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
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
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**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 2015

Dear Colleagues,

It is with great pleasure that we present our January – July 2016 catalog. Of particular note is the conversion of our Live Seminars to a more flexible format, allowing participants the flexibility to participate in these “core curriculum” offerings either in-person or via the web. Also included are several new high-priority training programs, all designed with practical, on-the-job focused content and the needs of our learners in mind. Barnett’s new training offerings include the following:

**New Core Curriculum Offerings:**
- Monitoring Oncology Clinical Trials

**New On-Boarding Certification Course:**
- 30-Hour Clinical Data Management On-Boarding Program

**New Interactive Web Seminars:**
- Annual GCP Training Update: MHRA Inspection Findings for 2015
- Centralized TMF Management: The CRO Sponsor Partnership
- CMS-Medicare Coverage Analysis, Budgeting and Billing Compliance
- EMA and MHRA Inspections: Successful Planning and Execution Tips and Techniques
- eTMF Implementation Strategies
- eTMF Quality Oversight: A Risk-Based Approach
- EU Clinical Trial Regulation 536/2014: Are You Ready?
- ICH E-6 GCP Proposed Revisions 2016 Review: Impact on Sites, Sponsors, and CROs
- Overseeing Teams and Projects
- Preparation, Management, and Response to Inspections and Audits
- Principal Investigator/Site GCP Compliance and Performance: What it Really Takes to Be GCP Compliant
- TMF/eTMF Audit Strategies
- TMF/eTMF Regulatory Agency Expectations, Inspections, and Findings

**New eLearning Course:**
- Foundations of Good Clinical Practice

Barnett also provides a complete and up-to-date library of numerous publications, regulatory reference guides and job aides, and we regularly assist clients with in-house training needs. These services include courses delivered at your location, customized content development, role-based training assessments, competency mapping, gap and needs analysis 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 seeing you at an upcoming course!

Kind regards,

Naila Ganatra, M.Ed.
General Manager
Barnett International

Phillips Kuhl
President
Cambridge Healthtech Institute

Barnett International: A division of Cambridge Healthtech Institute
250 First Avenue • Suite 300 • Needham, MA 02494 USA • Phone: +1 781.972.5400 or toll-free in the U.S. 800.856.2556 • barnettinternational.com
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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 (Choose 2)**
- Adverse Events: Managing and Reporting for Medical Devices
- Adverse Events: Managing and Reporting for Pharmaceuticals
- Conducting Clinical Trials Under ICH GCP

**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
- Fraud in Clinical Research: An Overview
- Good Clinical Practice: Practical Application and Implementation

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

**Core Curriculum Training (Choose 2)**
- Auditing Techniques for Clinical Research Professionals
- The Highly Effective CRA: Soft Skills for Taking Your Work to the Next Level
- Monitoring Clinical Drug Studies: Intermediate

**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

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

**Core Curriculum Training (Choose 2)**
- Advanced Good Clinical Practice: Practical Application and Implementation
- The CRA Manager Course
- Detecting Risk Signals in Protocols, Data, and Monitoring
- Developing CRAs as Site Study Managers

**Web Seminars (Choose 4)**
- Adequate Sponsor Monitoring Systems In Anticipation of FDA Sponsor GCP Inspections
- Applied Clinical Statistics in Centralized Monitoring
- Cases in Advanced GCP: A Problem-Solving Practicum
- CMS-Medicare Coverage Analysis, Budgeting and Billing Compliance
- Corrective Action Plans: Essential Documentation of a Site’s Response to GCP Deficiencies
- Current FDA and EMA Inspection Findings: Lessons Learned
- Detecting Risk Signals in Protocols, Data, and Monitoring
- Informed Consent Guidance: Regulatory Updates

**Included with All Levels:**
- Barnett’s On-Demand GCP Refresher Training

**Recommended Reading:**
- 2015 Good Clinical Practice: A Question & Answer Reference Guide
- 2015 CFR Regulations, ICH, and EU Directives Reference Book

**Cost:** $5,000

*For the 10-Week Clinical Research Associate (CRA) On-Boarding 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.
## 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!

