legal review
• Project Feasibility: What it takes to run a successful study; completing a study feasibility; risk factor analysis and management
• Subject Recruitment: Identifying accurate potential subject numbers; methods and strategies; formal recruitment plans
• Quality Systems and Audit Readiness: FDA inspection program and site deficiencies; quality system components; establishing audit readiness
• Performance Improvement: How to keep your site on top; evaluation and improving never ends; conflict resolution; root cause analysis and effective interventions; changing with the times

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556. Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Understanding Clinical Data Management for the Non-CDM Professional

Course Description
This course will review Clinical Data Management (CDM) operations as they relate to the conduct of clinical trials. The seminar will begin with an introduction to the regulations that directly impact CDM. From there, it will provide a high level overview of CDM processes and the stages of their execution, allowing clinical research professionals to understand the interconnectivity of CDM with other trial procedures. Study start-up, timeline considerations, metrics generation, and a description of the differences between electronic data capture vs. paper-based studies will also be introduced.

Learning Objectives
- Identify regulatory issues specific to CDM
- Outline the overall CDM study procedures and where they impact other research disciplines
- Explain the considerations for CDM study "start-up"
- Discuss the rationale regarding timeline differences between a paper vs. EDC study
- Describe the Data Management documentation required in clinical trial conduct

Interactive Activities
- Map a typical clinical trial conduct and recognize the CDM contributions
- Identify CDM study start-up activities as they coincide with other study activities
- Review a Data Management Plan to identify components pertaining to potential timeline issues
- Organize tasks for database lock

Who Should Attend
- Clinical Trial Managers
- Project Managers
- Clinical Operations Personnel
- Clinical Research Professionals associated with the conduct of clinical trials who want to have a better understanding of what is actually involved in the Clinical Data Management portion of a clinical trial

Instructor
Denise G. Redkar-Brown, MT

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

What Participants Say About Barnett Seminars:
"The learning activities were very helpful toward reinforcing concepts in a practical way."
Working with CROs: Building a Partnership for Project Success

Course Description
This course provides an in-depth overview of Contract Research Organization (CRO) evaluation, selection, management, and trouble shooting. Various types of CRO relationships will be addressed including outsourcing to lab vendors, niche specialty providers, data management, and overall study management and monitoring. Beginning with a review of the Request for Proposal (RFP) process, the course will take you through follow-up analysis and debriefing of the CRO partnership.

Learning Objectives
- Assess the need for a CRO and determination of services
- Analyze approaches for RFPs
- Evaluate the selection and qualification process of a CRO partner
- Analyze budgets for completeness and fair market value
- Determine communication pathways for outsourced providers
- Prepare and conduct a study kick-off meeting
- Measure the performance of your CRO
- Apply Root Cause Analysis (RCA) techniques to CRO management challenges
- Manage and solve partnership problems
- Prepare and conduct an end of project meeting

Interactive Activities
- Identifying CRO issues and concerns
- Development of challenges and solutions reference tool
- Application of budget management techniques
- Clarifying performance expectations
- Review of metrics, tools and SOP application to management
- Choosing a CRO and establishing communication pathways
- Problem solving critical issues/RCA and CAPA application

Who Should Attend
- Clinical Research Associates
- Clinical Research Associate Managers
- Clinical Research Professionals with responsibility for vendor selection and management
- Project Managers

Instructor
Treena Jackson, M.S., C.Q.A., R.A.C., C.S.S.G.B.

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Introductions
- CRO Introduction: Review types of CROs, assess the need for services, RFP process, and selection of a partner
- Scope of work and budget review: Evaluate the scope of work assignment and how to evaluate the proposed and expected budget. Discuss common sources of error, fair market value, or problems with expectations. Focus on feasibility techniques for protocol evaluation and site selection to determine the true value of the budget.
- Expectation establishment: Determine responsibilities, communication expectations, and planning for the kick-off meeting. Review of regulations and Transfer of Regulatory Obligations (TORO).
- CRO Management: Oversight and review of expectations and delivery for partnership. Strategic, pro-active management plans and activities review. Discussion of sponsor oversight obligations.

Day Two: 8:30 a.m. – 5:00 p.m.
- Review of Day 1 materials and concepts
- CRO oversight tools, metrics, and SOPs: Practical discussion and examples of tools and metric tracking. Development and recommendations for SOPs in relation to CRO partnerships. Standardization of CRO management and deliverables within a sponsor organization.
- CRO auditing, issues and escalation: Review audit practices and findings. Discuss root cause analysis and identify potential issues. Determine pathway for escalation and CAPA for non-compliance.
- Putting methods into practice: Discuss problem solving approaches and planning for study wrap up and lessons learned. Review case studies and regulatory act

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Writing Clinical Evaluation Reports

Course Description
This course will include a review of the Medical Devices (MEDDEV) 2.7.1, Rev 4 guideline issued in June 2016 and a discussion of the Therapeutic Goods Administration (TGA) guideline. In this interactive program, participants will also have the opportunity to share their experiences with Clinical Evaluation Reports (CERs) in general. All devices are required to have a CER for products marketed in the EU and globally. This course will explore good writing skills and techniques needed to create a CER and to respond to reviewer comments.

Learning Objectives
- Summarize the MEDDEV 2.7.1, Rev 4 guideline
- Create a work plan for CER development
- Summarize key CER features evaluated by Notified Bodies
- Use CER template (provided) to complete a CER
- Engage and respond to a critique from an experienced CER reviewer to complete CER

Instructor
Joy Frestedt, Ph.D., C.P.I., R.A.C., F.R.A.P.S.

Who Should Attend
- Project Managers
- Clinical Data Specialists/Analysts/Managers
- Technical Communication Specialists/Medical Writers
- Clinical Affairs Directors
- Clinical Program Managers
- Clinical Nurse Specialists
- Post Market Surveillance Managers
- Clinical Evaluation Report/Reporting Specialists
- Evaluation and Research Directors
- Clinical Education Specialists
- Corporate Librarians
- Regulatory Specialists/Managers

Interactive Activities
- SOP Template and Examples (Review, identify questions or concerns, report to group)
- Current CER/SOP Review (Review, identify questions or concerns, report to group)
- CER Checklist (Review, identify questions or concerns, report to group)
- Notified Body Activities (Review, identify questions or concerns, report to group)
- Literature Searches (Review databases, identify questions or concerns, report to group)

Course Dates and Locations
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Course Materials and Background
- Regulatory Requirements and Guidelines
- Evaluating Data and Telling the Story
- Literature Searching
- Appraising and Selecting Clinical Data - Inclusion/Exclusion Coding
Day Two: 8:30 a.m. – 5:00 p.m.
- Analyzing Clinical Data
- Writing CER – Technical Components
- Drawing Conclusions – Team/Medical Review
- Notified Body (NB) Review
- Conclusions
What Is an Interactive Web Seminar?
Barnett International teams with WebEx™ meeting services to provide you with Interactive Web Seminars. Ask questions, chat, learn from industry leaders, and network with your fellow attendees all from the convenience of your own office. No travel, no travel expenses, and no time away from the office! The resources required are already at your fingertips – an Internet connection and an audio connection (via phone or VoIP).
A Barnett Interactive Web Seminar offers you a seamless, secure, multimedia learning experience. After registering, you will receive an email confirmation that provides you with the web seminar link and audio connection information. You can then participate in the Web Seminar individually or, with most web seminars, as a team. For team training, simply put your phone or headset on speaker and either gather around your computer, or project the seminar to a screen. The live Interactive Web Seminar will enable you to ask questions, provide feedback, and learn the information critical to your business needs. Upon completion, attendance certificates will be provided to all participants.

NOTE: The only exceptions to the web seminar team training are: The Web Seminar Workshops and the online 30-Hour/10-Week series which are for individual registrants only. In addition, select web seminars qualify for a reduced individual participant fee as designated.

Enjoy the convenience of interactive training without the hassle of travel. Real-time learning at an affordable price — Barnett Interactive Web Seminars!

What Are the Benefits?
- A seamless, secure, real-time multimedia learning experience
- No travel, no travel expenses, and no time away from the office
- Resources required are already at your fingertips — an Internet connection and a phone or headset
- You can ask questions, chat, learn from industry leaders, and network with your fellow attendees, all from the convenience of your own office
- Convenient, customizable learning environment where you will have your specific questions answered
- Learn the information critical to your business needs, when you need it

The Barnett Difference
- Engagement-focused instructional format designed for online learning
- Direct interaction with experienced trainers and subject matter experts
- Learning activities focused on application and information retention
- Availability of course and reference materials
- Accredited content and cost-effective group training

Web Seminar Archives
Unable to attend an Interactive Web Seminar? Archived recordings are available and they will allow you to watch previous Interactive Web Seminars any time you want. Pricing is available for single users and site licenses. See page 205 for more details.

System Requirements:
WebEx offers cross-platform, unmatched support across a wide range of devices. Supported computer operating systems include Windows, Mac, Linux, and Solaris. Browser support includes Internet Explorer, Microsoft Edge, Google Chrome, Mozilla Firefox, and Safari. You can also download the free WebEx Meetings app to your Apple, Android, or Amazon smartphone or tablet. You can always test your system at: BarnettWebSeminars.webex.com. In the panel on the left side, select Setup – Training Manager and follow the on-screen prompts.

Registration:
Registration for Web Seminars can be accessed online at: barnettinternational.com. Or by calling +1 781.972.5400 or toll-free in the U.S. 800.856.2556. After registering, you will receive an email confirmation that provides you with the Web Seminar link and audio connection information. Upon completion, Barnett International attendance certificates will be provided.

Accreditation:
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education (ACPE). Web Seminar participants will receive continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

Custom Web Seminars Available:
Have multiple team members who need training? Want to tailor course material to your organization’s processes and SOPs? Barnett Web Seminars can be customized to fit your needs.
For more information, please contact Naila Ganatra at +1 215.413.2471 or nganatra@barnettinternational.com.
10-Week CRA & CRC Beginner Program

Course Description
The online 10-Week CRA & CRC Beginner Program provides a comprehensive introduction to clinical research and the job functions of the Clinical Research Associate (CRA) and Clinical Research Coordinator (CRC) for drug, biologic, and device trials. This program is geared toward individuals seeking a new career or career change into clinical research, but haven’t decided which job track to pursue. Case studies and industry best practices are presented to emphasize how the learning objectives apply directly to the responsibilities of the CRA and CRC.

Learning Objectives
- Describe and discuss the investigational product development process, including FDA regulations, ICH guidelines, and Good Clinical Practice (GCP)
- Explain the roles and responsibilities of a CRA and CRC
- Describe the four types of monitoring visits, including the responsibilities of the CRA and CRC in preparation, activities, and follow-up
- Explain the Key Pre-Study Concepts: Role of the Principal Investigator, Site Selection, Clinical Trial Agreement and Budget Negotiation
- Discuss the role of the Institutional Review Board in clinical trials, define informed consent requirements, and discuss the informed consent process
- Discuss the study site initiation, interim monitoring activities, and data management
- Define safety definitions and reporting requirements for both drugs and devices
- Examine accountability for the investigational product and study closeout visits
- Discuss regulatory compliance and quality assurance as it relates to audits and inspections

Course Outline
- Module 1: Investigational Product Development, the FDA, and Good Clinical Practice Guidelines
- Module 2: Clinical Research Team: Roles and Responsibilities
- Module 3: The Principal Investigator, Site Selection, and Budget Negotiation
- Module 4: Clinical Study Protocol Elements
- Module 5: Institutional Review Boards, the Consent of Human Volunteers, and HIPAA
- Module 6: Study Monitoring, Data Management, and Study Initiation Visit
- Module 7: Safety Reporting: Definitions and Reporting Requirements
- Module 8: Accountability for the Test Article and Trial Termination Visits
- Module 9: Regulatory Compliance and Quality Assurance: Audits and Inspections
- Module 10: Managing Your Time and Preparing for the Interview

Who Should Attend
- Aspiring Clinical Research Associates and Clinical Research Coordinators (This course is also appropriate for Clinical Research Associates and Clinical Research Coordinators with less than six months of experience)
- College Students and New Graduates in a Scientific Field
- Nurses

Instructors
This course will be taught by one of the following instructors:
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.
Elizabeth Ronk Nelson, M.P.H.
Susan Torchio, R.N., B.S.N.

Course Length and Time
3 hours/week, 1:00 – 4:00 p.m. and 6:00 – 9:00 p.m. Eastern
10 weeks

Course Dates
February 26, 2020 – April 29, 2020
Wednesday Evenings
$1,795 by January 24
$1,995 after January 24

March 17, 2020 – June 9, 2020
No class: March 31, April 7, May 5
Tuesday Afternoons
$1,795 by February 14
$1,995 after February 14

May 6, 2020 – July 22, 2020
No class: July 1, July 8
Wednesday Evenings
$1,795 by April 3
$1,995 after April 3

Resume support is available as an add-on option!
ACRP Members: Receive 10% off!

NOTE: This course is for individual registrants only.

Logistical Details
The resources required to take this online course are an Internet connection and a phone. After registering, you will receive an email confirmation that provides you with the Web Seminar link and audio connection information.

Prior to the start of the course, participants will receive Module 1 materials. Course materials for subsequent modules will be sent weekly prior to class. Come to class prepared to interact – you will be able to ask questions, provide feedback, and participate in discussions and group work. Upon course completion, participants will be provided training certificates. In order to receive accreditation CEUs, participants are required to pass both a mid-term and final exam. Upon completion of the exams, CEU certificates will be provided.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Participants will receive 30 hours (3.0 CEUs) of continuing education credit for full participation, including the completion of a mid-term exam, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-20-019-L01-P. Released: 2/20.

What Participants Say About The Course
“I thought it was fantastic and it did help me land my job – a CRA. My satisfaction with the class was high because there was interaction AND online – a tough combo to find.”

“I am a CRC and am running four studies now. The class was such a great class to start with and I am using what I learned daily. I am very happy to be in research.”
Course Description
The online 10-Week Clinical Research Associate (CRA) On-Boarding Program is appropriate for individuals with less than two years of experience as a CRA. The course provides practical, hands-on training as it relates to the CRA job function, and covers core sponsor and research site activities that promote the successful monitoring of studies for drug, biologic, and device trials. Good Clinical Practice (GCP) skills are reinforced through a combination of activities, including lecture, case studies, and scenario review, as well as application-based homework assignments.

The course is built on Barnett’s deep in-person CRA training experience and is designed for “on-boarding” of individual new hires or entire teams. If you are a CRA manager or human resources professional responsible for the orientation and training of one new CRA or 100, this course provides a convenient, cost-effective, comprehensive, and interactive training method. You’ll have peace of mind knowing that you are training your new hires to the highest industry standards.

Learning Objectives
- Describe the drug development process, the importance of Good Clinical Practice (GCP), and the roles and responsibilities of the research team
- Define the regulatory requirements, explain the differences between ICH GCP E6 and FDA requirements, and describe the elements of a protocol
- Outline required elements of the informed consent
- Identify the investigational product accountability requirements and impact of the reconciliation process on the study
- Define the safety definitions and comprehend the safety reporting requirements
- Prepare for and perform source document verification
- Perform the steps involved in monitoring the investigational site: Pre-visit, during the visit, and post-visit
- Create cohesive, well-written protocol deviations and action items, and accurately complete the monitoring visit report and site follow-up letter
- Define the impact of quality assurance and audits in clinical research

Course Outline
- Module 1: Investigational Product Development Process: Drug and Medical Device, Good Clinical Practice (GCP), and Clinical Research Team Roles and Responsibilities
- Module 2: IRB, Clinical Study Protocol Elements and Amendments
- Module 3: Informed Consent
- Module 4: Investigational Product Accountability
- Module 5: Safety Definitions and Reporting Requirements
- Module 6: Source Document Verification
- Module 7: Monitoring the Study
- Module 8 and Module 9: Monitoring Visit Reports, Follow-Up Letters, and Contact Reports
- Module 10: Regulatory Compliance and Quality Assurance: Audits and Inspections

Who Should Attend
- Clinical Research Associates with less than two years of experience – in-house or field-based
- Those currently working in the industry in a different role seeking to change roles
- The course is also ideal for “on-boarding” of individual new hires or entire teams (individual registrations required)

Instructor

Course Length and Time
3 hours/week, 9:30 a.m. – 12:30 p.m., 1:00 – 4:00 p.m. and 6:00 – 9:00 p.m. Eastern
10 weeks

Course Dates
- February 7, 2020 – April 17, 2020
  No class: April 3
  Friday Afternoons
  $1,795 by January 10
  $1,995 after January 10
- February 25, 2020 – May 19, 2020
  No class: March 31, April 7, April 21
  Tuesday Evenings
  $1,795 by January 17
  $1,995 after January 17
- May 8, 2020 – July 24, 2020
  No class: June 19, July 3
  Friday Mornings
  $1,795 by April 10
  $1,995 after April 10

Resume support is available as an add-on option!
ACRP Members: Receive 10% off!!

NOTE: This course is for individual registrants only.

Logistical Details
The resources required to take this online course are an Internet connection and a phone. After registering, you will receive an email confirmation that provides you with the Web Seminar link and audio connection information.

Prior to the start of the course, participants will receive Module 1 materials. Course materials for subsequent modules will be sent weekly prior to class. Come to class prepared to interact – you will be able to ask questions, provide feedback, and participate in discussions and group work. Upon course completion, participants will be provided training certificates. In order to receive accreditation CEUs, participants are required to pass both a mid-term and final exam. Upon completion of the exams, CEU certificates will be provided.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 30 hours (3.0 CEUs) of continuing education credit for full participation, including the completion of a mid-term exam, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-20-020-L01-P. Released: 2/20.

What Participants Say About The Course
“...The CRA course increased my awareness of the importance of developing strategies and risk-based approaches to monitoring. The breadth of knowledge and experience of the trainers was impressive. The overview of quality systems and regulatory expectations will surely have a place in my daily monitoring activities.”

“This program opened the door for me to really understand what a CRA does and how to document everything. It gave me a true guideline as I manage expectations of all parties and what to look out for during visits, as well as how to document findings in a responsible, accurate way.”

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 30 hours (3.0 CEUs) of continuing education credit for full participation, including the completion of a mid-term exam, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion. ACPE#: 0778-0000-20-020-L01-P. Released: 2/20.
Interactive Web Seminars

10-Week Clinical Research Coordinator (CRC) On-Boarding Program

Course Description
The Clinical Research Coordinator (CRC) has a vital role in the conduct of a clinical trial and is a key liaison between the investigator, subject, IRB, and sponsor. The online 10-Week Clinical Research Coordinator (CRC) On-Boarding Program will provide a comprehensive introduction to clinical research and the job functions of the CRC for both drug/biologic and device trials. This program will provide core skills and encourage critical thinking to those individuals looking to support, facilitate, and coordinate the daily activities of clinical trials.

Case studies and industry best practices will be presented to underscore how the learning objectives apply directly to the responsibilities of the CRC.

Learning Objectives
- Understand the roles and responsibilities of the Clinical Research Coordinator
- Prepare for what a pharmaceutical or device sponsor is looking for in a research site during a pre-study evaluation or site selection visit
- Understand the requirements for source documentation, case report forms, study tool development, and standard operating procedures (SOPs)
- Define informed consent requirements and learn the process of conducting informed consent
- Define safety reporting: Definitions and reporting requirements
- Discuss regulatory compliance and quality assurance as it relates to audits and inspections

Course Outline
- Module 1: Introduction to Clinical Research, Investigational Product Development: Drug and Device, Regulatory Oversight, and Good Clinical Practice Guidelines
- Module 2: The Clinical Research Team: Roles and Responsibilities
- Module 3: The Principal Investigator and Site Selection
- Module 4: Clinical Study Protocol Breakdown and Feasibility Evaluation
- Module 5: Source Documentation, Case-Report Forms, Study Tool Development, and Standard Operating Procedures
- Module 6: Informed Consent Requirements and Process
- Module 7: Study Initiation, Start-up, and Ongoing Management Activities and Sponsor Expectations
- Module 8: Safety Reporting: Definitions and Reporting Requirements
- Module 9: Accountability for the Test Article and the Trial Termination Visit
- Module 10: Regulatory Compliance and Quality Assurance: Audits and Inspections

Who Should Attend
- Aspiring CRCs (This course is also appropriate for CRCs with less than six months of experience)
- College Students and New Graduates in a Scientific Field
- Nurses interested in developing skills in clinical research

Instructor
Janet Ellen Holwell, C.C.R.C., C.C.R.A.

Course Length and Time
3 hours/week, 9:30 a.m. – 12:30 p.m. and 1:00 – 4:00 p.m. Eastern
10 weeks

Course Dates
February 7, 2020 – April 17, 2020
No class: April 3
Friday Mornings
$1,795 by January 10
$1,995 after January 10
May 8, 2020 – July 24, 2020
No class: June 19, July 3
Friday Afternoons
$1,795 by April 10
$1,995 after April 10
Resume support is available as an add-on option!
ACRP Members: Receive 10% off!
NOTE: This course is for individual registrants only.

Logistical Details
The resources required to take this online course are an Internet connection and a phone. After registering, you will receive an email confirmation that provides you with the Web Seminar link and audio connection information.

Prior to the start of the course, participants will receive Module 1 materials. Course materials for subsequent modules will be sent weekly prior to class. Come to class prepared to interact – you will be able to ask questions, provide feedback, and participate in discussions and group work. Upon course completion, participants will be provided training certificates. In order to receive accreditation CEUs, participants are required to pass both a mid-term and final exam. Upon completion of the exams, CEU certificates will be provided.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 30 hours (3.0 CEUs) of continuing education credit for full participation, including the completion of a mid-term exam, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-20-021-L01-P. Released: 2/20.

What Participants Say About The Course

“The course provided useful tools. It was easy to ask questions and the weekly online course format allowed time for the new material to be absorbed, before adding new content. It was manageable, even with a full time job.”

“Lessons learned in this seminar are already being put to practice in my day-to-day Oncology Research Coordinator position. This course has given me a clear picture and understanding of the drug development process to the time study closes and the drug is marketed. This is a great wealth of knowledge and the course was very informative. Thank you!”

“I am already using almost everything that we went over in class in my day-to-day activities! Thank you so much for a wonderful class!”
WHO SHOULD ATTEND
- Clinical Research Coordinators
- Clinical Trial Managers
- Clinical Research Associates
- Clinical Research Managers/Directors
- Administrative Directors
- Financial Analysts

LEARNING OBJECTIVES
- Discuss federal and billing regulations while building a compliant clinical research billing program
- Describe the financial feasibility process and deciding to conduct/participate in a clinical research study
- Describe the creation of the Medicare Coverage Analysis (MCA) process, determining coverage of items and services and incorporating MCA into the clinical trial budget
- Discuss integrating MCA into an electronic health record and managing patient billing
- Review sponsor billing and leverage system integrations to mitigate organizational risk

COURSE OUTLINE
- Module 1: Financial Feasibility and Decision to Participate in a Clinical Research Study
- Module 2: Creating a Medicare Coverage Analysis (MCA) – A Step-By-Step Approach; Billing Regulation Review
- Module 3: Creating a Clinical Trial Budget and Incorporating MCA
- Module 4: Negotiating a Clinical Trial Budget
- Module 5: Integrating MCA into an Electronic Health Record; Creating a Billing Grid
- Module 6: Consenting Patients, Creating Timelines, and Ordering Services
- Module 7: Patient Billing: Charge Review Process and Medical Documentation
- Module 8: Sponsor Billing: Milestone Payments
- Module 9: Leveraging Data: Using Patient and Study Data to Manage Current and Future Studies
- Module 10: Study Close Out: Reconciliation Process and Ensuring All Payments Are Received

INSTRUCTOR
Victoria Johnson, M.B.A., CPC

COURSE LENGTH AND TIME
3 hours/week, 1:00 – 4:00 p.m. Eastern, 10 weeks Monday Afternoons

COURSE DATES
January 13 – March 16, 2020
$1,795 by December 13
$1,995 by December 13
March 23, 2020 – June 8, 2020
$1,795 by February 21
$1,995 after February 21
July 13, 2020 – September 14, 2020
$1,795 by June 12
$1,995 after June 12

ACRP Members: Receive 10% off!
NOTE: This course is for individual registrants only.

LOGISTICAL DETAILS
The resources required to take this online course are an Internet connection and a phone. After registering, you will receive an email confirmation that provides you with the Web Seminar link and audio connection information.

Prior to the start of the course, participants will receive Module 1 materials. Course materials for subsequent modules will be sent weekly prior to class. Come to class prepared to interact – you will be asked to provide feedback, and participate in discussions and group work. Upon course completion, participants will be provided training certificates. In order to receive accreditation CEUs, participants are required to pass both a mid-term and final exam. Upon completion of the exams, CEU certificates will be provided.

ACCREDITATION
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 30 hours (3.0 CEUs) of continuing education credit for full participation, including the completion of a mid-term, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.


WHAT PARTICIPANTS SAY ABOUT BARNETT’S 10-WEEK COURSES
"
Great course! Instruction is expertly led and engaging. I will recommend Barnett to any colleague and will seek out topics for my own future training and professional development needs.
"

"The course has been so incredibly helpful thus far...I look forward to Thursday evenings!"

"This class exceeded my expectations of an online learning experience. The instructor was knowledgeable, came equipped with great examples to keep the class interesting and is a strong presenter. Thank you!"

EXPERIENCE THE BARNETT WEB SEMINAR DIFFERENCE:
Engagement-focused instructional format • Learning activities focused on application
Interaction with subject matter experts • Accredited content • Cost-effective group training

115
10-Week Final ICH GCP E6 R2: Risk-Based Monitoring Plan Development Series

Course Description
Risk-based approaches to clinical trials and risk-based monitoring are now required for clinical trial sponsors under ICH GCP E6 R2 Addendum. This comprehensive 10-week series provides a step-by-step approach for developing the content of the clinical trial monitoring plan. Specific attention is given to translating the Trial Risk Assessment (TRA) output and Integrated Quality Risk Management Plan (IQRMP) into a well-orchestrated document that is concise, comprehensive, and clearly articulates the complete strategy for all aspects of the monitoring to be undertaken and how risks will be mitigated.

Learning Objectives
- Describe the monitoring responsibilities of a risk-based quality management trial and the key areas to focus on and include in the monitoring plan
- Explain how the TRA and IQRMP outputs are integrated into the monitoring plan
- Identify the stakeholders necessary for monitoring plan development
- Explain inclusion of roles, responsibilities, and communication strategies in the monitoring plan
- Identify content and the components needed for developing a clear and concise risk-based monitoring plan
- Discuss how critical and non-critical data are to be incorporated into the monitoring framework
- Define centralized monitoring activities based on a case study and how to include these activities in the monitoring plan

Course Outline
- **Module 1:** Monitoring Plan Overview, Stakeholders, and Planning for Success
- **Module 2:** Deriving Input: Risks, Critical Data/Processes, Mitigation Plans
- **Module 3:** Case Study: Let’s Get Started
- **Module 4:** On-Site Visit and Site Management
- **Module 5:** Off-Site (Remote) Site Monitoring
- **Module 6:** Centralized/Statistical Monitoring
- **Module 7:** Escalation and De-escalation/Management of Noncompliance
- **Module 8:** End of Study Activities and Other Monitoring Plan Components
- **Module 9:** Drivers for Revisions and Updates
- **Module 10:** Regulatory Agency Inspections: Helpful Tips

Who Should Attend
- Clinical Trial Managers/Study Leads
- Project Managers
- Clinical Trial Management/Clinical Operations Directors
- Quality Compliance Professionals
- Data Managers and Statisticians

Instructors
This course will be taught by one of the following instructors:
- Mary Mills, R.N., C.C.R.A.,
- Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
2 hours/week, 10:30 a.m. – 12:30 p.m. and 1:00 – 3:00 p.m. Eastern
10 weeks

Course Dates
- **January 21, 2020 – March 24, 2020**
  - Tuesday Afternoons
  - $1,795 by December 20
  - $1,995 after December 20
- **April 14, 2020 – June 16, 2020**
  - Tuesday Mornings
  - $1,795 by March 13
  - $1,995 after March 13

ACRP Members: Receive 10% off!

NOTE: This course is for individual registrants only.

Logistical Details
The resources required to take this online course are an Internet connection and a phone. After registering, you will receive an email confirmation that provides you with the Web Seminar link and audio connection information.

Prior to the start of the course, participants will receive Module 1 materials. Course materials for subsequent modules will be sent weekly prior to class. Come to class prepared to interact – you will be able to ask questions, provide feedback, and participate in discussions and group work. Upon course completion, participants will be provided training certificates. In order to receive accreditation CEUs, participants are required to pass both a mid-term and final exam. Upon completion of the exams, CEU certificates will be provided.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 20 hours (2.0 CEUs) of continuing education credit for full participation, including the completion of a mid-term exam, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-17-106-L01-P. Released: 9/17.

What Participants Say About Barnett’s 10-Week Courses
- “Great course! Instruction is expertly led and engaging. I will recommend Barnett to any colleague and will seek out topics for my own future training and professional development needs.”
- “The course has been so incredibly helpful thus far...I look forward to Thursday evenings!”
- “This class exceeded my expectations of an online learning experience. The instructor was knowledgeable, came equipped with great examples to keep the class interesting and is a strong presenter. Thank you!”
10-Week Fundamentals of Clinical Research Series: Getting Started in Clinical Research

Course Description
The 10-Week Fundamentals of Clinical Research Series provides a comprehensive introduction to clinical research for those who are new to or interested in working on pharmaceutical and medical device clinical trials. Participants will learn about the basics of clinical research, including industry practices and rationale, and how key concepts apply directly toward clinical research efforts, which are often mandated by regulations and guidelines. The series covers core sponsor and investigator site activities to help learners understand the key considerations in the real-life work of clinical researchers.

Learning Objectives
- Define clinical research and discuss how preclinical development leads to clinical development
- Explain the roles and responsibilities of all members of the clinical team: Sponsor, vendor, CRO, investigator, Institutional Review Board, subject and regulatory authority
- Describe the investigational product development process including study design and the logic involved
- Define the regulatory requirements, including principles of Good Clinical Practice from the International Council for Harmonization, FDA regulations (Code of Federal Regulations), ethical considerations for a study and the need for Standard Operating Procedures
- Define the steps involved in preparing with the study: Sponsor development of protocol, case report form, informed consent document, budget, database and identifying an investigational site
- Describe the conduct of the study including monitor visits to the site and site performance management and communication
- Describe the management of adverse events and completion of study reporting and retention of documents
- Identify career opportunities and reference materials available

Course Outline
- Module 1: Clinical Research: What’s it all about?
- Module 2: Players: Who participates and what is their role?
- Module 3: Game Plan: How are new drugs/medical devices developed?
- Module 4: Rule Book: There are always rules – which ones apply to research?
- Module 5: Designing: Are all studies the same?
- Module 6: Preparation: Where do you start with involving clinical sites?
- Module 7: Daily Life: What’s involved in day-to-day clinical research life?
- Module 8: After the Game: What’s involved in follow-up and reporting?
- Module 9: Pay-back: What’s involved in bringing a product to market?
- Module 10: After life: Does the FDA get involved and which career pathways might be available?

Who Should Attend
- Those who are new to clinical research
- Aspiring Clinical Research Coordinators and Clinical Research Associates
- Nurses interested in clinical research
- Aspiring and Entry Level Project Managers (looking to gain experience in clinical research)
- College Students and New Graduates in a Scientific Field

Instructor

Course Length and Time
2 hours/week, 9:30 – 11:30 a.m. and 1:00 – 3:00 p.m. Eastern
10 weeks

Course Dates
January 21, 2020 – March 24, 2020
Tuesday Mornings
$1,795 by December 20
$1,995 after December 20

March 26, 2020 – June 4, 2020
No class: April 2
Thursday Afternoons
$1,795 by February 21
$1,995 after February 21

Resume support is available as an add-on option!
ACRP Members: Receive 10% off!
NOTE: This course is for individual registrants only.

Logistical Details
The resources required to take this online course are an Internet connection and a phone. After registering, you will receive an email confirmation that provides you with the Web Seminar link and audio connection information.
Prior to the start of the course, participants will receive Module 1 materials. Course materials for subsequent modules will be sent weekly prior to class. Come to class prepared to interact – you will be able to ask questions, provide feedback, and participate in discussions and group work. Upon course completion, participants will be provided training certificates. In order to receive accreditation CEUs, participants are required to pass both a mid-term and final exam. Upon completion of the exams, CEU certificates will be provided.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 20 hours (2.0 CEUs) of continuing education credit for full participation, including the completion of a mid-term, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-18-027-L01-P. Released: 2/18.

What Participants Say About Barnett’s 10-Week Courses
"Great course! Instruction is expertly led and engaging. I will recommend Barnett to any colleague and will seek out topics for my own future training and professional development needs.""""The course has been so incredibly helpful thus far...I look forward to Thursday evenings!"
"This class exceeded my expectations of an online learning experience. The instructor was knowledgeable, came equipped with great examples to keep the class interesting and is a strong presenter. Thank you!"
10-Week Risk Management/Risk-Based Quality Management for Clinical Trials Certification Program

Course Description
Are you prepared for Quality Risk Management (QRM), Risk Management (RM), Risk-Based Quality Management (RBQM)? With ICH GCP E6 R2 now requiring risk-based approaches to managing quality in clinical trials, this 10-Week series takes you through, step-by-step, how to execute these requirements. We will focus on the critical elements for clinical trial sponsors and CROs included in the ICH GCP E6 R2 expectations, while highlighting key points from other regulatory bodies such as ISO 31000 Risk Management. Each step of risk identification, assessment, control, review, reporting, management, and communication are also reviewed.

Learning Objectives
• Describe the expectations of QRM in relation to the ICH E6 R2 updates
• Discuss how to analyze risks and develop a risk register
• Describe how to use multiple risk analysis tools including: Failure Mode Effect Analysis (FMEA), Bow Tie, and Affinity Diagram
• Describe how to formulate risk mitigation strategies

Course Outline
• Module 1: Quality Risk Management: Quality Risk Management/ Risk Management Policy/Program, Accountability and Resources
• Module 2: Risk Management Plan and Culture: Framework for Communicating Risk Within an Organization/Program, Strategies and Challenges for Risk Stakeholders, Required Commitment and Mandate
• Module 3: Risk Identification: Risk Identification and When to Start, System Level Risks and Project (Clinical Trial) Level Risks, Risk Register (Risk Log) for Tracking Risks
• Module 4: Risk Evaluation: Impact of Error, Detection of the Error, Risk Priority Number (RPN) Values
• Module 5: Risk Analysis Tools Part I: FMEA, Bow Tie, and Delphi technique
• Module 6: Risk Analysis Tools Part II: SWOT (Strengths, Weakness, Opportunities, Threats), Affinity Diagram, Cause and Effect Analysis
• Module 7: Risk Control: Risk Mitigation Strategies, Risk Mitigation Options, Priority Rankings of Risk Mitigation Plans
• Module 8: Risk Communication: Risk Mitigation Plans in the Risk Register/Log, Impact of Internal and External Stakeholders, Escalation Processes and Plans
• Module 9: Risk Review: Periodic Review, Risk Assessment, and Risk Detection
• Module 10: Risk Reporting: Risks, Deviations, Predefined Quality Tolerance Limits, Lessons Learned/Continuous Learning, S/Logs

Instructors
This course will be taught by one of the following instructors:
Susan M. Leister, M.B.A., Ph.D., CQA, CSSBB
Suzi Tran, M.B.A., CMQ/OE, CQA, CSQE

Course Length and Time
2 hours/week, 1:00 – 3:00 p.m. Eastern, 10 weeks Thursday Afternoons

Course Dates
March 19, 2020 – June 4, 2020
No class: April 30, May 14
$1,795 by February 14
$1,995 after February 14
ACRP Members: Receive 10% off!!
NOTE: This course is for individual registrants only.

Logistical Details
The resources required to take this online course are an Internet connection and a phone. After registering, you will receive an email confirmation that provides you with the Web Seminar link and audio connection information.

Prior to the start of the course, participants will receive Module 1 materials. Course materials for subsequent modules will be sent weekly prior to class. Come to class prepared to interact – you will be able to ask questions, provide feedback, and participate in discussions and group work. Upon course completion, participants will be provided training certificates. In order to receive accreditation CEUs, participants are required to pass both a mid-term and final exam. Upon completion of the exams, CEU certificates will be provided.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 20 hours (2.0 CEUs) of continuing education credit for full participation, including the completion of a mid-term, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-20-022-L01-P. Released: 3/20.

What Participants Say About Barnett’s 10-Week Courses
“Great course! Instruction is expertly led and engaging. I will recommend Barnett to any colleague and will seek out topics for my own future training and professional development needs.”
“The course has been so incredibly helpful thus far...I look forward to Thursday evenings!”
“This class exceeded my expectations of an online learning experience. The instructor was knowledgeable, came equipped with great examples to keep the class interesting and is a strong presenter. Thank you!”

Who Should Attend
• Quality Control/Assurance Professionals
• Regulatory Affairs Professionals
• Clinical Research/Operations Personnel
• Information Technology/Security Personnel
• Data Managers
• Study Managers
• Project Physicians/Medical Monitors
• Pharmacovigilance Professionals
• Biostatisticians

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
30-Hour Clinical Data Management On-Boarding Program

Course Description
The online 30-Hour Clinical Data Management On-Boarding Program is designed to provide a comprehensive and foundational study of the best practices which have been identified in the discipline of Clinical Data Management (CDM). From protocol review and identifying study design to the required data elements and the final steps at the milestone of database lock, we will identify and discuss crucial CDM processes.

Information presented will give new Clinical Data Management personnel a robust view of all CDM processes. This on-boarding program will also assist individuals to refresh their knowledge if they are preparing to sit for the certification examination.

Learning Objectives
- Define best practices as they apply to CDM processes
- Describe CDM processes from study start-up to database lock
- Apply best practice rationale when assessing data collection requirements/instruments
- Evaluate the benefits of standardization in establishing CDM processes
- Discuss current technology/methods of data collection and associated documentation
- Define best practices as they apply to CDM processes

Course Outline
- **Module 1:** FDA Guidelines, Protocol Review, and Data Management Plan Creation and Content
- **Module 2:** Case Report Form Design (CRF/eCRF), and Edit Check Creation
- **Module 3:** Electronic Data Capture: Selecting an Application, Implementing the System, and Study Conduct
- **Module 4:** Database Validation, Data Entry Processes (EDC/Paper-based Studies), and Data Standards (CDISC/CDASH)
- **Module 5:** Data Quality and Metrics
- **Module 6:** External Data: Data Transfer Agreements, Patient Reported Outcomes, and Laboratory Data
- **Module 7:** Safety Data Management and Reporting, Serious Adverse Event Reconciliation, and Medical Coding Dictionaries
- **Module 8:** Database Lock, Clinical Data Archiving, and Data Storage
- **Module 9:** Project Management for the Clinical Data Manager including Vendor Selection
- **Module 10:** CDM Presentations at Investigator Meetings and CDM Training

Who Should Attend
- New or aspiring Clinical Data Managers
- Clinical Data Managers
- Data Coordinators
- Project Managers
- College Students and New Graduates in a Scientific Field
- This course is also ideal for “on-boarding” of individual new hires or entire teams (individual registrations required)

Instructor
Denise G. Redkar-Brown, MT

Course Length and Time
3 hours/week, 8:30 – 11:30 a.m. and 5:00 – 8:00 p.m. Eastern
10 weeks

Course Dates
February 26, 2020 – April 29, 2020
Wednesday Mornings
$1,795 by January 24
$1,995 after January 24

May 6, 2020 – July 22, 2020
No class: July 1, July 8
Wednesday Evenings
$1,795 by April 3
$1,995 after April 3

Resume support is available as an add-on option!
ACRP Members: Receive 10% off!
NOTE: This course is for individual registrants only.

Logistical Details
The resources required to take this online course are an Internet connection and a phone. After registering, you will receive an email confirmation that provides you with the Web Seminar link and audio connection information.

Prior to the start of the course, participants will receive Module 1 materials. Course materials for subsequent modules will be sent weekly prior to class. Come to class prepared to interact – you will be able to ask questions, provide feedback, and participate in discussions and group work. Upon course completion, participants will be provided training certificates. In order to receive accreditation CEUs, participants are required to pass both a mid-term and final exam. Upon completion of the exams, CEU certificates will be provided.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 30 hours (3.0 CEUs) of continuing education credit for full participation, including the completion of a mid-term exam, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-004-L01-P. Released: 1/19.

What Participants Say About The Course

“I have thoroughly enjoyed this course and I sincerely believe that the information I learned will serve me well as a designer of the EDC system for studies. The presenter was an absolute delight! Thank you.”

“This course is relevant to my day-to-day activities, particularly on CRF design, EDC maintenance, and data cleaning. I really appreciated the content of the materials that were provided, which helped me broaden my understanding of data management.”

“The program was an excellent refresher for me and re-familiarized me with the state of the industry. Module 3 – Electronic Data Capture was particularly helpful.”
30-Hour Clinical Project Management Fundamentals Certification Program

Course Description
Theoretical concepts from the Project Management Institute, PMBOK® are introduced in this comprehensive introductory project management course for the clinical research professional working in the pharmaceutical, medical device, biologics and biotech industries. Whether you are looking to become a clinical research project manager, are already in an entry-level project manager role, or a project manager without formal project training, this hands-on program will provide you with project management skills as well as the necessary tools and processes required to successfully manage projects in clinical research settings. The course includes an emphasis on the need to anticipate, understand, and implement detailed project management activities in a proactive manner. Case studies, discussions, and interactive exercises are used to aid the learner in the application of clinical project management concepts and principles.

Learning Objectives
- Describe project management as it applies to clinical research and in the management of clinical trials
- Identify how project managers develop high performance project teams
- Develop a project plan and work breakdown structure for identified aspects of a clinical trial
- Apply the essentials of project management in clinical research settings
- Describe the fundamentals of process maps, flow charts and other project management tools
- Apply time management principles and properly scope a project
- Identify clinical trial project budgeting and tracking techniques
- Define project risk management, processes, planning, identification, and controlling
- Utilize appropriate communication skills and effectively motivate team members
- Apply strategies for seamless project close out and continuous improvement

Course Outline
- Module 1: Clinical Project Management Essentials
- Module 2: Project Planning Fundamentals
- Module 3: Process Mapping as a Planning and Management Tool
- Module 4: Project Management Technical Knowledge
- Module 5: Project Schedule Management
- Module 6: Management of Project Budgets
- Module 7: Project Tracking
- Module 8: Ongoing Project Management Needs
- Module 9: Communication and Team Building
- Module 10: Closing the Project and the Trial

Who Should Attend
- Aspiring and Entry-Level Project Managers and Clinical Trial Managers
- Project Managers looking to gain experience in clinical research project management
- Project Leaders that are unfamiliar with project management tools and principles
- Clinical Research Members and Leaders at investigative sites seeking project management skills to aid in the execution of clinical research projects within their organization
- Clinical Research Professionals transitioning to project management roles/ functions

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Length and Time
3 hours/week, 10:00 a.m. – 1:00 p.m., 12:00 – 3:00 p.m. and 6:00 – 9:00 p.m. Eastern
10 Weeks

Course Dates
January 9, 2020 – March 12, 2020
Thursday Evenings
$1,795 by December 6
$1,995 after December 6
March 6, 2020 – May 29, 2020
No class: March 27, April 3, May 1
Friday Afternoons
$1,795 by February 7
$1,995 after February 7
July 10, 2020 – September 11, 2020
Friday Mornings
$1,795 by June 12
$1,995 after June 12

Resume support is available as an add-on option!
ACRP Members: Receive 10% off!
NOTE: This course is for individual registrants only.

Logistical Details
The resources required to take this online course are an Internet connection and a phone. After registering, you will receive an email confirmation that provides you with the Web Seminar link and audio connection information.

Prior to the start of the course, participants will receive Module 1 materials. Course materials for subsequent modules will be sent weekly prior to class. Come to class prepared to interact – you will be able to ask questions, provide feedback, and participate in discussions and group work. Upon course completion, participants will be provided training certificates. In order to receive accreditation CEUs, participants are required to pass both a mid-term and final exam. Upon completion of the exams, CEU certificates will be provided.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 30 hours (3.0 CEUs) of continuing education credit for full participation, including the completion of a mid-term exam, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-20-023-L01-P. Released: 1/20.

What Participants Say About The Course
"I have learned several valuable tools in this course which I will apply to my projects. I really enjoyed using the PERT formula and will use this moving forward. Thank you!"

"I have gained very valuable information regarding Clinical Project Management and have learned procedural and knowledge-based processes to execute various stages of clinical trials. I will take these learnings and implement them in day-to-day professional practice towards success of my present and future studies. This is very valuable."
30-Hour Clinical Research Auditing Certification Program

Course Description
The online 10-Week Clinical Research Auditing Certification Program provides a comprehensive introduction to clinical research and the job function of the Clinical Quality Assurance Auditor for drug, biologic, and device trials. This program is geared toward individuals seeking a new career or transitioning into Good Clinical Practice (GCP) auditing. Case studies and industry best practices are presented to emphasize how the learning objectives apply directly to the responsibilities of the GCP auditor.

Learning Objectives
- Describe and discuss the investigational product development process, including FDA regulations, ICH guidelines, and Good Clinical Practices (GCPs)
- Explain the roles and responsibilities of a Clinical Quality Assurance Auditor
- Describe the types of audits, including the responsibilities of the auditor in preparation, activities, and follow-up
- Examine and apply the FDA’s methods for inspections of Clinical Investigators, IRBs, sponsors/CROs
- Discuss regulatory compliance and quality assurance issues and documentation

Course Outline
- Module 1: Investigational Product Development, the FDA, and Good Clinical Practice Guidelines
- Module 2: Auditing as a Profession and Compliance Tool
- Module 3: The Types of Clinical Research Audits and Preparation
- Module 4: Quality Systems for Auditing
- Module 5: Risk-Based Auditing and Developing Risk-Based Auditing Plans
- Module 6: The Auditing Process: Clinical Investigator
- Module 7: The Auditing Process: Institutional Review Board/Ethics Committee
- Module 8: The Auditing Process: Sponsor/CRO
- Module 9: Gathering and Disseminating Information: Verbal and Written Communication
- Module 10: Regulatory Classification and Communication: Recent Inspection Findings

Who Should Attend
- Clinical Quality and Compliance Professionals
- New or Aspiring Auditors
- Clinical Research Associates
- Project Managers
- Medical Monitors
- Regulatory Affairs Professionals
- Clinical Research Coordinators
- Clinical Principal Investigators
- IRB Administrators and Members

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
3 hours/week, 8:30 – 11:30 a.m. and 6:00 – 9:00 p.m. Eastern
10 weeks

Course Dates
January 9, 2020 – March 19, 2020
No class: March 5
Thursday Evenings
$1,795 by December 6
$1,995 after December 6
February 14, 2020 – May 1, 2020
No class: March 6, March 27
Friday Mornings
$1,795 by January 17
$1,995 after January 17
April 16, 2020 – July 9, 2020
No class: May 7, May 14, June 25
Thursday Mornings
$1,795 by March 13
$1,995 after March 13

Resume support is available as an add-on option!
ACRP Members: Receive 10% off!
NOTE: This course is for individual registrants only.

Logistical Details
The resources required to take this online course are an Internet connection and a phone. After registering, you will receive an email confirmation that provides you with the Web Seminar link and audio connection information.
Prior to the start of the course, participants will receive Module 1 materials. Course materials for subsequent modules will be sent weekly prior to class. Come to class prepared to interact – you will be able to ask questions, provide feedback, and participate in discussions and group work. Upon course completion, participants will be provided training certificates. In order to receive accreditation CEUs, participants are required to pass both a mid-term and final exam. Upon completion of the exams, CEU certificates will be provided.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
● Participants will receive 30 hours (3.0 CEUs) of continuing education credit for full participation, including the completion of a mid-term, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-17-097-L01-P. Released: 8/17.

What Participants Say About The Course
“‘I will apply the knowledge gained from this extremely informative course in all aspects of my day-to-day activities as an Audit Specialist.’”
“‘Great course, thank you. Enjoyed the interactions between attendees in this course – LOTS of great comments, questions and discussion. Also kudos to our instructor – she was very professional and respectful, and she was great in encouraging group interactions and answering everyone’s questions!’”
ABCs of Clinical Research for Clinical Administrative Support Staff

Course Description
This course provides the background needed to become an integral part of the clinical research team (for drugs and devices) and explores the need to understand the rationale behind quality performance and team-playing. The roles and responsibilities of Clinical Administrative Support will be discussed in terms of obligations to the study team and the importance of compliance with Standard Operating Procedures and Standard Office Practices. Although the course is designed for administrative staff with less than one year experience, those with some experience may also find this course helpful in providing the rationale for doing tasks in a specific manner, refining their skills, and sharing their experiences and helpful techniques with their colleagues.

Learning Objectives
• Recognize the importance of a knowledgeable clinical support staff
• Define the common terms used in the field of drug and device research
• Describe the basics of the drug/device development process
• Describe the basic principles of Good Clinical Practice and the regulations that govern clinical research
• Discuss the basics of clinical trial design and use of a study protocol
• List essential Standard Operating Procedures needed
• Describe the responsibilities of various members of the clinical team
• List the essential documents needed for clinical trials and become familiar with the proper preparation of the documents needed to support the trial process
• Discuss the importance of training and maintenance of current training records
• Describe the rationale behind building quality into the filing system
• Discuss the “dos and don’ts” in the event of a regulatory agency audit

Who Should Attend
• Clinical Research Administrative Support Staff

Instructor
Nikki Christison, B.S., C.C.R.A., T.I.A.C.R.