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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 (Choose 2)**
- Clinical Project Management: Introduction to Practical Clinical Trial Planning for Project Managers
- Conducting Clinical Trials Under ICH GCP
- Developing Clinical Study Budgets
- Developing Effective Training and Facilitation Skills in Clinical Research: An Application-Based Course
- Introduction to the FDA
- Medical Device GCP Overview
- Statistical Concepts for Non-Statisticians

**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
- CRO Selection Criteria, Evaluation, and Establishing the Relationship
- 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 (Choose 2)**
- Clinical Project Management: Intermediate
- Developing Clinical Study Budgets
- Effective Recruitment Planning and Management for Sponsors and CROs
- Planning and Conducting Global Clinical Trials
- Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) in Site Management
- Statistical Concepts for Non-Statisticians
- Working with CROs: Building a Partnership for Project Success

**Web Seminars (Choose 4)**
- Corrective Action Plans: Essential Documentation of a Site’s Response to GCP Deficiencies
- CRO Partnership Management
- Developing Clinical Study Budgets for Sponsors
- 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
- Investigational Product Accountability Best Practices
- Overseeing Teams and Projects
- Preparing Clinical Research Sites for FDA Inspections
- Protocol Deviations: Documenting, Managing, and Reporting
- Root Cause Analysis: Applying the Concept for Better Study Compliance Management
- Strategies for Managing Difficult Clinical Research Sites

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

**Core Curriculum Training (Choose 2)**
- Advanced Good Clinical Practice: Practical Application and Implementation
- Clinical Project Management: Advanced
- Effective Recruitment Planning and Management for Sponsors and CROs
- Optimizing Protocol Design and Strategies to Achieve Efficient, Lower Cost Trial Execution
- Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) in Site Management
- Statistical Concepts for Non-Statisticians
- Working with CROs: Building a Partnership for Project Success

**Web Seminars (Choose 4)**
- Approaches to Address Challenges in Vendor Management
- Cases in Advanced GCP: A Problem-Solving Practicum
- Corrective Action Plans: Essential Documentation of a Site’s Response to GCP Deficiencies
- CRO Selection Criteria, Evaluation, and Establishing the Relationship
- Current FDA and EMA Inspection Findings: Lessons Learned
- Fraud in Clinical Research: An Overview
- Managing Risks in Outsourced Clinical Trials: Practical Approaches and Tools
- Risk-Based Auditing: Effective Compliance Strategies
- Root Cause Analysis: Applying the Concept for Better Study Compliance Management
- Social Media in Clinical Research: Effective, Innovative, and Compliant Applications
- Sponsor Management of Investigator Non-Compliance
- Subject Enrollment: Creating Effective Enrollment Models

**Included with All Levels:**
- eLearning: Barnett’s On-Demand GCP Refresher Training

**Recommended Reading:**
- **2015 Good Clinical Practice: A Question & Answer Reference Guide**
- **2015 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.
“Hands-On” In-Person and Web Seminar Workshop Series

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 support, so you do not have to worry about what operating system you use. WebEx provides unmatched support for Windows, Mac, Linux, and Solaris. Browser support includes Internet Explorer, Mozilla, Firefox, Netscape, and Safari. 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 Naila Ganatra at +1 215.413.2471 or nganatra@barnettinternational.com.
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 E6 Good Clinical Practice guidelines, 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 determining what data collection is required and the current standards for CRF data content.

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

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 GCP Guideline ICH E6 and two sample CRFs (provided). Based on what they have read, learners will make the necessary amendments to the CRF to ensure compliance with these guidelines
- 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 “convince” their management that the CDASH initiative will be beneficial for their company

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

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<th>Course Dates and Details</th>
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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.

ACEPE#: 0778-0000-13-014-L01-P. Released: 2/13.
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 data 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 module 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 module 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 them 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

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

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
Gary B. Freeman, M.S., C.C.R.A.

Course Dates and Locations

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| March 1, 2016             |
| Philadelphia, PA 19103    |
| The Hub Meeting Center – CityView |
| Course #: SMRA0316        |
| $800 by January 29        |
| $1,000 after January 29   |

| March 8, 2016             |
| San Diego, CA 92101      |
| Courtyard San Diego Downtown |
| Course #: SMRD0316        |
| $800 by February 5        |
| $1,000 after February 5   |

| April 7, 2016             |
| Online via WebEx          |
| Course #: BI12358         |
| $800 by March 4           |
| $1,000 after March 4      |

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.
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, 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 be provided to them for inspection. Therefore, the timely filing and organization of these documents is of utmost importance. There needs to be a consistent system employed such that documents can be located and provided for study team use as well as regulatory inspection in a timely manner.

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
- Examine the importance of a well-written Standard Operating Procedure for Trial Master Files
- 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

Instructors
This course will be taught by one of the following instructors:
Donna W. Dorozinsky, R.N., M.S.N., C.C.R.C.
Gary B. Freeman, M.S., C.C.R.A.

Course Dates and Locations

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<td>$800</td>
<td>by February 18</td>
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**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#: 0778-0000-13-017-L01-P. Released: 3/13.

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.
What Are Core Curriculum Courses?