Course Length and Time
2.5 hours 9:00 – 11:30 a.m. and 12:30 – 3:00 p.m. Eastern

Course Dates
March 23, 2020 (9-11:30)
June 22, 2020 (12:30-3)

Archived Recording Available in Multiple Formats!

FEE: $835*
ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2.5 hours (0.25 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-005-L01-P. Released: 2/19.

ABCs of GCP and the 13 Principles of ICH GCP E6

Course Description
This web seminar provides the basic concept of Good Clinical Practice (GCP). Participants will learn the goals of GCP and its common elements (FDA regulations and the ICH GCP E6 Guideline, including R2 updates) defining the quality system of mutual accountability between the sponsor, investigator, IRB/IEC, and the regulatory authority. The basic roles and responsibilities of each stakeholder will be discussed in relation to these criteria. The 13 principles of the ICH GCP E6 Guideline will be discussed in a practical manner to ensure compliance with all regulatory requirements.

Learning Objectives
• Describe the goals of GCP
• Discuss the various regulations affecting drug, device, and biologic investigational products related to GCP
• Recognize the mutual accountability and responsibilities for each of the stakeholders: Sponsor, investigator, IRB/IEC, and regulatory authority
• Apply the 13 principles of ICH GCP E6 to quality research studies to ensure compliance

Who Should Attend
• Clinical Research Associates
• Project Managers
• Study Coordinators
• Investigators
• Regulatory Affairs Professionals
• Institutional Review Board Professionals
• All other personnel responsible for ensuring compliance with GCP regulations

Instructor
Nikki Christison, B.S., C.C.R.A., T.I.A.C.R.

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates
March 23, 2020 (1-2:30)
June 22, 2020 (9:30-11)

Archived Recording Available in Multiple Formats!

FEE: $735* ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-17-017-L01-P. Released: 4/17.
Adverse Event Monitoring for CRAs

Course Description
During monitoring visits, one of the most important and impacting activities that a Clinical Research Associate (CRA) performs is the source document verification of Adverse Events (AEs). The CRA serves as the eyes for the research sponsor when it comes to proper collection and documentation of subject safety information. Incorrect and inadequate monitoring of AEs can lead to inaccurate labeling for clinical trials and impact market application inspectional reviews, as well as post-marketing labeling. This includes causality, expectedness/unanticipated, and other important concepts. This includes Causality, Expectedness/Unanticipated, and other important concepts. Case scenarios will be used to apply the information for better learning.

Learning Objectives
- Define safety concepts and reporting requirements
- Recognize the importance of verifying the subject baseline history
- Determine when to start and stop monitoring AEs
- Apply a detailed presentation of the source document verification process of AEs
- Manage challenges in monitoring AEs
- Determine appropriate credentialing for site AE evaluation of event relationship
- Describe the impact of monitoring on future product labeling
- Discuss reporting trends

Who Should Attend
- Device and Drug Study Clinical Research Associates
- Contract Clinical Research Associates
- Clinical Research Associate Managers
- Project Managers

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Length and Time
2 hours 12:00 – 2:00 p.m. Eastern

Course Dates
January 28, 2020
July 14, 2020

Archived Recording Available in Multiple Formats!

FEE: $735*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.866.2596 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

EXPERIENCE THE BARNETT WEB SEMINAR DIFFERENCE:
- Engagement-focused instructional format • Learning activities focused on application
- Interaction with subject matter experts • Accredited content • Cost-effective group training

Applied Clinical Statistics in Risk-Based Monitoring

Course Description
With the release of FDA’s guidance on risk-based monitoring (RBM), the FDA is requiring centralized monitors to have adequate training to perform centralized monitoring activities. Moreover, with the increase in the availability of clinical operational data, and with more biopharmaceutical and medical device enterprises outsourcing, clinical operations teams need to have the necessary skills to centrally and efficiently monitor and manage their clinical trials. This web seminar will provide a brief background as to how the industry is changing, address why centralized and RBM is gaining importance, and offer applied clinical statistical training and tools that can be utilized towards centralized clinical trial monitoring applications and identifying site underperformance. These tools are also flexible towards clinical business operations. Attendees will learn to interpret and graph histograms, quantify risk in histograms and datasets, identify clinical trial underperformance, and utilize minimum random sampling for RBM in histograms and datasets.

Learning Objectives
- Describe the role of centralized monitoring
- Interpret P-values, histograms, and confidence intervals and distribution
- Identify risk and clinical trial underperformance

Who Should Attend
- Clinical Operations Personnel
- Clinical Affairs Professionals
- Clinical Research Associates
- Principal Investigators
- Clinical Research Coordinators
- Research Nurses and Scientists
- Clinical Project Managers

Instructor
Moe Alsumidaie, M.B.A., M.S.F.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

ACPE#: 0778-0000-20-024-L01-P. Released: 1/20.
Interactive Web Seminars

Approaches to Address Challenges in Vendor Management

Course Description
The stipulation of taking a more proactive approach to managing risk in clinical trials is a major component of ICH GCP E6 R2. As outsourcing in clinical development continues to grow, so do the challenges of ensuring quality outcomes. In this web seminar, recommendations for sponsor oversight practices are discussed, as well as tools and best practices for managing vendor relationships. Managing a vendor vs. micro-managing a vendor will also be discussed.

Learning Objectives
- Identify key approaches to planning and preparing to outsource while managing clinical trial risk
- Identify key components for formal study of vendor performance management
- Identify adequate oversight SOPs and other practices
- Employ end of project analysis to pave the way for improvement in future relationships

Who Should Attend
- Sponsors
- CROs/Vendors
- Those that choose, manage, or evaluate external service providers

Instructors
This course will be taught by one of the following instructors:
Debbie Harper, B.Sc., P.M.P.
Jeanne Morris, B.S., MT (ASCP)

Course Dates
March 3, 2020

Course Length and Time
2.5 hours 12:00 – 2:30 p.m. Eastern

FEE: $835*
ACRP Members: Receive 10% off!

Archived Recording Available in Multiple Formats!

Auditing Clinical Research Studies: An Overview for Assessing GCP Compliance

Course Description
Quality assurance is defined as a “systematic and independent examination of trial-related activities and documents” that allows an auditor to determine whether or not the clinical trial was conducted according to the regulations and guidance that govern clinical research. This web seminar will provide an overview of auditing skills and techniques and a review of recent GCP audit findings from Clinical Investigators (Sites), Sponsors, and IRBs.

Learning Objectives
- Discuss how quality assurance differs from quality control and who is responsible for each
- Determine who gets audited and factors and metrics for assessing when or why to audit
- Discuss guidelines on how the FDA trains its investigators to audit Clinical Investigators (Sites), Sponsors, and Institutional Review Boards (IRBs)
- Review recent noncompliance trends and regulatory focus for Sites, Sponsors, and IRBs

Who Should Attend
- Clinical Quality Assurance Auditors
- Clinical Quality and Compliance Professionals
- Clinical Research Associates
- Project Managers
- Medical Monitors
- Regulatory Affairs Professionals
- Clinical Research Coordinators
- Clinical Principal Investigators
- IRB Administrators and Members

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Dates
February 17, 2020 (12:30-2:30)
May 19, 2020 (9:30-11:30)

Course Length and Time
2 hours 9:30 – 11:30 a.m. and 12:30 – 2:30 p.m. Eastern

FEE: $835*
ACRP Members: Receive 10% off!

Archived Recording Available in Multiple Formats!

Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.


Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 2.5 hours (0.25 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-17-099-L01-P. Released: 8/17.

ACPE#: 0778-0000-17-099-L01-P. Released: 8/17.

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold This Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Auditing Sponsors and CROs: Deconstruction and Application of the FDA’s Compliance Program Guidance Manual

Course Description
As scrutiny of sponsors, Contract Research Organizations (CROs), and monitors involved in the conduct of clinical research intensifies, companies are using their quality assurance resources to review internal (and vendor) systems to ensure compliance within a changing regulatory environment. A systematic application of the Compliance Program Guidance Manual (CPGM) permits identification of regulatory risks during qualification and in-process audits. This web seminar will review the FDA’s current guideline for conducting inspections and how to apply them to assess Quality Systems. Assessment of the SOPs that are expected for sponsors and CROs, including registration of trials and informed consent document issues, will also be discussed.

Learning Objectives
- Integrate new regulatory requirements and processes into audits
- Translate inspection criteria to Quality Systems that support changes in inspection focus
- Assess the FDA’s application of the CPGM as reflected in regulatory communication
- Examine steps for preparation of an inspection

Who Should Attend
- Professionals from Academia whose institutions or investigators hold INDs or IDEs, or whose institutions support clinical research with Site Management Organizations (SMOs)
- Clinical Quality Assurance Auditors
- Clinical Quality and Compliance Professionals
- Clinical Research Associates
- Project Managers
- Medical Monitors
- Regulatory Affairs Professionals
- Clinical Research Coordinators

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
2 hours 12:30 – 2:30 p.m. Eastern

Course Dates
February 18, 2020

Archived Recording Available in Multiple Formats!

FEE: $735*
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
- Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-18-010-L01-P Released: 1/18.

Auditing Techniques: A Problem-Solving Practicum

Course Description
An audit is defined as a systematic and independent examination of trial-related activities and documents. Beyond the review of documents and interviews, auditors are tasked with using factual, objective evidence to support conclusions regarding compliance and assessing whether proposed interventions are acceptable to effectively address the underlying concerns. Utilizing real-life examples and information, participants will work individually and within a group of their peers to review material, assess significance of findings, determine whether or not compliance issues exist, and develop plans for efficient compliance solutions. This interactive web seminar will allow participants to further develop auditing skills.

Learning Objectives
- Discuss current Good Clinical Practice (GCP) compliance issues
- Assess patterns in data using data trend analysis
- Review information for accuracy and validity
- Perform root cause analysis for a study scenario and develop a corrective and preventive action plan (CAPA), including impact assessment to facilitate review of intervention

Who Should Attend
- Clinical Quality Assurance Professionals
- Auditors
- Project Managers
- Clinical Investigators
- Clinical Operations Professionals
- Personnel responsible for ensuring compliance with Good Clinical Practice (GCP) regulations

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
3 hours 9:00 a.m. – 12:00 p.m. and 12:00 – 3:00 p.m. Eastern

Course Dates
March 17, 2020 (9-12)
July 9, 2020 (12-3)

FEE: $835*
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
- Participants will receive 3 hours (0.3 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-19-026-L01-P Released: 2/19.
Auditor Emotional Intelligence

Course Description
Audits are often viewed as transactional and factual – and rightly so! They are transactional (a process carried out) and must be factual, devoid of as much personal bias and emotion as possible. However, the power of advanced soft skills in enhancing both the transactional and factual aspects of an audit cannot be underestimated. We have all heard stories of painful audits with auditors who possessed little to no soft skills. The use of appropriate, advanced soft skills serves to reinforce a culture of quality with the auditee. The most important soft skill a quality professional can possess is emotional intelligence.

Using real case scenarios, this web seminar will provide learners the information needed to understand auditor emotional intelligence, including practical skills for enhancing their emotional intelligence and encouraging emotional intelligence in others. The use of such skills reinforces a culture of quality both inside and outside organizations. Further, participants will be able to carry this information into their interactions, enhancing their professional as well as personal lives.

Learning Objectives
- Define emotional intelligence
- Describe why emotional intelligence is important for your job
- Develop or enhance emotional intelligence

Who Should Attend
- Clinical Quality Assurance Auditors
- Clinical Quality and Compliance Professionals
- Regulatory Affairs Professionals responsible for GCP regulatory compliance

Instructor
Tabitha Westbrook, M.A., LPCA, CCTP, RQAP-GCP

Course Length
2 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215-413-2471 to inquire about holding this course at your location.

Archived Recording Available in Multiple Formats!

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Best Practices for Hosting a Client Audit

Course Description
Hosting a client audit can be a stressful experience for all involved when there is a lack of preparation, communication, and understanding of expectations for the audit. As the audit host, there are ways to gain a sense of control in your work environment while providing the auditor(s) with the best audit experience possible. Meeting their audit needs while reducing unnecessary lost work time and increased stress by the company being audited can be accomplished by way of audit preparation efficiencies. In this web seminar, we will discuss preparation techniques for hosting a client audit including room staging, strategies for responding to audit requests, and the audit follow-up process. During the course, learners will walk through the process for hosting a client audit, discuss the various roles and responsibilities, as well as review strategies for successful audit results.

Learning Objectives
- Describe the potential roles involved in hosting a client audit
- Utilize preparation techniques for hosting a client audit and how to prepare the group/person(s) being audited
- List typical documentation requested during client audits
- Explore options in staging at the host facility
- Implement strategies for responding to audit requests
- Utilize best practices in audit follow-up that will result in reduced audit observations

Who Should Attend
- Quality Assurance Managers and Auditors
- Functional Group Members
- Personnel participating in an audit

Instructor
Treena Jackson, M.S., C.Q.A., R.A.C., C.S.S.G.B.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

What Participants Say About Barnett Interactive Web Seminars:

“...The course presenter was excellent. I have attended many online courses and this class was one of the best. The speaker was to the point and she made the seminar interactive. We were provided tips and hints of how to be a better leader.”
Bringing the Clinical Perspective into ISO 14971 Risk Management Discussions

Course Description
The clinical perspective is crucial to understanding risk and implementing effective decision-making in the risk management of medical devices. ISO 14971 is an international standard used by companies around the world as a basis for developing a risk management process for analyzing the risk associated with a medical device. Risk management for medical devices is typically handled by engineers responsible for designing and building a product and can have a tendency to focus on the mechanical risks instead of the clinical risks. A clinician needs to be available to discuss those risks in ways that are understandable to those outside of patient care, while understanding how the engineers discuss and view the device.

Learning Objectives
- Explain the requirements of ISO 14971
- Discuss how to predict severity and probability of risks based on clinical data
- Describe the product lifecycle and how to use clinical data to guide risk mitigation

Who Should Attend
- Clinical Data Specialists/Analysts
- Clinical Data Managers
- Clinical Operations Professionals
- Clinical Project Managers
- Clinical Safety Experts
- Production, Quality, and Safety Engineers

Instructor
Joy Frestedt, Ph.D., C.P.I., R.A.C., F.R.A.P.S.

NEW! Building Quality by Design (QbD) and Risk-Based Quality Management (RBQM) Systems into Clinical Operations

Course Description
The premise behind RBQM is that monitoring quality can be improved by leveraging existing data. The development of quality and risk management metrics involves identifying the values of an organization, and this web seminar will focus on developing measures to assess meeting those goals, building infrastructure to capture data to support the metrics, and establishing adequate and timely responses to drive improvement. As the industry’s utilization of risk-based monitoring continues to increase along with the development and expansion of RBQM, the need for integrating these two concepts is necessary.

Learning Objectives
- Describe the principles of QbD and new regulatory requirements for risk-based monitoring
- Develop relevant metrics as quality and performance indicators for RBQM systems
- Identify and manage risks of clinical trials
- Perform cause-effect analysis for identified risks and develop mitigation strategies
- Review recent noncompliance trends and regulatory focus for Sites, Sponsors, and IRBs
- Develop effective Corrective and Preventive Action (CAPA) Plans

Who Should Attend
- Clinical Quality Assurance Auditors
- Clinical Quality and Compliance Professionals
- Clinical Research Associates
- Project Managers and Medical Monitors
- Regulatory Affairs Professionals
- Clinical Principal Investigators and Research Coordinators
- IRB Administrators and Members

Instructor
Marina Malikova, Ph.D., MSci, M.A., C.C.R.A., RAC

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 2:00 – 3:30 p.m. Eastern

Course Dates
March 10, 2020 (2-3:30) June 8, 2020 (9:30-11)

Archived Recording Available in Multiple Formats!

Fee:
$735*  ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-053-L01-P. Released: 8/19.
Building Relationships with Clinical Research Sites

Course Description
Relationships between sites and sponsors are often strained, and poor communication can interfere with having a productive study. Sites are contacted by multiple personnel during the study start-up process, and perhaps even during the study. By focusing on building relationships with the sites, the delays and errors in the startup and ongoing study process can be avoided. It is critical that the individuals working with the sites are in a position through training, knowledge, and support to positively reflect the sponsor and to ensure there is no gap in communication. This web seminar will focus on a variety of techniques for clinical study teams to use in building stronger relationships with the sites. Real-life scenarios and problem solving techniques will be discussed based on what can appear to be unreasonable monitor and sponsor requests to the site research staff.

Learning Objectives
- Evaluate the study start-up process and build relationships right from the beginning
- Implement advanced monitoring and communication techniques for Clinical Research Associates and staff interacting with the sites during the study
- Utilize problem solving techniques based on a variety of real-life scenarios to allow sponsors/CROs and sites to work as partners during all phases of study execution

Who Should Attend
- Study Coordinators
- Site Regulatory Managers
- Clinical Research Associate Managers
- Clinical Research Associates
- Principal Investigators
- Site Managers

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
1.5 hours 11:00 a.m. – 12:30 p.m. Eastern

Course Dates
March 16, 2020

CAP and CLIA Requirements for Clinical Research Laboratories

Course Description
This web seminar will provide an introduction to the College of American Pathologists (CAP) and Clinical Laboratory Improvements Amendments (CLIA) requirements for laboratories that perform routine and non-routine testing of clinical samples for clinical trials. We will review the laboratory requirements for patient care and the requirements for clinical research. Similarities and differences of CAP requirements from ISO 15189 Medical Laboratories Requirements for Quality and Compliance, as applicable, will be discussed. This web seminar is an introductory course and not intended for experienced users.

Learning Objectives
- Describe CAP/CLIA’s goals to patient safety and privacy
- Describe the general CAP/CLIA requirements
- Distinguish similarities and differences of laboratory requirements from CAP and ISO 15189
- Identify inspection and/or audit a laboratory’s compliance to CAP/CLIA

Who Should Attend
- Laboratory Staff new to CAP and CLIA
- Auditors
- Regulatory Agency Inspectors
- Laboratory Managers/Directors
- Laboratory Quality Professionals

Instructor
Suzi Tran, M.B.A., CMQ/OE, CQA, CSQE

Course Length and Time
2 hours 1:00 – 3:00 p.m. Eastern

Course Dates
May 12, 2020

Archived Recording Available in Multiple Formats!

FEE: $835*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
Case Narrative Writing for Reporting Adverse Events

Course Description
A narrative is a short document that is required by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) to briefly describe the events in the life of a patient. These narratives are required when a patient enrolled in a study, after taking the study medication or approved drugs (post-marketing), has discontinued the study because of an adverse event, had one or more serious adverse events, or died. FDA, EMA, and International Council for Harmonization (ICH) guidance documents call for the submission of a study subject’s experience in narrative form for those who meet these specific criteria. This web seminar will provide a set of guidelines, instructions, and templates for the writing of clinical and post-marketing case narratives for reporting adverse events.

Learning Objectives
• Describe relevant regulatory requirements in producing good quality case narratives
• Define and evaluate the critical data elements
• Examine special situations and challenges
• Describe and practice the skills necessary for generating well-written case narratives

Who Should Attend
• Drug Safety Professionals
• Pharmacovigilance Personnel
• Regulatory Affairs Professionals
• Clinical Development Personnel

Instructor
Azita Ahmadi, B.S.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215-413-2471 to inquire about holding this course at your location.

Archived Recording Available in Multiple Formats!

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Case Report Form Design, Strategy, and Standards

Course Description
The phrase “garbage in, garbage out” can be applied to the data collection efforts in clinical trials. To avoid this pitfall, it’s important to be thorough in the evaluation of the data collection items that will validate the protocol hypothesis endpoints and statistical analysis. It’s also important to consider the future compilation of data from multiple clinical trials for agency submission and the assurance that the data are in compatible format. With this goal in mind, it’s essential for data collection to be consistent, concise and compatible – hence the need for standards. CDISC and CDASH are instrumental in the establishment of these standards.

This web seminar will discuss the timing of case report form (CRF) design in relation to clinical trial startup and the team that will contribute to the data collection recommendations. We will review the resources utilized in determining what data collection is required and the current standards – CDISC and CDASH – for CRF data content. Best practices for CRF design as documented by the Society for Clinical Data Management Good Clinical Data Management Practices (SCDM GCDMP) will also be presented.

Learning Objectives
• Outline the clinical data management (CDM) focus on protocol review to identify data requirements
• Implement “best practices” for eCRF design
• Discuss the need for “customization” of CRFs
• Discuss CDASH standards for data collection in CRFs
• Identify data compatibility issues and solutions to ensure appropriate data integration

Who Should Attend
• Clinical Data Managers
• Clinical Database Developers
• Clinical Research Associates
• Statisticians
• Project Managers

Instructor
Denise G. Redkar-Brown, MT

Course Length and Time
2 hours 12:30 – 2:30 p.m. Eastern

Course Dates
April 29, 2020

Archived Recording Available in Multiple Formats!

FEE: $735* ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

Cases in Advanced GCP: A Problem-Solving Practicum

Course Description
This application-based web seminar covers advanced concepts and challenges encountered in the application of Good Clinical Practice (GCP). During this highly interactive course, participants will review and discuss cases that include GCP challenges in topic areas such as IRB/IEC approval, informed consent, drug accountability and reconciliation, SUSAR submissions, communications with ethics committees and health authorities, as well as the management of investigational product. Cases are based on actual industry examples, and participants are expected to solve cases by applying Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) principles, which are briefly reviewed.

Learning Objectives
• Apply your understanding of the GCP standards most critical to core clinical research job functions
• Explain the role of Quality Systems in the GCP environment
• Apply GCP through critical thinking in the context of real-world clinical research scenarios and simulations
• Explain the concepts of RCA and CAPA to improve site and sponsor performance and compliance

Who Should Attend
• Clinical Quality Assurance Professionals
• Clinical Research Associates
• Project Managers
• Investigators
• Study Coordinators
• GCP-focused Regulatory Affairs Professionals
• Clinical Operations Professionals

Instructor

Course Length and Time
3 hours 9:00 a.m. – 12:00 p.m. and 12:00 – 3:00 p.m. Eastern

Course Dates
March 5, 2020 (12-3)
June 11, 2020 (9-12)

Archived Recording Available in Multiple Formats!
FEE: $835* ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Participants will receive 3 hours (0.3 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

Centralized TMF Management: The CRO Sponsor Partnership

Course Description
Many sponsor organizations transfer responsibility for Trial Master File (TMF) management to their Contract Research Organization (CRO) partners. However, the CRO maintains TMF content for those activities for which they have been delegated. Generally a TMF is comprised of sponsor, CRO, and vendor content. The relationship between the CRO and the sponsor is critical in ensuring a quality inspection-ready TMF. This web seminar will explore critical activities and responsibilities on the part of the CRO and the sponsor. A successful partnership between these two groups is critical to ensuring an inspection ready file during and at the conclusion of the study. Both partners must understand the activities of each other to ensure that all artifacts within the TMF have been collected and are available within the TMF. A key tool in centralized TMF Management is the TMF Study Map. We will explore the process of developing and managing the TMF Study Map in tracking the content of the TMF during the active phase of the study and at completion. Use of a TMF Plan by the sponsor and the CRO will also be discussed.

Learning Objectives
• Identify the responsibilities of the sponsor and CRO for TMF Management
• Discuss the key components of the TMF Plan
• Demonstrate understanding of the key components of a TMF Study Map

Who Should Attend
• Trial Master File Directors
• Trial Master File Managers
• Trial Master File Coordinators
• Clinical Operations Directors
• Trial Managers
• Records Management Team Members

Instructor
Donna W. Dorozinsky, R.N., M.S.N., C.C.R.C.

Course Length and Time
1.5 hours 11:00 a.m. – 12:30 p.m. Eastern

Course Dates
April 24, 2020

Archived Recording Available in Multiple Formats!
FEE: $735* ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
cGMP for the Quality Control Laboratory

Course Description
This web seminar will provide a general overview of the cGMP regulations that are applicable to a quality control (QC) laboratory following ICH guidelines and 21 CFR 211. We will discuss the requirements for lab equipment, such as calibration, maintenance, and validation, as well as review analytical method validation, reference standard qualification, and documentation practices. This web seminar will also cover regulatory requirements for stability testing per 21 CFR 211.166 and ICH Q1. The session will conclude with a discussion around the requirements of proper Out of Specification (OOS) investigation.

Learning Objectives
- Review the requirements of laboratory equipment, including calibration, preventative maintenance, and validation
- Review the requirements of analytical method validation, reference standard qualification, and general documentation practices
- Describe the regulatory requirements of stability testing
- Describe the requirements of investigating OOS test results

Who Should Attend
- Quality Control Staff
- Lab Management
- Lab Analysts
- Quality Assurance Staff
- Production Personnel

Instructor
Susan M. Leister, M.B.A., Ph.D., CQA, CSSBB

Course Length
3 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215-413-2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank: Draft Guidance

Course Description
The Food and Drug Administration Amendments Act of 2007 (FDAAA) requires that responsible parties for applicable clinical trials register with, and submit the results information to, the ClinicalTrials.gov data bank. The FDA has been given compliance/enforcement responsibilities related to the failure to submit required clinical trial information under 42 CFR Part 11. This web seminar will discuss the FDA’s processes for assessing compliance of, and implementing civil monetary penalties against, those responsible parties who fail to meet these regulatory obligations.

Learning Objectives
- Assess responsible parties’ regulatory requirements for registering, certifying, and reporting the results of applicable clinical trials
- Discuss the FDA’s procedures for communicating with responsible parties and seeking civil monetary penalties
- Evaluate the approach for answering and contesting the FDA’s findings
- Review the triggers and limits of civil monetary penalties

Who Should Attend
- Sponsor, CRO, or Clinical Investigator/Sponsor-Investigators Responsible Parties
- Regulatory Affairs Professionals
- Project Managers/Directors
- Clinical Quality Assurance/Compliance Personnel
- Clinical Operations Professionals

Instructor
Elizabeth Ronk Nelson, MPH

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 2:00 – 3:30 p.m. Eastern

Course Dates
January 16, 2020 (2-3:30)
April 6, 2020 (9:30-11)
July 10, 2020 (2-3:30)

FEE: $735*
ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-024-L01-P. Released: 3/19.

What Participants Say About Barnett Interactive Web Seminars:
“The seminar provided me new strategies and elements to empower my team.”
Clinical Evidence Writing for Medical Device Regulatory Submissions

Course Description
Data used to support regulatory submissions comes from many sources. Clinical evidence can be found in the published literature, company complaints, and in publicly available databases like the U.S. Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database. In this web seminar, we will review how to gather and extract pertinent data from these sources to develop an appropriate analysis for your product and submission. Attendees will learn how to identify quality clinical evidence and utilize it in regulatory submissions.

Learning Objectives
- Discuss the different types of clinical evidence available
- Identify the limitations of clinical evidence
- Describe the content of clinical evidence analysis

Who Should Attend
- Regulatory Affairs Professionals
- Medical Writers

Instructor
Joy Frestedt, Ph.D., C.P.I., R.A.C., F.R.A.P.S.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Clinical Research Financial Management for Investigative Sites

Course Description
Frequently, clinical research financial regulations, the budget process, clinical trial revenue cycle, and patient remuneration are obscure topics to not only the investigator, but also to the study team delegates. This web seminar describes the significance of ensuring that the investigator and study team are integrated into the financial components of the study to mitigate the risks associated with non-compliance with federal research billing regulations. Strategies for developing operational efficiencies and establishing communication channels to enhance sponsor reimbursements while reducing insurance denials will also be discussed.

Learning Objectives
- Describe the significance of incorporating the investigator and study team into the financial phases of a clinical study
- Discuss the importance of integrating the development and approval of the protocol with the budget/contract process
- Discuss the impact of sponsor data capture systems, vendors, monitors, and auditors on clinical trial financial milestones
- Describe standard operating procedures and communication channels required for compliant clinical study financial billing (sponsor/patient), insurance authorizations, and participant remuneration

Who Should Attend
- Clinical Research Coordinators
- Clinical Trial Managers
- Clinical Research Associates
- Clinical Research Managers/Directors
- Administrative Directors
- Financial Analysts
- Research Nurses/Research Nurse Manager

Instructor
Linda Yancey, R.N., C.C.R.A.

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates
February 28, 2020 (9:30-11)
June 5, 2020 (1-2:30)

FEE: $735*
ACRP Members: Receive 10% off!

"Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-031-L01-P Released: 2/19.
NEW! Clinical Trial Registration: Requirements, Record Maintenance and Reporting of Results

Course Description
The registration and summary results reporting of clinical trials has two main purposes: To inform potential subjects, and to increase transparency of conducted clinical trials and the likelihood that negative results of trials will be publicized. This web seminar will explore the requirements and challenges clinical teams and sponsoring organizations face in determining if a clinical trial is qualified and required to be registered, including determining the time frame for updates to be posted and the reporting of results.

Learning Objectives
- Discuss key factors to consider for the registration of clinical trials
- Review rules, policies and guidelines to identify operational processes and best practices to register clinical trials, provide updates in a timely manner and file final reports.
- Provide overview of the registration process on ClinicalTrials.gov
- Discuss record maintenance and results reporting requirements

Who Should Attend
- Regulatory Affairs Professionals working in biotech, pharmaceutical products and medical device companies
- Medical Affairs Professionals
- Project Managers
- Clinical Research Associates involved in the planning, monitoring, and execution of clinical trials, and responsible for clinical trial reporting
- Grant Managers
- Principal Investigators

Instructor
Marina Malikova, Ph.D., MSci, M.A., C.C.R.A., RAC

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates
March 3, 2020 (1-2:30)
June 9, 2020 (9:30-11)

Fee: $735*  ACRP Members: Receive 10% off!
“Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-19-054-L01-P. Released: 8/19.

Clinical Trial Start-Up: Using a Work Breakdown Structure (WBS) for Effective Planning

Course Description
A Work Breakdown Structure (WBS) defines the work, tasks, assignments, and timelines for work to be completed. This web seminar identifies how WBS aids team members involved in study start-up from the sponsor/CRO and investigative site to address clinical trial start-up challenges once an investigative site has been selected. Recommendations on how sponsors/ CROs and investigative sites work collectively to improve turnaround times in clinical trial start-up are addressed, including IRB/IEC approval, clinical trial agreements, and how site initiation visits are mapped out using a WBS. Case studies, schematics, handouts, and tools will be provided.

Learning Objectives
- Identify three benefits of a communication plan during clinical trial start-up
- Examine a WBS in clinical trial start-up
- Identify situations where a WBS would have a positive impact on clinical trial start-up planning

Who Should Attend
- Clinical Project Managers
- Clinical Trial Managers
- Clinical Research Associates
- Clinical Trial Assistants
- Other team members from Sponsor/CROs who are responsible for clinical trial start-up activities with investigative sites
- Clinical Research Coordinators
- Clinical Research Team Leaders/Managers
- Other team members at the investigative site who are responsible for clinical trial start-up activities

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-P.M., P.M.P.

Course Length and Time
3 hours 1:00 – 4:00 p.m. Eastern

Course Dates
April 13, 2020
July 13, 2020

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 3 hours (0.3 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

EXPERIENCE THE BARNETT WEB SEMINAR DIFFERENCE:
Engagement-focused instructional format • Learning activities focused on application Interaction with subject matter experts • Accredited content • Cost-effective group training
Clinical Trials and the “Sunshine Act”: The Effect on the Clinical Research Industry

Course Description
In an effort to increase transparency, highlight potential conflicts of interest, and ultimately decrease healthcare costs, one element of the Patient Protection and Affordable Care Act (PPACA) — the Sunshine Act — requires disclosure of payments or transfer of value to physicians. These physicians can also be involved in clinical research as Investigators, in which case additional information is required to be reported. Released in February 2013, the final rule requires applicable manufacturers of covered drugs, devices, and biological supplies to gather and report information to be listed on the public website. This web seminar will address the requirements for reporting information derived from clinical research as well as exceptions for reporting.

Learning Objectives
• Discuss who is “covered” and who is responsible for reporting
• Describe the purpose and procedures for gathering and reporting information
• Explore the effect on publication
• Explain the impact on sponsors, Contract Research Organizations (CROs), Investigators, Institutions, and Institutional Review Boards (IRBs)
• Examine timelines for reporting and extensions
• Review timelines for obtaining and reporting information
• Evaluate expectations for databases, record retention, and personnel
• Evaluate challenges in complying with the requirements and consequences for noncompliance

Who Should Attend
• Clinical Research Associates
• Clinical Research Coordinators
• Project Managers
• Principal Investigators
• Regulatory Affairs Professionals
• Medical Affairs Professionals

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
1.5 hours 9:30 a.m. – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates
January 17, 2020 (1-2:30)  June 10, 2020 (1-2:30)
March 18, 2020 (9:30-11)

Archived Recording Available in Multiple Formats!

FEE: $735*   ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-18-012-L01-P Released: 1/18.

ClinicalTrials.Gov Requirements: Clinical Trial Registration and Trial Results Reporting, Expanded Registry and Results Data Bank

Course Description
The purpose of the U.S. Department of Health and Human Services (HHS) final rule is to clarify and expand the requirements for the submission of clinical trial registration and results information to the ClinicalTrials.gov database. This web seminar reviews the new requirements published in September 2016, under FDAAA 801 and 42 CFR Part 11, with an implementation date of January 2017, for applicable clinical trials: Submitting registration and clinical trial summary results information, including adverse event information, of drug products (including biological products) and device products to ClinicalTrials.gov. Discussion of the expanded registry and results data bank will be provided along with a summary of all trial registration and results reporting requirements.

Learning Objectives
• Explain the role and expectations of the responsible party
• List clinical trial registration requirements
• Identify two trial documents that are required to be submitted with the clinical trial results information
• Describe the trial results reporting requirements for unapproved/unlicensed/unapproved products and approved products

Who Should Attend
• Trial Managers
• Project Managers/Directors
• Clinical Quality Assurance/Compliance Personnel
• Principal Investigators
• Regulatory Professionals
• Clinical Operations Professionals

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
2 hours 9:30 – 11:30 a.m. and 12:30 – 2:30 p.m. Eastern

Course Dates
February 18, 2020 (9:30-11:30)
May 20, 2020 (12:30-2:30)

Archived Recording Available in Multiple Formats!

FEE: $835*   ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-20-027-L01-P Released: 2/20.
Coaching Skills for Leaders

Course Description
The notion of managers coaching their employees is now well-entrenched in best business practices. As leaders, we know we need to engage in coach-like conversations to help our teams and direct reports achieve both personal and professional goals. Coaching skills, however, are different from mentorship, supportive management, and simple feedback. They look very different from other conversations and for leaders, are situational by nature. This web seminar will explore the various competencies required to develop coaching skills to help lead from a place of influence rather than top-down authority. Participants will learn about active listening and inquiry-based advocacy, appropriate coaching moments, and will be provided a tool to help navigate these generative conversations in the workplace.

Learning Objectives
- Identify and define specific coaching skills
- Distinguish between managing and coaching
- Describe and practice coaching skills in group scenarios
- Distinguish appropriate timing to employ coaching skills
- Combine authentic leadership style with coach-like presence

Who Should Attend
- Site Managers
- Sponsor Managers
- Project Managers
- Project Leads
- Principal Investigators
- Clinical Research Associates

Instructors
This course will be taught by one of the following instructors:
- Tamar Kagan M.Ed., PCC
- Michelle Rothstein, PCC, CPCC

Course Length and Time
1.5 hours 11:00 a.m. – 12:30 p.m. and 1:30 – 3:00 p.m. Eastern

Corrective Action Plans: Essential Documentation of a Site’s Response to GCP Deficiencies

Course Description
Non-compliance at research sites requires corrective action planning to address the deficiencies. The corrective action plan should include more than just the identification of the deficiency and intervention chosen to address the issue. Effective corrective action planning includes other important components that lead to promoting improved performance for future activities: Ultimately improved human subject protections and data integrity. Lack of these components can lead to repeated non-compliance and in some cases to rejection of corrective action plans by regulatory authorities.

Learning Objectives
- Define non-compliance
- Determine who is responsible for corrective action planning
- Recognize components of corrective action planning
- Identify examples of corrective action plans for different levels of non-compliance (case scenarios)

Who Should Attend
- Site Research Directors/Managers
- Clinical Research Coordinators
- Principal Investigators
- Clinical Research Associates
- Project Managers
- Clinical Research Associate Managers
- Quality Assurance Personnel

Instructors
This course will be taught by one of the following instructors:
- Jeanne Morris, B.S., MT (ASCP)
- Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
1.5 hours 3:00 – 4:30 p.m. Eastern

EXPERIENCE THE BARNETT WEB SEMINAR DIFFERENCE:
Engagement-focused instructional format • Learning activities focused on application
Interaction with subject matter experts • Accredited content • Cost-effective group training
The CRA Role in Risk-Based Monitoring: Strategies for Effective Remote Monitoring

Course Description
Strategies for saving time and money, without compromising oversight and quality, are an ongoing challenge within the industry. In an age where technology is ever present from ordering medications online, consulting with a physician, and having “live” conversations in chat rooms about medical issues, the clinical research industry has been slow to maximize the use of technology. With sponsors/CROs implementing the FDA’s final guidance on a risk-based approach to monitoring, time on site is being reduced to one day visits and/or on-site visits are scheduled few and far between per monitoring plans. Better utilization of remote monitoring is critical to ensure sites are compliant and the data is accurate and consistent. During this web seminar, strategies for remote monitoring will be discussed, including the review of data for trends, how to make the most of writing queries, and what “red flags” to look for that may indicate issues on site.

Learning Objectives
• Describe approaches and techniques for remote data review
• Explain techniques for query writing to ensure clear communication of issues
• Implement strategies to identify problem areas and how to maximize time on site following remote monitoring

Who Should Attend
• Study Coordinators
• Clinical Research Associate Managers
• Clinical Research Associates
• Project Managers

Instructor

Course Length and Time
1.5 hours 2:00 – 3:30 p.m. Eastern

Course Dates
May 13, 2020

Archived Recording Available in Multiple Formats!

FEE: $735*  ACRP Members: Receive 10% off!!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

This web seminar qualifies for a reduced individual participant fee of $159.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
• Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
• ACPE#: 0778-0000-18-039-L01-P. Released: 12/18.

What Participants Say About Barnett Interactive Web Seminars:
“I will use the techniques presented to help in site issue resolution.”

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
CRO Partnership Management

Course Description
In an environment where we are outsourcing multiple tasks, it is valuable to understand the dynamics of relationship building and the application of practical management. Extensive knowledge and skill are required to manage large teams, especially when the majority of the team functions outside of your organization. This web seminar provides an overview of Contract Research Organization (CRO) partnership building, management, application of root cause analysis (RCA) and strategies for problem solving.

Learning Objectives
- Identify sponsor oversight requirements included in ICH GCP E6 R2
- Determine communication and escalation pathways for outsourced providers
- Determine accountability structures, communication and escalation pathways for outsourced providers
- Prepare and conduct an end of study meeting to best address and apply “lessons learned” for the future enhancement of partnerships

Who Should Attend
- Clinical Research Associates
- Clinical Research Associate Managers
- Clinical Research Professionals with responsibility for vendor selection and management
- Project Managers

Instructor
Debbie Harper, B.Sc., P.M.P.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
March 4, 2020

Current FDA and EMA Inspection Findings: Lessons Learned

Course Description
Failure to follow the investigational plan, inadequate Principal Investigator (PI) oversight, and informed consent irregularities remain high on the list of leading findings in U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) inspections. In this web seminar, we will examine real-world examples of some of the top 10 inspection findings from the Annual BIMO Inspection Metrics, and discuss appropriate corrective and preventive actions (CAPAs), equipping learners with solutions to avoid common pitfalls and ultimately avoid inspection findings in the future. Correct conduct according to GCP will be discussed and lessons learned applied to help prevent these findings from occurring again. Learners are encouraged to share their experiences as participants discuss methods and tools to aid in compliance through appropriate techniques for ICH-GCP compliance. Tools will be provided to assist clinical research personnel in their efforts to be ICH-GCP compliant.

Learning Objectives
- Critically assess the number of major and critical Annual BIMO inspection findings
- Provide examples of the Annual BIMO top inspection findings
- Discuss how to prevent major and critical inspection findings
- Apply the right corrective actions to resolve the major and critical inspection findings

Who Should Attend
- Principal Investigators
- Compliance Personnel
- Clinical Research Coordinators
- Clinical Research Associates/Monitors
- Trainers and Educators
- Investigators
- Auditors and Inspectors

Instructor

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
May 27, 2020

EXPERIENCE THE BARNETT WEB SEMINAR DIFFERENCE:
Engagement-focused instructional format • Learning activities focused on application • Interaction with subject matter experts • Accredited content • Cost-effective group training
Data Management Plan Creation: Content and Rationale

Course Description
A well-designed Data Management Plan (DMP) provides a detailed description of how to handle data under any foreseeable circumstances and establishes processes for how to deal with unplanned issues. The DMP is study specific, is considered a “living document,” and is subject to audit; therefore, it is important to understand the content requirements and rationale for its creation.

In this web seminar, we will focus on the importance of the creation of a DMP and the expected content that this document should contain. Attendees will be provided with a sample template for review.

Learning Objectives
• Identify the rationale for creation of a robust DMP
• Describe the documentation required for a DMP when utilizing both paper and Electronic Data Capture (EDC) applications
• List the components of a DMP as defined in the Society for Clinical Data Management (SCDM) Good Clinical Data Management Practices (GCDMP) document
• Apply standards for creating, approving, and maintaining DMPs

Who Should Attend
• Clinical Data Managers
• Project Managers
• Clinical Research Personnel

Instructor
Denise G. Redkar-Brown, MT

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
May 6, 2020

Archived Recording Available in Multiple Formats!

FEE: $735*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

ACPE#: 0778-0000-17-025-L01-P. Released: 5/17.
**Data Quality in Clinical Trials: Rationale and Impact**

**Course Description**
Good Clinical Practice (GCP) is the universal ethical and scientific quality standard for conducting clinical trials. The GCP standard applies to all aspects of the clinical trial process. Adherence to the GCP quality standard during the clinical trial process provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of the trial subjects are protected.

In this web seminar, we will explore the data quality definitions, processes involved in determination of quality, and the rationale utilized in ensuring data quality. It’s not about the individual data point anymore.

**Learning Objectives**
- Describe a quality system approach for assuring appropriate data quality
- Identify data discrepancies, errors, outliers and bias and how to assess their importance
- Describe how poor data quality may or may not impact study operations or analysis
- Compare and contrast common approaches to discrepancy identification and resolution

**Who Should Attend**
- Clinical Data Managers
- Quality Assurance Personnel

**Instructor**
Denise G. Redkar-Brown, MT

**Course Length and Time**
2 hours 12:30 – 2:30 p.m. Eastern

**Course Dates**
April 8, 2020

**FEE:** $735*  
ACRP Members: Receive 10% off!  
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

**Accreditation**
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

**ACPE#:** 0778-0000-17-026-L01-P. Released: 4/17.

---

**Design Considerations for GCP Training Programs**

**Course Description**
Regulatory authority inspection trends are identifying a need for truly effective Good Clinical Practice (GCP) training. GCP training should ensure that clinical research stakeholders not only “know GCP” but know how to apply the principles of GCP in their work lives. The decision to develop and implement a GCP Training Program is a time-consuming and expensive project for any clinical research organization. How can you maximize the effectiveness of the training to ensure return on this investment in both financial and compliance terms? By designing GCP training with a focus on engaging adult learners, which is critical to ensuring both acceptance by the learners and the transfer of knowledge into everyday professional practice. This web seminar will identify key elements to consider throughout the phases of program development and design, training deployment, and post-course assessment.

**Learning Objectives**
- Describe the training elements that effectively “connect” with adult learners
- Compare and contrast the pros and cons of face-to-face, web-based, and eLearning venues for GCP training
- Identify strategies for assessing training outcomes such as short-term knowledge transfer and long-term impact on the organization

**Who Should Attend**
- Clinical Research Training Professionals and/or Subject Matter Experts
- Pharma/Device Professionals with responsibility for internal and/or investigator GCP training
- Clinical Research Site Professionals

**Instructor**
Nikki Christison, B.S., C.C.R.A., T.I.A.C.R.

**Course Length**
2 hours

**Course Dates**
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

**Archived Recording Available in Multiple Formats!**

**What Participants Say About Barnett Interactive Web Seminars:**

“I can immediately apply almost everything I learned into my current role. I was aware of a lot of the ICH GCP information provided but the tips, pointers, and examples were especially useful to me.”
Interactive Web Seminars

Detecting Risk Signals in Protocols, Data, and Monitoring

Course Description
In an environment where remote monitoring and management techniques are becoming the daily practice, preventive measures need to be implemented to identify risks. You need to be able to identify protocol data thresholds and parameters for risks to establish management and escalation triggers. As data becomes available in real time, you should not be waiting to intervene until deviations become a “trend” before intervention is implemented; you need to know how to look for outliers and “red flags” on a daily basis. With the increasing use of CROs and vendors, it is essential that best practices are established for identifying risk signals in management and monitoring practices. In this web seminar, we will discuss how to detect risk signals in protocols, data, and monitoring based on risk-based quality management, industry guidances, and practical application.

Learning Objectives
- Describe quality risk management and regulatory expectations based on industry and international guidance
- Apply proactive quality management techniques through signal detection and training for operational and scientific management of clinical trials
- Identify key risk factors, thresholds, and issues in protocols, reports, and data listings
- Apply signal detection techniques and preventive measures through hands-on application

Who Should Attend
- Clinical Research Associates
- Project Managers

Instructor
Nikki Christison, B.S., C.C.R.A., T.I.A.C.R.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Archived Recording Available in Multiple Formats!

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. • Accreditation available upon request.

Blended Curriculum Course

Developing and Negotiating Research Site Clinical Study Budgets and Contracts

Course Description
Negotiating study contracts and budgets is critical for the future success of the clinical research site. This web seminar provides strategic skills and best practices for contract negotiations and budget development. Learners will also review and practice the art of negotiation.

Learning Objectives
- Prepare for negotiations: Define steps in the negotiation process; integrate strategies for effective negotiating; review success factors and risks in negotiations; discuss ethical considerations
- Review industry study start-up basic contract content: Discuss state law, institutional vs. sponsor required language; “boilerplate” terms; indemnification; other agreements including data use, confidentiality, HIPAA, master agreements
- Develop study budget presentations: Based on objective market data; subject vs. visit based
- Assess protocol feasibility and resource needs: Look for hidden costs; study start-up to final query resolution
- Translate information in a study protocol to successful study budgets: Plan for protocol amendments and procedure changes; financial checks and balances

Who Should Attend
- Research Site Representatives that have some direct and/or indirect responsibility in contract and budget negotiations
- Project Managers and Site Managers
- Contracts and Budget Department Representatives
- Clinical Research Coordinators and Research Nurses
- Investigators
- Sponsor Representatives working with sites on study start-up

Instructor
Mary L. Veazie, M.B.A., CPA, CHC, CHRC

Course Length and Time
3 hours 8:30 – 11:30 a.m. and 12:00 – 3:00 p.m. Eastern

Course Dates
February 6, 2020 (8:30-11:30)
May 7, 2020 (12-3)

Archived Recording Available in Multiple Formats!

FEE: $835*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. • Participants will receive 3 hours (0.3 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-20-030-L01-P. Released: 2/20.

Register: Online at BarnettInternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Blended Curriculum Course

### Developing Clinical Study Budgets for Sponsors

#### Course Description
In an environment where studies are becoming more challenging to execute and taking more resources and time than anticipated, it is key to develop a solid and flexible budget to allow for study execution challenges. In developing a budget it is critical to address all standard line items such as reimbursement for procedures, but how can the oversight and follow-up time be accurately calculated? How does Fair Market Value (FMV) criteria factor into budget development? What questions should be asked to determine additional, unwritten, study expectations? What are some key elements leading to delayed budget negotiation and approval? This web seminar will address the fundamentals of budget development and considerations for ensuring that budgets are developed fairly to ensure that sites are appropriately reimbursed for study expectations.

#### Learning Objectives
- Discuss the elements of Fair Market Value (FMV)
- Review key questions and items to address prior to developing the budget
- Review techniques and tools for use in budget development at the sponsor and site level

#### Who Should Attend
Sponsor and CRO representatives in the following roles:
- Project Managers
- Clinical Research Associates
- Clinical Research Associate Managers
- Contract and Budget Management Personnel
- Directors in Clinical Operations
- Site Managers
- Principal Investigators
- Study Coordinators
- Site Budget and Contract Representatives

#### Instructor
Mary L. Veazie, M.B.A., CPA, CHC, CHRC

#### Course Length and Time
2 hours 12:30 – 2:30 p.m. Eastern

#### Course Dates
March 19, 2020

**Archived Recording Available in Multiple Formats!**

**FEE:** $735*  
ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

#### Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.  
Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

**ACPE#: 0778-0000-19-039-L01-P. Released: 9/19.**

Interactive Web Seminars

### Drug and Device Regulatory Submissions: A Comparison

#### Course Description
This web seminar is designed to provide details on what goes into FDA regulatory submissions for drugs and devices, and highlight the differences between the programs and Centers (CDER and CDRH) dealing with these products. Drug submissions may include an Investigational New Drug Application (IND), a New Drug Application (NDA), 505(b)(2) application, an Abbreviated New Drug Application (ANDA) for generic drugs, orphan drugs and supplemental filings, and contain information on manufacturing controls and clinical trial outcomes. Device submissions may include 510(k), PMA and PDPs, and de novo applications. Requirements for device submissions will depend on the device type and classification, as well as the available performance and safety information. The decision pathways needed to ensure the necessary information has been provided will be presented.