Barnett International’s Core Curriculum courses are provided to you either In-Person at a state-of-the-art meeting venue or in the form of live, interactive Web-based training offered via WebEx. 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. Once you choose the training delivery platform that is most convenient to you (either in-person or on the web), 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?

- Either face-to-face or live, web-based 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 206) 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. For in-person courses, your 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 in electronic format for easy access and future reference. 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). 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
• Understand the relevant regulations and guidelines
• Discuss trends in clinical research
• 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 CFRs, ICH E6 Guidelines, 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:
Nikki Christison, B.S., C.C.R.A.
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. 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
• Develop and implement site-specific approaches for corrective action of non-compliance
• Describe the elements of a functional Quality System
• Define key GCP terms
• Examine recent trends in non-compliance
• Identify the universal and local components of GCP
• Explain the differences between the legal and procedural elements of GCP
• Recognize key differences in pharmaceutical, device, and biologics GCP
• Describe the overlap between GCP and GMP

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:
Elizabeth Ronk Nelson, M.P.H.
Lily Romero, P.A., C.C.R.C.

Course Outline
• GCP Terminology: Beyond the ABCs
• New Developments and Emerging Trends in GCP
• Principles of GCP: Different Perspectives: Examination; application; implementation
• The “Forgotten” Elements of GCP: Regulations; laws; guidelines
• Quality Systems: The Roadmap to GCP: Quality control; quality assurance; quality improvement
• 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

In-Person Offerings
February 22-23, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SADA0216
$1,595 by January 22
$1,795 after January 22
May 2-3, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SADD00416
$1,595 by March 4
$1,795 after March 4
June 6-7, 2016
Boston, MA 02110
Metro Meeting Centers
Course #: SADB0616
$1,595 by May 6
$1,795 after May 6

Web-Based Offerings*
April 6, 2016 (8:30 a.m. – 12:15 p.m. Eastern)
April 8, 2016 (8:30 a.m. – 12:15 p.m. Eastern)
April 13, 2016 (8:30 a.m. – 12:15 p.m. Eastern)
April 15, 2016 (8:30 a.m. – 12:15 p.m. Eastern)
Course #: SAD00416
$1,595 by May 6
$1,795 after May 6
June 8, 2016 (10:30 a.m. – 2:15 p.m. Eastern)
June 10, 2016 (10:30 a.m. – 2:15 p.m. Eastern)
June 15, 2016 (10:30 a.m. – 2:15 p.m. Eastern)
June 17, 2016 (10:30 a.m. – 2:15 p.m. Eastern)
Course #: SADB0616
$1,595 by May 6
$1,795 after May 6

*See page 97 for system requirements
NOTE: Web-Based Offerings are for individual registrants only.

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.

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

Instructor
Vaska Tone

Course Dates and Locations
July 19-20, 2016
Philadelphia, PA 19103
The Hub Meeting Center – Commerce Square
Course #: SPPA0716
$1,595 by June 17
$1,795 after June 17

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.

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. Medical Affairs Personnel responsible for safety-related decisions regarding product labeling, regulatory interactions, or customer communication.

Learning Objectives
- Discuss the history of, need for, purpose of, and capabilities of pharmacovigilance
- 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

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., ROAP-GCP
Glenda Guest, ROAP-GCP, C.C.R.A.

Course Dates and Locations

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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#: 0778-0000-14-001-L01-P. Released: 2/14.
**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

**Course Dates and Locations**

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**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.  
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 special, not often taught, auditing techniques as part of your daily monitoring or auditing activities
- Develop Simple, Efficient, and Effective Quality Systems (SEEQS – pronounced See Q’s)
- Utilize SEEQS 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 and Sponsor-Monitor-CRO audits
- Detect, prove, and prevent scientific fraud and misconduct
- Write 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
- Prepare for a Trial Center Audit
- Accomplish an Audit of Source Documents and CRFs
- Work on an Audit Team to Discuss and Present Findings

In-Person Offerings

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Web-Based Offerings*

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*See page 97 for system requirements

NOTE: Web-Based Offerings are for individual registrants only.

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.

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

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#: 0778-0000-16-009-L01-P. Released: 2/16.
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 and device marketed products. 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
- Auditors transitioning into pharmacovigilance auditing
- Drug Safety Staff
- Quality Assurance Staff responsible for pharmacovigilance self-inspections
- Medical Information Staff
- Safety Physicians

Instructor
Vaska Tone

Course Dates and Locations
April 26–27, 2016
Boston, MA 02110
Metro Meeting Centers
Course #: SPVB0416
$1,595 by March 25
$1,795 after March 25

June 7–8, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SPVD0616
$1,595 by May 6
$1,795 after May 6

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.