#### Learning Objectives
- Differentiate between drug and device FDA submissions
- Identify information and decisions needed to complete submissions
- Discuss the purpose of submission sections
- Discuss the impact of clinical data in submissions

#### Who Should Attend
- Regulatory Affairs Professionals who require an understanding of the pharmaceutical and medical device approval systems
- Management, Legal, and other personnel who must be familiar with the various approval process systems and submissions of related documents

#### Instructor
Joy Frestedt, Ph.D., C.P.I., R.A.C., F.R.A.P.S.

#### Course Length
1.5 hours

#### Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

#### Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.  
Accreditation available upon request.
Drug Development and FDA Regulations

Course Description
This web seminar provides an overview of the drug development process. Included are the Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Good Manufacturing Practice (GMP) regulations and how they interact in the drug development process.

Learning Objectives
- Describe the FDA’s role in drug development
- Review the logic behind the drug development process
- Discuss IND/NDA submissions
- Describe the basics of the clinical trial process
- Describe the FDA review process for IND/NDA submissions
- Navigate the three major FDA regulations: GCP, GLP and GMP

Who Should Attend
- Those who want an understanding or greater understanding of the drug development process
- Clinical Research Associates
- Auditors
- Regulatory Affairs Professionals
- Quality Assurance Personnel
- Manufacturing Personnel

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
3 hours 9:00 a.m. – 12:00 p.m. and 12:00 – 3:00 p.m. Eastern

Course Dates
January 13, 2020 (12-3)
April 7, 2020 (9-12)
July 6, 2020 (12-3)

Archived Recording Available in Multiple Formats!

FEE: $735*    ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 3 hours (0.3 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-008-L01-P. Released: 7/19.

NEW! Effective Use of Tools, Job Aids, Process Maps, and Checklists for Project Managers and Clinical Research Teams

Course Description
The clinical protocol is a complex document that must be understood by the clinical research sponsor, vendors and clinical research sites for successful implementation. Effective use of job aids, process maps and checklists can improve team members’ understanding of what is being requested. This web seminar will explore how various tools can be utilized to improve project team members’ understanding of tasks, and to enhance the training of internal teams, vendors, and investigational sites. We will explore the best use of flow charts, checklists, and job aids to enhance team performance, as well as provide examples to aid in eligibility requirements, exclusionary criteria, and safety and efficacy endpoint collection.

Learning Objectives
- Define a job aid and the benefits of using them
- Define types of job aids, formatting and when to use: Step-by-Step Job Aid, Form or Worksheet, Checklist, Decision Table, Flow Chart, Process Map, and Reference Source Job Aid
- Identify effective design methods for creation of job aids
- Describe how job aids can improve clinical project tasks

Who Should Attend
- Project Managers
- Clinical Trial Managers
- Clinical Research Associates
- Clinical Training Managers

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
June 1, 2020

FEE: $735*    ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.


What Participants Say About Barnett Interactive Web Seminars:
“Excellent trainer — very knowledgeable and kept our interest for the length of the session.”
Electronic Informed Consent Guidance: Regulatory Updates

Course Description
Conducting the informed consent process is one of the most critical tasks to be completed by a research site. It’s essential that a subject clearly understands the information and language in the consent form and that their rights, safety, and welfare are not jeopardized. This web seminar will review the essential language in the informed consent document through review of the FDA regulations and guidance documents, including the December 2016 final guidance, “Use of Electronic Informed Consent in Clinical Investigations: Questions and Answers.” Additionally, there will be discussion of some of the challenges faced in consenting pediatric subjects in trials of greater than minimal risk, the use of translators, and review of the use of electronic informed consent and electronic signatures.

Learning Objectives
- Explain the content of the recent guidances related to informed consent
- Discuss the implications of the guidance on current practices and policy
- Analyze the use of electronic media and processes to obtain electronic informed consent (eIC)
- Discuss implications and best practices of electronic signatures on consent documents

Who Should Attend
- Research Site Managers
- Investigators
- Clinical Research Coordinators
- Clinical Research Associates
- Project Managers
- Sponsor/CRO Staff
- Clinical Quality Compliance and Quality Assurance Professionals

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
1.5 hours 11:00 a.m. – 12:30 p.m. and 12:30 – 2:00 p.m. Eastern

Course Dates
January 16, 2020 (11-12:30)
April 6, 2020 (12:30-2)
July 7, 2020 (11-12:30)

FEE: $735*
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-17-100-L01-P. Released: 1/17.


Course Description
Current societal events have influenced the increased use of an electronic medical record (EMR), one being the promotion of a national EMR. More research sites are using an EMR for all or part of their case histories for research subjects. The industry has defined the characteristics that source documents in any form must include, and 21 CFR Part 11 includes standards for electronic source data. Challenges in monitoring the original source document have been growing and unaddressed in many situations. This web seminar will discuss assessment of EMRs, ideal monitoring vs. contingency planning, and risk management.

Learning Objectives
- Define source documents (FDA and ICH GCP E6 Guideline)
- Explain required characteristics for source documents in any form
- Describe requirements of electronic source documents (21 CFR Part 11)
- Apply these concepts to electronic medical records at research sites
- Apply contingency planning for electronic source document deficiencies
- Manage site and sponsor activities regarding electronic medical records

Who Should Attend
- Investigators
- Clinical Research Coordinators
- Device and Drug Study Clinical Research Associates and Managers
- Project Managers
- Quality Assurance Personnel

Instructor

Course Length and Time
2.5 hours 8:30 – 11:00 a.m., 11:00 a.m. – 1:30 p.m. and 12:30 – 3:00 p.m. Eastern

Course Dates
January 14, 2020 (12:30-3)
March 19, 2020 (8:30-11)
July 16, 2020 (11-1:30)

FEE: $835*
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

 Archived Recording Available in Multiple Formats!

ACPE#: 0778-0000-20-031-L01-P. Released: 1/20.
Electronic Source Data in Clinical Investigations: Navigating the Final FDA Guidance

Course Description
As the use of electronic source documentation (eSource) increases, so does the scrutiny for ensuring the integrity of the systems used to generate and retain electronic source data. In late 2010, the FDA issued a draft guidance regarding the use of eSource, providing direction on capturing, using, and archiving electronic data. A final FDA guidance was released in September 2013 focusing on identification and specification of authorized source data originators, the creation of data element identifiers to facilitate examination of the data audit trail, capture of source data into the eCRF, and Investigator responsibilities. This web seminar will review how the requirements for paper source documentation translate to the electronic source document as well as examine real-world examples of the FDA's review of eSource.

Learning Objectives
• Navigate initiatives in the regulatory climate leading to the eSource guidance
• Examine the three tiers of data management
• Discuss the Clinical Investigator's responsibilities for eSource data origination, integrity, review, release for processing and retention
• Assess the implications of the guidance on source documentation practices and policy
• Review the FDA's expectations and inspection processes for eSource

Who Should Attend
• Clinical Research Associates and Managers
• Project Managers
• Clinical Investigators and Staff
• Personnel involved in site and IRB assessment and/or selection
• Academia Professionals involved in oversight, documentation, and conduct of clinical research
• Quality Assurance and Compliance Professionals
• Data Management Professionals

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
2 hours 9:30 – 11:30 a.m. and 12:30 – 2:30 p.m. Eastern

Course Dates
January 14, 2020 (12:30-2:30)  July 8, 2020 (12:30-2:30)
April 8, 2020 (9:30-11:30)

FEE: $735*  ACRP Members: Receive 10% off!
Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-20-032-L01-P. Released: 1/20.

EMA and MHRA Inspections: Successful Planning and Execution Tips and Techniques

Course Description
In recent years, the European Medicines Agency (EMA) and the UK’s Medicines and Healthcare products Regulatory Agency (MHRA) have increased the frequency and reach of their inspections. The outcome of the inspection can determine whether a product will be granted a marketing authorization in Europe or the UK, and good preparation will enable the research to be shown in the most favorable light. This web seminar will help learners to know how best to prepare their organizations for inspections by the EMA and MHRA inspectorates, to know what the inspectors are looking for, to understand what to expect during the inspection and to learn from real inspection experiences.

Learning Objectives
• Describe how to be inspection ready at all times
• Explain the differences between EMA and MHRA inspections, and their significance
• Identify tools to prepare the organization to perform at its best during the inspection
• Describe how to mitigate inspection findings
• Identify which records should be made available for the inspection

Who Should Attend
• Clinical Operations Staff
• Facilitators of the inspection
• Senior Management Personnel who have a role in the inspection

Instructors
This course will be taught by one of the following instructors:
Elizabeth Ronk Nelson, M.P.H.
Vaska Tone

Course Length and Time
3 hours 12:00 – 3:00 p.m. Eastern

Course Dates
June 9, 2020

FEE: $945*  ACRP Members: Receive 10% off!
Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 3 hours (0.3 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

Ensuring Success Through Smarter Site Selection and Study Feasibility

Course Description
Site selection is a complex dance between sponsors and sites. The wrong choice can have serious consequences, impacting quality, time, and finances for both the sponsor and investigator. In this web seminar, the steps for site selection and study feasibility will be discussed. Sponsors will learn the most critical questions to ask an investigator and staff to ensure quality and timely data as well as appropriate enrollment. Sites will learn how they can be proactive in the selection process and how to ensure the study is feasible. The process of site feasibility and selection will be outlined with key decision points for both sponsors and sites. Sites and sponsors will also learn what tools can help sites become “preferred” and achieve excellence. Tips for improving documentation and communication will be demonstrated through tools and worksheets, leading to successful collaboration between the site and sponsor and avoiding some common pitfalls. With careful consideration of placement of a clinical trial, learners can find success at closeout, audit, or inspection.

Learning Objectives
- Discuss the steps in evaluating a site from both the sponsor and site perspectives
- Identify the key questions to ask during a feasibility assessment/site visit
- Explore how a site may become preferred by sponsors by implementing best practices

Who Should Attend
- Clinical Research Coordinators
- Investigators
- Principal Investigators
- Clinical Research Associates
- Site Management Personnel

Instructor

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
June 10, 2020

Archived Recording Available in Multiple Formats!

FEE: $735*  
ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.


eSource and Mobile Technology Initiatives: Data Management Considerations

Course Description
The utilization of personal, mobile technology to monitor health activity is becoming a basis for potential electronic source data which may be included in clinical research. Advances in technology and its inclusion in the clinical trials initiative will impact participants and clinical research, which will require a systematic approach in examining any new standards and processes affecting the collection and analysis of these data. In this web seminar, we will review the benefits and potential risks of using mobile health technology in clinical trials along with the considerations to ensure data integrity.

Learning Objectives
- Review the standards and the regulatory mindset on the use of mobile health technology
- Discuss the benefits and potential risks when utilizing mobile health technology
- Define considerations for data integrity in the evaluation and selection of mobile health technology
- List the types of device provisioning models

Who Should Attend
- Clinical Data Managers
- Clinical Data Scientists
- Clinical Quality Assurance Professionals
- Clinical Compliance Personnel

Instructor
Denise G. Redkar-Brown, MT

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
June 24, 2020

FEE: $735*  
ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-17-101-L01-P. Released: 10/17.
Establishing a Risk Management Framework for Clinical Trial Conduct and Oversight

Course Description
As many organizations move to, or contemplate, a risk-based approach to trial conduct and quality management, the published regulatory agency documents and industry think tank publications fall short in providing sponsors, CROs, and clinical vendors the framework—a comprehensive, systematic, structured approach to implementing risk management. This web seminar will provide an overview of a risk management reference model for use that has been adopted by other industries and is referenced in the FDA Guidance of 2013, “Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring.”

Learning Objectives
• Describe the guiding principles when implementing a risk management framework
• Describe the attributes of a risk management framework
• Explain the rationale for knowing an organization’s definition for risk

Who Should Attend
• Sponsor and Vendor Personnel responsible for trial oversight
• Clinical Research, Operations, and Development Professionals

Instructor
Debbie Harper, B.Sc., P.M.P.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Archived Recording Available in Multiple Formats!

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-20-034-L01-P. Released: 1/20.

FEE: $735*
ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Who Should Attend
• Sponsor and Vendor Personnel responsible for trial oversight
• Clinical Research, Operations, and Development Professionals

Instructor
Debbie Harper, B.Sc., P.M.P.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Archived Recording Available in Multiple Formats!

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-20-034-L01-P. Released: 1/20.

FEE: $735*
ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.
Establishing Quality Tolerance Limits

Learning Objectives
- Define QTLs and understand their purpose
- Evaluate the requirements that propel the development of QTLs
- Examine the protocol to identify critical processes that may impact subject protection and/or data integrity
- Document the development process
- Implement established QTLs
- Track and assess data to establish whether they are within QTLs
- Respond when the QTLs are exceeded
- Recognize evolution of QTLs over the life of a clinical trial
- Modify QTLs depending on circumstances
- Document to justify any changes to QTLs

Who Should Attend
- Managers/Directors: Clinical Operations, Quality Management, Compliance
- Clinical Quality Assurance Professionals

Instructor
Celeste M. Gonzalez, B.S., CVT, RQAP-GCP, CCRP

Course Description
ICH GCP E6 R2 Section 5.0 has given the clinical research industry the guidance to incorporate and customize all facets of risk management in clinical trials. Section 5.0.4, Risk Control, asks that predefined quality tolerance limits (QTLs) be established considering the medical and statistical variables that can impact subject safety or the reliability of trial results through the identification of systematic issues. Once detected, those issues can be evaluated and acted upon. In this webinar, participants will learn the methodology for establishing, evaluating, and maintaining appropriate QTLs as they relate to research trials.

Learning Objectives
- Define QTLs and understand their purpose
- Evaluate the requirements that propel the development of QTLs
- Examine the protocol to identify critical processes that may impact subject protection and/or data integrity
- Document the development process
- Implement established QTLs
- Track and assess data to establish whether they are within QTLs
- Respond when the QTLs are exceeded
- Recognize evolution of QTLs over the life of a clinical trial
- Modify QTLs depending on circumstances
- Document to justify any changes to QTLs

Who Should Attend
- Managers/Directors: Clinical Operations, Quality Management, Compliance
- Clinical Quality Assurance Professionals

Instructor
Celeste M. Gonzalez, B.S., CVT, RQAP-GCP, CCRP

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates
February 13, 2020 (9:30-11) May 8, 2020 (1-2:30)

FEE: $735*
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-022-L01-P. Released: 2/19.

What Participants Say About Barnett Interactive Web Seminars:
"I will apply tips from the lesson when on-site. The instructor was great and I look forward to participating in future trainings."
**European Pharmacovigilance Modules: What Are They and Why They Are Important**

**Course Description**
The European Medicines Agency (EMA) has developed, published, and modified directives regarding Post-Marketing Pharmacovigilance (PV), simply known as the EMA PV Modules. These modules and the inspectors’ expectations are currently considered the pharmaceutical, biotechnology, and device industries “gold” standard for PV processes for companies that market products on a global basis. In this web seminar, learners will be provided with the basics of the EMA PV Modules, specifically, what are they and why they are important for the U.S.

**Learning Objectives**
- Identify the basics of what is included in the EMA PV Modules
- Review recent updates
- Describe the consequences of non-adherence

**Who Should Attend**
- Quality Assurance Personnel (Auditors, Compliance Officers)
- Clinical Trial Managers
- Clinical Research Associates
- Project Managers
- Drug Safety Personnel
- Post-Marketing Pharmacovigilance Personnel

**Instructor**
Vaska Tone

**Course Length**
1.5 hours

**Course Dates**
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

**Accreditation**
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

---

**eTMF Quality Oversight: A Risk-Based Approach**

**Course Description**
When applied to electronic Trial Master File (eTMF) oversight, risk-based management is the combination of the potential of quality issues occurring and the impact these deficiencies may have on the integrity of the TMF and the overall Good Clinical Practice (GCP) impact on the study. The TMF is comprised of many records and documents, and a quality TMF is defined as a collection of records, which is complete, collected in a timely manner and comprised of quality records. In the past several years, regulatory agencies have been very clear in their expectation that a sponsor presents a quality TMF during an inspection. This web seminar will examine the concept of a risk-based approach to TMF management and oversight, and, its application to TMF oversight. Included are processes for conducting and documenting quality control (QC) activities that will ensure a high quality eTMF. Quality review findings can then drive the need for additional quality review activities, and by applying these concepts, the sponsor ensures TMF inspection readiness.

**Learning Objectives**
- Discuss the application of risk-based assessment to establish a plan for conducting eTMF QC activities
- Explain various QC activities to ensure a high quality eTMF
- Identify key TMF artifacts with significant risk for quality issues

**Who Should Attend**
- Trial Master File Directors
- Trial Master File Managers
- Trial Master File Coordinators
- Clinical Operations Directors
- Trial Managers
- Records Management Team Members

**Instructor**
Donna W. Dorozinsky, R.N., M.S.N., C.C.R.C.

**Course Length and Time**
2 hours 9:30 – 11:30 a.m. and 1:00 – 3:00 p.m. Eastern

**Course Dates**
March 6, 2020 (1-3)
June 5, 2020 (9:30-11:30)

Archived Recording Available in Multiple Formats!

**FEE:** $835*  
ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

**Accreditation**
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-011-L01-P. Released: 1/19.
EU Clinical Trial Regulation 536/2014: Are You Ready?

Course Description
The effective date for the implementation of the European Union (EU) Clinical Trial Regulation of 2014, which establishes the rules for conducting clinical trials throughout the EU, is rapidly approaching. The regulation ensures that Member States, in authorizing and supervising the conduct of a clinical trial, adhere to ‘one set of rules’. The regulation also brings harmonization with the ICH GCP E6 Guideline R2 proposed addendum of 2015, various draft and final European Medicines Agency (EMA) Reflection Papers (e.g., risk-based quality management, Trial Master File and Archiving), and the UK’s Medicines and Healthcare products Regulatory Agency (MHRA) serious breaches reporting requirements. In this web seminar, the instructor systematically presents select regulation requirements so learners will be able to swiftly, efficiently, and effectively perform an internal review and gap analysis of their organization’s procedures, processes and personnel training in order to be ‘ready’ by the effective implementation date.

Learning Objectives
• Distinguish between the EU Clinical Trial Regulation and the EU Clinical Directive
• Describe the EU Clinical Trial Regulation requirements for Sponsors, CROs, Investigators, Member States and Independent Ethics Committees
• Identify organizational practices requiring implementation or modification to ensure compliance by the effective date

Who Should Attend
• Managers/Directors: Clinical Operations, Quality Management, Compliance, Process Improvement, Quality Assurance
• Study Managers
• Project Managers
• Clinical Research Associates
• Investigators
• Study Coordinators

Instructor
Debbie Harper, B.Sc., P.M.P.

Course Length
2 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

FDA and MHRA: Annual GCP Inspection Findings

Course Description
The UK’s Medicines and Healthcare products Regulatory Agency (MHRA) and the U.S. Food and Drug Administration (FDA) are two of the most exacting regulatory authorities in the world. Their specialist inspectors are highly trained to identify problems, deviations and discrepancies in clinical research. One of the best ways to learn about the inspectorate and its areas of focus is to consider the inspection findings which they have made. This web seminar will bring learners up-to-date on the current findings of the MHRA and FDA, which areas cause the regulators the most concern, and how they interpret the regulations and guidance to which they hold researchers accountable.

Learning Objectives
• Describe the remit of the MHRA and FDA
• Explain the main areas of concern to the MHRA and FDA
• Identify the most common and most significant findings being written by the MHRA and FDA
• Describe where the MHRA and FDA apply enforcement discretion

Who Should Attend
• Clinical Researchers from Industry, Academia and CROs
• Quality Assurance Professionals from Industry, Academia and CROs
• Personnel with an interest in the quality of clinical research

Instructors
This course will be taught by one of the following instructors:
Elizabeth Ronk Nelson, M.P.H.
Vaska Tone

Course Length
3 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
**FDA Drug Approval Process**

**Course Description**
This web seminar provides an overview of the regulations and obligations of a sponsor and investigator in the development of a new device using FDA and ICH GCP E6 Guideline — Investigational Device Exemption (IDE) and abbreviated IDE processes. We will begin by reviewing the contents of an IND, and then follow the process of an IND submission. From there, the contents and approval process of an NDA submission will be discussed. This web seminar will also provide a foundation for those who require an understanding of the FDA new drug approval process, and help attendees become familiar with the regulatory landscape in which INDs and NDAs are developed and approved.

**Learning Objectives**
- Navigate the FDA approval process for a new drug
- Describe what an IND is, and identify the contents of an IND
- Describe what an NDA is, and identify the contents of an NDA
- Discuss the FDA IND and NDA review process

**Who Should Attend**
- Regulatory Affairs Personnel
- Quality Assurance Personnel
- Manufacturing Personnel
- Research Personnel
- Those that have to be familiar with the preparation of INDs and NDAs
- Those that have to understand the FDA new drug approval process

**Instructor**
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

<table>
<thead>
<tr>
<th>Course Length and Time</th>
<th>3 hours 12:30 – 3:30 p.m. Eastern</th>
</tr>
</thead>
<tbody>
<tr>
<td>Course Dates</td>
<td>April 22, 2020</td>
</tr>
<tr>
<td>Archived Recording</td>
<td>Available in Multiple Formats!</td>
</tr>
<tr>
<td>FEE:</td>
<td>$735*</td>
</tr>
<tr>
<td>ACRP Members:</td>
<td>Receive 10% off!</td>
</tr>
<tr>
<td><strong>Participants will receive 3 hours (0.3 CEUs)</strong> of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.</td>
<td></td>
</tr>
</tbody>
</table>

**Accreditation**
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 3 hours (0.3 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.


---

**FDA Medical Device Approval Process**

**Course Description**
This web seminar provides an overview of the regulations and obligations of a sponsor and investigator in the development of a new device using FDA and ICH guidance — Investigational Device Exemption (IDE) and abbreviated IDE processes. This is done by reviewing sponsor and investigator obligations, along with the principles of Good Clinical Practice (GCP). Definitions used by sponsors and regulatory authorities for device development will be reviewed. Participants will become familiar with the regulatory decision-making process used by the FDA and learn to navigate the approval pathways to market.

**Learning Objectives**
- Discuss the FDA regulations and practical application of sponsor and investigator obligations defined in 21CFR812
- Describe the structure, purpose, and practical application of the ICH Guideline and its principles of GCP
- Describe the technical standards defined in ISO
- Define common terms used in device research
- Describe the three decisions in device development (classification, equivalence, and risk)
- Define the two pathways to market (PMA and 510(k))
- Navigate the FDA approval process
- Describe what an IDE and PMA are, identify their contents, and discuss the FDA review process

**Who Should Attend**
- Clinical Research Managers
- Principal Investigators
- Regulatory Associates
- Quality Assurance Personnel
- All other personnel responsible for the device approval process

**Instructor**
Shana Zink, B.S.

<table>
<thead>
<tr>
<th>Course Length and Time</th>
<th>1.5 hours 3:00 – 4:30 p.m. Eastern</th>
</tr>
</thead>
<tbody>
<tr>
<td>Course Dates</td>
<td>April 16, 2020</td>
</tr>
<tr>
<td>Archived Recording</td>
<td>Available in Multiple Formats!</td>
</tr>
<tr>
<td>FEE:</td>
<td>$735*</td>
</tr>
<tr>
<td>ACRP Members:</td>
<td>Receive 10% off!</td>
</tr>
<tr>
<td><strong>Participants will receive 1.5 hours (0.15 CEUs)</strong> of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.</td>
<td></td>
</tr>
</tbody>
</table>

**Accreditation**
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

FDA’s Role in Device Safety Inspections

Course Description
The primary role of the FDA or other regulatory authority is to protect public health and ensure that devices are safe and effective. This is done by systematically reviewing all data to ensure it is valid and obtained under proper conditions. The FDA has authority to conduct inspections according to the Code of Federal Regulations. This web seminar examines the types of inspections conducted by the FDA and the mechanics of the inspection of a device sponsor as well as an investigational site. Participants will learn the most common audit findings and possible regulatory actions. Several FDA Warning Letters will be reviewed to demonstrate the thoroughness of a regulatory review. Tips will be provided for the management of the inspection activities both during and after the inspection.

Learning Objectives
• Describe the purpose, types, and mechanics of a regulatory inspection at a device company and an investigational site
• Recognize the Compliance Program Guidance Manual used by the Inspectors
• Discuss common audit findings of sponsors and investigational sites and possible FDA actions
• Recognize common ‘dos’ and ‘don’ts’ in the event of a regulatory inspection

Who Should Attend
• Clinical Research Managers
• Clinical Research Associates
• Regulatory Associates
• Quality Assurance Personnel
• Clinical Study Coordinators
• Principal Investigators

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

EXPERIENCE THE BARNETT WEB SEMINAR DIFFERENCE:
Engagement-focused instructional format • Learning activities focused on application interaction with subject matter experts • Accredited content • Cost-effective group training
Final AE Regulatory Guidance: Reporting/Communication of Safety Information from Clinical Trials to IRBs

Course Description
This web seminar presents content and impact discussion of the FDA and Office of Human Research Protections (OHRP) Adverse Event reporting guidance documents. The guidance documents address issues of Adverse Event information exchange between stakeholders and propose solutions to the issues of the quality of information being sent to the IRBs. The guidance impacts the activities of the research site, IRB, and sponsor/CRO’s role in compiling and/or communicating Adverse Event information during a research study, changing the industry’s current practices.

Learning Objectives
• Appreciate the changing regulatory climate and the impact on safety reporting in clinical trials
• Explain the global response and recommendations for more meaningful safety reporting between stakeholders
• Describe the FDA’s response: January 2009 Final Guidance
• Describe the OHRP’s response: January 2007 Final Guidance
• Recognize implications for current practices
• Examine case scenarios

Who Should Attend
• Sites: Principal Investigators, Clinical Research Coordinators, Managers
• Sponsors: Clinical Research Associates, Sponsor Clinical Operations, Safety Information Specialists, Regulatory Professionals

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates
July 10, 2020

Archived Recording Available in Multiple Formats!

FEE: $625* ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-040-L01-P. Released: 10/19.

Final FDA Guidance: How to Complete the Form FDA 1572, Adequately and Accurately

Course Description
Proper completion of the Statement of Investigator has been greatly debated. Many stakeholders differ in opinions on what is accurate and adequate in completing this form. For example, who should be listed as sub-investigators, do we need to complete a 1572 for certain projects, and so forth. This web seminar will review the 2010 FDA information sheet and answer many of the questions about how to properly complete the form. The course will also discuss what is still not clear even after the guidance and how to get the answers.

Learning Objectives
• Review significant final guidance content
• Detail form completion clarifications for key debated sections
• Assess impact on current practices
• Review case studies of documented deficiencies of the form in warning letters and map the guidance to other FDA initiatives

Who Should Attend
• Site Research Managers and Coordinators
• Investigators
• Clinical Research Monitors
• Project Managers
• Clinical Research Associate Managers
• Clinical Research Directors
• Regulatory Affairs Professionals
• Sponsors/CROs
• Clinical Research Associates
• Clinical Research Coordinators

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Length and Time
2 hours 1:00 – 3:00 p.m. Eastern

Course Dates
April 21, 2020

Archived Recording Available in Multiple Formats!

FEE: $625* ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.


Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556. Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Final ICH GCP E6 R2: Changes Impacting Clinical Investigators, Sites, and IND Holders (Sponsors-Investigators and Institutions)

Course Description
The updated ICH GCP E6 R2 is more descriptive than the previous version and describes 36 items of change. These changes consist of new items in definitions; new sections on investigator responsibilities, including oversight; a substantial new sponsor section on quality management, including risk assessment; monitoring plans defined and implemented; introducing Risk-Based Quality Management; serious breaches, and, a new section on computer validation and electronic records, to name a few. This web seminar explores the changes in detail to promote a better understanding of how they impact clinical trials. Practical information and a systematic approach in assessing organizational SOPs, processes and practices as well as designing modifications to assist with implementation will also be provided.

Learning Objectives
• Identify the changes impacting investigator responsibilities and roles
• Explain the impact of the revisions to sites and Sponsors-Investigators
• Evaluate solutions for applicability/modification of organizational SOPs, processes, procedures and staff training
• Apply lessons learned for effective implementation of the new ICH GCP E6 R2 guideline

Who Should Attend
• Quality Assurance/Compliance Personnel
• Principal Investigators/Sub-Investigators
• Research Site Staff (Managers, CRCs, Data Managers/Data Entry)
• Managers/Directors: Clinical Operations, Clinical Research, Data Management, Quality Management, Compliance, Process Improvement, Risk Management, Quality Risk Management
• Study Managers/Project Managers, CRAs/Monitors (Centralized, On-site)

Instructor
Nikki Christison, B.S., C.C.R.A., T.I.A.C.R.

Course Dates
March 31, 2020 (1-3)
July 28, 2020 (9-11)

Course Length and Time
2 hours 9:00 – 11:00 a.m. and 1:00 – 3:00 p.m. Eastern

FEE: $835* ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-17-075-L01-P. Released: 2/17.

ExperIeNce the Barnett Web Seminar Difference:
Engagement-focused instructional format • Learning activities focused on application 
Interaction with subject matter experts • Accredited content • Cost-effective group training
Final ICH GCP E6 R2: Impact on Clinical Data Management

Course Description
Clinical Data Management plays a significant role in the performance of clinical trials. ICH GCP E6 R2 reinforces the requirements in regards to electronic systems and the Standard Operating Procedures (SOPs) that govern processes specific to these systems. In this web seminar, a review of these requirements as well as an examination of the components of quality management are covered. Further, the role that risk has on the overall conduct of clinical trials will be discussed, particularly since this concept will be the standard way forward (rather than an option). We will also review recommended approaches, industry standards/best practices to achieve compliance with the requirements.

Learning Objectives
• Define the recommended SOPs associated with electronic systems used to collect clinical trial data
• Discuss data integrity issues described in the final guideline
• List the considerations of risk associated in clinical trial conduct and its connection to Clinical Data Management
• Review the principles of quality management as related to clinical trials and the tools utilized to implement a quality approach

Who Should Attend
• Clinical Data Managers
• Clinical Data Scientists
• Clinical Quality Assurance Professionals
• Clinical Compliance Personnel

Instructor
Denise G. Redkar-Brown, MT

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates
January 22, 2020 (9:30-11)
April 15, 2020 (1-2:30)
July 22, 2020 (9:30-11)

Archived Recording Available in Multiple Formats!
FEE: $735*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-20-037-L01-P. Released: 1/20.

Final ICH GCP E6 R2: Implementing Risk Management Approaches for Compliance

Course Description
The most profound change in the updated ICH GCP E6 R2 is the new sponsor responsibility, Section 5.0, Quality Management. This section provides detail on implementing a system of quality management; critical process and data identification; risk identification; risk evaluation; risk control; risk communication; risk review; and risk reporting. Further, risk assessment and risk mitigation plans are required, regardless of whether Risk-Based Quality Management (RBQM) is being utilized by the sponsor. These requirements also address: Efficient clinical trial protocol design; data collection tools/procedures; and, collection of information that is essential to decision making. This web seminar takes an in-depth look at the updated guideline with respect to quality management, as well as the methodology of RBQM. How to apply these guidelines in a step-by-step process with strategies for effective implementation will be reviewed and an example provided.

Learning Objectives
• Define the three-way risk evaluation methodology
• Distinguish between the concepts of risk mitigation and risk acceptance
• Describe the concept of “predefined tolerance limits”
• Describe centralized monitoring
• Define a best practice implementation process based on practical experience

Who Should Attend
• Managers/Directors: Clinical Operations, Clinical Research, Data Management, Quality Management, Compliance, Process Improvement, Risk Management, Quality Risk Management
• Study Managers/Project Managers, Clinical Research Associates/Monitors (Centralized, On-site)
• Business Process Owners

Instructor
Nikki Christison, B.S., C.C.R.A., T.I.A.C.R.

Course Length and Time
2.5 hours 9:00 – 11:30 a.m. and 1:00 – 3:30 p.m. Eastern

Course Dates
January 14, 2020 (9-11:30)
April 21, 2020 (1-3:30)
July 7, 2020 (9-11:30)

Archived Recording Available in Multiple Formats!
FEE: $835*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2.5 hours (0.25 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-18-071-L01-P. Released: 10/18.
Final ICH GCP E6 R2: Sponsor Quality Management – Risk-Based/Risk Management Requirements and Approaches for Compliance

Course Description
ICH GCP E6 R2 provides significant detail on implementing a system of quality management with a focus on a risk-based/risk management approach for the trial, also referred to as Risk-Based Quality Management. This web seminar reviews this new sponsor requirement and describes the clinical quality management system (cQMS) that should be used to oversee quality during the design, conduct, recording, evaluation, reporting and archiving phases – notably the lifecycle of the clinical trial. Additionally, cQMS industry benchmarks, standards and practices will also be discussed.

Learning Objectives
• Describe two new requirements for the sponsor’s quality management (QM) of clinical trials
• Identify two approaches to achieve compliance with QM for the clinical trial lifecycle
• Determine next steps for evaluation and implementation of the new requirements

Who Should Attend
• Trial Managers
• Project Managers/Directors
• Clinical Quality Assurance/Compliance Personnel

Instructor
Debbie Harper, B.Sc., P.M.P.

Course Length and Time
2 hours 9:00 – 11:00 a.m. and 1:00 – 3:00 p.m. Eastern

Course Dates
January 21, 2020 (9-11)
April 21, 2020 (1-3)
July 21, 2020 (9-11)

Archived Recording Available in Multiple Formats!

FEE: $835*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-17-076-L01-P. Released: 1/17.

Final ICH GCP E6 R2 Addendum: Overview of Changes Impacting Sponsors, CROs, Clinical Investigators/Sites

Course Description
For the first time in over 20 years, the International Council for Harmonization (ICH) Good Clinical Practice (GCP) E6 R2 Guideline has been significantly updated. The revisions are intended to encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording and reporting while continuing to ensure human subject protection and reliability of trial results. But, the changes have resounding effects on the conduct of clinical research by sponsors/CROs and investigators.

This web seminar provides a targeted overview of the changes with summary explanations of the changes, per the Guideline. Topics include: ICH principles, ICH definitions, sponsor/CRO responsibilities, investigator responsibilities, and essential documents. Understanding these changes and how they impact your organization is the first critical step towards organizational analysis implementation.

Learning Objectives
• Explain the rationale for the ICH GCP addendum (E6 R2)
• Describe the E6 R2 terms that are new/updated
• Identify the individual changes that comprise E6 R2
• Recognize the importance and impact of the E6 R2 changes for the sponsor/CRO and investigators/sites responsibilities

Who Should Attend
• Managers/Directors: Clinical Operations, Clinical Research, Quality Management, Compliance
• Study Managers, Project Managers
• Clinical Research Associates/Monitors
• Quality Assurance Personnel

Instructor
Debbie Harper, B.Sc., P.M.P.

Course Length and Time
2.5 hours 9:00–11:30 a.m. and 12:00 – 2:30 p.m. Eastern

Course Dates
March 11, 2020 (9-11:30)
June 3, 2020 (12-2:30)

Archived Recording Available in Multiple Formats!

FEE: $835*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2.5 hours (0.25 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-041-L01-P. Released: 9/19.
Fraud in Clinical Research: An Overview

Course Description
Fraudulent activities in clinical research undermine clinical research professionals’ ability to meet their obligations for ensuring credible data is obtained from protected participants. This web seminar provides an overview of fraud in clinical research and its potential impact on the industry and the public’s health. It also includes a group discussion of best practices.

Learning Objectives
- Discuss significant and current examples of fraud in clinical research
- Describe the current focus of regulatory and Congressional bodies and their findings
- Explain the Sponsor/CRO, IRB, Clinical Investigator, and Study Staff role in detection and prevention
- Recognize the impact and consequences of fraud in clinical research
- Examine landmark and recent cases of fraud in clinical research

Who Should Attend
- Clinical Quality Assurance Professionals
- Clinical Research Associates
- Project Managers
- Clinical Investigators
- Study Coordinators
- Institutional Review Board Professionals
- Institutional Officials involved in oversight of clinical research
- Data Management Professionals
- Regulatory Affairs Professionals

Instructors
This course will be taught by one of the following instructors:
Jeanne Morris B.S., MT (ASCP)
Elizabeth Ronk Nelson, M.P.H.

Course Length
2 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215-413-2471 to inquire about holding this course at your location.

Archived Recording Available in Multiple Formats!

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

The Fundamentals of Clinical Research Project Management

Course Description
Participants will explore the principles of project management and apply project management tools to ensure the success of their clinical research projects. Participants will learn to develop a project charter, a work breakdown structure, a risk assessment and contingency plan, a process improvement plan, as well as how to lead without authority. Each participant will leave the session with tools and checklists to apply to their projects.

Learning Objectives
- Develop a project charter
- Develop a work breakdown structure
- Determine your project’s critical path
- Evaluate risk and develop contingency plans

Who Should Attend
- New Project Managers and Project Leaders
- Clinical Trial Site Managers
- Clinical Research Associates
- Clinical Research Coordinators
- Clinical Operations Professionals
- Study/Regulatory Coordinators
- Pharmaceutical Professionals at clinical research sites, pharmaceutical companies, or Contract Research Organizations who are interested in learning more about clinical research project management or who want to pursue project management career opportunities

Instructor
Natalie Currie, B.Sc.

Course Length and Time
1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates
March 2, 2020

FEE: $735*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-042-L01-P. Released: 10/19.

What Participants Say About Barnett Interactive Web Seminars:
“Kudos again for a nicely paced, interactive presentation!”
GCP Training for Investigators

Course Description
This web seminar provides a brief review of new drug development and the clinical trial process as it affects the investigator, and explains where Good Clinical Practice (GCP) fits in. Relevant sections of the Code of Federal Regulations (CFR), International Council for Harmonization (ICH), and Form FDA 1572 are discussed in-depth and in relationship to the investigator’s responsibilities for proper conduct of clinical trials. This course will highlight the 13 principles of the ICH GCP E6 Guideline as the foundation for all clinical studies, and demonstrate to the investigator the rationale for sponsor requirements throughout clinical development of an investigational drug.

Learning Objectives
- Identify the key stages of the drug development process
- Describe the elements involved in the clinical trial process
- Apply the principles of ICH GCP to current clinical trials
- Examine the investigator’s responsibilities in the conduct of clinical trials as required in the regulations (CFR) and guidelines (ICH)
- Recognize the commitment made in executing the Form FDA 1572

Who Should Attend
- New Principal Investigators
- Seasoned Principal Investigators interested in reviewing responsibilities
- Sub-Investigators
- Physicians interested in participating in clinical research
- Site Research Managers/Directors

Instructor
Jeanne Morris B.S., MT (ASCP)

Course Length
3 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Archived Recording Available in Multiple Formats!

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

The GCPs of Essential Documents

Course Description
Understanding the big picture of how essential study documents impact the approval and ethics of a clinical research trial often gets overlooked in the rush of document collection and requests. The foundation of this web seminar is the site study file, what the documents are, and why they are important as related to the ICH GCP E6 Guideline Essential Documents and 21 CFR 50, 54, 56 and 312. This web seminar will also provide a reference point for why the paperwork is so critical within the process of a study.

Learning Objectives
- Describe the investigational product development process and the role of documentation
- Discuss the roles and responsibilities during the study document handling process
- Review the importance of study files and essential documents handling including review of FDA audit findings

Who Should Attend
- Study Coordinators
- Site Regulatory Managers
- Clinical Research Associates
- Project Assistants
- Regulatory Assistants
- Site Managers

Instructor
Debbie Harper, B.Sc., P.M.P.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
May 6, 2020

Archived Recording Available in Multiple Formats!

FEE: $735*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-18-056-L01-P. Released: 7/18.

What Participants Say About Barnett Interactive Web Seminars:
“The presentation was very thorough and informative. I enjoyed the delivery style and appreciate the wealth of experience the trainer draws from.”
Good Clinical Practice: Practical Application and Implementation

Course Description
This web seminar provides an overview of the structural elements of Good Clinical Practice (GCP). Participants will learn practical application of GCP regulations and guidelines for critical components of the clinical research process. Specific attention will be given to how quality systems, or a lack thereof, impact overall data quality and regulatory risk. This web seminar is designed for professionals with at least two years of experience in the clinical research industry.

Learning Objectives
- Describe the elements of a functional quality system
- Examine recent trends in non-compliance
- Discuss the role of SOPs in GCP
- Characterize the differences between the legal and procedural elements of GCP
- Recognize key differences in pharmaceutical, device, and biologics GCP

Who Should Attend
- Clinical Quality Assurance Professionals
- Clinical Research Associates
- Project Managers
- Investigators
- Study Coordinators
- GCP-Focused Regulatory Affairs Professionals

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
2 hours 9:30 – 11:30 a.m. and 12:30 – 2:30 p.m. Eastern

Course Dates
February 20, 2020 (12:30-2:30)
June 8, 2020 (9:30-11:30)

Archived Recording Available in Multiple Formats!

FEE: $835* ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-18-042-L01-P. Released: 8/18.

Good Clinical Practice (GCP) for Medical Devices: ICH GCP E6 and ISO 14155

Course Description
Both the ICH GCP E6 Guideline and ISO 14155 address the elements of Good Clinical Practice in the design, conduct, recording, and reporting of human subject research. Although many sponsors of medical device studies use the ICH GCP E6 Guideline as an ethical and scientific quality standard, ISO is written specifically to protect the rights, safety, and well-being of human subjects, ensure the scientific conduct of the clinical investigation and the credibility of the results, define the responsibilities of the sponsor and Principal Investigator, and assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.

Learning Objectives
- Discuss the purpose and governing bodies of ICH and ISO
- Explore the core principles of each document
- Describe similarities and key differences in content and approach
- Identify additional sources of information relating to the compliant conduct and oversight of medical device studies

Who Should Attend
- Project Managers
- Clinical Research Associate Managers
- Clinical Research Associates
- Clinical Investigators
- Study Coordinators
- Clinical Quality Assurance Professionals
- Institutional Review Board Professionals

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 2:00 – 3:30 p.m. Eastern

Course Dates
February 19, 2020 (2-3:30)
May 20, 2020 (9:30-11)

Archived Recording Available in Multiple Formats!

FEE: $735* ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-17-088-L01-P. Released: 9/17.
Good Laboratory Practice for Non-Clinical Studies

Course Description
This web seminar will provide a general overview of the regulatory requirements for non-clinical studies conducted at both pre-clinical facilities as well as bio-analytical laboratories. The course is divided into two sessions: The first session will focus on general regulatory requirements from the facility and the organization’s perspective and the second session will focus on audits conducted per study. This web seminar provides training for the pre-clinical facility and the bio-analytical laboratory personnel as well as quality assurance staff on maintaining compliance to 21 CFR Part 58.

Learning Objectives
• Describe the general regulatory requirements for non-clinical studies
• Describe the pre-clinical facility requirements and the bio-analytical laboratory requirements
• Describe pre-clinical study specific requirements

Who Should Attend
• Pre-Clinical Facility Personnel
• Facility Management
• Study Directors/Research Personnel
• Quality Professionals

Instructor
Suzi Tran, M.B.A., CMQ/OE, CQA, CSQE

Course Length and Time
4 hours, two days from 1:00 – 3:00 p.m. Eastern each day

Course Dates
Offering #1:
Day 1: March 24, 2020
Day 2: March 26, 2020

FEE: $1,045*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
* Participants will receive 4 hours (0.4 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-20-039-L01-P. Released: 3/20.

HIPAA Compliance Monitoring and Auditing

Course Description
In this web seminar, participants will learn strategies for conducting effective HIPAA compliance audits. We will review the compliance process while focusing specifically on the Administrative Simplification Rules of HIPAA, including transactions, code sets, and identifiers (which are all key elements in the HIPAA-mandated electronic health care transmissions). Real-world examples will be provided to discuss HIPAA and the Privacy Rule, which govern patient rights and disclosure of protected health information (PHI). Given that computerized systems currently are an integral part of health care and clinical research, how they fit into the Security Rule will also be discussed. Most importantly, strategies for how to implement effective HIPAA monitoring and auditing programs within your institution will be provided.

Learning Objectives
• Discuss current HIPAA laws and regulations as they pertain to clinical research
• Describe key elements of a strong HIPAA compliance program
• Discuss practical aspects of HIPAA compliance program implementation
• Develop effective HIPAA compliance monitoring and auditing practices

Who Should Attend
• HIPAA Professionals
• Compliance Officers
• Project/Program Managers
• Compliance and QC/QA Directors
• Clinical Trial Office Directors
• Research Nurses
• Clinical Research Coordinators
• Clinical Research Associates

Instructor
Marina Malikova, Ph.D., MSci, M.A., C.C.R.A., RAC

Course Length
3 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
* Accreditation available upon request.
HIPAA Team Training: Fundamental Training Specifically for Clinical Research Settings

Course Description

HIPAA Team Training has been designed as a course presenting concepts and terminology of HIPAA specific to conducting clinical trials. The web seminar presents the core elements with methodologies for blending the concepts into established clinical trial best practices. The focus of the course is to train sponsors/CROs and site clinical researchers HIPAA concepts for later application in day-to-day roles. This web seminar is ideal for new employee orientations and/or initial annual HIPAA training specific to clinical trials. Presented in understandable terms, this course is also ideal for those who never quite understood HIPAA or are confused about what their role involves. Concepts discussed include the HIPAA Privacy Rule and Enforcement Rule and the Omnibus HIPAA Rulemaking Act specific to clinical research.

Learning Objectives

- Review the history of HIPAA and the impact on clinical research
- Define key terminology and concepts specific to HIPAA in clinical research
- Describe covered entities’ roles and responsibilities
- Examine the Enforcement Rule for HIPAA
- Discuss the impact of the Omnibus HIPAA Rulemaking Act

Who Should Attend

- Research Site Managers
- Clinical Research Coordinators
- Research Nurses
- Principal Investigators and Sub-Investigators
- Project Managers
- Clinical Research Associate Managers
- Clinical Research Associates
- Regulatory Professionals
- Quality Assurance Personnel
- Others involved in use and disclosure of subject data at site or sponsor

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

2 hours 12:00 – 2:00 pm. Eastern

Course Dates

June 11, 2020

Implementing Quality Agreements

Course Description

Quality Agreements are a mainstay of the Good Manufacturing Practice (GMP) sphere as defined in ICH Q7 Section 16.12, and in Good Laboratory Practice (GLP) as inferred in 21 CFR Part 58.1 and 58.35. They have become more common in the Good Clinical Practice (GCP) arena of clinical trial operations as risk-based study management becomes firmly established. Quality Agreements delineate the quality expectations of both the sponsor and outsourced provider and are structured in a shared agreement. Web seminar participants will learn the purpose of, factors that are considered in, and explore possible content of Quality Agreements.

Learning Objectives

- Define the purpose of a Quality Agreement
- Examine the differences between a Quality Agreement and a Contract for Services
- Identify the critical factors that should be addressed in order to have an effective Quality Agreement
- Evaluate and determine who is responsible for developing Quality Agreements
- Determine who is responsible for enforcing Quality Agreements
- Strategies for managing reticence from vendors about Quality Agreements
- Determine when Quality Agreements should be developed and agreed upon
- Explore possible content of Quality Agreements

Who Should Attend

- Managers/Directors: Clinical Operations, Quality Management, Compliance
- Clinical Quality Assurance Professionals

Instructor

Celeste M. Gonzalez, RQAP-GCP, C.C.R.P.

Course Length and Time

1.5 hours 9:30 – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates

February 13, 2020 (1-2:30)
May 8, 2020 (9:30-11)

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-021-L01-P. Released: 2/19.

FEE: $735*  ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.

Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Implications of the FDA Guidance for a Risk-Based Approach to Monitoring and the EMA Reflection Paper on Risk-Based Quality Management in Clinical Trials

Course Description
The FDA and EMA describe their expectations for risk-based approaches to quality management and monitoring in the ‘FDA Guidance Oversight of Clinical Investigations: A Risk- Based Approach to Monitoring’ and the ‘EMA Reflection Paper on risk-based quality management in clinical trials,’ both of which are reviewed in this web seminar, which also includes industry think tank contributions.

Learning Objectives
- Discuss the FDA Guidance and EMA Reflection Paper for clinical trial risk management and monitoring
- Evaluate industry think tank trends (TransCelerate, CTTI)
- Review best practices for risk management for trial oversight and monitoring

Who Should Attend
- Clinical Investigators and Staff
- Clinical Research Associates
- Study and Clinical Research Associate Managers
- Sponsors/CROs Clinical Operations
- Clinical Quality Compliance and Quality Assurance Professionals

Instructor
Debbie Harper, B.Sc., P.M.P.

Course Length and Time
1.5 hours 3:00 – 4:30 p.m. Eastern

Course Dates
June 8, 2020

Archived Recording Available in Multiple Formats!

FEES:
ACRP Members: Receive 10% off!

This web seminar qualifies for a reduced individual participant fee of $159.

Incorporating Denials Management into Clinical Research Billing

Course Description
Clinical Research Billing (CRB) is a very complex process that depends on a multitude of factors to align in order to be compliant. Organizations with clinical research activity face the challenge of maintaining a compliant CRB program without adversely impacting patients. This web seminar will explain the process of analyzing patient denials for trends related to participation in a clinical research study and leveraging this information to influence the coverage determination during the Medicare Coverage Analysis (MCA) process. Participants will learn a 360 approach to increasing CRB compliance and reducing the burden to the patients participating in clinical research studies.

Learning Objectives
- Describe the dynamics of the MCA process
- Explain the impact of MCA on patient billing and the revenue cycle
- Understand denials management and identify trends
- Apply denials management into the MCA process

Who Should Attend
- Analysts involved in the Medicare Coverage Analysis process
- Study Coordinators
- Managers of Clinical Research Billing

Instructor
Mary L. Veazie, M.B.A., CPA, CHC, CHRC

Course Length and Time
2 hours 1:00 – 3:00 p.m. Eastern

Course Dates
January 28, 2020
April 9, 2020
July 16, 2020

FEE:
ACRP Members: Receive 10% off!

This web seminar qualifies for a reduced individual participant fee of $159.

Institutional Purchases
For groups larger than 20 or for additional sites, contact Barnett International at 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-17-036-L01-P. Released: 3/17.

What Participants Say About Barnett Interactive Web Seminars:

“I learned a lot of new information from this course and the materials are all relevant!”
Interactive Web Seminars

The IND in a CTD/eCTD Format

Course Description
The Common Technical Document (CTD) format is now the required format for all marketing applications in the U.S., EU, Japan, Canada, and Australia. Clinical Trial Applications (CTAs), the required format of INDs in most countries, are required to be in the CTD format. Currently, the U.S. does not require INDs to be in the CTD format, but rather the traditional format (per regulations in 21 CFR 312.23). However, since all marketing applications are required in the CTD format, it is more efficient to start the IND in the CTD format. If you use the traditional format, the IND and all amendment information must be converted to the CTD format prior to marketing application submission. This conversion time can impact the timeline for marketing application submission, so why not plan ahead for a successful marketing application and start the IND in the CTD format?

Currently, there is no guidance document to facilitate the transfer or mapping of information from the IND requirements contained in 21 CFR 312.23 to the CTD format. There is often a difference of opinion on where information should be stored. This web seminar will give an overview of the IND requirements and where they can most effectively “fit” into the CTD format requirements for a streamlined FDA review and building of the IND into a marketing application.

Learning Objectives
- Describe the CTD and how and why it came into existence
- Describe the eCTD and basics tools for eCTD implementation
- Define a style guide and describe why it’s important for eCTD implementation
- Map the contents of the traditional IND to the CTD format

Who Should Attend
- Regulatory Affairs Professionals
- Research and Development Professionals
- Manufacturing Personnel
- Clinical Research Professionals
- Medical Writers

Instructor
Caroline Ritchie, Ph.D., M.B.A.

Course Length and Time
1.5 hours 2:30 – 4:00 p.m. Eastern

Course Dates
May 13, 2020

FEE: $735*  ACRP Members: Receive 10% off!

Archived Recording Available in Multiple Formats!

Informed Consent Procedure: Lessons Learned from Inspection Findings

Course Description
Informed consent irregularities remain one of the leading findings in U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) inspections. In this web seminar, we will examine real-world examples of FDA Warning Letters addressing informed consent inspection findings, and discuss appropriate corrective and preventive actions (CAPA). Learners will come away with solutions to avoid common informed consent pitfalls, and ultimately, avoid inspection findings. Participants are encouraged to share their experiences as we discuss methods to aid in compliance through appropriate techniques for the informed consent process.

Learning Objectives
- Examine the major and critical inspection findings related to the informed consent procedure
- Discuss how to prevent major and critical inspection findings related to the informed consent procedure
- Implement the right corrective actions to resolve the major and critical inspection findings related to the informed consent procedure

Who Should Attend
- Principal Investigators
- Compliance Professionals
- Clinical Research Coordinators
- Clinical Research Associates
- Regulatory Affairs Professionals
- Auditors and Inspectors
- Trainers and Educators

Instructor

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
June 3, 2020

FEE: $735*  ACRP Members: Receive 10% off!

Archived Recording Available in Multiple Formats!

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
- Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

NEW! Inspection Readiness:
Understanding BIMO Inspection Requirements for Sponsors, CROs, Monitors and Investigators

Course Description
The primary reason the FDA performs inspections is to support its mission to protect the public by ensuring the safety and efficacy of drugs, biologics, and medical devices. In 2006, the FDA announced an initiative to modernize the regulation of clinical trials, including the Compliance Program Guidance Manual (CPGM) Bioresearch Monitoring Program (BIMO). The purpose of the FDA compliance program is to provide instructions to the FDA field investigator and the FDA center personnel in the conduct of FDA inspections. This web seminar will review both the FDA CPGM BIMO for sponsors, CROs, monitors and the FDA CPGM BIMO for Clinical Investigators and Sponsor-Investigators.

Learning Objectives
• Describe how the FDA CPGM BIMO is used in FDA inspections
• Define the types of FDA inspections
• Identify the most common type of Inspection findings for sponsors, CROs, and Investigators
• Examine how the FDA CPGM BIMO can aid in preparation for an inspection prior, during, and at the completion of a clinical trial

Who Should Attend
• Clinical Investigators
• Clinical Research Coordinators
• Clinical Quality Assurance and Compliance Auditors
• Clinical Research Associates
• Medical Monitors
• Project Managers
• Regulatory Affairs Professionals

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Length and Time
2 hours 1:00 – 3:00 p.m. Eastern

Course Dates
March 5, 2020

FEE: $735*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

Institutional Review Board (IRB) Written Procedures: Final Guidance for Institutions and IRBs

Course Description
Having inadequate written procedures continues to be one of the most commonly cited findings for institutional review boards (IRBs) during the FDA’s Bioresearch Monitoring (BIMO) inspections. Both the U.S. Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) regulations state that IRBs must follow written procedures for their functions and operations to protect the rights and welfare of human subjects. This web seminar will review the FDA’s Final Guidance on IRB Written Procedures to include a Written Procedures Checklist that incorporates the HHS and FDA regulatory requirements for written procedures for the IRB and recommendations on the type of operational details to support each of these requirements.

Learning Objectives
• Discuss the background of the guidance
• Identify the required and suggested elements of Written Procedures
• Review the key similarities and differences in HHS and FDA requirements
• Consider the process for development and review of Written Procedures

Who Should Attend
• Clinical Research Associates
• Project Managers
• Clinical Investigators
• Clinical Research Coordinators
• Regulatory Affairs Professionals
• Institutional Officials
• Institutional Review Board Members and Administrators
• Academic Medical Center and Research Institution staff supporting clinical research
• Personnel responsible for ensuring compliance with Good Clinical Practice (GCP) regulations

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates
February 20, 2020 (9:30-11)
May 21, 2020 (1-2:30)

FEE: $735*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-19-027-L01-P. Released: 1/19.
**Introduction to Clinical Research**

**Course Description**
Have you ever wondered what clinical trials are and how they are conducted? This web seminar is designed to answer those basic questions. We will look at how drugs progress from discovery to testing in humans, and learn what it takes to obtain approval to treat a disease or condition. We will discuss the similarities and differences between drug and medical device development. Finally, we will review how Good Clinical Practice (GCP) is applied to clinical trials around the world and how it is designed to protect clinical trial participants and ensure that the information obtained during a clinical trial is accurate and reliable.

**Learning Objectives**
- Describe the different phases of drug development
- Differentiate between drug development and medical device development
- Discuss the historical events and importance of GCP throughout the world in clinical research

**Who Should Attend**
- Aspiring Clinical Research Associates and Clinical Research Coordinators
- Clinical Research Associates and Clinical Research Coordinators with less than six months experience
- College Students and New Graduates in a Scientific Field
- Nurses
- Individuals considering participating in a clinical trial or know of someone who is considering participating in a clinical trial

**Instructor**
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

**Course Length and Time**
1.5 hours 9:30 – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

**Course Dates**
- January 16, 2020 (9:30-11)
- April 30, 2020 (1-2:30)

**Accreditation**
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

**FEE:** $735*  
**ACRP Members:** Receive 10% off!  
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

**What Participants Say About Barnett Interactive Web Seminars:**
"The trainer was very well-spoken and very knowledgeable. Used great examples and kept the class engaged and involved!"

---

**Introduction to Data Management**

**Course Description**
This web seminar provides an excellent introduction to clinical research data management, focusing on processes and their rationale, making it ideal for the new data manager and other individuals who wish to learn basic clinical data management functions.

**Learning Objectives**
- Identify the roles and responsibilities of the Clinical Data Management (CDM) Research Team
- Discuss the protocol design and development process and data management
- Recognize the CDM start-up activities/documentation
- Discuss case report form design, data tracking and collection, data entry and capture
- Discuss data review, validation, and queries
- Recognize the rationale of the MedDRA dictionary
- Discuss database lock and release
- Examine Adverse Event reporting and reconciliation
- Apply suggestions for future study

**Who Should Attend**
- Sponsor/CRO staff with less than one year of experience and whose function is to review, correct, enter, or manage data
- Individuals who desire a basic understanding of the function of clinical data management

**Instructor**
Denise G. Redkar-Brown, MT

**Course Length and Time**
2 hours 9:30 – 11:30 a.m. and 12:30 – 2:30 p.m. Eastern

**Course Dates**
- January 29, 2020 (9:30-11:30)
- April 22, 2020 (12:30-2:30)
- July 29, 2020 (9:30-11:30)

**FEE:** $735*  
**ACRP Members:** Receive 10% off!  
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

**Accreditation**
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

**Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.**

**ACPE#: 0778-0000-20-040-L01-P. Released: 1/20.**
Introduction to Medicare Coverage Analysis: Impact on Site Revenue Cycles

Course Description
This web seminar will describe the Medicare Coverage Analysis (MCA) process, the creation of the MCA, the multiple uses for this document, and its impact on site revenue cycles. Participants will learn how to utilize the MCA in the financial consultation process when a patient is considering participating in a clinical research study. This web seminar will help revenue cycle personnel enhance the pre-authorization process and ensure an understanding of the appropriate coverage for tests/procedures included in the clinical research study.

Learning Objectives
- Learn how to create a Medicare Coverage Analysis (MCA) and the importance of ensuring its accuracy
- Understand multiple uses for the MCA
- Learn how to incorporate the MCA into the revenue cycle

Who Should Attend
- Personnel responsible for the financial aspects of a clinical research study
- Research Nurses
- Clinical Research Coordinators
- Patient Business Service Personnel

Instructor
Mary L. Veazie, M.B.A., CPA, CHC, CHRC

Course Length and Time
2 hours 9:30 – 11:30 a.m. and 1:00 – 3:00 p.m. Eastern

Course Dates
February 6, 2020 (1-3)
May 7, 2020 (9:30-11:30)

FEE: $735*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-029-L01-P. Released: 2/19.

Introduction to Statistics for Non-Statisticians

Course Description
This web seminar is intended for clinical research professionals who have little or no background in statistics. In it, we will cover the basic statistical concepts needed to understand the roles statistics play in health research. The topics addressed include types of variables, levels of measurement, descriptive statistics, precision, confidence intervals, and an introduction to hypothesis testing. This web seminar is beneficial to all clinical research professionals involved in the design, monitoring, interpretation, and reporting of clinical trials. Emphasis will be placed on understanding statistical information and not on calculations or statistical formulae.

Learning Objectives
- Recognize and interpret descriptive statistics
- Summarize continuous data with appropriate descriptive statistics
- Interpret confidence intervals, and explain how they are calculated
- Interpret P-values, and explain the concepts behind hypothesis testing (using Student’s t-test as an example)
- Employ statistical terms used in clinical research
- Identify approaches to be comfortable communicating with statisticians

Who Should Attend
- Monitors who assist in designing and evaluating studies
- Clinical Research Associates who communicate with statisticians
- Clinical Project Leaders who design and evaluate studies
- Regulatory Professionals who utilize statistical concepts in their reports
- Medical Writers who must interpret statistical reports

Instructor
Stella Stergiopoulos, M.S., M.PH.

Course Length and Time
3 hours 12:00 – 3:00 p.m. Eastern

Course Dates
March 2, 2020
June 1, 2020

Archived Recording Available in Multiple Formats!

FEE: $835*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 3 hours (0.3 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

Investigational Product Accountability Best Practices

Course Description
One of the top regulatory findings both in the U.S. and in global inspections is related to investigational product (IP) accountability. In this web seminar, we will discuss the common sources of error, recommend procedures and training techniques, and evaluate the differences in investigational and non-investigational products. Investigator and sponsor responsibilities will be described, as well as “best practices” for implementation of those responsibilities.

Learning Objectives
- Describe IP accountability requirements and regulatory considerations
- Discuss non-investigational medicinal product and rescue medication management and documentation
- Define the responsibilities of the research site in IP accountability
- Develop strategies for identifying and solving IP accountability errors or deficiencies

Who Should Attend
- Investigators
- Coordinators
- Pharmacists
- Clinical Research Associates
- Project Managers

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Length and Time
1.5 hours 9:00 – 10:30 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates
January 14, 2020 (9-10:30)
April 23, 2020 (1-2:30)

Archived Recording Available in Multiple Formats!

FEE: $735* ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-061-L01-P. Released: 7/19.

What Participants Say About Barnett Interactive Web Seminars:

“The seminar content fully addressed each course objective. It included an impressive amount of detail for a 3-hour course.”

Investigator Initiated Trials: Roles and Responsibilities

Course Description
Investigator Initiated Trials (IITs), also referred to as Sponsor-Investigator (SI) Trials are increasing in popularity. A Sponsor-Investigator is anyone who functions as the Clinical Investigator (CI) of a given study and who also holds the investigational marketing application, i.e., the IND or IDE. How does the CI ensure compliance to both the investigator and sponsor responsibilities? This web seminar will present the responsibilities, discuss risk, and provide suggestions for compliance.

Learning Objectives
- Define an Investigator Initiated Trial (IIT)
- Review the applicable federal regulations for IITs, including sponsor and investigator responsibilities
- Review the steps involved in initiating an IIT with a sponsor and review regulatory reporting requirements
- Identify essential documentation (Trial Master File) for the Sponsor-Investigator using the DIA TMF Reference Model to remain audit ready
- Identify approaches to minimize risks associated with IITs by avoiding common pitfalls – learn from existing FDA Warning Letters of deficiencies

Who Should Attend
- Investigators/Site Study Team Members
- Sponsor Study Team Members
- Ethics Committee Members

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
2 hours 9:30 – 11:30 a.m. and 12:00 – 2:00 p.m. Eastern

Course Dates
March 19, 2020 (12-2)
July 8, 2020 (9:30-11)

Archived Recording Available in Multiple Formats!

FEE: $735* ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-043-L01-P. Released: 8/19.
NEW! Key Considerations in Medical Writing: The Clinical Study Protocol, Investigator’s Brochure, Informed Consent Form, and Adverse Events Narratives

Course Description
This web seminar includes a high-level review of the key considerations and the current trends for the clinical study protocol, the Investigator’s Brochure (IB), the informed consent form, and adverse event narratives. While these documents form the basis and often predict the success of any drug or device development program, there is much variation between companies and individuals on how to approach writing these critical documents. In this web seminar, key considerations that should be taken into account in the development and maintenance of these documents will be discussed.

Learning Objectives
• Describe current trends and key considerations for clinical study protocol writing
• Review required and optional elements of informed consent, criteria for language and comprehension by research subjects
• Review serious adverse event reporting requirements and narrative writing
• Discuss how to translate safety updates into informed consent and Investigator’s Brochure amendments

Who Should Attend
• Medical Directors and Physician Investigators
• Medical Writers/Regulatory Affairs Professionals
• Clinical Research Associates and Project Team Leaders
• Research and Development Personnel/Grant Administrators

Instructor
Marina Malikova, Ph.D., MSci, M.A., C.C.R.A., RAC

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates
March 25, 2020 (1-2:30)
June 25, 2020 (9:30-11)

Fee: $735*
ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-19-051-L01-P. Released: 8/19.

Interactive Web Seminars

Leading Teams in a Changing Clinical Research Environment

Course Description
Teams have become much more complex in the past 10 years. In the past, a team would be comprised of similar individuals in the same location driving on a fairly stable course towards its objectives. These tenets are no longer true. Trends are driving the need for more flexible, highly skilled teams. This leads to the following challenges:
• Not enough time to build a stable team that has an established record of working well together
• Persons of various backgrounds, skills, and experience need to quickly achieve a goal
• Members work in various locations and oftentimes, global locations
• Membership constantly changes
• Targets shift
• Project duration varies

This web seminar presents real-world practical tips for leaders of complex teams. The course will present learners with the concept of team development. By understanding the stages of team development, we as leaders can identify those tasks which are most critical to team alignment and collaboration in order to ultimately achieve successful outcomes.

Learning Objectives
• Define a team
• Explain Tuckman’s four stages of team development
• Define alignment and collaboration
• Provide 10 practical tips a team leader can implement to move her/his team from chaos to performing
• Describe five best practices for leading virtual teams

Who Should Attend
• Personnel leading complex (i.e., highly specialized, diverse, virtual, globally dispersed) teams who need to ensure their teams are aligned and collaborating in a way that helps them achieve the team’s goals

Instructors
This course will be taught by one of the following instructors:
Holly J. Deiaco-Smith, M.S.Ed.
Debbie Harper, B.Sc., P.M.P.

Course Length and Time
2 hours 2:30 – 4:30 p.m. Eastern

Course Dates
May 27, 2020

Archived Recording Available in Multiple Formats!
FEE: $735*
ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
Managing CRAs to Improve Performance and Study Outcomes

Course Description
Monitoring a clinical trial is a required activity completed by sponsors of FDA regulated research that significantly affects the outcomes of product development and approval. Effectively managing the performance of Clinical Research Associates (CRAs) by sponsors is essential. Performance Management and Improvement is a science involving logical processes and applications. This web seminar will present the concepts of the Human Performance Improvement (HPI) Model and apply it directly to the management of the CRA to promote improvements. The HPI CRA Management Model will be presented and applied via case scenarios for better understanding.

Learning Objectives
• Define the Human Performance Improvement Model
• Recognize an HPI CRA Management Model
• Apply the model into current practice: Proactive CRA management
• Apply the model into current practice: Managing CRA performance issues
• Analyze case scenarios

Who Should Attend
• Project Managers
• Lead Clinical Research Associates
• Clinical Research Associate Managers

Instructor

Course Length and Time
2.5 hours 2:00 – 4:30 p.m. Eastern

Course Dates
July 8, 2020

Archived Recording Available in Multiple Formats!

FEE: $625*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2.5 hours (0.25 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-17-039-L01-P. Released: 3/17.

Managing Observational Studies

Course Description
Observational studies in the biopharmaceutical and medical device industries encompass various designs and purposes, including post-approval safety studies, product or disease registries, pregnancy registries, medical chart reviews, and cohort studies. This web seminar offers practical approaches to the management of observational studies, focusing on issues and aspects that occur commonly, differ from clinical trial management, and are key to program success. Topics to be addressed include project oversight, ethics/Institutional Review Board (IRB) approvals, data quality management, site and subject recruitment and retention, and protocol adherence.

Learning Objectives
• Employ techniques for managing observational studies differently than clinical trials
• Explain common pitfalls with observational studies
• Utilize proactive strategies to improve observational study conduct

Who Should Attend
• Staff from biopharmaceutical, medical device, or contract research companies who are or who will be involved in observational studies
• Project Managers and Team Leaders
• Clinical Research Professionals
• Clinical Safety/Pharmacovigilance Professionals

Instructor
David Stier, M.D.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Archived Recording Available in Multiple Formats!

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
NEW! Managing Phase I Clinical Trials

Course Description
Phase I clinical trials aim to determine the safety, tolerability and pharmacokinetics (PK) of a compound. This web seminar will explore the challenges of developing Phase I clinical study protocols to ensure that the right patients are enrolled and that the right data are collected to demonstrate a drug is safe and efficacious, while at the same time managing study costs and complexity, especially in trials that involve early-phase drug metabolism, imaging and interventional procedures. Key factors to consider when developing protocols and techniques to minimize complexity while ensuring trial success will also be discussed.

Learning Objectives
- Understand the FDA requirements for Phase I clinical trials and review the different Phase I trial designs
- Discuss challenges with early phase studies for Sponsors, Contract Research Organizations (CROs), third-party vendors and sites
- Discuss how to optimize protocol design for a special population
- Identify risks in early phase clinical trials and mitigation strategies
- Address strategic planning and budgetary considerations for Phase I designs

Who Should Attend
- Clinical Operations and Clinical Research Associates
- Medical Affairs Specialists and Leaders
- Project Managers/Team Leaders
- New Clinical or other Project Team Leaders who will be managing projects
- Physician Investigators and Coordinators
- Regulatory Affairs Professionals
- Quality Assurance/Control (QA/QC) Professionals

Instructor
Marina Malikova, Ph.D., MSci, M.A., C.C.R.A., RAC

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates
March 25, 2020 (9:30-11)
June 25, 2020 (1-2:30)

Fee:
$735* ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-055-L01-P. Released: 8/19.

Managing Risks in Outsourced Clinical Trials: Practical Approaches and Tools

Course Description
Partnerships with clinical vendors are critical to the success of the trial. Sponsors, as well as vendors who hire other vendors, require both performance and quality oversight. Whether your organization hires different vendors per protocol/program, or you’re in a preferred provider partnership model, you always encounter potential risks. This web seminar will provide a systematic, structured, proactive approach to risk management in outsourced clinical trials. We will discuss the internal and external factors for the organization to identify, assess, manage, and continuously monitor throughout the life of a project and/or partnership (e.g., protocol, investigational plan, regions, sites, vendors, and resources).

Learning Objectives
- Describe the attributes of a risk management framework for use in outsourced clinical trials
- Identify sponsor’s oversight requirements included in ICH GCP E6 R2
- Identify potential risk areas with outsourced trials

Who Should Attend
- Sponsor Personnel that choose, manage, or evaluate external service providers
- Vendor/CRO Personnel responsible for trial oversight
- Vendor Personnel that choose, manage, or evaluate other vendor partners

Instructor
Debbie Harper, B.Sc., P.M.P.
Medical Writing Fundamentals: How to Write Regulatory Documents

Course Description
Medical writing has its own standard practices and idiosyncrasies. Knowing what to write, how to format, and how to navigate corporate processes can require a big learning curve. This web seminar will give learners an overview of writing practices, formatting, working with tables/figures, and communicating effectively. Practical applications of these skills will be described as they apply to writing all types of documents for submission to global regulatory authorities, including protocols, clinical study reports, investigator’s brochures, data management plans, statistical analysis plans, documents for modules in the Common Technical Document (CTD) format, and briefing books. Real-life examples of strategies for generating a great document by understanding the what and why of the different documents will also be presented.

Learning Objectives
- Review basic medical writing skills, including correct abbreviation practices, consistent captioning, and table generation
- Utilize styles and templates
- Describe style guides and their importance
- Describe the communication process needed for document review and completion
- Conduct a literature search
- Apply these skills to all regulatory documents

Who Should Attend
- New Medical Writers
- Clinical Research Professionals (i.e., CRAs, Data Managers)
- Statisticians
- Study Coordinators
- Document Signatories (i.e., Chief Medical Officers, Clinical Pharmacologists)
- Personnel who review regulatory documents or are involved with investigator-sponsored studies

Instructor
Caroline Ritchie, Ph.D., M.B.A.

Course Length and Time
1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates
May 20, 2020

Minimizing Risk in Negotiating Clinical Trial Contracts and Budgets

Course Description
Most of the attention in negotiating clinical trial budgets and contracts is focused on fair compensation for the conduct of clinical research. Experience has shown however, that the greatest risk in such negotiations arise from rules and regulations outside Good Clinical Practice (GCP) that can result in heavy fines and penalties to the unwary. This web seminar will clarify these rules and regulations and provide practical direction on how to navigate these waters safely.

Learning Objectives
- Discuss the implications of Stark Law, Anti-Kickback Statute, False Claims Act and Medicare Secondary Payer Rule in clinical trial contracts and budgets negotiation
- Identify contract and budget risks and how to negotiate them safely
- Discuss creative processes to maximize revenue while minimizing risk
- Demonstrate skills with live exercises

Who Should Attend
- Research Managers
- Research Compliance Professionals
- Business Managers

Instructor
Robert Romanchuk, B.S.H.S., CIP, C.C.R.C., C.C.R.C.P.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
June 8, 2020

FEE: $735*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-17-104-L01-P. Released: 10/17.
Monitoring Medical Device Trials: An Introduction

Course Description
This web seminar will provide the core concepts involved in monitoring medical device studies, including activities conducted at the investigator site, communication between monitor visits, and monitoring with centralized systems. We will explore the monitoring concepts as provided by the FDA in the Risk-Based Monitoring Guidance, as well as the ICH as interpreted for medical device trials. The basics of clinical monitoring and appropriate documentation to support adequate oversight of the study will be covered. Sponsor responsibilities and the role of the Clinical Research Associate/ Monitor will be explored.

Learning Objectives
- Describe the regulatory purpose of monitoring device studies
- Define the basic types of monitoring visits and documentation requirements
- Explore the roles and responsibilities of the Clinical Research Associate (Monitor) for the various types of visits
- Discuss the meaning of protocol and regulatory (GCP) compliance
- Recognize the rationale behind adequate documentation of monitoring including identification of issues, corrective and preventive action and evaluation of effectiveness for issues (both site and sponsor)

Who Should Attend
- Clinical Research Associates
- Project Managers
- Personnel responsible for monitoring or managing medical device trials

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Length and Time
2 hours 1:00 – 3:00 p.m. Eastern

Course Dates
April 15, 2020

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.


What Participants Say About Barnett Interactive Web Seminars:

“The webinar was very easy to navigate and allowed for questions, comments and active participation of the learners.”

Monitoring Oncology Clinical Trials

Course Description
This web seminar will provide attendees with a general overview of oncology clinical trials and their distinct characteristics. We will review how oncology clinical trials differ from those in other therapeutic areas, with a special emphasis on the unique challenges of monitoring oncology clinical trials. Distinctions will be drawn between early and later phase trials. Attention will be paid to Adverse Event (AE) and Serious Adverse Event (SAE) reporting. All aspects of oncology clinical trials and how to successfully monitor them will also be discussed.

Learning Objectives
- Identify the differences between monitoring oncology early phase clinical trials vs. later phase clinical trials
- Identify ways in which oncology clinical trials differ from those in other therapeutic areas
- Describe the complexities of AE and SAE monitoring in oncology clinical trials
- Utilize Common Terminology Criteria for Adverse Events (CTCAE) grading and apply CTCAE to AE source data
- Describe the common challenges in monitoring and apply tools and techniques to overcome them

Who Should Attend
- Monitors who are new to or are interested in learning more about oncology clinical trials

Instructor
Vanessa Laroche, B.S., CIP, CQA, C.C.R.P.

Course Length and Time
2 hours 12:30 – 2:30 p.m. Eastern

Course Dates
April 1, 2020
January 30, 2020
July 22, 2020

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-20-044-L01-P. Released: 1/20.
Interactive Web Seminars

Monitoring Phase I Clinical Trials

Course Description
Phase I trials require an additional monitoring skill set. The Clinical Research Associate (CRA) assessment focus changes in many monitoring practices, from the Informed Consent Form to data review of PK sampling. Most CRA trainings do not test or provide practicum for the unique focus of a Phase I trial. This webinar will identify the differences in skills and review specific components for monitoring studies in this phase of research. References from GCP to support monitoring activities will be presented, as well as case studies to apply presented concepts.

Learning Objectives
• Identify the importance of Pharmacokinetics (PK) and timed blood drawing
• Describe the differences between Phase I research sites and others
• Distinguish Phase I monitoring activities from other types of trials
• Describe safety monitoring in Phase I trials
• Recognize common compliance issues at Phase I research sites
• Identify additional essential document requirements
• Discuss appropriate GCP references to support Phase I monitoring activities

Who Should Attend
• Clinical Research Associate Managers
• Clinical Research Associates

Instructor
Daniel J. Filoramo, R.N., B.S.

Course Length
2 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Archived Recording Available in Multiple Formats!

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. 
Accreditation available upon request.

Blended Curriculum Course

Monitoring Plan Development

Course Description
Although monitoring plans are not defined or specifically required by FDA regulations, the FDA endorses the use of this tool in a Quality Systems management approach to clinical research. The traditional approach to monitoring plan development has relied upon reinforcing SOP-mandated monitoring activities with little focus on project and/or protocol-specific monitoring needs. This webinar provides participants with concepts and templates to develop a monitoring plan that supports unique project risks and links to valuable data regarding investigative site and Clinical Research Associate (CRA) performance.

Learning Objectives
• Identify the contents of a monitoring plan including affiliated monitoring procedural documents, tools
• Develop a monitoring plan to meet the unique needs of a project and protocol
• Determine the triggers for revisions to monitoring plans and the importance of version control
• Explain FDA recommendations for risk-based monitoring plans
• Describe the relationship of the monitoring plan to the CRA for monitoring and managing site performance, meeting project goals and promoting continuous improvement

Who Should Attend
• Clinical Research Associates
• Project Managers
• Clinical Research Associate Managers

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Length and Time
2 hours 8:30 – 10:30 a.m. and 1:00 – 3:00 p.m. Eastern

Course Dates
January 13, 2020 (8:30-10:30)
May 7, 2020 (1-3)

Archived Recording Available in Multiple Formats!

FEE: $735*
ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-20-045-L01-P. Released: 1/20.

What Participants Say About Barnett Interactive Web Seminars:

“We will apply the useful tools provided by the trainer to update the current plan and develop a new monitoring plan for an incoming study.”

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Monitoring Reports: 10 Rules of Effective Report Writing

Course Description
The Clinical Research Associate (CRA) creates reports that have many audiences, one being regulatory authorities reviewing essential documentation of clinical trials linked to marketing application approvals. This web seminar presents 10 categories of scientific report writing in the context of the role of the CRA and the reports that they write. The applicable reports are monitoring visit reports, e-mails, telephone reports, Memos to File, and more. The concepts of writing in a scientific voice versus first person, objective versus subjective, and many more are presented. This course is invaluable for the CRA, as well as the individual who critiques the various reports.

Learning Objectives
• Examine the impact of poor report writing
• Apply the definitions and concepts of scientific report writing
• Implement the 10 rules of quality report writing for CRAs
• Apply the 10 rules to CRA activities
• Write action items, deviations, queries
• Integrate essential document mapping within a monitoring report
• Describe the challenges of CRA report writing and report review

Who Should Attend
• Clinical Research Associates
• Contract Clinical Research Associates
• Clinical Research Associate Managers
• Project Managers

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
3 hours 8:30 – 11:30 a.m. and 12:00 – 3:00 p.m. Eastern

Course Dates
March 19, 2020 (8:30-11:30)
June 8, 2020 (12-3)

Archived Recording Available in Multiple Formats!

FEE: $835*
ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 3 hours (0.3 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.


Monitoring Visit Reports for Medical Device Studies

Course Description
In this web seminar, we will discuss how to write effective monitoring visit reports for medical device studies. Participants will learn the purpose for monitoring investigational sites and the importance of documenting the visit. We will examine the requirements for the documentation in the Code of Federal Regulations and ICH, and discuss how the report is used by various stakeholders. Tools will be provided to enable learners to scrutinize various sections of the report to better document what was accomplished on the visit. This documentation supports the adequate monitoring obligation expected by regulatory authorities.

Learning Objectives
• Describe the requirements of documenting monitoring activities for a device study
• Recognize the importance of a well written monitoring visit report, auditable by the regulatory authorities
• Describe the requirements of documenting monitoring activities for a device study

Who Should Attend
• Clinical Research Associates
• Contract Clinical Research Associates
• Lead Clinical Research Associates
• Clinical Research Managers
• All other personnel responsible for writing or reviewing monitoring visit reports for device studies

Instructor
Shana Zink, B.S.

Course Length and Time
2 hours 1:00 – 3:00 p.m. Eastern

Course Dates
July 9, 2020

Archived Recording Available in Multiple Formats!

FEE: $735*
ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-20-046-L01-P. Released: 7/20.

What Participants Say About Barnett Interactive Web Seminars:
“The best web seminar I have attended in my 10 years! A lot to take away.”
Negotiation Skills for Clinical Research Professionals

Course Description
The ability to negotiate effectively is a core competency for all clinical research professionals. Yet many people find negotiating to be an intimidating experience. Take this interactive web seminar and dramatically improve your ability to negotiate in any situation. With specific examples and real world case studies drawn from clinical research, you will be able to immediately implement the skills you learn with ease. This web seminar will provide a rich learning experience in implementing negotiation best practices.

Learning Objectives
• Formulate and approach to confidently influence without authority
• Explain how to persuasively communicate and negotiate in face-to-face and virtual settings
• Analyze a negotiation matrix
• Employ approaches to transform conflict and negotiating tactics into constructive collaboration

Who Should Attend
• Clinical Research Assistants
• Clinical Research Associates
• Clinical Research Managers
• Clinical Research Directors
• Project Managers
• Contract Associates and Managers
• Team Leaders
• Regulatory Associates and Managers

Instructor
Natalie Currie, B.Sc.

Course Length and Time
1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates
March 9, 2020

FEE: $735*
ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups of 20 or more at any additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Authorization
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

What Participants Say About Barnett Interactive Web Seminars:

“...The information presented was very thorough and I will reference the knowledge when writing my reports and preparing for my next monitoring visits...”
Phase I Study Management

**Course Description**
Because the early life of a compound is dependent on the data and analysis derived from Phase I Studies, it is imperative that these trials are managed and conducted with the highest quality and care. Therefore, well-honed project management skills that can address the unique issues associated with Phase I Studies are needed. This web seminar will examine the importance of Phase I Studies in drug development, the issues commonly associated with conducting a Phase I Study from a sponsor perspective and provide project management best practices specific to overseeing a Phase I Study.

**Learning Objectives**
- Define Phase I Studies
- Examine the importance of Phase I data in clinical development
- Review general considerations for planning and conducting a Phase I Study
- List project management best practices specific for Phase I clinical trials

**Who Should Attend**
- Project Managers
- Study Directors
- Site Monitors

**Instructor**
Daniel J. Filoramo, R.N., B.S.

---

Preparation, Management, and Response to Inspections and Audits

**Course Description**
Faced with an impending audit or inspection, how do you prepare? If inspection results in findings, do you have the skills and tools to best respond to these issues to avoid further actions? This web seminar will provide an overview of what to expect and how to prepare for an audit or inspection. Real case scenarios in a workshop format will be used to help solve the dilemmas faced by both sites and industry when faced with discoveries from regulatory authorities or auditors. Steps for preparation, on-site auditing and follow-up actions will be explained. Interactive exercises will be incorporated utilizing FDA Warning Letters. Participants will learn how to perform root cause analysis (RCA) and prepare corrective and preventive actions (CAPAs).

**Learning Objectives**
- Describe the anatomy of a regulatory inspection
- Recognize how to best prepare and manage expectations
- Discuss appropriate strategies for responding to inspection findings and implementing realistic and appropriate corrective and preventive actions (CAPA)
- Employ the right corrective actions to resolve the major and critical inspection findings

**Interactive Activities**
- Root Cause Analysis exercise
- Forensic examination of FDA Warning Letters

**Who Should Attend**
- Investigators
- Clinical Research Coordinators
- Clinical Research Associates
- Compliance Professionals
- Project Managers and Site Managers
- Quality Assurance Personnel

**Instructor**

---

**Course Length and Time**
4 hours 10:00 a.m. – 2:00 p.m. Eastern

**Course Dates**
January 7, 2020
July 7, 2020

**FEE:** $1,045*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

**Accreditation**
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants who participate in this course will receive 4 hours (0.4 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.  
Preparing Clinical Research Sites for FDA Inspections

Course Description
This web seminar is designed for participants that are sponsors/CROs and research site representatives preparing for a research site FDA inspection. From audit readiness to action item resolution, each site faces its own unique challenges. This course will prepare you and your site for expectations from the FDA and provide concrete steps you can take to prepare before, during and after the inspection.

Learning Objectives
• Recognize the anatomy of an audit: The foundation of preparation, the regulations and ICH, types and focus of FDA audits
• Review the dynamics of audit readiness: Starting at site selection, preparing sites with large deficiencies
• Discuss the mission of the FDA BIMO Program revisions
• Recognize the timing of an FDA audit: Audit readiness, action item resolution, follow up after the audit
• Identify mechanics of the audit: Start to finish

Who Should Attend
• Project Managers
• Clinical Research Associates
• Site Managers
• Research Site Personnel

Instructors
This course will be taught by one of the following instructors:
Jeanne Morris, B.S., MT (ASCP)

Course Length and Time
2.5 hours 12:00 – 2:30 p.m. Eastern

Course Dates
January 21, 2020
July 15, 2020

Archived Recording Available in Multiple Formats!

FEE: $625*
ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

This web seminar qualifies for a reduced individual participant fee of $159.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2.5 hours (0.25 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-20-047-L01-P. Released: 1/20.

Principal Investigator Oversight and the Appropriate Delegation of Tasks

Course Description
Principal Investigators (PIs) are required to provide adequate oversight of all clinical research activities at the site, whether the activity is conducted by the PI, by study team members, or by applicable third parties. Adequate oversight encompasses many activities and obligations, such as ensuring regulatory compliance, staff training, and subject medical care. In this web seminar, we will discuss the regulatory requirements and guidance regarding adequate investigator oversight and appropriate delegation of study tasks, review documentation requirements, and determine strategies for appropriate delegation of tasks.

Learning Objectives
• Recognize the industry concerns about adequate delegation and improper delegation of study activities
• Identify documentation requirements for proper delegation and investigator oversight
• Identify strategies for determining role assignment specific to a study project and requirements of PI oversight

Who Should Attend
• Site Research Managers
• Investigators
• Clinical Research Associates/Monitors
• Study/Clinical Research Associate Managers
• Clinical Research Coordinators
• Sponsors/CROs

Instructors
This course will be taught by one of the following instructors:
Elizabeth Ronk Nelson, M.P.H.
Jeanne Morris B.S., MT (ASCP)

Course Length and Time
1.5 hours 3:00 - 4:30 p.m. Eastern

Course Dates
March 17, 2020

Archived Recording Available in Multiple Formats!

FEE: $735*
ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-17-045-L01-P. Released: 3/17.
Protocol Deviations: Documenting, Managing, and Reporting

Course Description
According to both U.S. regulations and the ICH GCP E6 Guideline, Clinical Investigators are required to conduct a clinical trial in compliance with the investigational plan/protocol. Protocol deviations should not be implemented without sponsor agreement and the prior approval/favorable opinion from the IRB/IEC, except when necessary to eliminate an immediate safety issue for research subjects. However, unapproved protocol deviations occur in every study and at every site. There is a growing recognition within the industry as to the importance of appropriately managing protocol deviations. This web seminar provides tips and strategies to help participants anticipate, manage, and minimize the impact of protocol deviations. Investigators and Clinical Research Associates (CRAs) will learn how to appropriately document and report protocol deviations, with a focus on preventing recurrence. Internal study team members will learn how to implement a structured approach to managing significant deviations that impact subject safety and/or data integrity.

Learning Objectives
- Describe the components of protocol deviation documentation and reporting
- Identify stakeholder roles in the management of protocol deviations
- Describe a process to proactively identify, track, and evaluate deviations for greater effectiveness in study management

Who Should Attend
- Sponsor/CRO Project Managers
- Sponsor/CRO Study Managers
- Sponsor/CRO Clinical Research Associates
- Sponsor/CRO Clinical Research Associate Managers
- Clinical Investigators
- Clinical Research Coordinators
- Quality Assurance Professionals

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Length and Time
2 hours 9:00 – 11:00 a.m. and 1:00 – 3:00 p.m. Eastern

Course Dates
January 27, 2020 (9-11)
May 11, 2020 (1-3)

Archived Recording Available in Multiple Formats!

FEE: $735*
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Quality by Design in Clinical Research: Is This Only for the Protocol?

Course Description
Over the past few years, Quality by Design (QbD) for clinical trials has been a focus for protocol development and execution. However, even though it is increasingly expected of the industry by regulatory agencies, translating this QbD approach into “building in quality for the business” is rarely shared for the “how do I do this?” This web seminar will de-code and translate QbD and quality for the research enterprise with examples that will solidify the concepts and framework presented for use within any organization. We will discuss the critical first step of defining quality; how to simplify QbD; how QbD and Quality Management Systems (QMS) relate to each other; determining whether your organization has these in place; what the best QbD principles and methods are; how to go beyond plans and create checklists for quality; and, finally, strategies for effective implementation.

Case Study: QbD for a CRA Study Management Plan
Job Aid: QbD Worksheet

Learning Objectives
- Differentiate QbD and QMS in clinical research
- Determine if your organization’s practices reflect elements of a QMS and QbD principles and methods
- Identify QbD practices to utilize in the functional area and/or business enterprise

Who Should Attend
- Clinical Operations Professionals
- Project Managers
- Quality Assurance and Compliance Personnel
- Business Process Owners
- Risk Management Specialists

Instructor
Debbie Harper, B.Sc., P.M.P.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

EXPERIENCE THE BARNETT WEB SEMINAR DIFFERENCE:
Engagement-focused instructional format ● Learning activities focused on application
Interaction with subject matter experts ● Accredited content ● Cost-effective group training
Interactive Web Seminars

Quality Systems: A Controlled Approach to GCP Compliance

Course Description
A Quality Systems approach to establishing and maintaining regulatory compliance allows sponsors to better leverage their resources and Clinical Investigators to meet their obligations for clinical research oversight. This web seminar will review the elements of a Quality System at the Clinical Investigator site and how it functions to proactively control site-level noncompliance.

Learning Objectives
• Discuss an overview of sponsor and Clinical Investigator responsibilities
• Explain how to identify the active elements of a functional Quality System at the clinical research site
• Discuss how implementation of a Quality System can assist in the requirements for meeting obligations of sponsors and Clinical Investigators
• Determine how Quality System overlaps with FDA and ICH Guidance
• Examine recent compliance concerns and how applying the Quality System framework at the site level can address them

Who Should Attend
• Directors of Clinical Operations at clinical research sites
• Clinical Principal Investigators
• Clinical Research Coordinators
• Clinical Research Associates
• Project Managers
• All Clinical Research Personnel involved in selecting and/or overseeing clinical research sites

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
2 hours 12:30 – 2:30 p.m. Eastern

Course Dates
May 22, 2020

Archived Recording Available in Multiple Formats!

FEE: $735* 
ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Real-World Monitoring: Tips for Success and Sanity

Course Description
The Clinical Research Associate (CRA) position is both demanding and extremely rewarding. This web seminar provides tips and strategies to help the new CRA navigate his/her early years in the profession. Topics ranging from the practical (packing and travel tips) to the philosophical (how to earn trust and credibility) are covered. Participants will also learn how to set the stage for success as a CRA from a veteran monitoring professional.

Learning Objectives
• Identify key skills and personality traits for success as a CRA
• Describe the workflow of a successful monitoring visit
• List the top five activities required of new CRAs for quality performance

Who Should Attend
• Clinical Research Associates with two years of experience or less
• Clinical Research Associate Managers
• Trainers or those responsible for new Clinical Research Associate on-boarding
• Individuals pursuing a Clinical Research Associate career

Instructors
This course will be taught by one of the following instructors:
Nikki Christison, B.S., C.C.R.A., T.I.A.C.R.
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Length
2 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Archived Recording Available in Multiple Formats!

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Recent Trends in Noncompliance: Critical Review and Analysis of Recent Regulatory Letters and Communications from the FDA, EMA, and Health Canada

Course Description
As the clinical research environment evolves in response to both internal and external changes, regulatory agency communication appears to be focused on particular areas of GCP compliance. Regulatory agencies’ recent findings for Clinical Investigators, sponsors, and Institutional Review Boards (IRBs) tend to reflect historic areas of noncompliance; however, more attention is being placed on ensuring that corrective and preventive action plans are developed to secure compliance. This web seminar will examine the trends in recent regulatory communication and open discussion for review of acceptable versus unacceptable responses.

Learning Objectives
- Review recent FDA, European Medicines Agency (EMA), and Health Canada findings for Clinical Investigators (sites), sponsors, and IRBs.
- Determine areas of compliance concentration for regulatory agencies.
- Discuss what factors may be helping drive the present approach and what it may mean for future compliance considerations.
- Examine best practices for responding to a regulatory communication.

Who Should Attend
- Clinical Research Associates
- Project Managers
- Principal Investigators
- Clinical Research Coordinators
- IRB Administrators and Members
- Clinical Quality Assurance Auditors
- All other personnel responsible for ensuring compliance with GCP regulations.

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
2 hours 12:30 – 2:30 p.m. Eastern

Course Dates
January 15, 2020
April 7, 2020

ARCHIVED RECORDING AVAILABLE IN MULTIPLE FORMATS!

FEE: $735*
ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

This web seminar qualifies for a reduced individual participant fee of $159. Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.


EXPERIENCE THE BARNETT WEB SEMINAR DIFFERENCE:
Engagement-focused instructional format • Learning activities focused on application • Interaction with subject matter experts • Accredited content • Cost-effective group training.

RECIST 1.0 and 1.1: Overview and Data Challenges in Oncology Clinical Trials

Course Description
RECIST stands for Response Evaluation Criteria in Solid Tumors. The National Cancer Institute is the best resource for information, and defines RECIST criteria as “a voluntary, international standard, and not an NCI standard. They are based on a simplification of former methods (WHO, ECOG) and based on measurable disease, i.e., the presence of at least one measurable lesion.” RECIST criteria provide a way to standardize measurement of solid tumors worldwide for any clinical trials that include this data to define study endpoints.

Learning Objectives
- Differentiate between RECIST 1.0 and 1.1
- Describe the components of RECIST/tumor data
- Apply how to correctly calculate disease response
- Identify and predict common trends with tumor data
- Use working knowledge of common trends to help develop Case Report Forms for oncology trials.

Who Should Attend
- Clinical Research Coordinators
- Clinical Research Associates
- Clinical Team Managers
- Primary Investigators who are interested in participating in oncology clinical trials, but who do not specialize in oncology or radiology.

Instructor
Vanessa Laroche, B.S., CIP, CQA, C.C.R.P.

Course Length and Time
2 hours 12:30 – 2:30 p.m. Eastern

Course Dates
March 11, 2020
June 3, 2020

ARCHIVED RECORDING AVAILABLE IN MULTIPLE FORMATS!

FEE: $735*
ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-20-048-L01-P. Released: 3/20.
Regulatory Intelligence

Course Description
The constantly changing regulatory environment necessitates keeping abreast of current information from a variety of sources. Regulatory Intelligence (RI) is the act of gathering and analyzing regulatory information for impact or changes in laws, regulations, directives, guidance documents, etc. There is more to RI than keeping up with the latest regulations and guidelines. Regulatory precedence, industry practices, regulatory agency opinions, and competitor information are just a few of the valuable sources of information that can help regulatory affairs professionals to develop successful regulatory strategies.

This web seminar examines the scope of RI which encompasses: Information sources, monitoring the regulatory landscape (periodic vs. ongoing), using an RI database and other sources to research the regulatory question, and how to summarize, analyze, integrate, and present RI.

Learning Objectives
• Define Regulatory Intelligence and its importance to companies
• Identify multiple sources of Regulatory Intelligence
• Evaluate the constantly changing regulatory landscape
• Evaluate a regulatory research question in to researchable units, and conduct the research using a Regulatory Intelligence database
• Summarize and present Regulatory Intelligence findings back to a team

Who Should Attend
• Seasoned Regulatory Affairs Professionals looking to develop their skill set
• Research and Development Professionals who are interested in learning a new skill

Instructor
Treena Jackson, M.S., C.Q.A, R.A.C, C.S.S.G.B.

Course Length and Time
1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates
May 13, 2020

Archived Recording Available in Multiple Formats!

FEE: $735*
ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-20-049-L01-P. Released: 5/20.

Research Billing Processing: Appropriate Segregation of Charges and Medical Documentation

Course Description
This web seminar will describe the process for segregating patient care associated with a clinical research study. When a patient participates in a clinical research study, the charges applicable to the study can be divided into three categories: Related to the study, billable to the patient and/or their insurance carrier; related to the study, billable to the sponsor; and unrelated to the study. We will review the appropriate medical documentation and the associated codes to enable these charges to move through the insurance claims process with ease. Participants will leave this web seminar equipped with pertinent information to enhance the claims process associated with clinical research studies.

Learning Objectives
• Understand the patient care revenue cycle and the impact of clinical research
• Learn to collaborate with personnel from the patient business services office
• Enable appropriate processing of patient care services associated with a clinical research study

Who Should Attend
• Personnel responsible for the financial aspects of a clinical research study
• Research Nurses
• Clinical Research Coordinators
• Patient Business Service Personnel

Instructor
Mary L. Veazie, M.B.A., CPA, CHC, CHRC

Course Length and Time
2 hours 9:30 – 11:30 a.m. and 1:00 – 3:00 p.m. Eastern

Course Dates
March 19, 2020 (9:30-11:30)
June 11, 2020 (1-3)

FEE: $735*
ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-028-L01-P. Released: 1/19.

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
The Revised HHS Common Rule: What You Need to Know Now

Course Description
In January 2017, the Revised Common Rule (45 Part 46) was published, providing an update to GCP. The Rule is notable as much for what it does not contain as for what it does. This web seminar reviews the following changes: New/modified definitions; biospecimens and identifiable information; informed consent; broad consent; IRB continuing review; IRB limited review; new/modified exclusions and exemptions, and single IRB requirements for cooperative research. Implementation of the new Rule is required by January 19, 2018, while the cooperative research requirements are not effective until January 20, 2020. This web seminar will go beyond a simple review of the changes and focus on the immediate implications of the new Rule and next steps for each party in the clinical research enterprise to achieve compliance at the implementation deadlines.