What Participants Say About Barnett Seminars:
"You will not leave class uninformed."
Becoming a Preferred Site: Quality and Documentation Tips for Compliance

Course Description
What is a preferred site? 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 feasible? First impressions count, but best practices must be continued throughout the life of the trial to ensure preferred status. 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.

Learning Objectives
• Recognize the importance of quality in clinical trials
• Identify key factors in site selection
• Implement best practices that will ensure successful completion of trials and preferred site status with sponsors
• Identify key areas for improved documentation and communication leading to better quality
• Manage documentation of recruitment efforts effectively
• Manage potential document management inconsistencies proactively

Instructor
Janet Ellen Holwell, C.C.R.C., C.C.R.A.

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
• Review use of a site recruitment plan
• Review of Warning Letters and creation of appropriate CAPAs
• Review of tools and templates

Course Dates and Locations
February 25, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SAPD0216
$800 by January 22
$1,000 after January 22

June 3, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SAPA0616
$800 by May 3
$1,000 after May 3

Academic Discount
A $100 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 7 hours (0.7 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#: 0778-0000-14-066-L01-P. Released: 8/14.
Best Practices for Writing Clinical Evaluation Reports for Medical Devices

Course Description
This seminar will address the details and challenges of writing a Clinical Evaluation Report (CER). Learn what constitutes a CER and how to ensure your CER meets the requirements outlined in MedDev 2.7.1. CERs are required in the EU to document the safety and performance of a medical device by analyzing three broad types of clinical data including clinical trial information (where the company fully analyzes the clinical trial data for the specific device in question), clinical literature (including both published and unpublished reports about the device), and clinical use information (including reports from users of the device, for example, complaints or post-market vigilance data about the device). In this seminar, you will learn about the different parts of a CER and what information should be analyzed for each, including clinical trials, clinical literature, and clinical experience. Finally, we will discuss the importance of using the CER as part of a product lifecycle, and tying this document in to your current risk management strategy to improve the overall benefit: risk analysis of your device.

Learning Objectives
• Discuss the general outline of a robust CER
• Describe the MedDev 2.7.1 requirements
• Determine when it is most beneficial to conduct the review to support various product development design stages or claim substantiation processes
• Describe best practices for conducting a comprehensive/detailed literature search
• Discuss how to evaluate the literature acquired and analyze/interpret findings
• Discuss how to evaluate the clinical experience data and analyze/interpret findings
• Incorporate the process in your clinical quality systems; create standard procedures to outline required steps; understand how the CER fits into a Quality System; assess quality of information in manageable pieces

Who Should Attend
• Project Managers
• Clinical Data Specialists/Analysts/Managers
• Clinical Study Coordinators
• Clinical Research Associates

Interactive Activities
• Conduct a robust and reproducible search to identify appropriate clinical literature
• Navigate publicly available databases on the FDA website to extract clinical experience data
• Evaluate the literature acquired and analyze/interpret findings
• Evaluate the clinical experience data and analyze/interpret findings
• Incorporate the process in your clinical quality systems; create standard procedures to outline required steps; understand how the CER fits into a Quality System; assess quality of information in manageable pieces

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

Course Dates and Locations
February 4, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SBPA0216
$800 by January 4
$1,000 after January 4

June 1, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SBPD0616
$800 by April 29
$1,000 after April 29

Academic Discount
A $100 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 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#: 0778-0000-15-074-L01-P. Released: 10/15.
Clinical Project Management: Introduction to Practical Clinical Trial Planning for Project Managers

Course Description
This course is an introduction to clinical project management in the pharmaceutical industry. The focus is on individuals who want to learn basic project management skills and how they can be applied to the drug development process, especially in the management of clinical trials. The needs of relatively new project managers who are not familiar, or experienced, with specific technical tasks involved in clinical trial management are addressed. There is specific focus on the need to anticipate, understand, and implement detailed project management activities in a proactive manner. This course includes discussion of a highly detailed and fully developed clinical trial management process map. Discussions of the process map are practically oriented with emphasis given to useful advice that, when implemented, will assist with trial management.

Learning Objectives
- Develop a project plan and manage project timelines
- Use project management tools effectively
- Build high performance project teams
- Gather performance metrics and use them to improve project success
- Write optimal policies and procedures for clinical trial management

Who Should Attend
- Staff from Pharmaceutical Companies or Contract Research Organizations (CROs) involved with the management of clinical trials
- New Clinical or other Project Team Leaders who will be managing projects
- New Clinical, Regulatory, and Department Staff who will design clinical trial programs
- CRAs, Data Managers, or others interested in transitioning into clinical trial management

Instructors
This course will be taught by one of the following instructors:
Véronique Lallevee, Pharm.D., P.M.P.
Eric Morfin, Ph.D., M.B.A., P.M.P.