Learning Objectives
- Appraise the breadth and depth of the Revised Common Rule
- Distinguish the individual changes to each clinical research professional’s role in the research enterprise
- Design a plan for implementation and compliance
- Identify challenges and obstacles to implementation

Who Should Attend
- Clinical Research Managers
- Clinical Research Educators
- Regulatory Specialists
- Clinical Research Associates
- Clinical Research Coordinators
- Project Managers
- Quality Assurance Professionals
- Clinical Investigators
- IRB Members and Managers

Instructor
Robert Romanchuk, B.H.S.H., CIP, C.C.R.C., C.C.R.C.P.

Course Length and Time
2.5 hours 1:00 – 3:30 p.m. Eastern

Course Dates
March 30, 2020
July 27, 2020

Archived Recording Available in Multiple Formats!

FEE:
$835*  ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation; provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2.5 hours (0.25 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-17-105-L01-P. Released: 10/17.

Risk-Based Auditing: Effective Compliance Strategies

Course Description
An audit is defined as a systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, the sponsor’s standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s). Auditing focuses on the systems that generate this data, whereas monitoring tends to focus primarily on the data. Risk-based approaches to auditing, such as focusing on the most critical data elements, are more likely to ensure subject protection and overall study quality, and will permit sponsors to focus their compliance efforts more effectively. This web seminar will provide an overview of risk-based auditing skills and techniques, and a review of recent GCP audit findings from Clinical Investigators (sites), sponsors, and Institutional Review Boards (IRBs).

Learning Objectives
- Review similarities and differences in risk-based auditing and monitoring
- Examine the structure of the quality assurance/quality control relationship
- Apply risk assessment and management principles to clinical quality assurance
- Review elements of risk-based auditing and compare to traditional auditing practices
- Discuss how the timing of the audit impacts risk assessment and control
- Evaluate recent noncompliance trends and regulatory focus for sites, sponsors/CROs/monitors, and IRBs

Who Should Attend
- Clinical Quality Assurance Auditors
- Clinical Quality and Compliance Professionals
- Clinical Research Associates
- Project Managers
- Sponsor Investigators

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
2 hours 12:30 – 2:30 p.m. Eastern

Course Dates
March 18, 2020

Archived Recording Available in Multiple Formats!

FEE:
$735*  ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation; provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-049-L01-P. Released: 5/17.
Risk-Based Monitoring: The Data Management Connection

Course Description
The final guidance, “Guidance for Industry: Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring” was released in August 2013. To quote from the new guidance, “…monitoring refers to the methods used by sponsors of investigational studies, or CROs delegated responsibilities for the conduct of IND studies, to oversee the conduct of and reporting of data from clinical investigations, including appropriate Clinical Investigator supervision of study site staff and third party contractors.”

We will examine the expectations for the clinical data management (CDM) contributions to assist in this initiative, and the role that CDM can play in ensuring that risk is minimized when it applies to data quality.

Learning Objectives
• Recognize the rationale regarding risk-based monitoring
• Illustrate the active role that CDM is expected to exhibit in this approach
• List the potential CDM reports to assist in identification of data aberrations
• Interpret the way forward for future CDM activities

Who Should Attend
• Clinical Data Managers
• Clinical Research Associates
• Clinical Trial Managers
• Project Managers
• Quality Assurance Personnel

Instructor
Denise G. Redkar-Brown, MT

Course Length and Time
2 hours 12:30 – 2:30 p.m. Eastern

Course Dates
June 10, 2020

ARCHIVED RECORDING AVAILABLE IN MULTIPLE FORMATS!

FEE: $735*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.


Risk-Based Monitoring for Sites: Prepare Your Site for Success

Course Description
Over the past few years, a new term has emerged in the clinical research industry: Risk-Based Monitoring (RBM). What is it? Why is it becoming more widely used? How does it impact Investigators and sites? This web seminar will provide an overview of the principles of RBM and describe how this new approach to monitoring differs from “traditional” monitoring. Learners will gain an understanding of both regulatory and industry factors influencing the adoption of Risk-Based Monitoring. This web seminar will help participants anticipate the possible changes brought on by RBM, and provide strategies to prepare their sites for success.

Learning Objectives
• Describe the concepts and activities of a Risk-Based Monitoring approach
• Investigate the regulatory and industry rationales for Risk-Based Monitoring
• Identify expected changes for sites as a result of Risk-Based Monitoring adoption
• Formulate a transition plan to prepare your site for success in a Risk-Based Monitoring world

Who Should Attend
• Site Research Managers
• Investigators
• Clinical Research Coordinators

Instructor
Nikki Christison, B.S., C.C.R.A., T.I.A.C.R.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

ARCHIVED RECORDING AVAILABLE IN MULTIPLE FORMATS!

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Accreditation available upon request.
NEW! Risk-Based Quality and Compliance Management in Combination Product Trials

Course Description
A risk-based approach to clinical trials requires not only a strategy, but tools to define key indicators to measure specific risks. As referenced in the most recent U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) guidance documents, Key Risk Indicators (KRIs) and Critical to Quality (CTQ) metrics should focus on “what really matters,” and safety of research subjects and data integrity should be emphasized. Combination products can increase risks while being tested in clinical trials, therefore, these metrics should be linked to particular processes within a development program for combination products.

Learning Objectives
• Review the different types of combination products
• Review current regulatory updates and guidelines for combination products
• Discuss streamlined approach for combination products
• Describe principles of Quality by Design (QbD) and new regulatory requirements for risk-based monitoring and how it applies to trials with combination products
• Develop relevant metrics as quality and performance indicators for Risk-Based Quality Management (RBQM) systems for combination products
• Perform a cause-effect analysis for identified risks and develop mitigation strategies

Who Should Attend
• Clinical Quality Assurance Auditors
• Clinical Quality and Compliance Professionals
• Clinical Research Associates
• Project Managers
• Medical Monitors
• Regulatory Affairs Professionals
• Clinical Research Investigators and Coordinators

Instructor
Marina Malikova, Ph.D., MSci, M.A., C.C.R.A., RAC

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates
February 27, 2020 (9:30-11)
May 21, 2020 (1-2:30)

FEE: $735*
ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-20-050-L01-P. Released: 3/20.

Risk-Based Site Monitoring

Course Description
In the current GCP regulatory climate, risk-based decision-making should be supported within the clinical Quality System. A management approach used in many industries where performance is critical under tight timelines for regulated activities, risk-based decision-making makes sense for such activities as sponsor monitoring in clinical research. Applying a risk-based approach to the monitoring and site management should be based on a given project’s risk profile. A risk-based approach can address current monitoring practices that are costly and ineffective, and help projects meet financial and compliance goals. This web seminar will present the concepts and case scenarios of risk-based monitoring (RBM).

Learning Objectives
• Recognize where risk-based decision-making fits into the clinical quality system
• Identify risks for a project related to monitoring
• Identify components to include in building the project profile risk score
• Apply risk factors to various study decisions, i.e., monitoring plan, site assignments, and frequency

Who Should Attend
• Site Research Managers
• Clinical Research Associates/Monitors
• Study/Clinical Research Associate Managers
• Sponsors/CROs

Instructor

Course Length and Time
1.5 hours 11:00 a.m. – 12:30 p.m. and 12:00 – 1:30 p.m. Eastern

Course Dates
March 12, 2020 (11-12:30)
July 8, 2020 (12-1:30)

Archived Recording Available in Multiple Formats!

FEE: $735*
ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

This web seminar qualifies for a reduced individual participant fee of $159.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-20-050-L01-P. Released: 3/20.
“Risk-Based Thinking”: How Monitors Can Develop an Auditor’s Perspective

Course Description
The regulations require that sponsors ensure the selection of qualified monitors and the proper monitoring of clinical investigations. However, sponsors are frequently cited by the FDA for failure to meet those requirements. These regulatory communications note that although monitors might have identified issues, they did not appreciate the significance of those findings. As a result, opportunities to promptly secure compliance might be missed.

Clinical research is structured to incorporate monitoring processes more frequently than auditing. Yet as monitoring integrates a risk-based approach, monitors can utilize many auditing techniques to assist them in more effectively performing their tasks and meeting their obligations. This web seminar will explore the processes for critically reviewing findings to discern the implications and impact on subject safety and data integrity.

Learning Objectives
- Utilize auditing techniques when performing monitoring tasks
- Define “proper monitoring” and who is responsible for its conduct
- Discuss monitoring findings within the context of regulatory risk
- Review standard monitoring report templates and discuss ways to adapt them to develop a compliance assessment
- Describe processes for discerning patterns in information reviewed
- Explore methods for developing monitoring tools that facilitate a systems review and communication

Who Should Attend
- Clinical Research Associates
- Clinical Research Associate Managers
- Project Managers

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
April 10, 2020

Archived Recording Available in Multiple Formats!

FEE: $735*
ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.


Risk-Proof Your Sites: Monitoring Strategies for Managing Risks

Course Description
The concepts and processes of risk management are well known and often used in clinical research project management. Yet, few clinical research monitors realize the value of applying these activities to site management. This web seminar starts with an overview of risk assessment and management. The learner is then guided through the application of these techniques through all phases of study conduct: Site selection and initiation, routine monitoring, and site close-out. The course focuses on identification of site strengths and weaknesses and implementing strategies to address weaknesses before they lead to deviations or noncompliance.

Learning Objectives
- Perform a risk assessment for investigational sites focusing on the issues that matter most
- Identify key questions to evaluate potential risks during the site selection and initiation phase
- Recognize areas of greatest risk at investigative sites during study conduct
- Discuss techniques to monitor potential risks and take action if/when they become problematic
- Identify strategies to conduct site close-out visits so sites remain “audit-ready”

Who Should Attend
- Clinical Research Associates
- Clinical Research Associate Managers
- Clinical Research Professionals with responsibility for site selection and management
- Quality Assurance Professionals

Instructor
Nikki Christison, B.S., C.C.R.A., T.I.A.C.R.

Course Length
2 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Root Cause Analysis: Applying the Concept for Better Study Compliance Management

Course Description
Managing compliance in the research industry is vital to successful clinical trials. Regulatory authorities expect that all stakeholders identify non-compliance, intervene, and then evaluate the effectiveness of the intervention. Without root cause analysis, interventions cannot be effectively identified and designed. This web seminar will present the scientific concepts of root cause analysis and apply them specifically in the clinical trial setting. Root cause analysis is invaluable for all stakeholders in clinical research, the sponsor, CRO, site, and Institutional Review Board (IRB).

Learning Objectives
• Define root cause analysis concepts
• Implement Gilbert’s Root Cause Analysis Diagnostic Process
• Apply root cause analysis in clinical trial study site management
• Assign the right intervention for successful solutions
• Integrate proactive root cause analysis to manage stakeholder compliance: Research site management, Clinical Research Associate (CRA) management, and more

Who Should Attend
• Clinical Research Coordinators
• Clinical Research Associates
• Site Managers
• Clinical Research Associate Managers
• Project Managers

Instructors
This course will be taught by one of the following instructors:
Jeanne Morris, B.S., MT (ASCP)
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
2.5 hours 12:00 – 2:30 p.m. Eastern

Course Dates
June 12, 2020

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2.5 hours (0.25 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-10-052-L01-P. Released: 6/17.

Scientific and Ethical Considerations for Inclusion of Pregnant Women in Clinical Trials

Course Description
The inclusion of pregnant women in clinical trials has long been a complex balance between providing for the health of the mother and potential risks to the fetus. Current labeling information on drug products is typically based on nonclinical data with (or without) limited human safety data for use in pregnancy. The lack of information based on clinical data often leaves the health care provider and the patient reluctant to treat an underlying condition, which in some cases may result in more harm to the woman and the fetus than if she had been treated. This web seminar will discuss the scientific and ethical issues that should be addressed when considering the inclusion of pregnant women in drug development clinical trials.

Learning Objectives
• Discuss the scope of the draft guidance released by the FDA in April 2018
• Review regulations that govern the conduct and oversight of research in the pregnant population
• Examine reasons for considering inclusion of pregnant women in clinical trials in pre- and post-market studies
• Evaluate key differences between the U.S. Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) regulations as they pertain to pregnant women
• Discuss minimal versus research-related risks
• List additional resources for general trial design and statistical analysis

Who Should Attend
• Medical Affairs and Development Professionals
• Project Managers
• Clinical Investigators
• Regulatory Affairs Professionals
• Academic Medical Center and Research Institution staff supporting clinical research
• Personnel responsible for ensuring compliance with Good Clinical Practice (GCP) regulations

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates
March 16, 2020 (1-2:30)
June 12, 2020 (9:30-11)

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-025-L01-P. Released: 1/19.
Social Media in Clinical Research: Effective, Innovative, and Compliant Applications

Course Description
The use of social media in all aspects of the research enterprise has grown exponentially. Researchers from across disciplines and institutional types are finding innovative ways to facilitate research, from online recruitment mechanisms to informed consent portals. Concurrently, researchers and their ethics review boards have been grappling with ethical and regulatory challenges as technologies continue to change rapidly, resulting in a flurry of new questions: Can I use social media to find “lost to follow up” subjects? Can I join a support group to find subjects? What regulations exist around the use of social media? Just what is public information?

This web seminar will provide an overview of Institutional Review Board (IRB) considerations of social media in research, including those major ethical challenges and data security issues that may arise with the use of social media for recruitment, consent processes, data collection, and data dissemination.

Learning Objectives
• Describe IRB perspectives on using social media in research
• Review common forms of recruitment using social media
• Examine models of informed consent in social media research
• Explore examples of language related to privacy and confidentiality in consent documents

Who Should Attend
• Clinical Research Associates
• Principal Investigators
• Institutional Review Board Members

Instructor
Elizabeth A. Buchanan, Ph.D.

Course Length
2 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Archived Recording Available in Multiple Formats!

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Software as a Medical Device: Clinical Considerations

Course Description
In the EU, software has been considered a medical device since 2007. With the proliferation of software technology, this thinking is infiltrating the U.S. FDA regulatory policies as well. In this web seminar, we will discuss the clinical considerations for software as a medical device, including the importance of human factor studies, adverse event monitoring, linking clinical outcomes to software, and identifying and managing the risks unique to software as a medical device.

Learning Objectives
• Examine the clinical impact of human factors and the software interface
• Discuss how to connect clinical effects to software
• Describe risks attributable to software versus physical device

Who Should Attend
• Medical Device Professionals
• Project Managers
• Clinical Data Specialists/Analysts
• Clinical Data Managers
• Clinical Operations Professionals

Instructor
Joy Frestedt, Ph.D., C.P.I., R.A.C., F.R.A.P.S.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Archived Recording Available in Multiple Formats!

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
Source Documentation: What is Adequate and Accurate?

Course Description
Lack of adequate and/or accurate source documentation has been noted as a common deficiency in inspection findings of Clinical Investigators, and regulators report that quality source documents reinforce quality site data. Regulatory requirements (FDA, ICH) will be reviewed in this web seminar. Further, the following topics will be covered: Variability of stakeholder requirements (sponsor-to-sponsor, per study, sponsor to site), case report forms (CRFs) as source data, electronic medical records, shadow charts, source document worksheets, protocol deviations, telephone and email contacts, good documentation practices, making corrections to source documents, late entries, back-dating (oh no!), and details of FDA inspection methods and findings regarding source documents. Leading practices will be discussed to assist sites with implementing the regulatory requirements for source documents.

Learning Objectives
- Define source data and source documents
- Identify regulatory required characteristics of source data and source documents
- Identify three attributes of source document worksheets
- Describe three attributes of ALCOAC (attributable, legible, contemporaneous, original, accurate, complete) for source documents
- Discuss CRFs as source data

Who Should Attend
- Site Research Directors/Managers
- Clinical Research Coordinators
- Principal Investigators
- Clinical Research Associates
- Project Managers
- Clinical Research Associate Managers
- Quality Assurance Personnel

Instructor
Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM., P.M.P.

Course Length and Time
2 hours 9:30 – 11:30 a.m. and 1:00 – 3:00 p.m. Eastern

Course Dates
January 15, 2020 (1-3)
April 14, 2020 (9:30-11:30)
July 27, 2020 (1-3)

SAFETY NOTICEReceive 10% off!
Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-20-052-L01-P. Released: 1/20.

Sponsor Management of Investigator Non-Compliance

Course Description
Investigator non-compliance to the Statement of Investigator commitments has increased in many areas. One of the identified causes has been monitoring. Investigator compliance issues are great risks to product development success, but an even greater risk to sponsors is the lack of formal systems to manage compliance at research sites. With the promise of more sponsor inspections, the sponsor management of investigator non-compliance is an obligation that requires comprehensive management approaches that lead to control of investigational product, data integrity, and adequate documentation for regulatory inspection of sponsors monitoring programs and/or investigative sites. Seven steps in compliance management of research sites will be presented for the participants to assess their current practices for gaps and risks for preparing for potential regulatory inspection evaluating compliance management of research sites.

Learning Objectives
- Categorize investigator non-compliance
- Define adequate escalation of non-compliance
- Summarize proactive investigator training related to sponsor’s response to non-compliance
- Employ seven comprehensive steps in compliance management
- Detect trending to better anticipate compliance issues

Who Should Attend
- Sponsor Senior Management
- Project Managers
- Clinical Research Associate Managers
- Clinical Research Associates
- Quality Assurance/Compliance Personnel

Instructors
This course will be taught by one of the following instructors:
Jeanne Morris, B.S., MT (ASCP)

Course Length and Time
2 hours 12:00 – 2:00 p.m. Eastern

Course Dates
May 20, 2020

Archived Recording Available in Multiple Formats!

FEE: $735* ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

ExPERIENCE THE BARNETT WEB SEMINA R DIF FE R E NCE: | Engagement-focused instructional format • Learning activities focused on application • Interaction with subject matter experts • Accredited content • Cost-effective group training
Sponsor Responsibilities for Global Drug Studies

Course Description
This web seminar covers the sponsor’s responsibilities for the conduct of a global drug study. Participants will learn the 23 responsibilities assigned to a sponsor for a global clinical study based on the International Council for Harmonization (ICH) requirements. These essential requirements for compliance to regulations are useful when dealing with the FDA, Medicines and Healthcare Products Regulatory Agency (MHRA), European Medicines Agency (EMA), and Health Canada (HC), among other global regulatory authorities. Focusing on the importance of documentation, participants will learn how to put these concepts into practice.

Learning Objectives
• Discuss the 23 sponsor responsibilities assigned in ICH GCP E6 Guideline and expected by the regulatory authorities across the globe
• Describe how these concepts are put into practice, with special focus on documentation to support sponsor oversight of these responsibilities

Who Should Attend
• Clinical Operations Staff
• Project Managers
• Regulatory Affairs Professionals
• Quality Assurance Personnel
• All other personnel responsible for ensuring compliance with sponsor responsibilities in the conduct of a clinical trial (especially for start-up and smaller biotech companies)

Instructor
Debbie Harper, B.Sc., P.M.P.

Course Length and Time
1.5 hours 3:00 – 4:30 p.m. Eastern

Course Dates
June 2, 2020

Archived Recording Available in Multiple Formats!

FEE: $735*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-18-051-L01-P. Released: 12/18.

State Laws Governing Clinical Trial Regulatory Compliance

Course Description
Although many clinical trial sponsors and investigators focus primarily on FDA regulations related to the conduct and design of clinical trials, their failure to comply with state laws and regulations may expose sponsors, investigators, IRBs, institutions, or individuals may call into question the potential integrity of clinical data. Today’s U.S.-based clinical trials must meet not just federal requirements, but an increasingly complex array of state-specific requirements, many of which are critical and foundational to clinical studies. The capacity to consent to experimental therapy has its foundational basis and is governed by state law. In this web seminar, we will review many of these key areas, and discuss specific differences. Learners will be provided with examples from more than a dozen practical areas, including age of consent, capacity to consent, IRB and clinical protocol requirements, notification of state agencies, experimental drug dispensing requirements, HIV testing rules, genetic testing, and legal representatives. Also, we will explore strategic considerations that certain states afford specific therapeutic classes. Learners will have the opportunity to ask direct questions regarding clinical trial requirements in their research state.

Learning Objectives
• Recognize areas in which state-specific regulations may affect clinical trial research
• Reduce risk and liability by applying state-specific knowledge to clinical trials
• Utilize state licensing authorities and agencies to address state-specific concerns
• Describe the strategic aspects of clinical trial site selection

Who Should Attend
• Site Research Managers
• Clinical Research Associates
• Clinical Project Managers
• Principal Investigators
• Site Research Managers
• Clinical Research Coordinators

Instructor
John Serio, J.D.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
January 13, 2020  July 20, 2020

April 28, 2020

Archived Recording Available in Multiple Formats!

FEE: $735*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pretest, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-058-L01-P. Released: 9/19.

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Strategies for Active Listening

Course Description
Active listening is an essential skill for the development of our relationships, collaboration, and efficiency in our work. However, active listening is so rarely valued in this fast-paced, increasingly volatile landscape. With each new emerging technology, our skills are not only practiced less, we are losing our ability to listen more rapidly than expected. Active listening is not simply about understanding and storing the content of what another person is saying. It includes being able to hold a focus, attention, and communicate in an authentic and non-verbal manner to another that they have been heard. This web seminar will help learners develop deeper listening skills through a mix of behavioral science techniques, real-life scenarios, and hands-on practice.

Learning Objectives
- Define the multiple layers of active listening
- Distinguish between listening for content and active listening
- Describe and practice listening skills
- Develop a non-verbal lexicon
- Apply best practices to real-life scenarios

Who Should Attend
- Site Managers
- Sponsor Managers
- Project Managers
- Project Leads
- Principal Investigators
- Clinical Research Associates

Instructors
This course will be taught by one of the following instructors:
Tamar Kagan M.Ed., PCC
Michelle Rothstein, PCC, CPCC

Course Length and Time
1.5 hours 11:00 a.m. – 12:30 p.m. and 1:30 - 3:00 p.m. Eastern

Course Dates
February 25, 2020 (11-12:30)
May 26, 2020 (1:30-3)

FEE: $735*  ACPM Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-18-059-L01-P. Released: 10/18.

Strategies for Building High-Performing Clinical Research Teams

Course Description
Creating and maintaining strong, productive teams is essential for success in clinical research. Teams from all parts of the research organization, including the clinical research site, the sponsor organization, Contract Research Organizations and a variety of other vendors all need to work effectively together to meet study requirements including Good Clinical Practice, project schedules and the study budget. Leveraging and sustaining the teams’ strengths-based diversity ensures high-impact collaboration and accelerated results in these complex and challenging times. In this web seminar, participants will discover leading edge, strengths-based tools to build and foster strong team engagement and how to make the most of scarce resources in this complex clinical research environment.

Learning Objectives
- Discover how to create greater team alignment, focus and productivity
- Identify and leverage the inherent and complementary strengths of individual team members
- Develop skills for having high-stakes team conversations
- Navigate through transitions and transform conflict into high-impact collaboration
- Identify how to make the most of your teams’ strengths to prepare for audits and inspections

Who Should Attend
- Project/Study Managers
- Managers, Directors and Team Leaders
- Clinical Investigators
- Clinical Research Associates/Monitors
- Clinical Research Coordinators
- Site Managers
- IRB Administrators and Members

Instructor
Natalie Currie, B.Sc.

Course Length and Time
1.5 hours 2:00 – 3:30 p.m. Eastern

Course Dates
April 27, 2020

FEE: $735*  ACPM Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.
ACPE#: 0778-0000-17-066-L01-P. Released: 5/17.
Strategies for Conducting Vendor Audits

Course Description
Regulatory agencies hold companies accountable for delivering high quality products that meet all established requirements and specifications. Vendors play a key role in accomplishing these mandates and it is the sponsor’s responsibility to ensure their vendors meet all regulatory specifications for the supplied materials, equipment, and/or services. During this web seminar, we will discuss types of vendor audits, various methods/media to conduct vendor audits, planning for the audit, and follow-up to vendor audits.

Learning Objectives
- Describe the various types of vendors that might be audited
- Discuss types of vendor audits
- Implement processes that can be used for selection, audit, approval, and qualification of vendors based on the material/equipment/service being delivered
- Explore methods and tools that can be used to accomplish a vendor audit
- Discuss the importance of and methods for follow-up to vendor audits

Who Should Attend
- Quality Assurance Professionals
- Personnel responsible for vendor management and oversight

Instructor
Treena Jackson, M.S., C.Q.A, R.A.C, C.S.S.G.B.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Archived Recording Available in Multiple Formats!

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Strategies for Developing Effective Training and Facilitation Skills in Clinical Research

Course Description
In clinical research, there is an on-going need to conduct training whether it is at the onset of a study, due to a change in staff or new staff, as a result of an amendment, or because of an identified noncompliance issue during a study. If our goal in training is to pass on knowledge and to ask learners to apply that information, we need to consider our approach in how to make this happen.

It is important to consider how essential every communication is within research; the information shared can have a huge impact on study timelines, data integrity, and compliance. If information is not internalized by the learner, then the time spent discussing it is a waste and the consequences may be significant. In this web seminar, training and facilitation methodology, skills, and fundamentals will be discussed. We will focus on the practical application and tools needed to ensure that an audience is able to remember and apply the information shared.

Learning Objectives
- Review the application of training and good facilitation skills in clinical research
- Discuss adult learning principles and styles
- Identify successful training techniques applied to a clinical research setting

Who Should Attend
- Clinical Research Managers and Leads
- Clinical Research Associates
- Clinical Research Coordinators
- Research Professionals interested in building additional training and facilitation skills to apply to daily transference of knowledge

Instructor
Nikki Christison, B.S., C.C.R.A., T.I.A.C.R.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Archived Recording Available in Multiple Formats!

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

What Participants Say About Barnett Interactive Web Seminars:

“This was one of the BEST webinars I’ve participated in! The speaker was excellent, on target, to the point and it was nice that she cited literature to support her points. In today’s corporate world, it seems that we need to “justify” everything with metrics and data, and this helped me greatly in explaining why we are seeing the enrollment issues we are seeing as well as giving me a whole bunch of new ways to look at site selection and ultimately site enrollment.”
Strategies for Ensuring Good Documentation Practices (GDP)

Course Description
Good Documentation Practice (GDP) in clinical research is a baseline expectation; however, there are no set guidelines around what comprises GDP in a Good Clinical Practice (GCP) environment. In this web seminar, we will look closely at the key features of GDP by first examining the question: What is a document? At its core, a document is information (meaningful data) and its supporting medium, which could be in the form of paper, CD, computer files, or microfilm. Documentation is a process which comprises documents, issuance and disposal of documents, retrieval of documents, and presentation of documents. In addition, this web seminar will examine the issues identified when documentation has been subject to agency review, and the steps that can be taken to ensure that your approach to clinical trial documentation demonstrates the quality processes that have been applied to your documentation efforts.

Learning Objectives
• Review the features of good documentation
• Identify the connection between GDP and Quality Management
• Define responsibilities in relation to GDP
• Discuss the proper procedure for identifying and correcting documentation errors

Who Should Attend
• Clinical Research Personnel who are involved with creating documents, recording data, and signing off on clinical trial documentation

Instructor
Denise G. Redkar-Brown, MT

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Strategies for Having Difficult Conversations

Course Description
Conflict is an essential part of working with others. When done well, it helps to move an agenda forward in a creative and inspired way. When done poorly, it can end in toxicity and the dismantling of strategy and culture. Conflict is necessary for any organization that wants to succeed, it is therefore important to learn to do it well by being courageous and having difficult conversations. These conversations require a certain finesse and awareness to conduct them in a professional and generative manner, and not succumb to anxiety and reactivity. This web seminar will focus on what gets in the way of our ability to have difficult conversations, provide learners with a tool that will help to navigate these dialogues, plus will help to grow confidence and awareness to address conflict from a place of courage.

Learning Objectives
• Identify personal roadblocks and blind spots
• Translate latest behavioral research into real-world scenarios
• Utilize a tool to help navigate difficult conversations
• Compare various communication styles of conflict
• Develop a feedback strategy

Who Should Attend
• Site Managers
• Sponsor Managers
• Project Managers
• Project Leads
• Principal Investigators
• Clinical Research Associates

Instructors
This course will be taught by one of the following instructors:
Tamar Kagan M.Ed., PCC
Michelle Rothstein, PCC, CPCC

Course Length and Time
1.5 hours 11:00 a.m. – 12:30 p.m. and 1:30 – 3:00 p.m. Eastern

Course Dates
January 21, 2020 (1:30-3)
May 26, 2020 (11-12:30)
July 13, 2020 (1:30-3)

Archived Recording Available in Multiple Formats!

FEE:
$735*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

Strategies for Managing Difficult Clinical Research Sites

Course Description
Many Clinical Research Associates (CRAs) ask: “How do I best handle a difficult site?” In this webinar the question is addressed through real life case scenarios that deal with the different kinds of “difficult” sites, for example: The overwhelmed site, the unmotivated site, the passive aggressive site, the research naïve site. All of these types of behaviors at sites can lead to poor performance that does not respond to typical CRA action item management. Hear ideas on how to successfully work with the difficult site to promote efficiency and positive study outcomes that include helpful job aids, soft skill coaching, and diagnostic techniques to help improve approaches to interventions and management of the “difficult” site.

Learning Objectives
• Define the causes of why sites can be “difficult”
• Discuss approaches for dealing with the different types of “difficult” sites
• Develop trending techniques to anticipate site issues
• Implement proactive diagnosis techniques to develop a CRA communication plan
• Describe techniques for resolving conflict and promoting successful outcomes

Who Should Attend
• Clinical Research Associate Managers
• Clinical Research Associates
• Project Managers

Instructors
This course will be taught by one of the following instructors:
Jeanne Morris, B.S., MT (ASCP)
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
2 hours 9:00 – 11:00 a.m. and 12:00 – 2:00 p.m. Eastern

Course Dates
March 20, 2020 (12-2)
June 10, 2020 (9-11)

Archived Recording Available in Multiple Formats!

FEE: $835* ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556. Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
Study Feasibility: Eliminating Low and Late Enrollment

Course Description
This web seminar is designed for sponsor/CRO personnel responsible for protocol design and development, country allocation, site selection, and study feasibility assessments. The current study feasibility assessment process is inefficient and is incapable of identifying the best investigative sites to conduct a clinical trial. Feasibility questionnaires and the current process are often not effective in predicting site success in implementing a given clinical trial. This session will explore novel approaches and technologies that can be used to significantly improve the feasibility assessment process at the protocol, country, and site level.

Learning Objectives
- Evaluate the traditional approach to study feasibility assessment
- Examine what's working, what's not, and why not
- Define the concepts of study feasibility at the protocol, country, site level
- Discuss the purpose and objectives for conducting feasibility assessments
- Explore paradigm shifts in the methods for evaluating study feasibility
- Examine a live demonstration of several new methods, technologies, and approaches
- Identify the characteristics of a high-enrolling site for a given study
- Identify how a protocol can be optimized for enrollment and how the sponsor can maximize enrollment at each site
- Employ practical, statistical, and simulation based methods for country allocation and site selection practices

Who Should Attend
- Directors of Clinical Operations
- Regional Medical Directors
- Clinical Project Managers
- Site Selection Specialists
- Clinical Research Associates
- Clinical Research Associate Managers

Instructor
Beth D. Harper, B.S., M.B.A.

Course Length
2 hours

Study Initiation Strategies for Sponsors: Study and Site Start-Up

Course Description
Study start-up and initiation is one of the busiest times in the research study process. As sponsors and Contract Research Organizations (CROs) are faced with a tight timeline to get all sites up and running — critical elements of the training and communication process are often overlooked. This web seminar will focus on the steps that need to be taken to ensure start-up success at both the sponsor and site level, allow for proactive preparation, reduce the study learning curve, and eliminate study deviations and errors.

Learning Objectives
- Describe the steps of the study start-up process and roles and responsibilities of each team member
- Discuss critical elements that must be included for successful study execution
- Evaluate the use and effectiveness of different types of training and tools
- Discuss how to establish ongoing measures and techniques for continued protocol compliance and communication throughout the study

Who Should Attend
- Clinical Research Associates
- Study Coordinators
- Site Managers
- Clinical Research Associate Managers
- Project Managers

Instructor
Nikki Christison, B.S., C.C.R.A., T.I.A.C.R.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

What Participants Say About Barnett Interactive Web Seminars:

“Very helpful tools and suggestions that can be applied to a couple of very high visibility projects that we are just beginning.”
**Interactive Web Seminars**

### Study Site Start-Up: Organization and Management Tips for the Novice Clinical Research Site

**Course Description**
The role of the research site is vital in the success of a clinical trial. Quality research sites are in great demand in the current research environment. This web seminar presents an overview of the core components for a successful research site. Examples of successful sites for benchmarking will be included as well as resources for more information.

**Learning Objectives**
- Identify components of a successful research site through benchmarking elite performers
- Identify the primary elements of business and marketing planning for a research site
- Discuss the importance of site GCPs and components of SOPs
- Discuss marketing, staffing, recruitment, contracting, and budgeting concepts key to research sites

**Who Should Attend**
- Clinical Research Site Managers/Directors
- Clinical Research Coordinators
- Industry Consultants
- Principal Investigators or Potential Principal Investigators
- Entrepreneurs

**Instructor**
Lily Romero, P.A., C.C.R.C.

**Course Length**
2.5 hours

**Course Dates**
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

### Subject Recruitment: Proactive Project Plans and Issues Management

**Course Description**
This web seminar presents an overview of the patient recruitment arena, and focuses on strategies for successful clinical trials including: Systematic protocol feasibility, pre-screening approaches, insourcing and outsourcing options, and social media considerations. Included in the program are discussions for handling tough populations and the ethics of participant recruitment in clinical trials.

**Learning Objectives**
- Explore updates on clinical trial participant recruitment worldwide
- Discuss an overview of participant recruitment practices including the use of social media
- Examine keys to success: Systematic practice approaches to recruitment in clinical trials
- Employ pre-screen practices to improve screening successes
- Examine the consenting process in regard to subject recruitment and retention
- Determine approaches to retain quality subjects to support data integrity
- Evaluate efforts: The recruitment report card

**Who Should Attend**
- Clinical Research Coordinators
- Site Research Managers
- Clinical Research Monitors
- Sponsor Project Managers

**Instructor**

**Course Length and Time**
2 hours 12:00 – 2:00 p.m. and 1:00 – 3:00 p.m. Eastern

**Course Dates**
- January 28, 2020 (1-3)
- March 19, 2020 (12-2)
- July 14, 2020 (1-3)

**Accreditation**
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

**ACPE#: 0778-0000-20-053-L01-P. Released: 1/20.**

---

Register: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.

Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
NEW! A Systematic Approach to Study Start-Up: Improving Site Activation

Course Description
The success of a trial relies on the strong bond between trial operations and project management throughout the trial life cycle. It is important to develop a specific knowledge of the strengths, weaknesses, and pitfalls of assumed risks at inception in order to devise mitigation strategies throughout the implementation phase. Systematic assessment of risk factors and key performance indicators at the start-up phase can allow for more efficient execution of a clinical trial and ensure better accrual rates. Best practices to expedite the start-up phase will also be discussed.

Learning Objectives
• Develop a sound business strategy for a more efficient study start-up
• Identify key performance indicators and risk factors contributing to start-up delays
• Perform cause-effect analysis of factors attributing to delays of start-up phase
• Implement mitigation strategies to avoid delays and allow for a successful trial launch

Who Should Attend
• Directors of Clinical Operations
• New Clinical or other Project Team Leaders who will be managing projects
• Clinical, Regulatory, Research and Development (R&D) Staff
• Physician Investigators
• Clinical Research Coordinators and Clinical Research Associates, Data Managers or others working in biomedical product development
• Regulatory Affairs
• Quality Control Professionals, Quality Assurance Specialists

Instructor
Marina Malikova, Ph.D., MSci, M.A., C.C.R.A., RAC

Course Length and Time
1.5 hours 9:30 – 11:00 a.m., 1:00 – 2:30 p.m. and 3:00 – 4:30 p.m. Eastern

Course Dates
January 29, 2020 (3-4:30)
April 6, 2020 (9:30-11)
July 14, 2020 (1-2:30)

Archived Recording Available in Multiple Formats!

Fee: $735*
ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

TMF/eTMF Audit Strategies

Course Description
The process for managing the Trial Master File (TMF) has changed drastically in the last 10 years. Many organizations have moved to an electronic TMF (eTMF), yet some organizations still operate with a paper TMF or a hybrid of the two. A successful audit evaluates the processes that were used to manage the TMF to ensure that they are consistent with procedural documents and study plans. We will explore strategies for using the power of an eTMF to identify gaps that could result in inspection findings. The power of the TMF Reference Model in organizing the audit and identifying key artifacts that potentially impact Good Clinical Practice (GCP) compliance will also be discussed. Finally, we will examine strategies for the audit of a paper TMF as well as an eTMF, including critical files to review and how to spot trends in non-compliance.

Learning Objectives
• Explain the value of the TMF Reference Model in organizing an audit to ensure efficient identification of GCP non-compliance
• Identify strategies for conducting an audit of an eTMF that employ the enhanced capabilities of an eTMF
• Identify strategies for auditing a TMF that focuses on artifacts impacting the quality and GCP compliance of the TMF/eTMF

Who Should Attend
• Good Clinical Practice Auditors
• Trial Master File Directors
• Trial Master File Managers
• Trial Master File Coordinators
• Clinical Operations Directors
• Trial Managers
• Records Management Team Members

Instructor
Donna W. Dorozinsky, R.N., M.S.N., C.C.R.C.
Interactive Web Seminars

TMF/eTMF Regulatory Agency Expectations, Inspections, and Findings

Course Description
Recently the EMA has published guidance in managing the TMF. FDA’s regulations are general and require that sponsors and investigators maintain adequate and accurate records of any clinical investigations that are carried out. This web seminar will examine these expectations and discuss recent regulatory findings. We will also discuss strategies for implementing corrective and preventive actions (CAPAs) that result in successful outcomes to regulatory findings associated with TMF inspections.

Learning Objectives
• Explain regulatory expectations regarding TMF/eTMF management
• Identify two recent regulatory findings directed at TMF/eTMF management
• Describe strategies for preparing effective CAPAs that address regulatory findings
• Discuss plan for preparing for a regulatory inspection

Who Should Attend
• Good Clinical Practice Auditors and Quality Assurance Directors
• Trial Master File Directors, Managers, and Coordinators
• Clinical Operations Directors and Trial Managers
• Records Management Team Members

Instructor
Donna W. Dorozinsky, R.N., M.S.N., C.C.R.C.

Course Dates
January 31, 2020 (12-2:30)
April 3, 2020 (11-1:30)
July 17, 2020 (12-2:30)

FEE: $835* ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2.5 hours (0.25 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-19-018-L01-P. Released: 1/19.

Trial Master File (TMF) for Sponsors: Set-Up and Maintenance

Course Description
The Trial Master File (TMF) is a collection of the essential documents for a sponsor to demonstrate that they have fulfilled their obligations as sponsor for a clinical trial project as defined by the health authorities. This web seminar reviews the activities that a sponsor uses to set-up, maintain, and perform oversight of the TMF. It examines the changing regulatory landscape that defines sponsors responsibility in managing the TMF. This web seminar will also include handouts and discussion of the TMF Reference Model.

Learning Objectives
• Discuss the changing regulatory climate and apply this to the essential documentation practices of a sponsor of clinical trials
• Examine the required components of a TMF
• Recommend policy for the TMF
• Discuss maintenance and quality control of the TMF

Who Should Attend
• Project Managers
• Quality Assurance Personnel
• Policy Development and Maintenance Personnel
• Sponsor/CRO Personnel involved in the policy, set-up, maintenance, auditing of the TMF

Instructor
Donna W. Dorozinsky, R.N., M.S.N., C.C.R.C.

Course Dates
February 21, 2020 (11:30-1:30)
May 27, 2020 (12-2)

FEE: $835* ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-17-095-L01-P. Released: 9/17.

What Participants Say About Barnett Interactive Web Seminars:
"The information I learned in today's webinar will give me and my company an advantage with our client against other competing CROs."
Understanding Clinical Laboratory Regulatory Requirements

Course Description
This web seminar will provide a general overview of the regulatory requirements for clinical laboratories that perform routine safety testing of clinical samples for clinical trials. Routine safety testing generally includes hematology, chemistry, urine analysis, and coagulation. Most of the clinical safety testing laboratories in the U.S. are accredited by CAP/CLIA and/or JCAHO. This testing can be used for patient care as well as for collecting data for submission to the regulatory bodies in support of a clinical study. This web seminar provides training for clinical laboratory technicians/quality assurance staff on maintaining compliance.

Learning Objectives
• Describe the general regulatory requirements for a routine safety testing laboratory
• Identify why some laboratories follow CAP/CLIA and some follow JCAHO as well
• Define regulatory requirements specific to safety testing

Who Should Attend
• Laboratory Technicians/Technologists
• Laboratory Managers/Directors
• Laboratory Quality Professionals

Instructor
David Vanscoy, B.S.

Course Length
3 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.

Understanding the FDA/OHRP Joint Guidance on Minutes of IRB Meetings

Course Description
Institutions and institutional review boards (IRBs) are responsible for oversight of human subject research under HHS and FDA regulations. As part of meeting this responsibility, IRBs must prepare and maintain adequate documentation of IRB activities, including minutes of IRB meetings. Unfortunately, IRBs have routinely been cited in OHRP Determination Letters and FDA Warning Letters for failing to prepare and maintain adequate minutes. In this web seminar, we will discuss the FDA and OHRP Joint Guidance on Minutes of IRB Meetings recommendations and the responsibilities of institutions and IRBs in the preparation and maintenance of minutes of IRB meetings to ensure compliance with regulatory requirements.

Learning Objectives
• Discuss common noncompliance issues and top IRB findings from FDA BIMO inspections
• Describe the purpose of minutes and meeting minute content requirements
• Review expectations for documenting attendance, actions, vote, modifications and/or disapproval, and resolution of controverted issues

Who Should Attend
• Clinical Research Associates
• Project Managers
• Principal Investigators
• Clinical Research Coordinators
• Regulatory Affairs Professionals
• Institutional Officials
• Institutional Review Board Members and Administrators
• Academic Medical Center and Research Institution Professionals supporting clinical research
• Personnel responsible for ensuring compliance with GCP regulations

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
2 hours 12:30 – 2:30 p.m. Eastern

Course Dates
April 9, 2020

FEE: $835*
ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Use of Electronic Health Record Data in Clinical Investigations

Course Description
The FDA recognizes Electronic Health Records (EHRs) as data originators and in many cases, source documentation, which therefore subjects them to inspection. In its draft guidance for the Use of Electronic Health Record Data in Clinical Trials, the FDA expands upon prior guidance and provides its recommendations on the use of EHRs as source, and also outlines the responsibilities for ensuring quality and integrity of EHR data. As such, EHRs should be able to be obtained from multiple sources, they should be shareable, interoperable, and accessible to authorized parties. This web seminar will address recommendations for the use of EHRs as source data in clinical trials.

Learning Objectives
• Describe the responsibilities and processes for assessing the validity, reliability, and integrity of EHR source data
• Review the FDA’s intentions to assess the compliance of EHRs with 21 CFR 11
• Evaluate best practices for using EHRs in clinical research
• Describe interoperability in EHR use
• Discuss the impact on recommendations for research conducted outside the U.S.

Who Should Attend
• Clinical Research Associates
• Project Managers
• Principal Investigators
• Clinical Research Coordinators
• Regulatory Affairs Professionals
• Academic Medical Center and Research Institution Professionals supporting clinical research
• Personnel responsible for ensuring compliance with GCP regulations

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
2 hours 9:30 – 11:30 a.m. and 12:30 – 2:30 p.m. Eastern

Course Dates
March 17, 2020 (12:30-2:30)
June 9, 2020 (9:30-11:30)

Archived Recording Available in Multiple Formats!

FEE: $835* ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

- Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-20-054-L01-P. Released: 3/20.

Use of Notes to File in Clinical Trial Essential Documentation

Course Description
Notes to File (NTF), also known as Memo to File, are commonly used as essential documentation in sponsor and site files. Many times the content of the NTF does not serve the purpose for use or serves no purpose at all. This web seminar will discuss the appropriate and inappropriate uses of NTF, the questions to ask to determine if NTF would be beneficial, and the components of a quality NTF, if being used.

Learning Objectives
• Discuss the current overuse and misuse of NTF, including FDA Warning Letters noting deficiencies in interventions that include NTF
• Identify what is an appropriate NTF, patient and non-patient specific
• Compose an effective NTF, when applicable
• Describe reference industry tools relating to NTF

Who Should Attend
• Quality Assurance Personnel
• Clinical Research Associates
• Clinical Research Coordinators
• Investigators
• Clinical Research Associate Managers
• Project Managers

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
1.5 hours 8:30 – 10:00 a.m., 9:00 – 10:30 a.m. and 12:00 – 1:30 p.m. Eastern

Course Dates
January 13, 2020 (9-10:30)
April 8, 2020 (12-1:30)
July 10, 2020 (8:30-10)

Archived Recording Available in Multiple Formats!

FEE: $835* ACRP Members: Receive 10% off!

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

- Participants will receive 1.5 hours (0.15 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-17-096-L01-P. Released: 9/17.
Warning Letters: Applying Lessons Learned from Misbranding and Adulteration Noncompliance Findings

Course Description
In this web seminar, we will focus on common themes such as misbranding and adulteration found in warning letters issued by the FDA to pharmaceutical, medical device, and biotechnology companies. Specifically, we will review the concepts of misbranding and adulteration in detail, and provide examples of where compliance issues commonly arise in these areas. We will discuss best practices for responding to warning letters, as well as strategies that can be implemented to help avoid them. Whether you are new to the warning letter experience or you are working on issues in response to one, you will find this web seminar useful.

Learning Objectives
- Describe examples of misbranding that have been cited by the FDA
- Describe examples of adulteration that have been cited by the FDA
- Implement strategies to help avoid future actions by the FDA

Who Should Attend
- Regulatory Affairs Professionals
- Quality Assurance Personnel
- Research and Development Personnel
- Engineering Professionals
- Manufacturing Personnel
- Clinical Development Personnel

Instructor
Joy Frestedt, Ph.D., C.P.I., R.A.C., F.R.A.P.S.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Instructor
Joy Frestedt, Ph.D., C.P.I., R.A.C., F.R.A.P.S.

NEW! Working with Clinical Research Sites: Strategic Planning and Operations for Sponsors and CROs

Course Description
This web seminar will examine the concepts and applied techniques for cost estimation, budget development, risk management, quality assurance, strategic planning, and operations for clinical research conducted at academic centers vs. private clinics. Project management principles and methodology will be reviewed with a special focus on planning, controlling, and coordinating individual and group efforts in managing the life cycle of the clinical research project in different settings.

Learning Objectives
- Apply an in-depth understanding of infrastructure in clinical research and clinical operations in biopharmaceutical companies and clinical sites
- Develop skills for strategic planning of clinical trials
- Perform cost estimation for a project in different settings (private clinics vs. academic centers) and develop a schedule for completion of milestones
- Establish systems for quality control, risk management, and monitoring of clinical trials
- Identify resources needed to complete projects and reasons to outsource
- Utilize performance metrics to improve project success

Who Should Attend
- Clinical Operations Professionals involved in project planning and execution throughout life cycle of the clinical research project
- Medical Affairs Professionals
- Project Managers
- Clinical Research Associates, Clinical Research Coordinators involved in the planning, monitoring, and execution of clinical trials
- Grant Managers
- Principal Investigators
- Financial Planning and Billing Compliance Specialists
- Legal Professionals involved in contract negotiations with clinical sites

Instructor
Marina Malikova, Ph.D., MSci, M.A., C.C.R.A., RAC
Interactive Web Seminars

Writing and Maintaining the EU Clinical Trial Authorization

Course Description
The Regulatory Affairs department must prepare documents that inform European Regulatory Agencies about the proposed development plan; submit a Clinical Trial Authorization (CTA) to initiate human clinical trials; answer questions about on-going investigations; and construct and submit any updates to the CTA in a concise and informative manner. Regulatory submissions are more than just writing – they encompass strategy, research, writing, organizing and leading a team, compiling, editing, publishing, and tracking of the information. When initiating a global clinical trial program, many moving parts need to be brought into harmony to ensure compliance and that timelines are met. Attendees will walk away with tools to help plan, write, and manage multiple CTAs with all their differing requirements.

Learning Objectives
- Navigate Europe’s regulations, directives, and guidelines
- Describe the basic requirements of the CTA, the Investigational New Drug (IND) equivalent in the EU
- Identify the key documents that will be needed for the preparation of each country’s CTA
- Identify the documents required by each country to support the CTA
- Determine the timelines for review by Ministry of Health and Ethics Committees
- Determine what is needed to amend and maintain the CTA including safety and annual reports

Who Should Attend
- Regulatory Associates and Managers
- Quality Assurance Personnel
- Manufacturing Personnel
- Clinical Research Professionals
- Project Managers
- Pre-Clinical Personnel
- Other Members of the Drug Development Team who wish to know more about the global drug development and CTA submission process

Instructor
Caroline Ritchie, Ph.D., M.B.A.

Course Length and Time
3 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Writing and Updating the Investigator’s Brochure

Course Description
During the course of clinical research, the Investigator’s Brochure (IB) is the data repository for an investigational product; effectively this is the product’s “label” during the investigational stage. The IB is a dynamic document which changes as the information changes. It is critical in clinical research as physicians and Institutional Review Boards (IRBs) refer to the IB on an ongoing basis to answer questions about Serious Adverse Events, Adverse Events, dosing, manufacturing, and clinical and nonclinical study results. To facilitate the transfer of information, the IB must be concise, well-written, and provide a summary for a physician to quickly reference. ICH GCP E6 Guideline provides an outline of the requirements, how companies address these requirements and the degree of information provided differs. The required contents will be reviewed in this web seminar. Tips and techniques for effective writing, including pulling together the needed information, working with a team, and writing a summary will also be discussed.

Learning Objectives
- Identify who contributes to the IB
- Determine the timing of construction of the IB
- List IB requirements per the ICH GCP E6 Guideline and effectively implement these requirements
- Perform a research literature review for the background section, and re-use it in other documents
- Examine how a Target Product Profile or Draft Package Insert can be drafted based on the IB
- Examine approaches that support physician’s reading of the IB: The IB Summary
- Determine when the IB should be updated, by whom, and what documents the update effects

Who Should Attend
- Regulatory Affairs Professionals
- Medical Writers
- Clinical Research Professionals
- Research and Development Personnel

Instructor
Caroline Ritchie, Ph.D., M.B.A.

Course Length and Time
2 hours 1:00 – 3:00 p.m. Eastern

Course Dates
January 8, 2020 June 11, 2020

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 2 hours (0.2 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-18-053-L01-P. Released: 10/18.
Writing Clinical Study Protocols

Course Description
The basis and success of any drug or device development program is the clinical trial protocol. Clinical trials conducted under an IND or IDE cannot begin without a protocol, and yet there is variability between companies and individuals on how to approach writing this critical document. Clinical trials and entire programs have failed because the protocol was not scientifically sound. Knowing how to effectively research and write a clinical trial protocol is essential to a compound achieving IRB and market approval. Over the course of a development plan, new protocols, amendments, and concept sheets will be needed. Protocols for Phases 1, 2, 3 and 4 require different writing approaches and you must know what the agency expects at every development milestone to avoid the trial being put on clinical hold. Moreover, amendments, however unwelcome, are a necessary part of the development process.

Learning Objectives
• Describe the overall structure of a protocol and regulatory requirements
• Describe the requirements for a protocol, including:
  • Establishing the indication(s)
  • Understand the types of studies
  • Develop the protocol design (single blind, double blind, randomized, etc.)
  • Identify the hypothesis
  • Explain what safety and efficacy is and how you establish either or both
  • Determine inclusion/exclusion criteria
  • Determine the Schedule of Events
  • Determine adverse and serious adverse event reporting

Who Should Attend
• Medical Directors
• Medical Writers
• Clinical Research Associates
• Regulatory Affairs Professionals
• Research and Development Personnel

Instructor
Caroline Ritchie, Ph.D., M.B.A.

Course Length and Time
3 hours 12:00 – 3:00 p.m. Eastern

Course Dates
January 22, 2020
April 22, 2020

Archived Recording Available in Multiple Formats!

FEE: $835*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Archived Recording Available in Multiple Formats!

Writing Clinical Study Reports for Diagnostic Studies

Course Description
Diagnostic studies vary greatly from standard pharma and device studies, and the documents generated for these studies differ accordingly. This web seminar presents the basics tools required to generate Clinical Study Reports (CSRs) for sample collection, accuracy, and reproducibility studies. Participants will learn the elements of each of these CSRs, the guidances to follow for reference, basic skills for understanding the data (i.e., false positives, false negatives, and percent agreement), and other diagnostics output and results, as well as coordination with the 510(k) submission.

Learning Objectives
• Translate protocol and data into clear concise submission documents
• Describe the elements required for the CSR and how this differs from standard pharma CSRs
• Differentiate between the types of data and their interpretation
• Describe where the CSR fits into a 510(k) submission and some interdependencies

Who Should Attend
• Medical Directors
• Medical Writers
• Clinical Research Associates
• Clinical Scientists
• Research and Development Personnel
• Regulatory Affairs Professionals
• CRO Personnel
• Personnel planning a change from the pharma sector to the diagnostic sector

Instructor
Caroline Ritchie, Ph.D., M.B.A.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Archived Recording Available in Multiple Formats!

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive 3 hours (0.3 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-20-055-L01-P. Released: 1/20.
Writing Protocols for Diagnostic Studies

Course Description
Diagnostic studies vary greatly from standard pharma and device studies, and the documents generated for these studies differ accordingly. This web seminar presents the basic tools required to generate protocols for sample collection, accuracy, and reproducibility studies. Participants will learn the elements of each of these protocols, how they differ from the standard pharma protocols, the guidances to follow for reference, and the regulatory environment surrounding sample collection and informed consents for de-linked samples.

Learning Objectives
• Describe the sample collection process, de-linking, and sample handling
• Differentiate between the requirements of a traditional pharma protocol and a diagnostics protocol
• Identify the elements required for a sample collection protocol
• Identify the elements required for an accuracy study protocol
• Identify the elements required for a reproducibility study protocol
• Describe the regulatory documents required, and when they are required, including informed consent

Who Should Attend
• Medical Directors
• Medical Writers
• Clinical Research Associates
• Clinical Scientists
• Research and Development Personnel
• Regulatory Affairs Professionals
• CRO Personnel
• Personnel planning a change from the pharma sector to the diagnostic sector

Instructor
Caroline Ritchie, Ph.D., M.B.A.

Course Length
1.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

Writing Quality SOPs: Guidelines, Tools, and Templates for Easy SOP Creation

Course Description
Standard Operating Procedures (SOPs) are detailed written instructions that allow one to execute a process uniformly. Many SOPs are not well defined or well written, and actually fall short of providing the details needed for one to complete the process. In fact, many who are assigned the task of creating SOPs lack the basic understanding of what constitutes a well written SOP. Often SOPs appear to be no more than a brief Note to File, leaving gaps in the proper execution of the task delegated. Poorly written SOPs also leave organizations vulnerable in the event of an audit. In this web seminar, FDA Warning Letters will be reviewed to demonstrate the consequences of poorly written SOPs. This course offers guidance to those who recognize they need SOPs, or more detailed SOPs, but do not know how or where to start. Participants will be provided with guidelines and templates that ensure that new and updated SOPs are uniform and user-friendly.

Learning Objectives
• Describe the purpose of SOPs
• Identify the basic elements of well written SOPs
• Design an SOP from the templates provided
• Relate the SOP to other activities such as performance evaluations

Who Should Attend
• SOP Authors/Reviewers
• Research Site Administrators
• Clinical Monitors
• Study Coordinators
• Quality Assurance Auditors
• Project Managers

Instructor

Course Length
2.5 hours

Course Dates
This course is offered as on-site training only. Please contact Barnett at +1 215.413.2471 to inquire about holding this course at your location.

What Participants Say About Barnett Interactive Web Seminars:
“...This seminar provided me with a greater insight into identifying risks early, defining an action plan and maximizing time spent with my sites...”
Writing the Clinical Study Report

Course Description
The Clinical Study Report (CSR) is a critical document in the drug development and regulatory submission process. This web seminar presents the basic tools required to generate CSRs for the pharmaceutical industry. Participants will learn the elements of the CSR and the appendices, methods for turning the protocol and statistical outputs into one cohesive document, the basics of writing and preparing a document for submission, and the guidances to follow for reference.

Learning Objectives
• Translate protocol and data into clear concise submission documents
• Describe the elements required for the CSR and the appendices
• Differentiate the various types of statistical outputs and handling of the results
• Identify the phase of drug development differences and similarities
• Utilize style guides and templates

Who Should Attend
• Medical Directors
• Medical Writers
• Clinical Research Associates
• Clinical Scientists
• Research and Development Personnel
• Regulatory Affairs Professionals
• CRO Personnel

Instructor
Caroline Ritchie, Ph.D., M.B.A.

Course Length and Time
3 hours 12:00 – 3:00 p.m. Eastern

Course Dates
January 15, 2020
April 15, 2020
July 15, 2020

Archived Recording Available in Multiple Formats!

FEE: $735*  ACRP Members: Receive 10% off!
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 3 hours (0.3 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-20-056-L01-P. Released: 1/20.
Build Your Training Library with Barnett’s Web Seminar Archives

Take advantage of Barnett’s in-depth clinical research training at your convenience by accessing our wide selection of Web Seminar Archives. A Web Seminar Archive is an edited recording of a live Barnett Interactive Web Seminar offering, ranging from 60 - 180 minutes in length.

With more than 125 titles to choose from, Barnett’s Web Seminar Archive library is a great way to expand your company’s training library and resources. Whether you are a novice or experienced clinical research professional, a Barnett Web Seminar Archive is an opportune way to tap into the knowledge of industry experts and keep abreast of current trends in the field.

Barnett offers multiple courses for each of the following functional areas:

- Clinical Operations and Project Management
- Clinical Trial Monitoring
- Fundamentals of Clinical Research
- Good Clinical Practice
- Quality Systems
- Regulatory Affairs
- Risk-Based Monitoring
- Study Site Compliance

To access the complete list of Web Seminar Archives, visit barnettinternational.com

Single-User Licenses and Site Licenses are Available in Multiple Formats

Web Seminar Archives are available for both single-user licenses and site licenses. The single-user license is for individual usage only. Site licenses are ideal for group training at your facility and allow you to share this great educational tool with your full team. Web Seminar Archives are available in multiple formats to fit your needs — contact Barnett today to learn more.

Integrate Barnett’s Training Archives into your Learning Management System (LMS)! Build your internal training library with Barnett’s courseware. Contact nganatra@barnettinternational.com or call +1 215.413.2471 to discuss your approach.

The single-user license fee ranges from $625 - $945 and site license fee ranges from $1,625 - $1,945. SCORM files are quoted based on specific LMS requirements.

50% Alumni Discount

Barnett Alumni who purchase the recording of a web seminar they have attended in the past are eligible for a 50% alumni discount on non-SCORM files.

Watch Video Trailers

A complete listing of Web Seminar Archives and course video trailers are available at: barnettinternational.com

New titles are added to the Web Seminar Archives every month to further serve the constantly evolving training and educational needs of global clinical research professionals today. Be sure to check out our “just released” recordings of a live Barnett Interactive Web Seminar!

Two Easy Ways to Order:

Online: barnettinternational.com

Telephone: +1 781.972.5400 or toll-free in the U.S. 800.856.2556
Seminar Accreditation, Policies and Procedures

Important Notice
Barnett reserves the right to change the instructors and timing of our public seminars. Efforts will be made to notify participants in either event. We will not be responsible for any costs incurred, including airfare (or penalties) and hotel, as a result of a cancellation, instructor, or date and time change of any seminar. Barnett will not be responsible for costs incurred associated with errors or omissions in this catalog.

Seminar Policies

Seminar Cancellation Policy
Your notice of cancellation must be received in writing by mail, email, or fax to Barnett’s Customer Service Department prior to the start of the seminar. Note that Barnett does not refund your registration fee.

• Prior to 10 business days before the seminar: You will receive an Event Pass. This Event Pass may be applied toward a future Barnett seminar of equal value within twelve (12) months of issue date. The original Event Pass must be surrendered at the time you register for a future seminar. (This can be done by mail only. Original Barnett letterhead is required.) Event Passes are not transferable to any other type of program, such as conferences or product orders.

• Within 10 business days before seminar: No Event Pass will be issued.

Seminar Substitution Policy
If you are unable to attend a program, you may provide a substitute person (for the same program on the same date only). Your notice of substitution must be received in writing by mail or fax to Barnett’s Customer Service Department prior to the start of the seminar.

Force Majeure
The performance of this Agreement by either party is subject to Force Majeure, government authority, severe weather, disaster, strikes, civil disorders, or other emergencies, or causes beyond reasonable control of the parties hereto, any of which make it illegal or impossible to provide the facilities and/or services for your meeting. It is agreed that this Agreement may be terminated for any one or more of such reasons by written notice from one party to the other without liability.

Discounts (Excluding Web Seminars)
Team Discounts: We provide discounts for multiple enrollments from the same company in the same program. Registrations must be received at the same time.

• 10% discount for two participants
• 15% discount for three or more participants

Team Discounts CANNOT be combined with any other offer.

Accreditation
Program participants will receive continuing education units (CEUs) as indicated on each seminar description page for full participation (complete sign-in sheet, pre- and post-test, and evaluation form). Barnett must receive all completed documentation within 30 days of program completion or CEUs will not be issued. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Enrollment
Seminar registration is usually limited to 30 people due to the interactive nature of our programs. Please submit your registration form well in advance to secure a seat. Full payment must accompany registration form.

Meals and Breaks
A Networking Lunch will be served each day from 12:00 p.m. to 1:00 p.m. There will be a 15 minute morning break and a 15 minute afternoon break on each training day.

Special Requirements
If you have any special requirements, please contact Barnett at +1 781.972.5400 or toll-free in the U.S. at 800.856.2596

Hotel Information
Barnett’s seminar venues are located in centrally located hotels or state-of-the-art corporate meeting centers. To make hotel reservations, contact the hotel directly to book your room and reference the “Barnett Corporate” rate or “best available” rate. Where available the discounted rate is based upon availability, and hotel reservations must be made 31 days before program start date. These rates are available to individual seminar participants and may not be available through travel agency bookings. Availability is on a first-come, first-served basis and may fill prior to cut-off.

Boston, MA
Convene at One Boston
(note: meeting facility only; not a hotel)
201 Washington Street, 2nd Floor
Boston, MA 02108
Tel: +1 888-730-7307

Metro Meeting Centers – Boston
(note: meeting facility only; not a hotel)
101 Federal Street, 4th Floor
Boston, MA 02110
Tel: +1 617-737-1200

Club Quarters Boston
161 Devonshire Street (Between Milk & Franklin Streets)
Boston, MA 02110
Tel: +1 617-357-6400

The Langham Boston
250 Franklin Street
Boston, MA 02110
Tel: +1 617-451-1900

Hilton Boston Downtown Financial District
89 Broad Street
Boston, MA 02110
Tel: +1 617-556-0006

Hyatt Regency Boston
One Avenue de Lafayette
Boston, MA 02111
Tel: +1 617-912-1234

Philadelphia, PA
Convene – CityView
(note: meeting facility only; not a hotel)
30 South 17th Street
Duane Morris Plaza
13th & 14th Floor
Philadelphia, PA 19103
Tel: +1 215-561-8090

Convene – Commerce Square
(note: meeting facility only; not a hotel)
Two Commerce Square, Suite 210
Philadelphia, PA 19103
Tel: +1 215-561-8090

Convene Cira Centre
(note: meeting facility only; not a hotel)
2929 Arch Street
Mezzanine Level
Philadelphia, PA 19104
Tel: +1 888-730-7307

Sonesta Hotel Philadelphia
1800 Market Street
Philadelphia, PA 19103
Tel: +1 215-561-7500

The Westin Philadelphia
99 South 17th Street at Liberty Place
Philadelphia, PA 19103
Tel: +1 215-563-1600

The Latham Hotel
mention Convene and Barnett for a discounted rate
135 South 17th Street
Philadelphia, PA 19103
Tel: +1 215-563-7474

SOFITEL Philadelphia
120 South 17th Street
Philadelphia, PA 19103
Tel: +1 215-569-8300

AKA University City
2929 Walnut Street
Philadelphia, PA 19104
Tel: +1 215-372-9000

Homewood Suites
4109 Walnut Street
Philadelphia, PA 19104
Tel: +1 215-382-1111

San Diego, CA
San Diego Solamar
435 6th Avenue
San Diego, CA 92101
Tel: +1 619-819-9500

1 For Boston meetings being held at Convene at One Boston, attendees are encouraged to make hotel arrangements at Club Quarters, The Langham, or Hilton Boston Downtown/Financial District.

2 and “Club Quarters has loaded Barnett Educational Services in their member database. You can book online at www.clubquarters.com, using the password: Barnett (not case sensitive) or with Member Services at +1 203-905-2100. Be sure to mention Barnett.

For Philadelphia meetings being held at Convene CityView and Commerce Square attendees are encouraged to make hotel arrangements at one of the following hotels: The Westin Philadelphia, Club Quarters**, The Radisson Plaza-Warwick Hotel, The Latham Hotel or the Sonesta Hotel Philadelphia. All are conveniently located (near Philadelphia’s Rittenhouse Square) and are 1-2 short city blocks (walking distance) of Convene.

For Philadelphia meetings being held at Convene Cira Centre attendees are encouraged to make hotel arrangements at one of the following hotels: AKA University City or Homewood Suites and are 1-2 short city blocks (walking distance) of Convene.

15% discount for three or more participants
10% discount for two participants
Instructor Biographies

Nikki Christison, B.S., C.C.R.A., T.I.A.C.R., has worked extensively with both sponsors and CROs as a Study Coordinator, CRA, Project Manager, Auditor, and Director of Clinical Operations over the past 18 years, and has published articles in both The Monitor and The Journal of Clinical Research Best Practices on Risk Based Monitoring, Operational Advisory Boards, Study Feasibility, and CRO Relationship Management. Nikki has conducted hundreds of study visits and developed and facilitated training in multiple international venues. Nikki is an experienced speaker and has presented and conducted workshops at Association of Clinical Research Professionals (ACRP) Global Conferences, MAGI, Cambridge Healthtech Institute, iBIG, and Outsourcing Clinical Trials (OCT), and teaches seminars for Barnett International and ACRP.

Natalie Currie, B.Sc., is an instructional designer, facilitator, and learning and development consultant dedicated to academic research organizations, the pharmaceutical and biotechnology industries, and clinical research organizations. Harnessing her 18 years of broad-based clinical research experience, Natalie is sought after as a speaker and facilitator in the United States and Canada. Natalie’s breadth of roles has spanned from Clinical Research Coordinator, Clinical Research Associate, Clinical Research Project Manager, and management roles in Government and Health Economics. She worked at the Addiction Research Foundation (now the Centre for Addiction and Mental Health [CAMH]) and Janssen-Ortho Inc. (a division of Johnson & Johnson), participated on international project teams for pivotal Phase III studies, and led Canadian Phase IIIb-IV studies. Natalie holds an honors life science degree from the University of Toronto and is a member of the Society of Clinical Research Associates (SoCRA), the American and Canadian Societies of Training and Development (ASTD & CSTD), Toastmasters International, and is on the organizing committee for the World Creativity and Innovation Week in Toronto. Natalie designs and facilitates engaging, customized corporate and public workshops in the areas of clinical research study management, good clinical practice, and communications, all with visual thinking in mind.

Anil D’Mello, Ph.D., is a Professor of Pharmaceutical Sciences at the Philadelphia College of Pharmacy at the University of the Sciences in Philadelphia. He has over 18 years of experience in teaching Pharmacokinetics to Pharm.D. and Ph.D. students. Anil is the recipient of the Lindback Award for Distinguished Teaching and is listed in Who’s Who Among America’s Teachers. He has conducted Biopharmaceutics and Pharmacokinetics training courses at different pharmaceutical companies including Merck, Boehringer-Ingelheim, and Cephalon. His research examines the role of the maternal nutritional environment during pregnancy and lactation on the development of physiological systems in the offspring. He has numerous publications in peer reviewed journals in the area of pharmacokinetics, drug metabolism, and endocrinology. Anil is a member of the steering committee of the Delaware Valley Drug Metabolism Discussion Group.

Kelli J. Deiaco, Ph.D., is a licensed psychologist who brings over 20 years of experience working in behavioral health and higher education. She received a Ph.D. from Temple University’s APA accredited Counseling Psychology program where her research focused on coping and self-concept in women and trauma and narrative therapy. She completed a pre-doctoral internship in Rehabilitation Psychology and a post-doctoral residency in Health Psychology with a focus on Cognitive-Behavioral Interventions. Dr. Deiaco earned a master’s degree from Columbia University in Developmental Psychology. Most recently she completed specialized training from the Search Inside Yourself Leadership Institute in Mindfulness-Based Emotional Intelligence. She currently teaches for DeSales University and develops and implements customized seminars in the areas of mindful leadership and workplace wellness.

Holly J. Deiaco-Smith, M.S.Ed., brings over seventeen years of management consulting experience to her clients, helping them change to be more successful. Holly’s tenure in Big 4 consulting, including Accenture and IBM Global Services, grounded her with a foundation of best methodologies, leading practices, and outstanding client experience. It was these experiences that inspired and compelled her to found a management consulting organization serving the agriculture, education, financial services, pharmaceutical, and retail industries. Holly’s experience includes strategic planning, process improvement, benchmarking for leading practices, organizational improvement, learning design and development, and change management. Given the critical need today for organizations to develop a talented workforce, Holly has helped her clients define and improve their learning strategies. Holly’s unique collaborative approach of truly partnering with her clients and her strong focus on change management enable her to provide excellent service and results.

Sharon Donatucci is an experienced drug safety professional. In addition to the training she does with Barnett, she also serves as a consultant for Pharmacovigilance activities. Previously, Ms. Donatucci served as the Chief Pharmacovigilance Science Officer for Ashfield Pharmacovigilance (formerly Drug Safety Alliance). She also held the position of Vice President of PV Operations at Ashfield. In that role, she was responsible for overseeing APV’s case management function and ensuring that resources were properly allocated for optimal operating capacity and effective, efficient delivery of services. An employee of Drug Safety Alliance since its inception in 2000, Ms. Donatucci previously served as Senior Director of Training and Quality Control, overseeing the quality aspects of case processing in order to identify training needs and ensure client satisfaction. She also managed all aspects of DSA’s employee development training program, facilitating classes for new hires and audit compliance courses for all employees and developed the company’s Drug Safety Case Manager Certification Program. Prior to her training role, she served as a Drug Safety Associate and Project Manager for DSA.

Donna W. Dorozinsky, R.N., M.S.N., C.C.R.C., has over 25 years of experience in study operations that includes clinical operations, safety, data management, biostatistics, clinical supply management, and TMF management. She spent 15 years at SmithKline Beecham in early development and in 2005 founded DWD & Associates, Inc., which has most recently become Just in Time GCP. She has led the implementation of eSource and electronic Trial Master File solutions, and has expertise in clinical validation of these systems. She recently served as chair of the revisions to Zone 4 of the TMF Reference Model. Donna has presented numerous training programs in topics of GCP compliance, Quality Management Systems, and TMF Management and is a dynamic educator.
Daniel J. Filoramo, R.N., B.S., is a successful pharmaceutical professional with over 18 years of diversified clinical research experience. Daniel’s experience encompasses multiple roles in all phases of drug development and marketing. He has been employed with a large pharmaceutical company for the past 10 years as a Sr. Clinical Scientist in the department of Early Clinical Translational Research. In this capacity, he has had the opportunity to author protocols and clinical study reports, and monitor and manage operations for Phase I and Pharmacology studies. Daniel is also responsible for the overall operational management of early assets. With his strong clinical research background, he is instrumental with process improvement activities, authoring of Standard Operating Procedures, and providing training on various clinical research topics. In addition, Daniel’s experience spans across multiple therapeutic areas such as Anti-Infectives, Cardiovascular, Immunology, Metabolic, and the Neurosciences.

Joy Frestedt, Ph.D., C.P.I., R.A.C., F.R.A.P.S., has over 30 years of experience, and provides clinical, regulatory, and quality affairs consulting services to the pharmaceutical, medical device, and food industries. She recently served as interim Regulatory Director at the University of Minnesota Academic Health Center and as a member of the Allina IRB. She previously held key positions at Ortho Biotech, Medtronic, Mayo Clinical Trial Services, AstraZeneca, and Orphan Medical. She holds a B.A. from Knox College and a Ph.D. in pathobiology from the University of Minnesota Medical School. Dr. Frestedt is a member of American Society of Clinical Oncology (ASCO), American Association of Pharmaceutical Scientists (AAPS), Association of Clinical Research Professionals (ACRP), and Society of Clinical Research Associates (SoCRA), and is a Fellow of Regulatory Affairs Professionals Society (RAPS). Dr. Frestedt was honored in 2011 as one of the “100 Most Inspiring People in the Life Sciences Industry” by PharmaVOICE and one of the top 25 “Industry Leaders,” a “Women in Business Award” by the Minneapolis/St. Paul Business Journal.

Karen L. Gilbert, B.S., C.C.R.A., has worked in the clinical research industry since 1994 monitoring pharmaceutical and medical device trials, managing an investigational site, and serving as a global study manager. Her experience also includes two years serving as Clinical Trainer & Curriculum Manager with Barnett Educational Services. Karen’s training courses and presentations have been delivered internationally to industry clients and at global professional conferences. She has co-authored two articles published in the clinical research industry journal, Clinical Researcher (formerly The Monitor). Ms. Gilbert received her certification as a Certified Clinical Research Associate (CCRA) through the Association of Clinical Research Professionals (ACRP) in 2005 and remains active in this organization.

Celeste M. Gonzalez, ROAP-GCP, C.C.R.P., is a Clinical quality assurance expert with broad experience in the interpretation and application of US and foreign regulations, guidances, directives, and guidelines as applied to the conduct of pharmaceutical, medical device, and animal health clinical trials. She is well-experienced in the development of Clinical Quality Systems and has been responsible for the leadership of high performing quality and compliance teams. Some specific accomplishments include the completion of over 300 clinical investigator site audits of Phase I, II, III, IV, IDE and 510k studies, she completed over 75 vendor audits including contract research organizations (CROs), and she has developed quality systems for and brought contract research organizations (and related studies) into full GCP compliance within a 9-month period. In addition to numerous industry presentations and publications, Celeste is also a member of the ISO 14155: 2011 subcommittee on ICH E6 (R2) harmonization.

Glenda Guest, ROAP-GCP, C.C.R.A., specializes in medical device monitoring and project management, auditing and training on U.S.-regulated research, Quality Systems and Good Clinical Practices in clinical research settings. With her extensive background in a clinical CRO environment, she has developed a unique perspective, not only of the regulatory requirements for product development and market approval, but also the insights from collaboration with multiple sponsor companies’ varying approaches in meeting those requirements. Ms. Guest has had the opportunity to work with large and small manufacturers in both the premarket approval and 510(k) realms. She is an active member of the MedTech Association, as well as the Association of Clinical Research Professionals (ACRP), Model Agreements & Guidelines International (MAGI), and the Society of Quality Assurance (SQA). She has been an ACRP Certified Clinical Research Associate status since April of 2002 and an SQA Registered Quality Assurance Professional – Good Clinical Practices since April 2007.

Beth D. Harper, B.S., M.B.A., has extensive clinical research consulting experience, focused on the delivery of timely and predictable clinical trials, and enrollment and site performance management. Previously, Beth was President of Clinical Performance Partners, Inc., a clinical research consulting firm specializing in enrollment and site performance management. In addition to her 25+ years of clinical research experience, she is an Adjunct Assistant Professor at the George Washington University, and has published and presented extensively in the areas of study feasibility, site selection, patient recruitment, and protocol optimization. Beth received her B.S. in Occupational Therapy from the University of Wisconsin, and an M.B.A. from the University of Texas.

Debbie Harper, B.Sc., P.M.P., is a highly skilled Consultant and Trainer with broad and extensive knowledge (>20 years) of the global clinical research industry, covering all phases of drug development, in multiple therapeutic areas. She has a wealth of expertise in the development and execution of operational strategy, including serving as a VP of Operations for a large CRO. Ms. Harper has demonstrated abilities in leadership excellence, training design and delivery, early clinical development, process improvement and strategic initiatives. She is Project Management certified through PMI and possesses significant experience developing and delivering gold standard customized project management and clinical research related training courses for project leads and clinical operations.

Marla Hoelle, R.N., B.S.N., C.C.R.A.-PM, P.M.P., is a Clinical Training Manager for Barnett International. She has over 20 years of experience in clinical research. Marla began her career in clinical research as a study coordinator for an academic medical center, followed by working in a private physician group conducting clinical research. She continued her career path in clinical research working as a CRA and Project Manager. She has served as a clinical project manager for pharmaceutical and medical device trials managing all operational aspects of clinical trial activities from study start-up to FDA submission. In the projects she has managed, she has led a team of research professionals including CRAs, biostatisticians, data managers, regulatory, medical writers, safety, and vendors. She has a passion for the development and mentoring of study coordinators, CRAs, clinical project managers. Marla brings her experience and lessons learned from the various clinical trial projects.
she has managed to the trainings she delivers. Areas of therapeutic experience include: Cardiovascular, Infectious Diseases, Oncology, Orthopaedics, and Women's Health.

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P., Ms. Holwell specializes in maximizing excellence in GCP quality, compliance and training for both sites and industry. She works with domestic and international clients to provide training and mentoring in the clinical research process, specializing in ICH-GCP compliance and quality oversight. She prepares clients for inspections/audits as well as helps them write effective CAPAs and SOPs, develop quality plans and create internal QA processes. She began her career as a clinical research coordinator in academia over 35 years ago. She has held positions as a clinical research associate, site selection specialist, study manager with oversight of vendor CRAs, clinical operations quality management and trainer for several pharmaceutical companies. She is a fellow and dual-certified by the ACRP. Ms. Holwell has been an active member of the Association of Clinical Research Professionals (ACRP) since 1992, having served on the board of trustees, North American Council and various forums. She is a founding member, past president and presently an active board member of the New York Metropolitan Chapter of ACRP.

Treena Jackson, M.S., C.Q.A., R.A.C., C.S.S.G.B., is a consultant providing global quality auditing, regulatory, process improvement, and training services with a focus on GCP and GLP. She is also currently the GCP expert on staff at a major CRO, and teaches as an adjunct professor at Campbell University in the Clinical Research Program. At Campbell University, Treena has taught in the undergraduate and graduate degree programs for Clinical Research. She has been in the pharmaceutical industry for over 14 years working for a major pharmaceutical company, a small biotech, and a CRO prior to working as a consultant. She has also travelled to over 10 different countries for audits, including vendor audits, for-cause audits, process improvements, and routine site audits. Treena has her MS degree in Regulatory Affairs and Quality Assurance from Temple University and a BS degree in Laboratory Animal Science. She has been teaching and training on a College and University level since 2004 and has also spoken at several programs for American Society of Quality (ASQ) as well as other organizations. Treena is also very active on the board of directors for NC Society of Quality Assurance.

Victoria Johnson, M.B.A., C.P.C., is a healthcare leader with more than 15 years of clinical research billing and revenue cycle experience in both academic and corporate settings. Ms. Johnson’s specific experience in the financial management of clinical research, project management, revenue cycle management and technical/professional coding includes roles at the University of Texas MD Anderson Cancer Center as well as at a number of healthcare systems and specialty practice settings. She has developed compliant research billing programs and throughout her career, she has demonstrated a strong ability to improve processes and create efficiencies within cross functional teams while reducing costs, improving profitability, and maintaining compliance with applicable regulations. She is a certified professional coder with the American Academy of Professional Coders (AAPC) and also holds certifications in Claims and Insurance Follow Up with the Epic Certification group.

Tamar Kagan, M.Ed., PCC, partners with leaders and teams committed to growing their leadership capacity and impact. She has extensive experience with clients from the private, non-profit, and public sectors, and has worked with clients from a variety of industries including healthcare, education, finance, communications, marketing/sales, and media. Tamar is warm and inclusive with a talent for balancing practical outcomes for people and the environments in which they work and live. Tamar holds the International Coach Federation’s Professional Certified Coach designation. She is an Adler Certified Professional Coach, and also completed the Organization and Relationship Systems (ORSC) coaching program. Tamar completed her Master of Education in adult education with a focus on workplace, learning and change from the Ontario Institute for Studies in Education at U of T, and has a certificate in applied mindfulness meditation from the University of Toronto School of Continuing Studies. Finally, Tamar is a certified practitioner of the Leadership Circle Profile and the EQ-i 2.0 assessment.

Vanessa Laroche, B.S., C.I.P., CQA, C.C.R.P., is a clinical research professional with 19 years of experience specializing in the management and regulatory oversight of domestic and international clinical trials in multiple therapeutic areas. Ms. Laroche has advanced knowledge of federal regulations, ICH GxP guidelines and ethical codes governing the protection of human subjects in research. She has extensive experience in conducting site visits (qualification, initiation, interim monitoring, closeout), conducting QA audits (for-cause, routine, first party system, second party vendor), and evaluating quality management systems. Throughout her career, Ms. Laroche has served in many roles, including: Clinical Research Coordinator; Clinical Research Associate; Clinical Program & Operations Manager of a high-volume research unit, managing over 70 Phase II-IV drug and medical device clinical trials; Compliance Officer for the IRB oncology board at a prestigious academic medical center; and QA Auditor at a large CRO and mid-size biotech company.

Susan M. Leister, M.B.A., Ph.D., CQA, CSSBB, has over 19 years of experience covering the pharmaceutical, medical device, and clinical arena, including extensive working knowledge of GCP, cGMP, GLP, ICH E6 GCP, HSP, and 45CFR46. She has managed various inspections including: ISO, CE Mark, Health Canada, EMA, DEA, Maryland Board of Pharmacy, and FDA. Dr. Leister provides QM oversight to multiple government and commercial clients. She currently oversees a QA auditing team comprised of 13 FTEs who verify monitoring performance and internal audits with a global reach, conduct quality trend analysis including analysis of reports and associated data, and provides recommendations and quality consultant services. She is experienced in managing NIH drug repository and stability lab for domestic and international clinical trials and is skilled in developing plans for resolutions to deviations and CAPAs, analyzing QA/QC results, and recommending process improvements with 6Σ. In the past five years, Dr. Leister has overseen more than 500 quality audits with a 100% on-time delivery metric for audit reports and has managed review of ~approximately 175 clinical quality management plans for clinical research sites with a 100% on-time delivery.

Marina Malkova, Ph.D., MSc, M.A., C.C.R.A., RAC, has over 14 years of experience in the clinical research field. She has managed Phase I-IV studies involving investigational drugs, devices and biologics. She has worked on industry-sponsored and investigator-initiated trials in the fields of Surgery, Cancer Diagnostics and Interventional Radiology. In her current role, Dr. Malkova is responsible for clinical trials and basic biomedical research operations, quality assurance, risk management, safety monitoring, strategic planning, and macro-management of research programs at a large academic medical center. Dr. Malkova also has numerous years of teaching experience in both industry and academic programs.
Instructor Biographies

Angie Maurer, R.N., B.S.N., M.B.A., C.C.R.A., has spent over 20 years in healthcare and 16 years in the drug development and medical device industries spanning biopharmaceutical, diagnostic, medical device, and CRO organizations. Currently, Angie is a co-founder and CEO of an innovative clinical trial software solutions company that addresses clinical trial challenges. Angie has spent the last 11 years as a global Clinical Research consultant working with various companies from small start-ups to large companies providing expertise in Quality Risk Management (program and software development), process development and improvement, drug/device development programs, clinical trial management, and QA clinical audits. Angie has a clinical and business background holding a Bachelor’s in Science Nursing, Masters in Business Administration, a certificate in Lean Six Sigma, and a CCRA certificate through ACRP. She is also a speaker at various clinical research conferences across the United States and is on the editorial board for Clinicalleader.com. Angie enhances her expertise through continuing education as an active member of Association of Clinical Research Professionals (ACRP) and Watermark (a senior executive’s women’s organization).

Anne McDonough, M.P.H., C.C.R.A., M.I.C.R., C.Sci., has over 16 years of experience in a variety of roles in clinical research. Ms. McDonough started her career working in investigational sites for HIV trials, spent over 10 years working in the American and European divisions of an international CRO, and is currently a freelance clinical research consultant based in London providing monitoring, project management, clinical science, medical writing, and training services. She has broad international experience in a full range of clinical trials (Phases I to IV, pharmaceuticals, biotechnology products, diagnostics, devices, and vaccines) and in a variety of therapeutic areas. She also currently serves on the exam committee for the CCRA exam (Association of Clinical Research Professionals) and is past chair of the European exam committee.

Mary Mills, R.N., C.C.R.A., has over 25 years of experience in the pharmaceutical industry. Prior to beginning her “official” career in research, she gained extensive experience as an R.N., in the intensive care units at The Regional Medical Center in Memphis, a teaching hospital, where research was widely conducted. Since 1987, Mary has worked with biotech and pharmaceutical companies as a nursing consultant and educator. She has extensive experience as a Clinical Project Manager, Clinical Research Coordinator and Study Coordinator in a variety of clinical trial settings covering a wide-range of clinical therapies. In recent years, she has been involved as a Project Manager for one of the largest international risk-based clinical trials. Mary also works with federally funded trials where a risk-based approach to monitoring is practiced and is currently working on an International RBM Workgroup. Mary maintains her nursing licensure and has dedicated many hours as a nurse consultant, educator and preceptor for numerous clinical specialties. She is an active member of DIA (Drug Information Association) and ACRP (Association of Clinical Research Professionals) and spends many hours annually participating in continuing education activities in the areas of clinical trials and nursing. Mary is an industry expert on risk-based approaches/risk-based monitoring whereby she is a sought-after speaker at industry conferences on these topics. Additionally, Mary has presented at the FDA-CTTI QbD meetings as a member of the Boehringer-Ingelheim team presenting their risk-based approaches to clinical trials.

Kirsten Morasco brings over seventeen years of life sciences industry experience to her clients. She began her career in the pharmaceutical industry where she led teams that brought new products to market, managed global projects, and implemented training for new and existing employees. As a consultant, she has assisted her clients with change, process improvement, and meeting compliance standards and requirements. She is skilled in managing global process improvement/ harmonization engagements dedicated to developing and implementing management solutions that enhance the speed and efficiency of clients’ processes and enable the implementation of these processes among employees. In particular, Ms. Morasco has developed document management processes for companies implementing a document management system in a compliance environment; developed managed, and implemented controlled documents, including Standard Operating Procedures (SOPs) and Business Practices to ensure compliance with federal and state regulations; developed and delivered instructor-led training for pharmaceutical staff with regards to clinical trial procedures and monitoring; developed and conducted instructor-led Standard Operating Procedures training for pharmaceutical staff; developed educational materials and seminars for the marketing department and administrative staff of a pharmaceutical company; and worked with instructional designers to ensure development and delivery of instructor-led SOP training for a large pharmaceutical company.

Jeanne Morris, B.S., MT (ASCP), is an ASQ Certified Manager of Quality/Organizational Excellence. Ms. Morris provides GMP, GCP, GVP, and OMS expertise to the pharmaceutical and medical device industries. She has over 20 years of experience in regulated industry, including 15 years with the United States Food and Drug Administration. Her expertise includes risk assessment and mitigation, regulatory readiness support and mock inspections, process improvement project management, and procedure review and training. Prior to consulting, Ms. Morris held varied leadership positions at Takeda Global Research and Development, Inc., most recently as Director GxP Compliance, where she ensured drug development activities were conducted in compliance with regulations, guidance, and standards. While working for the FDA, Ms. Morris conducted over 300 inspections in the United States and internationally. She was a member of FDA’s national training cadre, and recipient of the prestigious FDA Commissioner’s Award of Merit.

Elizabeth Ronk Nelson, M.P.H., has over 20 years of experience in medical and clinical research. During her career, she has managed clinical trial site operations as a clinical research program coordinator and researcher, and has served as an IRB Quality Assurance Specialist and a Senior (GCP) Auditor, Trainer, and Compliance Director. Her professional areas of specialization include fraud detection and prevention; mock FDA audits; customized, audit finding-specific, risk-based training; independent GCP quality systems and compliance audits; SOP and training program development and gap analysis; corrective and preventive action (CAPA) and quality systems improvement plans for GCP; customized skill-based training for clinical research professionals; clinical investigator site and IRB development and quality improvement (QI) plans; vendor audits assessments; and site selection qualification assessments. Ms. Nelson has extensive experience in investigating and pursuing suspect clinical data cases and has worked professionally with industry and government representatives to pursue legal actions for severe noncompliance cases.
Denise G. Redkar-Brown, MT, began her career as a Medical Technologist working in a hospital laboratory environment. She made the transition to the pharmaceutical industry, and after more than 20 years she has held positions in basic and clinical research. She is published in the European Journal of Pharmacology for her work in pharmacology while at AstraZeneca, and was published in the Good Clinical Practices Journal in 2008. Denise has contributed to the successful submissions for Accolate® (the first leukotriene antagonist for asthma therapy) and Seroquel® (Serotonin receptor compound for treatment of Schizophrenia and bi-polar disorder). Denise also worked at Dupont Pharma (Immunology), Knoll (Humira®), Sanofi (vaccines), and as Associate Director of Scientific Affairs, Data Management for Cetero Research, and is serving as a member of the Board of Trustees for the Society of Clinical Data Management (SCDM).

Caroline Ritchie, Ph.D., M.B.A., is a regulatory medical writer and scientific publication professional with experience in both the pharmaceutical and medical device industries. She has led major regulatory submissions in the fields of oncology, autoimmune disorders, and rare genetic diseases. After working for several companies, including Covidien, Medtronic, and Ariad Pharmaceuticals, Caroline started her own scientific consulting and medical writing business. Caroline is passionate about contributing to the development of life-saving therapeutics and enjoys mentoring scientists and medical writers.

Robert Romanchuk, B.S.H.S., CIP, C.C.R.C., C.C.R.C.P., is a seasoned clinical research professional with experience in both research operations and human subjects protections. Currently serving as a vice-chair for a prominent independent IRB, his IRB experience includes management of a local IRB in a community hospital, site visits for independent IRBs, and membership on three local IRBs at different periods during his career. He is familiar with the conduct of research due to a 15-year tenure at a large community hospital system with 13 hospitals and 450 physician practices in a multistate footprint. During that time he oversaw and led the growth of research from a single site within this organization to a fully functional, centralized research operation serving the entire system with central contract negotiation, uniform clinical trial billing practices, CTMS and EMR. He is a frequent speaker at national and international venues and is passionate about human subjects protections.

Lily Romero, P.A., C.C.R.C., has over 30 years of experience in clinical research. Her experience includes positions as Director of Global Development Training at Elan Pharmaceuticals, an Associate Director of Clinical Operations at Quintiles, Inc., a Clinical Research Coordinator and Research Administrator at the Allergy & Asthma Medical Group and Research Center, and a P.C. in San Diego, CA. She has worked on Phase I-IV clinical trials including pediatric studies. She was an instructor for and assisted in the development of an investigator GCP training workshop for the American Academy of Pharmaceutical Physicians. She is on the Advisory Board and an instructor for the Clinical Trials Design and Management certificate program at the University of California at San Diego (UCSD) Extension. Currently, she is a member of the Academy Board for the Associates of Clinical Research Professionals (ACRP).

Michelle Rothstein, PCC, CPCC, is a leadership and communications coach and has coached with leaders and teams from across North America and the UK. She has worked with both private sector and not-for-profit executives and their employees to help them gain greater alignment with both personal and team goals. Michelle is a faculty member of Studio Y, a fellowship program for young innovators at the MaRS Discovery District in Toronto. She also holds the designation of Professional Certified Coach from the ICF, is a certified Professional Co-Active Coach, and is a certified practitioner of the Leadership Circle Assessment Tool. Michelle has also completed training with Organization and Relationship Systems Coaching (ORSC) and Group Coaching with Jennifer Britton of Potentials Realized. Michelle’s authentic, bold, and humorous approach both challenges and champions clients to advance their performance and enhance their fulfillment. Working with Michelle, clients quickly experience her infectious energy and ability to deliver the compassionate kicks forward that have made her a powerful coach and trusted confidant. She connects deeply with clients to create a safe space that is ripe for creativity and authentic engagement to develop and execute a resonant and sustainable action plan.

John Serio, J.D., represents pharmaceutical, biotechnology, nutraceutical, and medical device companies, particularly as to patent prosecution, licensing, and litigation matters. Mr. Serio also has extensive expertise in food and drug law involving pharmaceuticals and medical devices. He advises companies on a wide variety of regulatory issues, including the national and international conduct of clinical studies, manufacturing, the preparation and filing of regulatory documents, compliance with FDA regulations, and FDA enforcement matters. Mr. Serio is a recognized expert on direct to consumer advertising of pharmaceuticals. As a licensed pharmacist and a registered patent attorney, Mr. Serio has a multilateral understanding of complex scientific principles and drug development within the pharmaceutical industry. He is an accredited speaker with the American College of Pharmaceutical Education and regularly speaks and writes on pharmaceutical issues. Mr. Serio received his undergraduate degree at the University of Rhode Island College of Pharmacy, and his law degree from Western New England School of Law. His recent publications include State-by-State Clinical Trial Requirements Reference Guide, Barnett International, 2019; “Pharma and Social Media: The Leaders and Followers,” A FirstWord Market Intelligence Report (August 2009); and “Connecting with Patients, Overcoming Uncertainty,” Regulatory Issues in Social Media for Pharmaceutical Marketers (2008).

Stella Stergiopoulos, M.S., M.P.H., manages multi-sponsored and grant funded research projects at Tufts CSDD. She has experience conducting research on pharmaceutical industry practices and trends affecting pharmacovigilance, non-clinical drug development, pharmaceutical outsourcing practices, cycle time metrics, resource management, and protocol design. She has also been a speaker at conferences and has published articles in peer-reviewed and trade journals. Prior to joining Tufts CSDD, Ms. Stergiopoulos was a research associate at The Brattle Group and a researcher at Massachusetts General Hospital. She holds a BA from Brandeis University, and an MS and MPH from Tufts University.

Vaska Tone is an internationally respected professional in clinical research and quality assurance (QA) with wide ranging experience in varying GxP auditing, training, standard operating procedures (SOPs), and corrective and preventive actions (CAPA) consultancy gained through increasing positions of responsibility in the pharmaceutical and CRO industries. She has 25 years of experience in clinical development for the pharmaceutical, biotechnology, and device industries, including extensive experience in GCP quality assurance including support for pharmacovigilance. She has directly managed staff and quality deliverables ensuring oversight and effective communications of audit findings to allow for appropriate CAPA and any necessary SOP
Susan Torchio, R.N., B.S.N., has over 20 years of clinical research experience. For the past 10 years she has been an instructor for Barnett International’s CRA and CRC course. Sue started her career in clinical research as a study coordinator at a busy family practice site that participated in multiple studies in a wide range of therapeutic areas including cardiology, infectious disease, and gastrointestinal. After two years as a coordinator, Sue joined a large CRO as a Clinical Research Associate, conducting a variety of late phase clinical programs. She has been at two other CROs in her career as a Project Manager working in infectious disease, trauma, endocrinology, and cardiology. She joined a BioPharma company in 1998 as a consultant and later a Project Manager in Medical Affairs. Medical Affairs was combined with Clinical Operations and she was promoted to a Senior Manager working in the CNS group. In 2005, her role changed and she is now heading up leading the Resourcing Group as an Associate Director within Clinical Operations. In this role she is responsible for working with a Function Outsource Provider to manage a field force of Regional Managers and Regional CRAs. In addition to her other responsibilities, Sue is also heading up the Pain Program in Clinical Operations. In this role she is in charge of various pain compounds and the studies that are conducted with them.

Suzi Tran, M.B.A., CMQ/OE, CQA, CSQE, is an experienced Quality Assurance Manager with over 25 years of experience in developing and implementing quality management systems for various federal and private clients. She is a Certified Quality Auditor who has performed internal and external audits using criteria from ISO, ICH, and CFR requirements.

Lee Truax-Bellows, M.S., FNP, C.C.R.A., RQAP-GCP, has an extensive background in the pharmaceutical and medical device industries, having worked for both industry and a CRO as a Monitor, Medical Communications Associate, Project Manager, Senior Quality Auditor, Senior Trainer, and Regulatory and SOP Consultant. Lee has been involved in regulated research the past 25 years and currently specializes in product development, GCP auditing and SOP development and training on regulated research and Good Clinical Practice. She is an active member of the Association of Clinical Research Professionals (ACRP), New York State MedTech Association and Society of Quality Assurance (SOA). Lee is ACRP certified as a Certified Clinical Research Associate (CCRA) and registered through SOA as a Registered Quality Assurance Professional in Good Clinical Practices (RQAP-GCP).

Mary L. Veazie, M.B.A., CPA, CHC, CHRC, is a Certified Public Accountant with over 15 years of experience in clinical research finance. Collectively, she has over 25 years of financial and auditing experience. She is certified in Healthcare Research Compliance and Healthcare Compliance. Ms. Veazie’s skill set includes full comprehension of the clinical research billing process and its impact on an organization’s healthcare.

Tabitha Westbrook, M.A., LPCA, CCTP, RQAP-GCP, has more than 20 years of experience in the pharmaceutical industry, 15 of which have been in Clinical Quality Assurance. Ms. Westbrook has both conducted and provided training on such topics as clinical quality auditing processes, process audits, vendor audits and vendor management, investigator site audits (both routine and for cause), hosting sponsor audits and regulatory inspections, standard operating procedure (SOP) creation and maintenance, identifying and managing protocol deviations, root cause analysis, and corrective and preventive actions. She also teaches courses on conflict management and resolution and leveraging emotional intelligence in the workplace. Her teaching style is interactive and interpersonal, using real-world scenarios to bring the information to life and help learners generalize information across their various roles and jobs. Ms. Westbrook also provides mentoring to newer members of industry.