Interactive Activities
- Identification of Project Management Issues
- Troubleshooting Clinical Trial Issues
- Mastering Process Mapping Skills

Course Dates and Locations

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June 28-29, 2016
Philadelphia, PA 19103
The Hub Meeting Center - CityView
Course #: SPMA0616
$1,595 by May 27
$1,795 after May 27

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#: 0778-0000-14-002-L01-P. Released: 1/14.
Clinical Project Management: Intermediate

Course Description
The course builds on project management basics to examine some of the more difficult issues encountered by clinical project managers. It examines approaches for optimizing clinical trial conduct and includes discussion of current hot-button concerns facing clinical project managers.

Learning Objectives
- Develop a more strategic approach to management
- Assess trial design decisions
- Define best practices
- Recognize the use and abuse of metrics
- Implement resource planning techniques
- Implement risk management techniques
- Optimize site selection
- Enhance patient recruitment and retention
- Cite new issues and technologies in project management

Who Should Attend
- Clinical Project Managers who have mastered project management basics
- Experienced Project Managers with limited drug development or clinical trial experience
- Team Leaders or Managers with a basic knowledge of clinical project management
- Staff from pharma, biotech or CROs who wish to learn more about the clinical trial process
- Clinical, Regulatory and Development Staff who design clinical trial programs

Interactive Activities
- Identifying the Issues
- Risk Management Planning
- Global Case Study on Conduct of Ethical Research

Course Dates and Locations

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April 5-6, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SMID0416
$1,595 by March 4
$1,795 after March 4

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

Accreditation
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ACPE#: 0778-0000-15-042-LD1-P. Released 8/15.
Clinical Project Management: Advanced

Course Description
This course provides attendees with the skills they need to lead their domestic and global clinical trials to optimal performance. Building on basic and intermediate project management concepts, this course provides the experienced clinical professional with tactical information to overcome the most difficult issues encountered. Advanced concepts will be presented, including performance and time management, delay tracking and prevention, ensuring adequate regional patient supply and enrollment interest before beginning a trial, strategies when enrollment is not progressing, and ensuring high quality data on a global scale. Advanced concepts around root cause analysis and corrective and preventive action are also presented. This course provides best practices for managing international trials and international outsourced service providers. All concepts are presented in a dynamic, interactive manner to facilitate learning and retention.

Learning Objectives
- Master quality and timeline tracking and monitoring, and track and prevent delays
- Strategically approach negotiations in light of global cultural, language, and healthcare differences
- Employ best practices for managing global outsourced providers
- Identify and prioritize potential problems, and implement root cause analysis and corrective and preventive action plans
- Design a GCP and SOP compliant Project Operating Guideline (POG) for high performance clinical trials
- Employ effective communication within project teams
- Manage operational challenges in patient recruitment and retention

Instructors
This course will be taught by one of the following instructors:
- Véronique Lalevee, Pharm.D., P.M.P.
- Eric Morfin, Ph.D., M.B.A., P.M.P.

Who Should Attend
- Project Managers, Directors, and Leaders
- Clinical Research Investigators, Coordinators, Associates, Monitors, and Managers
- Regulatory, Medical, and Clinical Affairs Professionals
- Preclinical and R&D Directors/Associates/Scientists
- Toxicology, Pharmacology, Pharmacovigilance, and Labeling Professionals

Interactive Activities
- Select the best package for the international launch of a once daily pill
- Quickly identify the root cause of a disfigured pill launched in several countries
- Identify the potential risks related to a global trial and select the best set of preventive and contingent actions
- Learn to quickly assess the leadership style required by each situation
- Gain a better understanding of your cultural biases and how they impact the assessment and performance of the clinical trials you manage

Course Dates and Locations

<table>
<thead>
<tr>
<th>Location</th>
<th>Dates</th>
<th>Course #:</th>
<th>Fee Details</th>
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<td>Boston, MA 02110</td>
<td>February 9-10, 2016</td>
<td>SMVB0216</td>
<td>$1,595 by January 8, $1,795 after January 8</td>
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<td>April 26-27, 2016</td>
<td>SMVD0416</td>
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<td>Philadelphia, PA 19103</td>
<td>June 21-22, 2016</td>
<td>SMYA0616</td>
<td>$1,595 by May 20, $1,795 after May 20</td>
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Academic Discount
A $400 academic discount is available to those who qualify.