Linda Yancey, R.N., C.C.R.A., is a clinical research professional with a history of orchestrating successful multi-institutional academic clinical research consortia and strategic pharmaceutical collaborations designed to decrease clinical trial activation timelines and reduce financial operating associated costs. She has substantive leadership experience and a strong background in healthcare with over 20 years serving in varied progressive roles. In her role at UT MD Anderson Cancer Center, she has led numerous teams and has provided research operational oversight for 150 clinical trials (first in man, phase i -iii protocols, immune-modulating agents) with over 3,000 enrolled patients representing contractual awards over $60 million. Under her leadership, the rate of clinical research patient reimbursement increased from 25% to 81% during the fiscal year and she developed a centralized infrastructure that led to increased clinical trial revenues. Linda holds Bachelor of Science degrees in both business and nursing. She is a certified Clinical Research Associate and has an extensive background which includes mass tort legal nurse consulting, auditing/monitoring per GCP/FDA regulations, clinical trial management system development, clinical research billing compliance, project management, and pharmaceutical strategic alliances.

Shana Zink, B.S., has more than 25 years of research experience in the pharmaceutical and medical device arena with the past 15 years focused on global clinical research in various therapeutic areas including cardiovascular, orthopedic surgery, bariatric, oncology and plastic surgery. From 2013 - 2018, Shana served as Vice President of Clinical Affairs at AtriCure, Inc., an innovative leader in the treatment of atrial fibrillation. Prior to AtriCure, she held positions with a variety of responsibilities including quality assurance and clinical affairs at J&J, Proctor & Gamble, and Searle Pharmaceuticals (a Monsanto Company). She holds a B.S. in Biological Sciences from Northern Illinois University and obtained a certificate in Project Management from Boston University Corporate Education Center.
Courses Listed by Location and Month

January

Preparation, Management, and Response to Inspections and Audits ........................................ On the Web ........................................ January 7, 2020
Writing and Updating the Investigator’s Brochure ............................................................... On the Web ........................................ January 8, 2020
30-Hour Clinical Project Management Fundamentals Certification Program .............................. On the Web ...................................... January 9 - March 12, 2020
30-Hour Clinical Research Auditing Certification Program .................................................. On the Web ...................................... January 9 - March 19, 2020
Drug Development and FDA Regulations .................................................................................. On the Web ........................................ January 13, 2020
Use of Notes to File in Clinical Trial Essential Documentation ............................................... On the Web ........................................ January 13, 2020
State Laws Governing Clinical Trial Regulatory Compliance .................................................. On the Web ........................................ January 13, 2020
Monitoring Plan Development ................................................................................................. On the Web ........................................ January 13, 2020
Essential Documentation in Clinical Trials at Research Sites .............................................. On the Web ........................................ January 14, 2020
Investigational Product Accountability Best Practices ............................................................. On the Web ........................................ January 14, 2020
Final ICH GCP E6 R2: Implementing Risk Management Approaches for Compliance ........ On the Web ........................................ January 14, 2020
Writing the Clinical Study Report .............................................................................................. On the Web ........................................ January 15, 2020
Recent Trends in Noncompliance: Critical Review and Analysis of Recent Regulatory Letters and Communications from the FDA, EMA, and Health Canada ..................................................... On the Web ........................................ January 15, 2020
Electronic Informed Consent Guidance: Regulatory Updates .............................................. On the Web ........................................ January 16, 2020
Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank: Draft Guidance .......... On the Web ........................................ January 16, 2020
Introduction to Clinical Research ............................................................................................. On the Web ........................................ January 16, 2020
Clinical Trials and the “Sunshine Act”: The Effect on the Clinical Research Industry ................. On the Web ........................................ January 17, 2020
Audiencing Techniques for Clinical Research Professionals ................................................... Boston, MA ........................................ January 20-21, 2020
Preparing Clinical Research Sites for FDA Inspections ......................................................... On the Web ........................................ January 21, 2020
Coaching Skills for Leaders ...................................................................................................... On the Web ........................................ January 21, 2020
Strategies for Having Difficult Conversations ......................................................................... On the Web ........................................ January 21, 2020
Writing Clinical Study Protocols ............................................................................................... On the Web ........................................ January 22, 2020
Final ICH GCP E6 R2: Impact on Clinical Data Management .................................................. On the Web ........................................ January 22, 2020
Protocol Deviations: Documenting, Managing, and Reporting ............................................. On the Web ........................................ January 27, 2020
Subject Recruitment: Proactive Project Plans and Issues Management .................................. On the Web ........................................ January 28, 2020
Adverse Event Monitoring for CRAs ........................................................................................ On the Web ........................................ January 28, 2020
Incorporating Denials Management into Clinical Research Billing ........................................ On the Web ........................................ January 28, 2020
Introduction to Data Management ............................................................................................ On the Web ........................................ January 28, 2020
A Systematic Approach to Study Start-Up: Improving Site Activation .................................. On the Web ........................................ January 28, 2020
Monitoring Oncology Clinical Trials ....................................................................................... On the Web ........................................ January 30, 2020
TMF/eTMF Regulatory Agency Expectations, Inspections, and Findings ................................. On the Web ........................................ January 31, 2020

February

Developing and Negotiating Research Site Clinical Study Budgets and Contracts ............................ On the Web ........................................ February 6, 2020
Introduction to Medicare Coverage Analysis: Impact on Site Revenue Cycles .......................... On the Web ........................................ February 6, 2020
10-Week Clinical Research Associate (CRA) On-Boarding Program ........................................ On the Web ...................................... February 7 - April 17, 2020
10-Week Clinical Research Coordinator (CRC) On-Boarding Program .................................... On the Web ...................................... February 7 - April 17, 2020
Establishing Quality Tolerance Limits ..................................................................................... On the Web ........................................ February 13, 2020
Implementing Quality Agreements ............................................................................................ On the Web ........................................ February 13, 2020
30-Hour Clinical Research Auditing Certification Program ...................................................... On the Web ...................................... February 14 - May 1, 2020
Auditing Clinical Research Studies: An Overview for Assessing GCP Compliance ................. On the Web ........................................ February 17, 2020
ClinicalTrials.Gov Requirements: Clinical Trial Registration and Trial Results Reporting, Expanded Registry and Results Data Bank ............................................................. On the Web ........................................ February 18, 2020
Auditing Sponsors and CROs: Deconstruction and Application of the FDA’s Compliance Program Guidance Manual ............................................................................................................ On the Web ........................................ February 18, 2020
Good Clinical Practice (GCP) for Medical Devices: ICH GCP E6 and ISO 14155 ........................ On the Web ........................................ February 19, 2020
Good Clinical Practice: Practical Application and Implementation .......................................... On the Web ........................................ February 20, 2020
Trial Master File (TMF) for Sponsors: Set-Up and Maintenance ................................................ On the Web ........................................ February 21, 2020
Strategies for Active Listening ................................................................................................. On the Web ........................................ February 25, 2020

213
### March

<table>
<thead>
<tr>
<th>Course</th>
<th>Location</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction to Statistics for Non-Statisticians</td>
<td>On the Web</td>
<td>March 2, 2020</td>
</tr>
<tr>
<td>Approaches to Address Challenges in Vendor Management</td>
<td>On the Web</td>
<td>March 3, 2020</td>
</tr>
<tr>
<td>Clinical Trial Registration: Requirements, Record Maintenance and Reporting of Results</td>
<td>On the Web</td>
<td>March 3, 2020</td>
</tr>
<tr>
<td>CRO Partnership Management</td>
<td>On the Web</td>
<td>March 4, 2020</td>
</tr>
<tr>
<td>Cases in Advanced GCP: A Problem-Solving Practicum</td>
<td>On the Web</td>
<td>March 5, 2020</td>
</tr>
<tr>
<td>Inspection Readiness: Understanding BIMO Inspection Requirements for Sponsors, CROs, Monitors and Investigators</td>
<td>On the Web</td>
<td>March 5, 2020</td>
</tr>
<tr>
<td>30-Hour Clinical Project Management Fundamentals Certification Program</td>
<td>On the Web</td>
<td>March 6 - May 29, 2020</td>
</tr>
<tr>
<td>TMF/eTMF Audit Strategies</td>
<td>On the Web</td>
<td>March 6, 2020</td>
</tr>
<tr>
<td>eTMF Quality Oversight: A Risk-Based Approach</td>
<td>On the Web</td>
<td>March 6, 2020</td>
</tr>
<tr>
<td>Negotiation Skills for Clinical Research Professionals</td>
<td>On the Web</td>
<td>March 9, 2020</td>
</tr>
<tr>
<td>Building Quality by Design (QbD) and Risk-Based Quality Management (RBQM) Systems into Clinical Operations</td>
<td>On the Web</td>
<td>March 10, 2020</td>
</tr>
<tr>
<td>Final ICH GCP E6 R2 Addendum: Overview of Changes Impacting Sponsors, CROs, Clinical Investigators/Sites</td>
<td>On the Web</td>
<td>March 11, 2020</td>
</tr>
<tr>
<td>RECIST 1.0 and 1.1: Overview and Data Challenges in Oncology Clinical Trials</td>
<td>On the Web</td>
<td>March 11, 2020</td>
</tr>
<tr>
<td>Risk-Based Site Monitoring</td>
<td>On the Web</td>
<td>March 12, 2020</td>
</tr>
<tr>
<td>Building Relationships with Clinical Research Sites</td>
<td>On the Web</td>
<td>March 16, 2020</td>
</tr>
<tr>
<td>Scientific and Ethical Considerations for Inclusion of Pregnant Women in Clinical Trials</td>
<td>On the Web</td>
<td>March 16, 2020</td>
</tr>
<tr>
<td>Corrective Action Plans: Essential Documentation of a Site’s Response to GCP Deficiencies</td>
<td>On the Web</td>
<td>March 16, 2020</td>
</tr>
<tr>
<td>10-Week CRA &amp; CRC Beginner Program</td>
<td>On the Web</td>
<td>March 17 - June 9, 2020</td>
</tr>
<tr>
<td>Auditing Techniques: A Problem-Solving Practicum</td>
<td>On the Web</td>
<td>March 17, 2020</td>
</tr>
<tr>
<td>Use of Electronic Health Record Data in Clinical Investigations</td>
<td>On the Web</td>
<td>March 17, 2020</td>
</tr>
<tr>
<td>Principal Investigator Oversight and the Appropriate Delegation of Tasks</td>
<td>On the Web</td>
<td>March 17, 2020</td>
</tr>
<tr>
<td>Clinical Trials and the &quot;Sunshine Act&quot;: The Effect on the Clinical Research Industry</td>
<td>On the Web</td>
<td>March 18, 2020</td>
</tr>
<tr>
<td>Risk-Based Auditing: Effective Compliance Strategies</td>
<td>On the Web</td>
<td>March 18, 2020</td>
</tr>
<tr>
<td>10-Week Risk Management/Risk-Based Quality Management for Clinical Trials Certification Program</td>
<td>On the Web</td>
<td>March 19 – June 4, 2020</td>
</tr>
<tr>
<td>Required Components</td>
<td>On the Web</td>
<td>March 19, 2020</td>
</tr>
<tr>
<td>Investigator Initiated Trials: Roles and Responsibilities</td>
<td>On the Web</td>
<td>March 19, 2020</td>
</tr>
<tr>
<td>Research Billing Processing: Appropriate Segregation of Charges and Medical Documentation</td>
<td>On the Web</td>
<td>March 19, 2020</td>
</tr>
<tr>
<td>Developing Clinical Study Budgets for Sponsors</td>
<td>On the Web</td>
<td>March 19, 2020</td>
</tr>
<tr>
<td>Subject Recruitment: Proactive Project Plans and Issues Management</td>
<td>On the Web</td>
<td>March 19, 2020</td>
</tr>
<tr>
<td>Strategies for Managing Difficult Clinical Research Sites</td>
<td>On the Web</td>
<td>March 19, 2020</td>
</tr>
<tr>
<td>ABCs of Clinical Research for Clinical Administrative Support Staff</td>
<td>On the Web</td>
<td>March 23, 2020</td>
</tr>
<tr>
<td>ABCs of GCP and the 13 Principles of ICH GCP E6</td>
<td>On the Web</td>
<td>March 23, 2020</td>
</tr>
<tr>
<td>Good Laboratory Practice for Non-Clinical Studies</td>
<td>On the Web</td>
<td>March 24 &amp; 26, 2020</td>
</tr>
<tr>
<td>Managing Phase I Clinical Trials</td>
<td>On the Web</td>
<td>March 25, 2020</td>
</tr>
<tr>
<td>Key Considerations in Medical Writing: The Clinical Study Protocol, Investigator’s Brochure, Informed Consent Form, and Adverse Events Narratives</td>
<td>On the Web</td>
<td>March 25, 2020</td>
</tr>
<tr>
<td>Monitoring Clinical Drug Studies: Beginner</td>
<td>San Diego, CA</td>
<td>March 25–27, 2020</td>
</tr>
<tr>
<td>WORKSHOP: Trial Master Files: Why They Are Important and How to Organize Them</td>
<td>Philadelphia, PA</td>
<td>March 26, 2020</td>
</tr>
<tr>
<td>Conducting Clinical Trials Under ICH GCP E6</td>
<td>Philadelphia, PA</td>
<td>March 26-27, 2020</td>
</tr>
<tr>
<td>The Revised HHS Common Rule: What You Need to Know</td>
<td>On the Web</td>
<td>March 30, 2020</td>
</tr>
<tr>
<td>Auditing Techniques for Clinical Research Professionals</td>
<td>Philadelphia, PA</td>
<td>March 30-31, 2020</td>
</tr>
<tr>
<td>Clinical Project Management: Fundamentals of Project Management</td>
<td>San Diego, CA</td>
<td>March 30-31, 2020</td>
</tr>
<tr>
<td>Final ICH GCP E6 R2: Changes Impacting Clinical Investigators, Sites, and IND Holders</td>
<td>San Diego, CA</td>
<td>March 31, 2020</td>
</tr>
<tr>
<td>(Sponsors-Investigators and Institutions)</td>
<td>On the Web</td>
<td>March 31, 2020</td>
</tr>
<tr>
<td>Final ICH GCP E6 R2: Changes Impacting Sponsors/CROs</td>
<td>On the Web</td>
<td>March 31, 2020</td>
</tr>
<tr>
<td>Drug Safety and Pharmacovigilance: Effective Drug Safety Reporting and Surveillance</td>
<td>San Diego, CA</td>
<td>March 31-April 1, 2020</td>
</tr>
</tbody>
</table>
Courses Listed by Location and Month

April

- Monitoring Oncology Clinical Trials .......................................................... On the Web ................. April 1, 2020
- Managing Risks in Outsourced Clinical Trials: Practical Approaches and Tools ........................................ On the Web ................. April 1, 2020
- Clinical Trial Assistant Fundamentals ......................................................... Philadelphia, PA ......... April 2-3, 2020
- Introduction to Clinical Research .............................................................. Philadelphia, PA ......... April 2-3, 2020
- TMF/eTMF Regulatory Agency Expectations, Inspections, and Findings .............................................................. On the Web ................. April 3, 2020
- Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank: Draft Guidance ............................................. On the Web ................. April 6, 2020
- Electronic Informed Consent Guidance: Regulatory Updates ................. On the Web ................. April 6, 2020
- A Systematic Approach to Study Start-Up: Improving Site Activation .......... On the Web ................. April 6, 2020
- Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) in Site Management .............................................. Philadelphia, PA ............ April 6-7, 2020
- Drug Development and FDA Regulations ................................................. On the Web ................. April 7, 2020
- Recent Trends in Noncompliance: Critical Review and Analysis of Recent Regulatory Letters and On the Web ................. April 7, 2020
- Communications from the FDA, EMA, and Health Canada ...................... On the Web ................. April 7, 2020
- Soft Skills Development for Clinical Research Professionals ..................... Philadelphia, PA ............ April 7-8, 2020
- Data Quality in Clinical Trials: Rationale and Impact ................................. On the Web ................. April 8, 2020
- Electronic Source Data in Clinical Investigations: Navigating the Final FDA Guidance ................................................. On the Web ................. April 8, 2020
- Use of Notes to File in Clinical Trial Essential Documentation .................. On the Web ................. April 8, 2020
- Monitoring Clinical Drug Studies: Intermediate ................................. Philadelphia, PA ............ April 8-9, 2020
- Overseeing Teams and Projects ............................................................ On the Web ................. April 9, 2020
- Understanding the FDA/OHRP Joint Guidance on Minutes of IRB Meetings .................................................. On the Web ................. April 9, 2020
- Incorporating Denials Management into Clinical Research Billing .......................................................... On the Web ................. April 9, 2020
- "Risk-Based Thinking": How Monitors Can Develop an Auditor's Perspective .......................................................... On the Web ................. April 10, 2020
- Clinical Trial Start-Up: Using a Work Breakdown Structure (WBS) for Effective Planning ................................................. On the Web ................. April 13, 2020
- 10-Week Final ICH GCP E6 R2: Risk-Based Monitoring Plan Development Series ................................................. On the Web ................. April 14 - June 16, 2020
- Essential Documentation in Clinical Trials at Research Sites ...................... On the Web ................. April 14, 2020
- Writing the Clinical Study Report ........................................................... On the Web ................. April 15, 2020
- Final ICH GCP E6 R2: Impact on Clinical Data Management .................. On the Web ................. April 15, 2020
- Monitoring Medical Device Trials: An Introduction .................................... On the Web ................. April 15, 2020
- 30-Hour Clinical Research Auditing Certification Program ....................... On the Web ................. April 16 – July 9, 2020
- FDA Medical Device Approval Process .................................................... On the Web ................. April 16, 2020
- Final ICH GCP E6 R2: Sponsor Quality Management – Risk-Based/Risk Management Requirements and Approaches for Compliance ........................................ On the Web ................. April 21, 2020
- Final FDA Guidance: How to Complete the Form FDA 1572, Adequately and Accurately .................................................. On the Web ................. April 21, 2020
- Final ICH GCP E6 R2: Implementing Risk Management Approaches for Compliance ................................................. On the Web ................. April 21, 2020
- Writing Clinical Study Protocols ............................................................. On the Web ................. April 22, 2020
- Introduction to Data Management .......................................................... On the Web ................. April 22, 2020
- FDA Drug Approval Process ................................................................. On the Web ................. April 22, 2020
- Investigational Product Accountability Best Practices ............................... On the Web ................. April 23, 2020
- Centralized TMF Management: The CRO Sponsor Partnership ................ On the Web ................. April 24, 2020
- eTMF Implementation Strategies ........................................................... On the Web ................. April 24, 2020
- Strategies for Building High-Performing Clinical Research Teams ............ On the Web ................. April 27, 2020
- State Laws Governing Clinical Trial Regulatory Compliance .................. On the Web ................. April 28, 2020
- Introduction to Clinical Research ............................................................ On the Web ................. April 30, 2020

May

- 10-Week CRA & CRC Beginner Program .................................................. On the Web ................. May 6 – July 22, 2020
- 30-Hour Clinical Data Management On-Boarding Program ....................... On the Web ................. May 6 – July 22, 2020
- The GCPs of Essential Documents .......................................................... On the Web ................. May 6 – July 22, 2020
- Data Management Plan Creation: Content and Rationale .......................... On the Web ................. May 6, 2020
- Monitoring Plan Development ............................................................... On the Web ................. May 7, 2020
- Introduction to Medicare Coverage Analysis: Impact on Site Revenue Cycles .......................................................... On the Web ................. May 7, 2020
- Developing and Negotiating Research Site Clinical Study Budgets and Contracts .......................................................... On the Web ................. May 7, 2020
- 10-Week Clinical Research Associate (CRA) On-Boarding Program ........ On the Web ................. May 8 - July 24, 2020
- 10-Week Clinical Research Coordinator (CRC) On-Boarding Program .......... On the Web ................. May 8 - July 24, 2020
### Courses Listed by Location and Month

<table>
<thead>
<tr>
<th>Course Description</th>
<th>Location</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementing Quality Agreements</td>
<td>On the Web</td>
<td>May 8, 2020</td>
</tr>
<tr>
<td>Establishing Quality Tolerance Limits</td>
<td>On the Web</td>
<td>May 8, 2020</td>
</tr>
<tr>
<td>Protocol Deviations: Documenting, Managing, and Reporting</td>
<td>On the Web</td>
<td>May 11, 2020</td>
</tr>
<tr>
<td>CAP and CLIA Requirements for Clinical Research Laboratories</td>
<td>On the Web</td>
<td>May 12, 2020</td>
</tr>
<tr>
<td>The IN a in a CTD/ecto Format</td>
<td>On the Web</td>
<td>May 13, 2020</td>
</tr>
<tr>
<td>The CRA Role in Risk-Based Monitoring: Strategies for Effective Remote Monitoring</td>
<td>On the Web</td>
<td>May 13, 2020</td>
</tr>
<tr>
<td>Regulatory Intelligence</td>
<td>On the Web</td>
<td>May 13, 2020</td>
</tr>
<tr>
<td>WORKSHOP: Trial Master Files: Why They Are Important and How to Organize Them</td>
<td>On the Web</td>
<td>May 15, 2020</td>
</tr>
<tr>
<td>Auditing Clinical Research Studies: An Overview for Assessing GCP Compliance</td>
<td>On the Web</td>
<td>May 19, 2020</td>
</tr>
<tr>
<td>FDA's Bioresearch Monitoring (BIMO) Program: Inspection of Sponsors, CROs, and Monitors</td>
<td>On the Web</td>
<td>May 19, 2020</td>
</tr>
<tr>
<td>Medical Writing Fundamentals: How to Write Regulatory Documents</td>
<td>On the Web</td>
<td>May 20, 2020</td>
</tr>
<tr>
<td>Good Clinical Practice (GCP) for Medical Devices: ICH GCP E6 and ISO 14155</td>
<td>On the Web</td>
<td>May 20, 2020</td>
</tr>
<tr>
<td>ClinicalTrials.gov Requirements: Clinical Trial Registration and Trial Results Reporting, Expanded Registry and Results Data Bank</td>
<td>On the Web</td>
<td>May 20, 2020</td>
</tr>
<tr>
<td>Sponsor Management of Investigator Non-Compliance</td>
<td>On the Web</td>
<td>May 20, 2020</td>
</tr>
<tr>
<td>Working with Clinical Research Sites: Strategic Planning and Operations for Sponsors and CROs</td>
<td>On the Web</td>
<td>May 21, 2020</td>
</tr>
<tr>
<td>Risk-Based Quality and Compliance Management in Combination Product Trials</td>
<td>On the Web</td>
<td>May 21, 2020</td>
</tr>
<tr>
<td>Quality Systems: A Controlled Approach to GCP Compliance</td>
<td>On the Web</td>
<td>May 22, 2020</td>
</tr>
<tr>
<td>WORKSHOP: Case Report Form Design, Strategy, and Standards</td>
<td>On the Web</td>
<td>May 26, 2020</td>
</tr>
<tr>
<td>Strategies for Having Difficult Conversations</td>
<td>On the Web</td>
<td>May 26, 2020</td>
</tr>
<tr>
<td>Strategies for Active Listening</td>
<td>On the Web</td>
<td>May 26, 2020</td>
</tr>
<tr>
<td>Leading Teams in a Changing Clinical Research Environment</td>
<td>On the Web</td>
<td>May 27, 2020</td>
</tr>
<tr>
<td>Trial Master File (TMF) for Sponsors: Set-Up and Maintenance</td>
<td>On the Web</td>
<td>May 27, 2020</td>
</tr>
<tr>
<td>Current FDA and EMA Inspection Findings: Lessons Learned</td>
<td>On the Web</td>
<td>May 27, 2020</td>
</tr>
</tbody>
</table>

### June

<table>
<thead>
<tr>
<th>Course Description</th>
<th>Location</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Use of Tools, Job Aids, Process Maps, and Checklists for Project Managers and Clinical Research Teams</td>
<td>On the Web</td>
<td>June 1, 2020</td>
</tr>
<tr>
<td>Introduction to Statistics for Non-Statisticians</td>
<td>On the Web</td>
<td>June 1, 2020</td>
</tr>
<tr>
<td>Sponsor Responsibilities for Global Drug Studies</td>
<td>On the Web</td>
<td>June 2, 2020</td>
</tr>
<tr>
<td>Final ICH GCP E6 R2 Addendum: Overview of Changes Impacting Sponsors, CROs, Clinical Investigators/Sites</td>
<td>On the Web</td>
<td>June 3, 2020</td>
</tr>
<tr>
<td>Informed Consent Procedure: Lessons Learned from Inspection Findings</td>
<td>On the Web</td>
<td>June 3, 2020</td>
</tr>
<tr>
<td>RECIST 1.0 and 1.1: Overview and Data Challenges in Oncology Clinical Trials</td>
<td>On the Web</td>
<td>June 3, 2020</td>
</tr>
<tr>
<td>eTMF Quality Oversight: A Risk-Based Approach</td>
<td>On the Web</td>
<td>June 5, 2020</td>
</tr>
<tr>
<td>TMF/eTMF Audit Strategies</td>
<td>On the Web</td>
<td>June 5, 2020</td>
</tr>
<tr>
<td>Clinical Research Financial Management for Investigative Sites</td>
<td>On the Web</td>
<td>June 5, 2020</td>
</tr>
<tr>
<td>Implications of the FDA Guidance for a Risk-Based Approach to Monitoring and the EMA Reflection</td>
<td>On the Web</td>
<td>June 8, 2020</td>
</tr>
<tr>
<td>Paper Risk Based Quality Management in Clinical Trials</td>
<td>On the Web</td>
<td>June 8, 2020</td>
</tr>
<tr>
<td>Good Clinical Practice: Practical Application and Implementation</td>
<td>On the Web</td>
<td>June 8, 2020</td>
</tr>
<tr>
<td>Monitoring Reports: 10 Rules of Effective Report Writing</td>
<td>On the Web</td>
<td>June 8, 2020</td>
</tr>
<tr>
<td>Building Quality by Design (QbD) and Risk-Based Quality Management (RBQM) Systems into Clinical Operations</td>
<td>On the Web</td>
<td>June 8, 2020</td>
</tr>
<tr>
<td>Minimizing Risk in Negotiating Clinical Trial Contracts and Budgets</td>
<td>On the Web</td>
<td>June 8, 2020</td>
</tr>
<tr>
<td>Use of Electronic Health Record Data in Clinical Investigations</td>
<td>On the Web</td>
<td>June 8, 2020</td>
</tr>
<tr>
<td>Recent Trends in Noncompliance: Critical Review and Analysis of Recent Regulatory Letters and Communications from the FDA, EMA, and Health Canada</td>
<td>On the Web</td>
<td>June 9, 2020</td>
</tr>
<tr>
<td>Clinical Trial Registration: Requirements, Record Maintenance and Reporting of Results</td>
<td>On the Web</td>
<td>June 9, 2020</td>
</tr>
<tr>
<td>EMA and MHRA Inspections: Successful Planning and Execution Tips and Techniques</td>
<td>On the Web</td>
<td>June 9, 2020</td>
</tr>
<tr>
<td>Risk-Based Monitoring: The Data Management Connection</td>
<td>On the Web</td>
<td>June 10, 2020</td>
</tr>
<tr>
<td>Clinical Trials and the &quot;Sunshine Act&quot;: The Effect on the Clinical Research Industry</td>
<td>On the Web</td>
<td>June 10, 2020</td>
</tr>
<tr>
<td>Strategies for Managing Difficult Clinical Research Sites</td>
<td>On the Web</td>
<td>June 10, 2020</td>
</tr>
<tr>
<td>Ensuring Success Through Smarter Site Selection and Study Feasibility</td>
<td>On the Web</td>
<td>June 10, 2020</td>
</tr>
<tr>
<td>Monitoring Clinical Drug Studies: Beginner</td>
<td>Boston, MA</td>
<td>June 10-12, 2020</td>
</tr>
<tr>
<td>Writing and Updating the Investigator's Brochure</td>
<td>On the Web</td>
<td>June 11, 2020</td>
</tr>
<tr>
<td>HIPAA Team Training: Fundamental Training Specifically for Clinical Research Settings</td>
<td>On the Web</td>
<td>June 11, 2020</td>
</tr>
<tr>
<td>Cases in Advanced GCP: A Problem-Solving Practicum</td>
<td>On the Web</td>
<td>June 11, 2020</td>
</tr>
<tr>
<td>Research Billing Processing: Appropriate Segregation of Charges and Medical Documentation</td>
<td>On the Web</td>
<td>June 11, 2020</td>
</tr>
<tr>
<td>Scientific and Ethical Considerations for Inclusion of Pregnant Women in Clinical Trials</td>
<td>On the Web</td>
<td>June 12, 2020</td>
</tr>
<tr>
<td>Root Cause Analysis: Applying the Concept for Better Study Compliance Management</td>
<td>On the Web</td>
<td>June 12, 2020</td>
</tr>
<tr>
<td>Clinical Project Management: Fundamentals of Project Management</td>
<td>Boston, MA</td>
<td>June 15-16, 2020</td>
</tr>
<tr>
<td>Drug Safety and Pharmacovigilance: Effective Drug Safety Reporting and Surveillance</td>
<td>Boston, MA</td>
<td>June 16-17, 2020</td>
</tr>
</tbody>
</table>
### July

<table>
<thead>
<tr>
<th>Topic</th>
<th>Location</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Development and FDA Regulations</td>
<td>San Diego, CA</td>
<td>July 6, 2020</td>
</tr>
<tr>
<td>Preparation, Management, and Response to Inspections and Audits</td>
<td>San Diego, CA</td>
<td>July 7, 2020</td>
</tr>
<tr>
<td>Electronic Informed Consent Guidance: Regulatory Updates</td>
<td>San Diego, CA</td>
<td>July 7, 2020</td>
</tr>
<tr>
<td>Final ICH GCP E6 R2: Implementing Risk Management Approaches for Compliance</td>
<td>San Diego, CA</td>
<td>July 7, 2020</td>
</tr>
<tr>
<td>Managing CRAs to Improve Performance and Study Outcomes</td>
<td>San Diego, CA</td>
<td>July 8, 2020</td>
</tr>
<tr>
<td>Risk-Based Site Monitoring</td>
<td>San Diego, CA</td>
<td>July 8, 2020</td>
</tr>
<tr>
<td>Electronic Source Data in Clinical Investigations: Navigating the Final FDA Guidance</td>
<td>San Diego, CA</td>
<td>July 8, 2020</td>
</tr>
<tr>
<td>Investigator Initiated Trials: Roles and Responsibilities</td>
<td>San Diego, CA</td>
<td>July 8, 2020</td>
</tr>
<tr>
<td>Auditing Techniques: A Problem-Solving Practicum</td>
<td>San Diego, CA</td>
<td>July 9, 2020</td>
</tr>
<tr>
<td>Monitoring Visit Reports for Medical Device Studies</td>
<td>San Diego, CA</td>
<td>July 9, 2020</td>
</tr>
<tr>
<td>Final AE Regulatory Guidance: Reporting/Communication of Safety Information from Clinical Trials to IRBs</td>
<td>San Diego, CA</td>
<td>July 10, 2020</td>
</tr>
<tr>
<td>30-Hour Clinical Project Management Fundamentals Certification Program</td>
<td>San Diego, CA</td>
<td>July 10, 2020</td>
</tr>
<tr>
<td>Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank: Draft Guidance</td>
<td>San Diego, CA</td>
<td>July 10, 2020</td>
</tr>
<tr>
<td>Use of Notes to File in Clinical Trial Essential Documentation</td>
<td>San Diego, CA</td>
<td>July 10, 2020</td>
</tr>
<tr>
<td>10-Week Clinical Research Financial Certification Program: Setting Up Compliant Financial Operations and Budgets</td>
<td>San Diego, CA</td>
<td>July 13 – September 14, 2020</td>
</tr>
<tr>
<td>Clinical Trial Start-Up: Using a Work Breakdown Structure (WBS) for Effective Planning</td>
<td>San Diego, CA</td>
<td>July 13, 2020</td>
</tr>
<tr>
<td>Coaching Skills for Leaders</td>
<td>San Diego, CA</td>
<td>July 13, 2020</td>
</tr>
<tr>
<td>Strategies for Having Difficult Conversations</td>
<td>San Diego, CA</td>
<td>July 13, 2020</td>
</tr>
<tr>
<td>Subject Recruitment: Proactive Project Plans and Issues Management</td>
<td>San Diego, CA</td>
<td>July 14, 2020</td>
</tr>
<tr>
<td>A Systematic Approach to Study Start-Up: Improving Site Activation</td>
<td>San Diego, CA</td>
<td>July 14, 2020</td>
</tr>
<tr>
<td>Adverse Event Monitoring for CRAs</td>
<td>San Diego, CA</td>
<td>July 14, 2020</td>
</tr>
<tr>
<td>Writing the Clinical Study Report</td>
<td>San Diego, CA</td>
<td>July 15, 2020</td>
</tr>
<tr>
<td>Preparing Clinical Research Sites for FDA Inspections</td>
<td>San Diego, CA</td>
<td>July 15, 2020</td>
</tr>
<tr>
<td>Required Components</td>
<td>San Diego, CA</td>
<td>July 16, 2020</td>
</tr>
<tr>
<td>Essential Documentation in Clinical Trials at Research Sites</td>
<td>San Diego, CA</td>
<td>July 16, 2020</td>
</tr>
<tr>
<td>Incorporating Denials Management into Clinical Research Billing</td>
<td>San Diego, CA</td>
<td>July 16, 2020</td>
</tr>
<tr>
<td>TMF/eTMF Regulatory Agency Expectations, Inspections, and Findings</td>
<td>San Diego, CA</td>
<td>July 17, 2020</td>
</tr>
<tr>
<td>State Laws Governing Clinical Trial Regulatory Compliance</td>
<td>San Diego, CA</td>
<td>July 20, 2020</td>
</tr>
<tr>
<td>Final ICH GCP E6 R2: Sponsor Quality Management – Risk-Based/Risk Management Requirements and Approaches for Compliance</td>
<td>San Diego, CA</td>
<td>July 21, 2020</td>
</tr>
<tr>
<td>Writing Clinical Study Protocols</td>
<td>San Diego, CA</td>
<td>July 22, 2020</td>
</tr>
<tr>
<td>Final ICH GCP E6 R2: Impact on Clinical Data Management</td>
<td>San Diego, CA</td>
<td>July 22, 2020</td>
</tr>
<tr>
<td>Monitoring Oncology Clinical Trials</td>
<td>San Diego, CA</td>
<td>July 22, 2020</td>
</tr>
<tr>
<td>Source Documentation: What is Adequate and Accurate?</td>
<td>San Diego, CA</td>
<td>July 27, 2020</td>
</tr>
<tr>
<td>The Revised HHS Common Rule: What You Need to Know Now</td>
<td>San Diego, CA</td>
<td>July 27, 2020</td>
</tr>
<tr>
<td>Final ICH GCP E6 R2: Changes Impacting Clinical Investigators, Sites, and IND Holders (Sponsors-Investigators and Institutions)</td>
<td>San Diego, CA</td>
<td>July 28, 2020</td>
</tr>
<tr>
<td>Final ICH GCP E6 R2: Changes Impacting Sponsors/CROs</td>
<td>San Diego, CA</td>
<td>July 28, 2020</td>
</tr>
<tr>
<td>Introduction to Data Management</td>
<td>San Diego, CA</td>
<td>July 29, 2020</td>
</tr>
</tbody>
</table>
Courses Listed By City

Clinical Research Training Weeks – East and West: Winter 2020

Barnett's Clinical Research Training Weeks offer industry professionals the opportunity to participate in core training courses focused on today’s most important clinical research training topics, while networking with Barnett’s subject matter expert trainers and industry colleagues in a dynamic setting. Whether you are new to industry or a seasoned industry professional, Barnett’s Clinical Research Training Weeks provide learners with hands-on experience based on today’s clinical research environment. Learn from trainers who are not only chosen for their ability to engage adult learners, but also for their deep subject matter expertise and hands-on experience. Choose your courses today!

Boston, MA

<table>
<thead>
<tr>
<th>Course</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auditing Techniques for Clinical Research Professionals</td>
<td>January 20-21, 2020</td>
</tr>
<tr>
<td>Monitoring Clinical Drug Studies: Beginner</td>
<td>June 10-12, 2020</td>
</tr>
<tr>
<td>Drug Safety and Pharmacovigilance: Effective Drug Safety Reporting and Surveillance</td>
<td>June 16-17, 2020</td>
</tr>
<tr>
<td>Statistical Concepts for Non-Statisticians</td>
<td>June 16-17, 2020</td>
</tr>
<tr>
<td>Comprehensive Monitoring for Medical Devices</td>
<td>June 16-18, 2020</td>
</tr>
<tr>
<td>Monitoring Clinical Drug Studies: Advanced</td>
<td>June 18-19, 2020</td>
</tr>
</tbody>
</table>

Philadelphia, PA

<table>
<thead>
<tr>
<th>Course</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>WORKSHOP: Trial Master Files: Why They Are Important and How to Organize Them</td>
<td>March 26, 2020</td>
</tr>
<tr>
<td>Conducting Clinical Trials Under ICH GCP E6</td>
<td>March 26-27, 2020</td>
</tr>
<tr>
<td>Auditing Techniques for Clinical Research Professionals</td>
<td>March 30-31, 2020</td>
</tr>
<tr>
<td>CRA &amp; CRC: Beginner Program</td>
<td>March 31-April 2,2020</td>
</tr>
<tr>
<td>Clinical Trial Assistant Fundamentals</td>
<td>April 2-3, 2020</td>
</tr>
<tr>
<td>Introduction to Clinical Research</td>
<td>April 2-3, 2020</td>
</tr>
<tr>
<td>Clinical Project Management: Advanced Concepts in Project Management</td>
<td>April 6-7, 2020</td>
</tr>
<tr>
<td>Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) in Site Management</td>
<td>April 6-7, 2020</td>
</tr>
<tr>
<td>Soft Skills Development for Clinical Research Professionals</td>
<td>April 6-7, 2020</td>
</tr>
<tr>
<td>Monitoring Clinical Drug Studies: Intermediate</td>
<td>April 8-9, 2020</td>
</tr>
</tbody>
</table>

San Diego, CA

<table>
<thead>
<tr>
<th>Course</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitoring Clinical Drug Studies: Beginner</td>
<td>March 25-27, 2020</td>
</tr>
<tr>
<td>Clinical Project Management: Fundamentals of Project Management</td>
<td>March 30-31, 2020</td>
</tr>
<tr>
<td>Drug Safety and Pharmacovigilance: Effective Drug Safety Reporting and Surveillance</td>
<td>March 31-April 1, 2020</td>
</tr>
<tr>
<td>Statistical Concepts for Non-Statisticians</td>
<td>March 31-April 1, 2020</td>
</tr>
<tr>
<td>Comprehensive Monitoring for Medical Devices</td>
<td>March 31- April 2,2020</td>
</tr>
<tr>
<td>Monitoring Clinical Drug Studies: Advanced</td>
<td>April 2-3, 2020</td>
</tr>
<tr>
<td>CRA &amp; CRC: Beginner Program</td>
<td>June 17-19, 2020</td>
</tr>
<tr>
<td>Introduction to Clinical Research</td>
<td>June 18-19, 2020</td>
</tr>
<tr>
<td>Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) in Site Management</td>
<td>June 18-19, 2020</td>
</tr>
<tr>
<td>Auditing Techniques for Clinical Research Professionals</td>
<td>June 22-23, 2020</td>
</tr>
<tr>
<td>Clinical Trial Assistant Fundamentals</td>
<td>June 22-23, 2020</td>
</tr>
<tr>
<td>Monitoring Clinical Drug Studies: Intermediate</td>
<td>June 22-23, 2020</td>
</tr>
<tr>
<td>Soft Skills Development for Clinical Research Professionals</td>
<td>June 23-24,2020</td>
</tr>
<tr>
<td>WORKSHOP: Trial Master Files: Why They Are Important and How to Organize Them</td>
<td>June 25, 2020</td>
</tr>
<tr>
<td>Conducting Clinical Trials Under ICH GCP E6</td>
<td>June 25-26, 2020</td>
</tr>
</tbody>
</table>
What Makes Barnett’s Publications Unique?
Unparalleled in industry, Barnett’s comprehensive reference guides, publications, self-study tools, and job aids are one-of-a-kind resources for the pharmaceutical and medical device professional. Barnett is the source for must-have publications for clinical research, regulatory affairs, and research and development professionals with sponsor companies, CROs, and clinical research sites.

What Type of Information is Included?
Barnett publications cover the basics, address emerging issues, and answer your toughest questions:

- Barnett’s annually updated publications provide up-to-the-minute data and regulations, best practices, and compliance insights that affect every clinical research professional.
- Our reference manuals contain valuable analysis, case studies, and insights garnered from thought leaders on the most important new developments in the industry.
- Barnett’s unique question and answer format to reference guides brings readers’ questions to life, responded to by sought after subject matter experts.
- Self-study materials provide learners with self-paced training with comprehensive content and exercises that test their knowledge.
- Unique textbooks provide both novice and experienced regulatory professionals the direction and detail they need to meet regulatory challenges.
- Compendium that compile unparalleled statistics, trends, and proprietary market intelligence and analyses on the biopharmaceutical industry, supported by thousands of graphs, illustrations, and analyses.

Are Barnett Publications Offered Electronically?
Yes. Four of our most popular publications, the Good Clinical Practice: A Question & Answer Reference Guide, the State-by-State Clinical Trial Requirements Reference Guide, The Clinical Research Finance Roadmap Companion Reference Guide: Tools, Templates and Resources, and the PAREXEL Biopharmaceutical Statistical Sourcebook, are offered in electronic format. Contact us about electronic access for individuals, for groups, or for your whole company.

Can I Put My Company Logo on Barnett Books?
Yes. Custom covers are available for several Barnett publications, including the Good Clinical Practice: A Question & Answer Reference Guide and the CFR/ICH GCP Requirements Reference Guides (Drug and Device). Custom cover books are great for new hires, clinical research sites, and exhibition giveaways!

How Do I Order Barnett Publications?

<table>
<thead>
<tr>
<th>Online:</th>
<th>Telephone:</th>
<th>Mail Check to*:</th>
</tr>
</thead>
</table>
| barnettinternational.com | +1 781.972.5400 or toll-free in the U.S. 800.856.2556 | Barnett International  
250 First Avenue, Suite 300  
Needham, MA 02494 |

*To mail in your order, please complete the order form on either page 226 or page 240.
New Drug Development: A Regulatory Overview

“This book provides the most comprehensive and up-to-date analysis of FDA’s new drug development process available today. I recommend this well-written book for professionals engaged in the drug development and review process.”
- BioPharm International

“This book is superb! It is the single best source of information on the drug regulatory system.”
- Peter Barton Hutt, Covington & Burling

New Drug Development: A Regulatory Overview is considered an authoritative, critical, and “go-to” resource to navigate the FDA’s drug development approval process. The 400-page reference book addresses the most-cutting edge developments redefining how new drugs are developed and regulated today, including:

- How the FDA Amendments Act of 2007 affects everything from drug reviews to postmarketing requirements.
- How CDER’s efforts to integrate a “culture of drug safety” has affected the center’s structure and its new drug review and approval processes.
- How CDER’s January 2008 transition to the eCTD as the “only valid e-submission format” affects the FDA’s drug submission and review process.
- How the FDA and industry are already integrating pharmacogenomics, computer simulation, and other emerging technologies to inform key decisions.
- Which drug development strategies are fulfilling their promise and offering optimal returns for industry, given the explosion of accelerated development/approval programs and pilot programs to speed the drug development and review process.

Publication Code: NDD08 .................................. Price: $145.00

IND Submissions: A Primer

An in-depth guide to writing, tracking, and submitting the original IND and applicable IND amendments

“For those in Regulatory Affairs, IND Submissions: A Primer is a must. Whether one is new to Regulatory Affairs or a seasoned veteran, this book will provide you with the information you require to file a proper IND.”
- Albert A. Ghignone, M.S., R.A.C., CEO/President, AAG, Inc.

Note: This publication is currently unavailable as it is being updated for early 2020 release.

IND Submissions: A Primer provides a “hands-on” approach that teaches regulatory professionals, novice and veteran alike, to work with the regulations, guidance documents, content templates, and style guides necessary to write an IND. The book’s writing tips show regulatory professionals how to produce a range of US drug and biologics submissions that comply with the requirements and are clear to read. Included with the book is a CD filled with electronic examples.

The 600-page, spiral-bound, hardcover book is easy to use and outlines step-by-step how to plan, write, and submit regulatory documents. Each of the 62 chapters is divided by easy-to-read tabs. This is the ideal resource for new professionals entering the field, a useful training guide, and a valuable reference for the experienced professional.

Regulatory submissions are more than just writing – they encompass strategy, research, organizing and leading a team, compiling, editing, publishing, and tracking of the information. The IND Submissions book is the step-by-step reference guide to help you accomplish these initiatives and goals.

For each submission type, the book outlines:
- Regulations and guidance documents
- Overview and background on why the submission is required
- Submission structure
- Who contributes to the submission
- Where to pull, re-use, or get the information needed in the submission
- How biologics differ
- Applicable FDA Form(s) information
- Electronic CTD sections, where applicable
- Real-life examples from the media and approved NDAs, when available
- Electronic examples and content templates that can be utilized to begin working on the submission immediately
Medical Device Development:
Regulation and Law

"I can safely say this is the most practical and comprehensive book on the subject of FDA regulation of medical devices. This edition includes a detailed but understandable review of all the key device regulatory issues faced by the device industry as well as an up-to-date review of the most salient developments in device regulation such as the new Cures Act provisions relating to medical device software and the most recent developments in the regulation of combination products."

- Mary Monovoukas, Counsel, Boston Scientific

Newly updated for 2020!

The all-new Medical Device Development: Regulation and Law 2020 Edition, is the must-have practical reference for regulatory affairs professionals. This authoritative text provides the most comprehensive and updated analysis of U.S. medical device and diagnostics development and approval requirements anywhere. The new edition offers analysis of new updated analysis of U.S. medical device and diagnostics development and professionals. This authoritative text provides the most comprehensive and 2020 Edition, is the must-have practical reference for regulatory affairs regulation of combination products.

• New statutory provisions and guidance documents related to regulation of software as a medical device, cybersecurity, general wellness products, real-world evidence, use of benefit risk information for both premarket and post-market processes, and when post-clearance changes require submission of a new 510(k) notice.
• Update on the new TPLC organizational structure of CDRH.
• Updates to the pre-submission process, including new MDUFA IV goals for meetings and feedback.
• Updates to FDA’s “refusal to accept” and review policies relating to 510(k)s, PMAs, and pre-submissions.
• Update on the investigational device exemption process including new guidance documents and policies related to clinical trials, including IDE benefit-risk considerations, new Good Clinical Practices (GCPs) guidance and policy for use of foreign data, policies regarding ClinicalTrials.gov registration, as well as guidance documents on adaptive design, leveraging data for pediatric use, and demographic factors in clinical studies.
• Changes to the premarket approval application process including FDA guidance on distinguishing between 30-Day Notice PMA Supplements and Site Change PMA Supplements.
• New policies and guidance documents concerning in vitro diagnostic products, including updates on research and investigational use and laboratory developed tests.
• Update on device compliance issues, including the 2016 medical device reporting guidance.
• New guidance documents and cases relating to combination products incorporating medical devices.
• New changes to FDA’s review of requests for issuance of certificates to foreign governments.
• FDA policy regarding the regulation of third party reprocessors.

Publication Code: MEDDEV20 .......... Price: $195.00

State-by-State Clinical Trial Requirements Reference Guide

“...an excellent reference, and the only one on this topic.”
- Norman M. Goldfarb, Managing Director, First Clinical Research LLC

Update Due in 2020!

Although many clinical trial sponsors and investigators focus primarily on FDA regulations related to the conduct and design of clinical trials, their failure to comply with state laws and regulations may expose sponsors, investigators, IRBs, institutions, or individuals to significant liability risks and call into question the potential integrity of clinical data. Today’s US-based clinical trials must meet not just federal requirements, but an increasingly complex array of state-specific requirements as well. In fact, many areas critical and foundational to clinical studies – age of consent, capacity to consent, notification of state agencies, experimental drug dispensing requirements, genetic testing, and legal representatives, among many others – are driven by state, and not federal, laws. How do you monitor the requirements of all 50 states? State-by-State Clinical Trial Requirements Reference Guide provides totally updated and expanded profiles of the clinical trial standards in all 50 states. This newly updated resource breaks down each state’s requirements in more than a dozen practical areas critical to your clinical research programs, including:

• State statutory structures for clinical trials
• Required notifications to state officials/offices
• Legal representative standards
• Age of consent/Capacity to consent
• Drug dispensing/administration requirements
• Informed consent, IRB, and clinical protocol requirements
• State licensing authorities (medical, nursing, pharmacy)
• Special state rules for cancer research
• State HIV testing rules
• State requirements for genetic testing
• State-specific benefits afforded clinical research

Bulk Order Discounts Available, Customizable with Your Company Logo, Great for New Hires and Sites!

Publication Code: CT20 .................. Price: $99.95
Electronic Version: CT20E ................. Price: $89.95

Published by Barnett International

Also Available in Electronic Format!

• Fully searchable by keyword
• Active links internally and externally
• Bulk pricing and custom covers available

Two Easy Ways to Order: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Barnett’s Clinical Research Associate (CRA) Training Series: A 7-Volume CRA Self-Study Curriculum

This unique self-study curriculum is designed to provide a hands-on perspective surrounding the day-to-day work of the clinical research monitor. Newly updated to include requirements of ICH GCP E6 R2, this 7-volume set provides the fundamentals of being a Clinical Research Associate (CRA) in today’s environment. Each volume can be used as a stand-alone reference or as a complete self-study training series. The following content is included (by volume):

**Volume 1: An Overview of Drug Development** is written to introduce new CRAs to the drug development process, while contextualizing it to the role of the CRA. Included are important terms and acronyms encountered by CRAs, as well as what happens before and after a clinical study.