Accreditation
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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 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**
- Address the ethical considerations involved in conducting clinical trials
- Strategically plan for successful clinical trials
- Develop trial objectives and hypothesis testing
- Develop protocols in accordance with regulations
- 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 design a clinical trial and about protocol development

**Instructor**
Gary B. Freeman, M.S., C.C.R.A.

**Course Dates and Locations**

<table>
<thead>
<tr>
<th>Course Dates and Locations</th>
<th>Date</th>
<th>Location</th>
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**Academic Discount**
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**Accreditation**
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**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 ICH/GCP
- **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 hypothesis; Type I and Type II errors; single vs. multiple objectives; statistical concepts for non-diagnostic devices and diagnostic tests (IVD)
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 drug 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, and all of the activities, site visits, and documentation that occur along the way. Finally, site audits and inspections will be reviewed, with an emphasis on the CRC’s role in that process.

Learning Objectives
- Discuss the CRC role in the development of new drugs
- Prepare for all sponsor site visits
- Develop strategies for recruiting and retaining study subjects
- Discuss the informed consent process
- Review the reporting requirements of adverse events
- Employ study documentation requirements and standards for collecting and reporting clinical trial data and Investigational Product
- Develop strategies for preparing, implementing, and managing clinical studies, including budget considerations
- Prepare your site for an 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

Instructors
This course will be taught by one of the following instructors:
Nikki Christison, B.S., C.C.R.A.
Gary B. Freeman, M.S., C.C.R.A.

Course Dates and Locations
April 13-14, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SCRA0416
$1,595 by March 11
$1,795 after March 11

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.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Overview of Drug Development and Good Clinical Practice: terminology; phases of drug development 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
- Drug Accountability: Documentation, storage requirements and CRC responsibilities
- Close-Out Visits: Preparation and activities
- FDA Audits: Mechanics of an FDA inspection; common audit 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.
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 obligations 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 audit

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

In-Person Offerings

<table>
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<th>Date</th>
<th>City</th>
<th>Course #:</th>
<th>Date</th>
<th>Time</th>
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<td>SD004216</td>
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<td>1:00 – 4:45 p.m. Eastern</td>
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<td>April 26-28, 2016</td>
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<td>Boston, MA 02110</td>
<td>SD00616</td>
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*See page 97 for system requirements
NOTE: Web-Based Offerings are for individual registrants only.

Web-Based Offerings*

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*See page 97 for system requirements

Accreditation
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ACPE#: 0778-0000-14-006-L01-P. Released: 2/14.
Conducting Clinical Trials Under ICH GCP

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 brochures. 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.

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:
Nikki Christison, B.S., C.C.R.A.
Gary B. Freeman, M.S., C.C.R.A.
Janet Ellen Holwell, C.C.R.C., C.C.R.A.
Lily Romero, P.A. C.C.R.C.

In-Person Offerings
January 27-28, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SGCD0116
$1,595 by December 23
$1,795 after December 23
May 10-11, 2016
Boston, MA 02110
Metro Meeting Centers
Course #: SGB0516
$1,595 by April 8
$1,795 after April 8

In-Person Offerings
March 22, 2016 (8:30 a.m. – 12:15 p.m. Eastern)
March 24, 2016 (8:30 a.m. – 12:15 p.m. Eastern)
March 29, 2016 (8:30 a.m. – 12:15 p.m. Eastern)
March 31, 2016 (8:30 a.m. – 12:15 p.m. Eastern)
Course #: SGC00316
$1,595 by February 19
$1,795 after February 19

Web-Based Offerings*
June 20, 2016 (10:30 a.m. – 2:15 p.m. Eastern)
June 22, 2016 (10:30 a.m. – 2:15 p.m. Eastern)
June 24, 2016 (10:30 a.m. – 2:15 p.m. Eastern)
June 27, 2016 (10:30 a.m. – 2:15 p.m. Eastern)
June 29, 2016 (10:30 a.m. – 2:15 p.m. Eastern)
Course #: SGC00616
$1,595 by May 20
$1,795 after May 20

*See page 97 for system requirements
NOTE: Web-Based Offerings are for individual registrants only.

Academic Discount
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Accreditation
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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. This course includes an appendix of time management and interviewing tips.