**Volume 2: Identifying and Screening Investigators** focuses on the characteristics of good clinical investigators and the process of finding investigators who meet the needs of the protocol, the formal plan for the study. Included are procedures for investigator identification and screening, first contact and investigator selection.

**Volume 3: Conducting Prestudy Visits** describes the process of preparing for the site visit, conducting the visit, and assessing the site. Included are details regarding meeting agendas and scheduling, budget negotiation techniques, site assessment criteria and necessary discussion points, and recommended procedures and documentation.

**Volume 4: Conducting Study Initiation Visits** covers the training of site staff to conduct the study. Included are guidelines for planning, conducting and documenting a study initiation visit, including the objectives, preparation, task analysis and documentation and follow-up.

**Volume 5: Conducting Routine Monitoring Visits** describes how to prepare for, conduct, and follow up monitoring visits from the time that the first subject is enrolled to the final site visit. Included are strategies for ensuring that the study is being conducted according to the protocol and good clinical practice (GCP).

**Volume 6: The CRA’s Reference for Adverse Events** serves as a reference for the AE-reporting process and provides procedures for the monitor to follow.

**Volume 7: Test Your CRA Knowledge** is filled with exercises which test your knowledge and understanding of the material presented in the previous volumes. Answers for each of the questions are included in the second section of the manual, making immediate feedback available.

Purchase individually or as a complete 7-volume set!

Publication Code: CRAS18
Price: $599.00

For individual volume pricing, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 or visit our website at barnettinternational.com.

---

Barnett’s Study Site Training Series: A 6-Volume Self-Instructional Training Series for Investigative Teams

“A common sense, practical introduction to the roles of the study coordinator and investigator. It is excellent preparation for anyone at a research site — or at a study sponsor or CRO — who wants to understand how studies are conducted at sites.”

- Norman M. Goldfarb, Managing Director, First Clinical Research LLC

Designed to provide the essentials of roles and responsibilities of the clinical study team as well as the tasks involved, this 6-volume set provides the basics of conducting clinical research in today’s environment. Equipped with exercises and learning activities, each manual can be used as a stand-alone reference or as a complete self-instructional training series. The following content is included (by volume):

**Volume 1: The Clinical Study Site Team: Roles and Responsibilities**
Volume 1 is designed to provide readers with an understanding of the roles, responsibilities, and associated tasks of clinical research team members at investigative sites.

**Volume 2: FDA Clinical Research Regulations and GCPs: The Essentials**
This volume describes the “rules” and “guidelines” developed by regulatory agencies designed to regulate the conduct of clinical research, emphasizing those requirements that most directly impact investigative site teams.

**Volume 3: IRBs/IECs and Informed Consent: Protecting the Rights of Human Subjects**
This volume includes what investigative site team members need to know regarding protection of the rights and safety of human subjects. In addition to presenting applicable regulations and practical implications, the roles of the IRB/IEC and the study sponsor are also discussed.

**Volume 4: Sponsor Visits and Regulatory Audits: What You Need to Know**
Here, the several types of visits to study sites and when they each occur is described. Included are examples and learning exercises designed to prepare study site teams for sponsor visits, study closeout, audits and regulatory inspections.

**Volume 5: Your Role in Reporting Adverse Experiences**
Volume 5 covers how to observe, manage, classify, record and report AEs during clinical studies. It is also intended to familiarize study team members with the many specific procedures required by regulatory agencies to ensure patient safety.

**Volume 6: Understanding, Evaluating, and Implementing Clinical Protocols**
This volume is designed to assist teams in protocol implementation. Included are the features of protocols, evaluation strategies, implementation assessment, as well as basic protocol design and writing.

Purchase individually or as a complete 6-volume set!

Publication Code: SSSV181-6
Price: $499.00

For individual volume pricing, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 or visit our website at barnettinternational.com.
2019 CFR/ICH GCP Reference Guide

Updated each year, this convenient pocket guide puts the most commonly referenced U.S. regulations and international guidelines at your fingertips:

- FDA Code of Federal Regulations, Good Clinical Practice Parts 11, 50, 54, 56, 312, and 314
- Good Laboratory Practice Part 58
- ICH Guideline Good Clinical Practice E6 R2
- ICH Guideline Clinical Safety Data Management (E2A)
- The European Union Clinical Trials Directive
- The European Union Good Clinical Practice Directive
- Available in Spiral Binding

Publication Code (Spiral Bound): CFRS19 ....... Price: $17.95

The Form FDA 1572: A Reference Guide for Clinical Researchers, Sponsors, and Monitors

The Form FDA 1572: A Reference Guide for Clinical Researchers, Sponsors, and Monitors answers the difficult questions that real life creates from even the simplest regulations. The core of this book is a section-by-section guide to completing the 1572 form.

- Norman M. Goldfarb, Managing Director, First Clinical Research LLC

This state-of-the-art reference guide addresses an emerging reality in clinical research today: As the number of FDA-issued warning letters to clinical investigators has risen in recent years, so too have citations regarding investigators’ failure to complete the 1572 appropriately and correctly.

The Form FDA 1572 book was developed to help not only experienced clinical investigators who struggle to address the 1572 in the emerging complexities of modern clinical trials, but also the growing number of investigators who are conducting their first FDA-regulated trial each year. The reference guide addresses new 1572-related challenges facing clinical investigators and industry trial sponsors, as well as the most often-asked—but never answered—questions related to the growing complexity of today’s clinical trials.

Publication Code: INV08 .............................. Price: $45.00

2019 CFR/ICH GCP Reference Guide for Medical Devices

Newly updated in 2019, the spiral bound pocket guide is designed specifically for the medical device and combination product industry and covers the:

- FDA Code of Federal Regulations, Good Clinical Practice Parts 11, 50, 54, and 56
- Medical Devices and Quality Systems Parts 801, 803, 806, 807, 812, 814, 820, and 822
- Product Jurisdiction Part 3 for Combination Products
- ICH Guideline Good Clinical Practice E6 R2
- Available in Spiral Binding

Publication Code (Spiral Bound): DEVCFRS19 .... Price: $17.95

Good Clinical Practice: A Question & Answer Reference Guide 2018

This industry-leading GCP reference guide answers over 1,000 of the most common and difficult questions regarding the interpretation and implementation of U.S. and international GCP standards for drugs, biologics, and medical device clinical trials. The completely updated and expanded 2018 guide includes:

- Continued updates focused on the impact of changes to ICH GCP E6 R2, enforcement of the revisions and its impact on clinical trial processes and systems, including Quality-by-Design and Risk-Based Quality Management (QM) expectations.
- Dozens of new Q&As including FDA’s guidance on R2 implementation, status of the EU Directive update, and changes to U.S. FDA Compliance Program Guidance Manual 7348.10.
- Updates on the EU’s new General Data Protection Regulation (GDPR) and the MHRA 2018 Data Integrity Guidance.
- Coverage on updates to the “Common Rule” and NIH updates for clinical trials research.
- New questions focused specifically on how Risk-Based Quality Management (Section 5 of the Addendum) impacts monitoring activities.
- Updates to state- and country-specific regulations including the U.S., Brazil, Argentina, Peru, India and many others.
- Over 25 contributing authors with targeted expertise in QA, Monitoring, Compliance, Site Management, TMF, Data Management and many other core clinical research areas.
- Plus extensive graphs and charts on latest inspection trends and findings!

Publication Code: GCP18 ............................ Price: $79.95

Electronic Version: GCP18E ....................... Price: $69.95

Available in Electronic Format!
- Fully searchable by keyword
- Active links internally and externally
- Bulk pricing and custom covers available

Publications

Two Easy Ways to Order: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Biologics Development: A Regulatory Overview

Authorised by FDA and industry officials, Biologics Development: A Regulatory Overview is the first text to provide a detailed analysis of the FDA's regulation of the development process for... biological products. [It] gives special emphasis to the recent wave of organizational, management, and operating initiatives within... CBER... including lot release, user fees, and promotional labeling policies.

- RAPS News

Biologics Development: A Regulatory Overview is the first text to provide a detailed analysis of the FDA's regulation of the development process for... biological products. [It] gives special emphasis to the recent wave of organizational, management, and operating initiatives within... CBER... including lot release, user fees, and promotional labeling policies.

- RAPS News

A first-rate information source on the biologics approval process! This text provides an up-to-date reference for the expert, and an excellent overview for the novice. More important, it is one of the precious few sources for obtaining the detailed thoughts of current CBER officials.

- Gary E. Gamerman, M.S., J.D., Fenwick & West

Written by CDER and CBER officials and industry experts, Biologics Development: A Regulatory Overview offers an expansive examination of the FDA's regulation of biologic products, from preclinical testing to post-marketing regulatory requirements, and from user fees to electronic submissions. The book also provides the first detailed look inside the re-invented FDA that will regulate and approve today's biological products along with a detailed analysis of each stage of the biological product development process available anywhere, including:

- CDER's emerging organization and processes for regulating and reviewing therapeutic biological products.
- CDER's processes for regulating and reviewing cellular and gene therapies, vaccines, and blood products.
- How CDER and CBER are evolving their procedures and requirements to address new challenges presented by the user-fee program, risk management priorities, and internal agency initiatives.
- Emerging standards for the clinical and nonclinical testing of biological products.

Publication Code: BIODEV3
Price: $145.00

Expediting Drug and Biologics Development: A Strategic Approach

From the first preclinical testing to clinical trials to the NDA/BLA review, Expediting Drug and Biologics Development shows you how to use reverse-engineering techniques to drive and improve each aspect of a drug and biologic product development program’s design and implementation. Written by dozens of leading experts, this book is a real-world “doer’s” guide. It provides templates, forms, and tools to assist those “in the trenches” of new drug and biologic development today. With this book, you will learn how to:

- Apply the very latest and most advanced project management techniques directly to challenges presented by the drug development process.
- Critically evaluate the needs of the package insert and marketing application up front, before getting deeply into clinical trials.
- Leverage standardization to drive and expedite the entire development process, from the development of clinical trial protocols to the development of clinical data presentations.
- Critically assess the needs of the final report before developing the clinical protocol.
- Use draft case report forms (CRFs) to dictate the content of the procedures section of the clinical protocol.
- Constructively consider the methods for data analysis in developing the clinical protocol.
- Provide direct access to the expertise and recommendations of dozens of the most experienced and forward-thinking experts in the pharmaceutical and biotechnology industries today.

Publication Code: EXP06
Price: $145.00

In the age of technology, many organizations struggle with incorporating federal and billing regulations with electronic systems. This comprehensive guide takes the reader through the clinical research financial road map in a step-by-step fashion. It focuses on the financial feasibility of considering a clinical research study, incorporating the study into integrated systems, and managing patient and sponsor billing. The Clinical Research Finance Roadmap: A Comprehensive Guide to the Financial Aspects of Clinical Research provides an in-depth look at the applicable regulations, operational efficiencies and risk mitigation strategies through the implementation of a compliant Clinical Research Billing (CRB) program. Readers will learn how to leverage study and patient data to maintain and enhance a comprehensive and compliant CRB program.

- Chapter 1: History of Clinical Research and Protecting Human Subjects
- Chapter 2: The Feasibility Assessment Phase: Deciding to Participate in Clinical Research Study With a Focus on Financial Feasibility
- Chapter 3: Creating a Medicare Coverage Analysis (MCA): A Step-By-Step Approach; Billing Regulation Review
- Chapter 4: Clinical Trial Budgets and the Hidden Costs
- Chapter 5: Negotiating a Clinical Trial Budget
- Chapter 6: Integrating with the Electronic Health Record – Creating a Billing Grid
- Chapter 7: Investigator and Study Team Preparedness – Training and Study Initiation
- Chapter 8: Patient Billing: Charge Review Process and Medical Documentation
- Chapter 9: Participant Remuneration
- Chapter 10: Study Revisions/Contract and Budget Amendments
- Chapter 11: Sponsor Billing: Payment Milestones
- Chapter 12: Study Close-Out: Reconciliation Processes and Ensuring All Payments Received
- Chapter 13: Leverage Data: Using Patient and Study Data to Manage Current and Future Studies

Publication Code: FIN19 ............................................ $169.95

The Clinical Research Finance Roadmap Companion Reference Guide: Tools, Templates and Resources

This companion reference guide to The Clinical Research Finance Roadmap: A Step-by-Step Guide to Putting Regulations into Operation provides tools, templates and resources to assist the Principal Investigator and others with navigating through the clinical research finance processes. The Clinical Research Finance Roadmap Companion Reference Guide: Tools, Templates and Resources provides helpful forms, templates, standard operating procedure and policy outlines. The tools and resources aid with developing a risk-based approach to managing the clinical research portfolio, navigating decision trees for determining financial feasibility, development of Medicare Coverage Analysis (MCA), developing budgets, tracking milestones, managing sponsor payments, and patient remuneration. The guide is provided in electronic format.

Specific Tools, Templates and Resources Include:

- Calendar for the Identification of Procedures and Timepoints
- Charge Review Tracking Tool
- Clinical Research Decision-making Go/No-Go Decision Making Tool
- Clinical Research Patient Revenue Tracking Tool (ROI for Your Organization)
- Creating a Clinical Trial Budget Template
- Decision Tree for Reviewing NCD/LCD for Coverage
- Fee Justification Documents and Associated SOPs
- Financial Clearance for Subjects Forms: Insurance Pre-authorizations and Denials
- Monitor Visits Tracking Tool for Reconciliation with Contract Terms for Payments
- Participant Remuneration Worksheet
- Productivity Models
- Qualifying Clinical Trial Objectives Tool
- Risk-based Approach to Charges Review Tool
- Staffing Model Development Tool
- Study Close Out – Reconciliation Process Tool for Ensuring All Payments Received
- Study Metrics Tracking Tool
- Templates for Standardizing Study Notes
- Timeline Tool for Missed Patient Appointments and Schedule Adjustments

Electronic Edition: FINCOM19E ...................................... $119.95

Two Easy Ways to Order: Online at barnettinternational.com or Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556.
Three Easy Ways to Order:
- Online: www.barnettinternational.com
- Telephone/Fax: +1 781.972.5400 or toll-free in the U.S. 800.856.2556. Or Fax Order Form to: +1 781.972.5425
- Mail Check to: Barnett International, 250 First Avenue, Suite 300, Needham, MA 02494

<table>
<thead>
<tr>
<th>Publications</th>
<th>Code</th>
<th>Price</th>
<th>Qty</th>
<th>Subtotal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Guides and Job Aids</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good Clinical Practice: A Q&amp;A Reference Guide (2018)</td>
<td>GCP18</td>
<td>$79.95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CFR/ICH GCP Reference Guide for Medical Devices (Spiral Bound) (2019)</td>
<td>DEVCFRS19</td>
<td>$17.95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Self-Instructional Study Site Training Series (6 volume set)* (2018)</td>
<td>SSS18</td>
<td>$599.95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>State-by-State Clinical Trial Requirements Reference Guide (2020)</td>
<td>CT20</td>
<td>$99.95</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Compendia, Textbooks, and Trend Reports            |        |         |     |          |
| PAREXEL Biopharmaceutical R&D Statistical Sourcebook 2018/2019 (Hardcopy) | PRD18  | $545.00 |     |          |
| PAREXEL Biopharmaceutical R&D Statistical Sourcebook 2018/2019 (Electronic & Hardcopy) | PRD18E | $1,300.00 |     |          |
| Medical Device Development: Regulation and Law (2020) | MEDDEV20 | $195.00 |     |          |

Subtotal: $4,095.00

Standard Domestic Shipping (7-10 business days)
(Barnett uses the FedEx rate calculator for all shipments. Contact Barnett for specific rates/shipping options.)

TOTAL: $4,095.00

ORDER DATE: ________________________________________________

PAYMENT INFORMATION:  
☐ Credit Card (MC, Visa, AmEx)  ☐ Check (Order will NOT be processed until check is received)
☐ Visa  ☐ MC  ☐ AmEx  Card # ___________________________  Expiration ______ / ________

Check Number (Order will NOT be processed until check is received)

Signature (REQUIRED FOR CREDIT CARD ORDERS):

SHIPPING INFORMATION: (Please Print)
Name: ____________________________
Title: ____________________________
Organization: __________________
Address: ________________________
City/State/Zip: __________________
Phone: _________________________
Fax: ___________________________
Email: _________________________
(REQUIRED TO SEND CONFIRMATION AND TRACKING INFORMATION)

BILLING/INVOICING INFORMATION: (THIS IS THE PERSON WHO WILL RECEIVE AN INVOICE VIA EMAIL – an invoice will NOT be sent via regular mail)
Billing/Accounts Payable Contact: ____________________________
Title: _____________________________
Organization: __________________
Address: ________________________
City/State/Zip: __________________
Phone: _________________________
Fax: ___________________________
Accounts Payable/Billing Email (REQUIRED TO SEND INVOICE – Your order will NOT be processed without this information): ____________________________
What are Barnett’s Consulting Services?
Why start from scratch when you can put Barnett’s resources and expertise to use for your organization? Drawing on our 30 years of experience as a leading training provider, Barnett brings our expertise to clients through our highly refined training program development methodology in a variety of ways. From custom training program development through competency mapping and assessment, Barnett’s services are available to your organization in a cost effective approach.

What are Barnett’s Consulting Offerings?
Barnett offers services in the following areas:
• Customized content development
• Role-based assessments
• Competency map development
• Curriculum gap analysis and training curriculum plan development
• Employee satisfaction surveys
• Employee communications and logistics services
• Good Clinical Practice (GCP) training and assessment programs
• Licensing of Barnett’s Content
• Mock audits and findings-based training
• Virtual meetings support services
• eLearning module development
• Acquisition Integration: Strategy and Implementation Services
• SOP Development and Training

Who are Barnett’s Consultants?
Barnett’s consultants have deep experience in training and development programming, including training needs assessment, curriculum development, competency mapping and program development. In addition, by utilizing their hands-on experience in the roles in which they consult, Barnett consultants bring a unique approach to your organization.

How Do I Get Started?
To receive a quote for your project, contact Barnett today at +1 215.413.2471.
Good Clinical Practice (GCP) Training and Assessment Program

How do you ensure that your teams are following the same GCP processes and standards set forth by your organization? Barnett International is pleased to offer formal Good Clinical Practice (GCP) training and assessment for global clinical research professionals. Barnett’s training and assessment processes were created in response to an increase in requests for a third-party industry standard for GCP training, as well as recognition from the industry of Barnett’s years of experience and expertise in GCP education and training initiatives.

Using a rigorous test question development and validation process, Barnett assesses employees in the area of GCP compliance. Barnett’s approach includes a multi-tiered approach that ensures the exam is fully vetted by industry subject matter experts, and that test questions go beyond the simple recall of facts and require practical knowledge demonstration and application.

By passing Barnett's GCP training and assessment, you can be certain:
• Participants are fully aware of the regulations and their implications for practice
• Participants have demonstrated proficiency in the practical application of GCPs
• Participants have been tested by a credible third-party administrator
• Participants’ core GCP competency has been assessed

Deliverables include:
• Comprehensive role-based GCP exams which can be tailored to your organization’s SOPs
• Core GCP training in the training platform of your choice: in-person, live or recorded web-based training or self-paced online training modules
• Certification and accreditation for GCP training and assessment activities
• Tracking and record keeping of completion status by teams, studies, and across global organizations

For more information about Barnett’s GCP Certification, contact Barnett International at +1 215.413.2471 or nganatra@barnettinternational.com.

Curriculum Compliance Assessment and Development (C-CAD) Programs

Building on our deep expertise as a training organization, Barnett’s training consultants and subject matter experts work with your training departments or functional areas to develop exciting and interactive curriculum plans for your employees that combine technical, regulatory, and leadership development training. Through our curriculum compliance assessment and development services, your organization can leverage Barnett’s 30+ years of experience in clinical research training program planning, design and implementation. Focused on the adult learner, Barnett’s expertise includes working with your training leads to optimize performance of clinical research professionals worldwide, through the design of engaging and outcomes-oriented training program development.

Deliverables include:
• Competency map development for clinical research functional areas and specific roles
• Curriculum gap analysis
• Training curriculum plan development
• Employee satisfaction surveys
• Employee communications and logistics services
• Customized content development
• Role-based assessments

Let Barnett leverage our training experience and resources for your employees. To learn more and to receive a sample curriculum, contact Barnett International at +1 215.413.2471 or nganatra@barnettinternational.com.
Mock Audits and Findings-Based Training

Recent FDA 483s, warning letters, and other regulatory documents issued to Sponsors, CROs, IRBs, and Clinical Investigators indicate that the most frequently cited areas for noncompliance are also those that are most easily addressed with focused training programs. However, perhaps the most overlooked purpose of an audit is to provide an opportunity for education and training. Barnett Educational Services is pleased to provide your organization with Mock Audit and Findings-Based Training services, customized to address audit findings. Post-audit training allows you to disseminate information in real-time and therefore effect the timely development of corrective action plans.

An audit is defined as a systematic and independent examination of trial-related activities and documents to determine whether all elements of the clinical research infrastructure are functioning in accordance with the tenants of good clinical practice (GCP) and applicable regulatory requirement(s). Audits allow an opportunity to capitalize on identified strengths and develop process improvement plans for areas of potential weakness in a highly focused manner.

Deliverables include:

• Detailed audit agendas
• Detailed audit reports incorporating findings, global and regulatory risk assessment, and corrective and preventive action plan recommendations
• Audit certificates
• Tailored finding-specific training delivered at your facility or choice of venue, designed to incorporate the most current information available on the regulations, agencies, and guidance that govern the conduct of clinical research
• Current information on new developments and emerging trends within the clinical research industry for consideration

Move away from costly, reactive high-level quality control activities and further maximize resources by placing your training focus on areas that are of greatest regulatory risk.

For more information, contact Barnett International at +1 215.413.2471 or nganatra@barnettinternational.com.

Licensing of Barnett’s Content

Why start from scratch when you can access Barnett’s library of courses for your organization? With over 30 years of experience, Barnett’s expertise can be leveraged for your organization through the in-licensing of our core course content. From single courses to usage of Barnett’s comprehensive curriculum, your organization can access Barnett’s resources for your internal usage. The development of effective training content is time consuming and costly, and Barnett’s licensing services can help you to significantly reduce these costs for your organization. Developed by subject matter experts who are chosen not only for their experience working in the industry but also for their experience with learning engagement, Barnett’s content is unmatched in the industry.

Deliverables include:

• Licensing of Barnett’s content for usage within your organization
• Train-the-trainer programs and trainer certification
• Customization of modules to incorporate your organization’s SOPs, processes and culture
• Accreditation and certification
• Delivery of course modules by Barnett trainers as needed

Why reinvent the wheel when Barnett is already developing training content that includes industry proven approaches and up-to-date regulatory compliance details? Leverage our training library for your organization today.

For more details, contact Barnett International at +1 215.413.2471 or nganatra@barnettinternational.com.
Consulting and Support Services

Virtual Meetings Support Services

There is no denying that web-based meetings offer huge cost and time savings and allow for shorter and more focused meetings and training sessions while ultimately enhancing communication and understanding across remote teams. However, effectively managing your virtual meetings strategy and approach can be time consuming, and if not managed properly, it can also waste precious time and resources.

Barnett has developed a methodology and customized platform for virtual meetings and training support for our clients that has been tested by thousands of industry professionals. Using our proven approach,

Barnett supports our clients’ virtual training needs – from team meetings, in-house training, investigator meetings and global training. Let Barnett leverage our web-training resources for your organization.

**Deliverables include:**

- Web meeting interface development and platform support
- Invitation and registration management and reporting
- Comprehensive meeting hosting and technical support
- Speaker platform training and orientation on delivering engaging web-based sessions
- Facilitation and integration of interactive components: audience knowledge checks, polls, Q&A and breakout sessions
- Content, assessment and case study development
- Meeting recording, editing and archiving

Whether it is for your project teams, investigator meetings, or general corporate support, Barnett can custom-tailor web-based meetings and provide a company-specific experience. Let Barnett help you to maximize the usage of online platforms and create a memorable and outcomes-focused session for your users.

To plan a session, contact Barnett International at +1 215.413.2471 or nganatra@barnettinternational.com.

---

**eLearning Solutions**

Does your department have critical training needs that need constant reinforcement? Barnett’s customized eLearning development services allow you to train large groups of employees in a consistent and cost-effective manner. Designed as self-paced modules, Barnett’s eLearning programs offer highly interactive, fun, and engaging learning experiences for your teams. When you let Barnett develop your eLearning programs, you are leveraging our large base of subject matter experts, our technology partners and our eLearning development experience. Barnett’s subject matter experts have an average of over 15 years of hands-on industry experience in their specialty areas, including deep expertise and proven abilities in training and development. We at Barnett understand that strong eLearning programs start with clearly defined goals and objectives, and are rooted in best instructional design practices and engagement-focused technologies. Our research-based methodology and our years of training experience are used to design high-impact eLearning courses that are specially geared toward adult learners.

**Deliverables include:**

- eLearning module development in the platform of your choice
- Content development and instructional design support
- Content based on simulations, games, and interactive exercises
- Modules that are compatible with any SCORM or AICC compliant LMS or LCMS
- A variety of testing and assessment formats

Learn more about Barnett’s eLearning services and view our product demo. For more information, contact Barnett International at +1 215.413.2471 or nganatra@barnettinternational.com.
SOP Development and Training

Has your organization recently undergone changes such as merged with, acquired, or divested from another company? Have you experienced a change in organizational structure? If you answered “yes,” your Standard Operating Procedures (SOPs) must be reviewed and updated, and staff must be trained on the new procedures.

Barnett Can Help! Barnett appreciates that revising SOPs can be a time-consuming project. Our process development experts can efficiently lead the process and perform the majority of the work, with focused (and minimal) input from your staff, so that they may continue to maximize time on their everyday assignments. Using our experience and expertise in education and training, Barnett can also develop and/or deliver training on newly-revised procedures.

**Deliverables include:**
- Development of accurate, organization-specific SOP documents that are easy to read and follow
- Proven SOP development methodology that gains buy-in from stakeholders and end-users
- SOP consulting services provided by qualified industry experts
- SOP indices and recommended documentation

Alleviate this workload from your teams and allow Barnett to use our deep expertise in the clinical drug development process and industry best practices to your advantage.

For more information on Barnett’s SOP Development and Training Services, contact Barnett International at +1 215.413.2471 or nganatra@barnettinternational.com.

---

Acquisition Integration: Strategy and Implementation Services

Barnett can help Life Sciences organizations successfully plan for and execute the integration of a newly acquired company. For many life sciences organizations, acquiring other companies is a way to achieve their strategic goals. But what happens after the contracts are signed? How can an organization successfully manage the change that comes with acquiring a new organization? Barnett helps drive the integration process with a proven methodology focused on answering key questions such as:

- What are the integration goals for your organization?
- How will you know we’ve been successful?
- What is your approach: integration of processes and best practices or assimilation or something else?
- How will you handle the acquired company’s studies in progress?
- What newly acquired employees will be transitioned to your organization and how does that affect your structure?
- How will you handle SOPs, training, and systems while remaining in compliance?
- How will you align with and leverage shared services?
- How will you ensure those responsible for the integration are working in concert?
- How will you communicate about the acquisition to your organization?
- How will you minimize resistance and foster resilience to the change?

**Deliverables include:**
- Acquisition integration strategy plan development
- Integration Steering Committee formation and facilitation
- Liaising with other organizations to ensure alignment
- Development of implementation road maps, including transition plans, process maps, and technology integration plans
- Road map execution and project management

With something as important as an acquisition, you don’t have time to do it over. You have to do it right the first time. Choose Barnett to help you drive successful acquisition integration.

For more information, contact Barnett International at +1 215.413.2471 or nganatra@barnettinternational.com.
What is a Barnett eLearning Course?
Barnett’s eLearning courses offer a highly interactive experience, and require the user to engage with the content through consideration of core content, scenarios and situations experienced on the job, knowledge checks and assessments. The courses are self-paced modules designed to accommodate the busy schedules of clinical research professionals. Courses can be accessed at any time of day or night – whatever is convenient for each user. As participants move through the course, their learning is “bookmarked,” in case it is necessary to leave the course and return at another time. Access is completed when the final course assessment is passed and a score of 80% or higher is achieved.

What are the Benefits?
Barnett’s courses are unique in the following ways:
• Highly-relevant, scenario-based training modules that can be accessed anytime, anywhere
• Designed to engage learners with adult learning principles in mind
• Convenient, customizable and focused on application
• Include emphasis on most frequent audit and inspection findings globally

How Do I Pass the Course and Receive My Certificate?
Once the course is completed and the post-test is passed (80% or higher), participants are taken to a certificate screen and can print a completion certificate.

Registration:
Registration for Barnett’s eLearning courses is available online at: barnettinternational.com
Once you select your course and register, you will receive your login details to access the course within a 24-hour period.

Customized Courses Available:
All of Barnett’s “off-the-shelf” eLearning courses are available for customization and integration into your organization’s Learning Management System. For details about this option, contact Naila Ganatra at +1 215.413.2471.
**Barnett’s On-Demand Good Clinical Practice for Sponsors and CROs**

**Too Busy To Attend A Course?**
While covering the core concepts of Good Clinical Practice (GCP), this sponsor and CRO-focused course is based on a series of “challenge” scenarios, including real-life situations that are encountered at clinical research sites. The course also includes an application-based post exam and once successfully completed, a certificate is provided.

**Course Learning Objectives**
- Learn and practice the application of GCP principles to real-world clinical research situations through the use of warning letters, scenarios, and simulations
- Ensure participants are consistently trained on International Council for Harmonization Good Clinical Practice (ICH GCP) to achieve:
  - Consistent global interpretation of GCP
  - Increased focus on patient safety
  - Consistent delivery of quality data

**Key Features Include:**
- Comprehensive ICH GCP E6 R2 coverage as well as top findings from FDA and EMA
- Focus on practical application of GCP principles and application-based activities
- Glossary of terms, bookmarking tool, ongoing scenario-based “knowledge checks” and post-course exam
- Includes a Barnett certificate of training
- Applicable for global clinical research professionals

Customized versions available for company-specific teams, including regional adaptation and SOP inclusion. Contact Barnett today at +1 215.413.2471 to learn more!

For more details, visit: [https://www.barnettinternational.com/on-demand-courses/GCP-Training/](https://www.barnettinternational.com/on-demand-courses/GCP-Training/)

---

**Barnett’s On-Demand Good Clinical Practice for Investigators**

**Too Busy To Attend A Course?**
This scenario-based eLearning course is designed with the busy Principal Investigator in mind. Based on real-life issues encountered by investigative site teams, this highly focused 7-module training is designed to ensure comprehensive understanding of the key components of ICH GCP (including E6 R2). The structure includes two assessment and completion options, depending on experience level. Upon successful completion, a certificate is provided.

**Course Learning Objectives**
Upon completion of this scenario-based course, participants will be able to:
- Describe Investigator responsibilities in the context of study protocol oversight and GCP compliance
- Recognize critical elements of human subject protection
- Discuss the requirements for investigational product management and maintenance of adequate and accurate records for research trials
- Recognize key requirements for patient safety management and regulatory reporting
- Discuss mandatory critical interactions with Institutional Review Boards (IRBs) or Ethics Committees (ECs)

**Key Features Include:**
- Comprehensive ICH GCP E6 coverage as well as top findings from FDA and EMA
- Focus on practical application of GCP principles and application-based activities
- Glossary of terms, bookmarking tool, ongoing scenario-based “knowledge checks” and post-course exam
- Includes a Barnett certificate of training
- Applicable for global clinical research professionals

Customized versions available for company-specific teams, including regional adaptation and SOP inclusion. Contact Barnett today at +1 215.413.2471 to learn more!

For more details, visit: [https://www.barnettinternational.com/On-Demand-Courses/GCP-Training-for-Investigators/](https://www.barnettinternational.com/On-Demand-Courses/GCP-Training-for-Investigators/)
Barnett’s On-Demand Good Clinical Practice for Study Coordinators

Too Busy To Attend A Course?
This scenario-based eLearning course is designed specifically for Clinical Research Study Coordinators. Based on real-life issues encountered by investigative site teams, this highly focused 7-module training is designed to ensure comprehensive understanding of the key components of ICH GCP (including E6 R2). The structure includes two assessment and completion options, depending on experience level. Upon successful completion, a certificate is provided.

Course Learning Objectives
Upon completion of this scenario-based course, participants will be able to:
- Describe Investigative Team responsibilities in the context of study protocol oversight and GCP compliance
- Recognize critical elements of human subject protection
- Discuss the requirements for investigational product management and maintenance of adequate and accurate records for research trials
- Recognize key requirements for patient safety management and regulatory reporting
- Discuss mandatory critical interactions with Institutional Review Boards (IRBs) or Ethics Committees (ECs)

Key Features Include:
- Comprehensive ICH GCP E6 R2 coverage as well as top findings from FDA and EMA
- Focus on practical application of GCP principles and application-based activities
- Glossary of terms, bookmarking tool, ongoing scenario-based "knowledge checks" and post-course exam
- Includes a Barnett certificate of training
- Applicable for global clinical research professionals

Customized versions available for company-specific teams, including regional adaptation and SOP inclusion.
Contact Barnett today at +1 215.413.2471 to learn more!

For more details, visit: https://www.barnettinternational.com/On-Demand-Courses/GCP-Training-for-Study-Coordinators/

Barnett’s On-Demand Fundamentals of Good Clinical Practice

Too Busy To Attend A Course?
This introductory course provides learners with the necessary background required when working in a Good Clinical Practice (GCP) environment. Designed for those not directly interfacing with clinical research sites, the course includes application-based examples and the rationale behind GCP principles. Upon successful completion, a certificate is provided.

Course Learning Objectives
- Describe the foundations, background, principles and application of ICH GCP
- Identify key regional regulations that impact the conduct of clinical trials
- Recognize the importance of complying with ICH GCP, as well as the impact of noncompliance
- Describe ICH GCP key roles and responsibilities in the conduct of clinical trials

Key Features Include:
- High-level ICH GCP E6 R2 coverage
- Focus on practical application of GCP principles and application-based activities
- Glossary of terms, bookmarking tool, ongoing "knowledge checks" and post-course exam
- Includes a Barnett certificate of training
- Applicable for global clinical research professionals

Customized versions available for company-specific teams, including regional adaptation and SOP inclusion.
Contact Barnett today at +1 215.413.2471 to learn more!

For more details, visit: http://www.barnettinternational.com/on-demand/foundations-of-gcp/
Barnett’s On-Demand 30-Hour Clinical Research Coordinator On-Boarding Program

Too Busy to Attend a Course?
This recorded, self-paced course provides 24/7 access to a comprehensive introduction to clinical research and the job functions of the Clinical Research Coordinator (CRC). Focused on the core skills required of the CRC job role, the learning approach in this course encourages critical thinking for those looking to support, facilitate and coordinate the daily activities of clinical trials at research sites.

Course Learning Objectives
- Describe the roles and responsibilities of the CRC
- Prepare for what a sponsor is looking for in a research site during a pre-study evaluation or site selection visit
- Understand the requirements for source documentation, case report forms, study tool development, and standard operating procedures (SOPs)
- Define informed consent requirements and learn the process of conducting informed consent
- Define safety reporting including definitions and safety reporting requirements
- Discuss regulatory compliance and quality assurance as it relates to audits and inspections

Key Features Include:
- Practical application of Good Clinical Practice principles as they apply to the role of the CRC
- Glossary of terms, quizzes, practice exercises and a mid-term and final exam
- CEU certificate upon successful completion of the mid-term and final exam
- Applicable for global clinical research professionals

Customized versions available for company-specific teams, including regional adaptation and SOP integration.
Contact Barnett today at +1 215.413.2471 to learn more!
For more details, visit:
http://www.barnettinternational.com/30-hour-on-demand-crc-on-boarding-program/

Barnett’s On-Demand 30-Hour Monitoring Oncology Clinical Trials Program

Too Busy to Attend a Course?
This recorded, self-paced course provides 24/7 access to practical, hands-on training for those interested in gaining knowledge about monitoring in the oncology therapeutic area. As demand for CRAs in the oncology arena continues to grow, this course offers practical, hands-on training covering oncology-specific logistical, clinical and ethical considerations. The application of clinical monitoring skills is reinforced through core content, exercises, case studies, and practice-based activities. The course also includes an application-based post-course exam, and once successfully completed, a certificate is provided.

Course Learning Objectives:
- Manage challenges associated with oncology trials
- Describe common characteristics of the Institutional Review Board (IRB) review and communications in oncology trials
- Examine approaches for decision-making at sites for dosing toxicities and dose modifications
- Apply standardized grading criteria to adverse events in oncology studies
- Establish strategies for source documentation and monitoring visits

Key features Include:
- Application-based exercises and examples
- Includes a Barnett certificate of training
- Focus on practical application of principles and job functions
- Applicable for global clinical research professionals
- Knowledge checks, assessments and post-course exam

Customized versions available for company-specific teams, including regional adaptation and SOP integration.
Contact Barnett today at +1 215.413.2471 to learn more!
For more details, visit:
http://www.barnettinternational.com/on-demand-30-hour-monitoring-oncology-clinical-trials-program
Barnett International connects clients with core clinical research training solutions and resources focused on practical application and measurable results.

In-Person and Web-Based Training Programs:

- Comprehensive Monitoring Curriculum Offered at 3 Levels
- Complete Project Management Curriculum Offered at 3 Levels
- Key Operational, Regulatory, and Research Site Focused Courses for Industry
- On-Demand ICH GCP Training

Custom Programs and Services:

- GCP Knowledge Assessments and Certification
- Curriculum Development, including Gap Analysis and Compliance Assessments
- Mock Audit and Follow-Up Training, SOP Development and Training
- CRA and CRC Curriculum and Train-the-Trainer Programs

Publications:

- Collection of Easy-to-Use Reference Guides, Customizable with your Company Logo
- Regulatory Textbooks, Industry Compendium, Reference Manuals, and Trend Reports
- Clinical Job Aides to Effectively Manage a Clinical Trial
### OVER THE LAST 10 YEARS

<table>
<thead>
<tr>
<th>Category</th>
<th>Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>9,200+</td>
</tr>
<tr>
<td>Speakers</td>
<td>1,866</td>
</tr>
<tr>
<td>Countries</td>
<td>46</td>
</tr>
<tr>
<td>Exhibit Booths</td>
<td>1,000</td>
</tr>
<tr>
<td>Presentations</td>
<td>1,600+</td>
</tr>
<tr>
<td>Conferences</td>
<td>19</td>
</tr>
<tr>
<td>Participants</td>
<td>2,000+</td>
</tr>
<tr>
<td>Speakers</td>
<td>300</td>
</tr>
<tr>
<td>Countries</td>
<td>28</td>
</tr>
<tr>
<td>Organizations</td>
<td>700+</td>
</tr>
<tr>
<td>Exhibitors</td>
<td>180+</td>
</tr>
</tbody>
</table>

#### Record Attendance in 2019

<table>
<thead>
<tr>
<th>Category</th>
<th>Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conferences</td>
<td>19</td>
</tr>
<tr>
<td>Participants</td>
<td>2,000+</td>
</tr>
<tr>
<td>Speakers</td>
<td>300</td>
</tr>
<tr>
<td>Countries</td>
<td>28</td>
</tr>
<tr>
<td>Organizations</td>
<td>700+</td>
</tr>
<tr>
<td>Exhibitors</td>
<td>180+</td>
</tr>
</tbody>
</table>

#### Company Titles

- 35% CRO
- 20% Biotech
- 20% Pharma
- 12% Healthcare/Hospital
- 10% Services/Societies

#### Titles

- 52% Executives
- 24% Sales & Marketing
- 15% Managers
- 7% Scientists & Technologists

#### Scopesummit.com

**11th Annual**

**Summit for Clinical Ops Executives**

**ScopeSummit.com**
Seminar Registration Form

A) Complete and return this entire form by fax or mail. (Please photocopy form for additional attendees)

Course Number ___________________________________________________________________________________

Course Name ______________________________________________________________________________________

Course Date(s) ___________________________________________________________________________________

Dr.  Mr.  Ms. (First) ___________________________ (Last) ________________________________________________

Job Title ___________________________ Department ______________________________________________________

Company _______________________________________________________________________________________

Mailing Address ___________________________________________________________________________________

_______________________________________________________________________________________________

Phone (required) (Area Code) ________________________________________________________________

Cell Phone (Area Code) ________________________________________________________________

Fax (Area Code) ______________________________________________________________________

E-Mail (required for course confirmation) ____________________________________________________________

☐ YES! Add me to your mailing list.  ☐ YES! Add me to your e-mail list.

ACRP members! Include your member ID and receive 10% off your course ______________________________________

B) Method of Payment: Full payment must accompany registration form. Registrations received without payment will not be processed.

☐ *CHECK enclosed

Amount: $ ____________________________________________

(Make checks payable to Barnett International, in U.S. funds drawn on a U.S. bank)

*Signature: ________________________________________________________________________________

*CREDIT CARD (Please provide the information below)

☐ VISA ☐ MC ☐ AMEX

Name of Cardholder: ____________________________________________

Card #: ____________________________________________

Exp. Date: _________________________________________

Amount: $ ____________________________________________

*Signature: ________________________________________________________________________________

*By signing, I agree that I have read and understand Barnett’s cancellation and substitution policies.

Three Fast and Easy Ways to Register:

INTERNET: barnettinternational.com

FAX: +1 781.972.5425

MAIL: Registration Form with payment to:

Barnett International
250 First Avenue, Suite 300
Needham, MA 02494

REGISTER EARLY:

Seminars are limited to 30 participants! Team Discounts Available!

Seminar Cancellation Policy

Your notice of cancellation must be received in writing by mail, email, or fax to Barnett’s Customer Service Department prior to the start of the seminar. Please note that Barnett does not refund your registration fee.

• Prior to 10 business days before the seminar: You will receive an Event Pass. This Event Pass may be applied toward a future seminar of equal value within twelve (12) months of issue date.

• Within 10 business days before seminar: No Event Pass will be issued.

Seminar Substitution

If you are unable to attend a program, you may provide a substitute person (for the same program on the same date only). Your notice of substitution must be received in writing by mail or fax to Barnett’s Customer Service Department prior to the start of the seminar.

E-MAIL: customer.service@barnettinternational.com

PHONE: +1 781.972.5400 or toll-free in the U.S. 800.856.2556

Force Majeure

The performance of this Agreement by either party is subject to Force Majeure, government authority, severe weather, disaster, strikes, civil disorders, or other emergencies, or causes beyond reasonable control of the parties hereto, any of which make it illegal or impossible to provide the facilities and/or services for your meeting. It is agreed that this Agreement may be terminated for any one or more of such reasons by written notice from one party to the other without liability.
Clinical Guides, Resources, and Reference Manuals Published by Barnett
Publication Order Form

Three Easy Ways to Order:
Online:  www.barnettinternational.com
Telephone/Fax:  +1 781.972.5400 or toll-free in the U.S. 800.856.2556. Or Fax Order Form to: +1 781.972.5425
Mail Check to:  Barnett International, 250 First Avenue, Suite 300, Needham, MA 02494

<table>
<thead>
<tr>
<th>Publications</th>
<th>Code</th>
<th>Price</th>
<th>Qty</th>
<th>Subtotal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Guides and Job Aids</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New! The Clinical Research Finance Roadmap: A Comprehensive Guide</td>
<td>FIN19</td>
<td>$169.95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New! The Clinical Research Finance Roadmap Companion Reference</td>
<td>FINCOM19E</td>
<td>$119.95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good Clinical Practice: A Q&amp;A Reference Guide (2018)</td>
<td>GCP18</td>
<td>$79.95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Edition</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CFR/ICH GCP Reference Guide for Medical Devices (Spiral Bound)</td>
<td>DEVCFRS19</td>
<td>$17.95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2019)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Self-Study CRA Training Series (7 volume set) * (2018)</td>
<td>CRAS18</td>
<td>$599.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Self-Instructional Study Site Training Series (6 volume set) *</td>
<td>SSSV181-6</td>
<td>$499.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2018)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>State-by-State Clinical Trial Requirements Reference Guide (2020)</td>
<td>CT20</td>
<td>$99.95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>State-by-State Clinical Trial Requirements Reference Guide (2020)</td>
<td>CT20E</td>
<td>$89.95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electronic Edition</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Form FDA 1572: A Reference Guide for Clinical Researchers,</td>
<td>INV08</td>
<td>$45.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sponsors, and Monitors (2008)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compendia, Textbooks, and Trend Reports</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PAREXEL Biopharmaceutical R&amp;D Statistical Sourcebook 2018/2019</td>
<td>PRD18</td>
<td>$545.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Hardcopy)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PAREXEL Biopharmaceutical R&amp;D Statistical Sourcebook 2018/2019</td>
<td>PRD18E</td>
<td>$1,300.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Electronic &amp; Hardcopy)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Device Development: Regulation and Law (2020)</td>
<td>MEDDEV20</td>
<td>$195.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expediting Drug &amp; Biologics Development: A Strategic Approach</td>
<td>EXP06</td>
<td>$145.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2006)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Subtotal

Standard Domestic Shipping (7-10 business days)
(Barnett uses the FedEx rate calculator for all shipments. Contact Barnett for specific rates/shipping options.)

TOTAL

* Volume sets can also be purchased by individual volumes. Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for details.

ORDER DATE:

PAYMENT INFORMATION:  ☐ Credit Card (MC, Visa, AmEx)  ☐ Check (Order will NOT be processed until check is received)
☐ Visa  ☐ MC  ☐ AmEx  Card # ___________________________ Expiration _______ / _______

Check Number (Order will NOT be processed until check is received)

Signature (REQUIRED FOR CREDIT CARD ORDERS):

BILLING/INVOICING INFORMATION: (THIS IS THE PERSON WHO WILL RECEIVE AN INVOICE VIA EMAIL – an invoice will NOT be sent via regular mail)
Billing/Accounts Payable Contact:
Title: ___________________________
Organization: ___________________________
Address: ___________________________
City/State/Zip: ___________________________
Phone: ___________________________
Fax: ___________________________
Email: ___________________________

Accounts Payable/Billing Email (REQUIRED TO SEND INVOICE – Your order will NOT be processed without this information):

SHIPPING INFORMATION: (Please Print)
Name: ___________________________
Title: ___________________________
Organization: ___________________________
Address: ___________________________
City/State/Zip: ___________________________
Phone: ___________________________
Fax: ___________________________
Email: ___________________________

(REQUIRED TO SEND CONFIRMATION AND TRACKING INFORMATION)
The PAREXEL Biopharmaceutical R&D Statistical Sourcebook 2018/2019 is the leading resource for R&D statistics, trends, and proprietary market intelligence and analyses on the biopharmaceutical industry. Supported by thousands of graphs, illustrations, and analyses, the Sourcebook provides the latest intelligence on every aspect of biopharmaceutical development—from product discovery, to R&D performance and productivity, to time-to-market trends. With real-world analysis and key contributions from leading consultancies and experts, the Sourcebook includes:

- New proprietary analysis on US clinical trial starts, segmented by therapeutic category, as well as overall active clinical trials
- Assessments of personalized medicine/companion diagnostics, biosimilars, orphan drugs, and other factors reshaping biopharma R&D today
- The latest analyses on clinical trial success rates, broken down by clinical trial phase and therapy area
- All-new analyses on who "owns" today's R&D pipeline, R&D spending, and new drug/biologics approvals by company size and type (pharma vs. biotech)
- Emerging data on worldwide and company-specific R&D pipelines and product launch trends
- New analyses on emerging trends in pharma and biotech licensing deals and other partnerships critical to industry's R&D pipeline
- Drug approval statistics compiled from FDA, EMA, and other regulatory agencies
- New global R&D spending trends and other international R&D data from key markets

And much more!
- Spotlight analyses on emerging and re-emerging elements of industry's R&D pipeline, including immunology, microbiome R&D, and cell/gene therapy
- Assessments of several emerging industry controversies, including drug pricing, the wisdom of ultra-rapid new drug reviews, and R&D "overcrowding" in some parts of the new drug pipeline
- Spotlight analyses on the FDA's expedited programs (breakthrough therapy, fast track, accelerated approval) and how their increased use is reshaping new drug development today
- Analyses on the state, nature, and sustainability of industry's pipeline of R&D projects
- Analyses focused on the drug and biopharma markets and development pipelines within emerging countries, including brand new analyses on Korea and China

PAREXEL Biopharmaceutical R&D Statistical Sourcebook 2018/2019 is a must-have resource for the drug development industry. It is invaluable to executives and managers working in the pharma and biotech industries. The Sourcebook puts real-world data sets at your fingertips for presentations, reports, business development efforts, strategic meetings, and critical decision-making analyses.

The 2018/2019 edition is also offered in electronic format for individual users, small groups, business units, or company-wide access.

To purchase the PAREXEL Biopharmaceutical R&D Statistical Sourcebook 2018/2019:
Call: +1 781.972.5400 or toll-free in the U.S. 800.856.2556
Email: customer.service@barnettinternational.com
Visit the Publications section on barnettinternational.com

Publication Code: PRD18 (Hardcopy) ................................................................. Price: $545
Electronic Version: PRD18E (Electronic and Hardcopy) ................................. Price: $1,300