Learning Objectives
- Review FDA regulations and ICH guidelines for Good Clinical Practices (GCPs)
- Understand 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 and the IRB
- 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

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:
Linda Carter, R.N., B.S.N.
Nikki Christison, B.S., C.C.R.A.
Lily Romero, P.A., C.C.R.C.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Introduction to Clinical Research
- Clinical Research Team: Roles & Responsibilities
- Investigational Product (IP) Development
- Good Clinical Practice: GCPs, FDA Guidance, and ICH

Day Two: 8:30 a.m. – 5:00 p.m.
- The Clinical Study Protocol and Study Feasibility
- The Principal Investigator, Site Selection, and Study Initiation
- Institutional Review Board, the Consent of Human Volunteers, and HIPAA
- Safety Reporting: Definitions & Reporting Requirements

Day Three: 8:30 a.m. – 5:00 p.m.
- IP Accountability, Essential Documents, and Routine Monitoring Visits
- Source Document Verification, Data Management, and the Trial Close-out Visit
- Interactive Exercises I and II
- Regulatory Compliance & Quality Assurance: Audits & Inspections

Course Dates and Locations
February 9-11, 2016
Boston, MA 02110
Metro Meeting Centers
Course #: SCOB0216
$1,695 by January 8
$1,895 after January 8

May 3-5, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SCOD0516
$1,695 by April 1
$1,895 after April 1

June 21-23, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SCOA0616
$1,695 by May 20
$1,895 after May 20

Academic Discount
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Accreditation
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ACPE#: 0778-0000-16-010-L01-P. Released: 2/16.
The CRA Manager Course

Course Description
The focus of this course is to strengthen the skills required of the CRA Manager to effectively 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;
- Practice effective communication skills and 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;
- Understand the principles of effective delegation;
- Develop a more engaged team which contributes to quality performance;

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 Studies focused on Performance Improvement Topics
- Delegation: A Self-Test
- Delegation Personal Action Plan
- A Good Team Leader Checklist
- Teambuilding Personal Action Plan

Course Dates and Locations

February 25-26, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SCMD0216
$1,595 by January 22
$1,795 after January 22

June 1-2, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SCMA0616
$1,595 by April 29
$1,795 after April 29

Academic Discount
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Accreditation
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Data Management in the Electronic Data Capture Arena: Regulatory Considerations and Practical Applications for eCDM

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

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

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
- 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.

ACCME#: 0778-0000-15-044-L01-P. Released 10/15.

Course Outline
- 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 and 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
- 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

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

Instructor
Marina Malikova, Ph.D., M.S., M.A., C.C.R.A.

Course Dates and Locations
June 1-2, 2016
San Francisco, CA 92101
Hilton San Francisco
Course #: SD3F0616
$1,595 by April 29
$1,795 after April 29

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.

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
Nikki Christison, B.S., C.C.R.A.

Course Dates and Locations
March 9, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SSDD0316
$800 by February 5
$1,000 after February 5

May 18, 2016
Philadelphia, PA 19103
The Hub Meeting Center - CityView
Course #: SSDA0516
$800 by April 18
$1,000 after April 18

Academic Discount
A $100 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 7 hours (0.7 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.

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 resource needs required as a result of clinical research protocols.

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

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

Who Should Attend
- Clinical Trial Personnel (Clinical Research Coordinators, Investigators) responsible for preparing and implementing study budgets
- Sponsor Representatives in the pharmaceutical 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

Course Dates and Locations

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May 17, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SD8A0516
$800 by April 18
$1,000 after April 18

Academic Discount
A $100 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 7 hours (0.7 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#: 0778-0000-14-005-L01-P. Released: 1/14.

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.”

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 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

Instructors
This course will be taught by one of the following instructors:
Nikki Christison, B.S., C.C.R.A.
Beth Harper, B.S., M.B.A.

Course Dates and Locations
March 1-2, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SDDO316
$1,595 by January 29
$1,795 after January 29

June 7-8, 2016
Philadelphia, PA 19103
The Hub Meeting Center – Commerce Square
Course #: SDCA0616
$1,595 by May 6
$1,795 after May 6

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.
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
Nikki Christison, B.S., C.C.R.A.

Course Dates and Locations

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<td>$800 by April 4</td>
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Academic Discount
A $100 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 7 hours (0.7 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#: 0778-0000-14-080-L01-P. Released: 9/14.
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
Cheryl Vitow

Course Dates and Locations
June 21-22, 2016
Philadelphia, PA 19103
The Hub Meeting Center – Commerce Square
Course #: SDPA0616
$1,595 by May 20
$1,795 after May 20

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#: 0778-0000-13-031-L01-P. Released: 10/13.

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

What Participants Say About Barnett Seminars:
“This seminar is a ‘must’ for anybody working in clinical development.”
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 studies
- Discuss briefly the requirements for an NDA
- Explain briefly the post approval responsibilities of sponsors, including Phase 4 clinical studies
- 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

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

Instructor
Gary B. Freeman, M.S., C.C.R.A.

Course Dates and Locations
May 3, 2016
Philadelphia, PA 19103
The Hub Meeting Center – Commerce Square
Course #: SDDA0516
$800 by April 1
$1,000 after April 1

Academic Discount
A $100 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 7 hours (0.7 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#: 0778-0000-16-011-L01-P. Released: 5/16.
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., M.S., M.A., C.C.R.A.

Course Dates and Locations
May 10-11, 2016
Boston, MA 02110
Metro Meeting Centers
Course #: SD2B0516
$1,595 by April 8
$1,795 after April 8

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.
Drugs 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, but slow down the product approval process. 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
- Meet regulatory requirements for product safety
- Perform signaling analysis and risk assessment and management functions
- Collect, assess, report, and analyze adverse events
- Create signaling analyses based on FDA Good Pharmacovigilance Practices
- Identify differences between U.S. and European regulatory requirements

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
- Analysis of PSUR data by MedDRA System Organ Class, Preferred Term, Age Range, Sex, Country, Time to Onset, and Concomitant Medications

Instructors
This course will be taught by one of the following instructors:
Sharon Donatucci
Susan Gordon, R.N., M.S.N.

Course Dates and Locations
March 22-23, 2016
San Francisco, CA 92101
Hilton San Francisco
Course #: SSVF0316
$1,595 by February 19
$1,795 after February 19

June 21-22, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SSVAD616
$1,595 by May 20
$1,795 after May 20

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.


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)
- Quality Processes: Case metrics; quality assurance audit
- Clinical Trial Safety Data Collection: Audit trail; safety data management; statistical analysis; communication of safety information

Day Two: 8:30 a.m. – 5:00 p.m.
- 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
- PV Audits and Audit Issues: Regulatory inspections; preparation, problems and issues; checklists; ADR; inspection principles; inspection results; potential regulatory actions
- Characteristics of a Good Case Report: How to do a narrative evaluation for follow-up; active query; investigator’s brochure; safety; interim update for investigators; FDA time/report obligations; regulatory reporting and notification

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)

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

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

Course Dates and Locations
March 22, 2016
San Francisco, CA 94102
Hilton San Francisco
Course #: SPTF0316
$800 by February 19
$1,000 after February 19

Academic Discount
A $100 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 7 hours (0.7 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#: 0778-0000-14-065-L01-P. Released: 9/14.

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!”
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

Course Dates and Locations

March 1-2, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: STPD0316
$1,595 by January 29
$1,795 after January 29

June 14-15, 2016
Boston, MA 02110
Metro Meeting Centers
Course #: STPB0616
$1,595 by May 13
$1,795 after May 13

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#: 0778-0000-14-004-L01-P. Released: 3/14.
Facilitation Skills for Clinical Research Team Members

Course Description
A facilitator can be defined as an individual whose job is to help manage a process of information exchange. Clinical research team members’ roles include facilitation; yet few clinical research professionals have ever received training on this critical skill set. Facilitation has systemic impacts on the success of projects that depend on efficient information exchange. A Sponsor/CRO and/or Research Site team member’s success as a facilitator can greatly impact the success of a clinical trial, from patient recruitment to final report submission processes. This course defines facilitation specifically within a clinical research setting with a focus on successful clinical trials, including compliance and performance improvement. The presentation is in a workshop format, providing application of facilitation tools presented.

Learning Objectives
- Describe the role of facilitation in clinical research
- Define facilitation: an essential soft skill for managing clinical research today
- Implement facilitation core practices
- Apply facilitation techniques in clinical trials for different stakeholder needs: research sites, sponsors/CROs
- Design project communication to support effective facilitation
- Develop research team members’ skills for facilitation

Who Should Attend
- Sponsor/CRO Team Leaders
- Research Site Team Leaders
- CRA Managers
- Research Site Managers
- Project Managers
- Investigators
- CRAs
- CRCs

Interactive Activities
- Current Facilitator Level Self-Assessment
- Force Field Analysis
- Facilitator Core Practices Observation Sheet

Instructor
Linda Carter, R.N., B.S.N.

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.
- Current State of Affairs Between Clinical Research Stakeholders: Key problem issues in the industry will be discussed relating to the current approach’s successes and failures; a collection of success factors will be assessed for common themes; effective facilitation will be noted as one of the key leadership qualities of those successes and missing in many of the failures
- Facilitation: Definition of core terms and concepts; applying definitions to industry positive and negative examples
- Facilitation Core Practices: Each core practice will be presented and practiced with the attendees; combinations of practices will also be presented; industry case scenarios will be presented to emphasize the impact of strong and weak facilitation practices on projects
- Core Practice Application: Facilitation core practices will be applied to specific issues in clinical trials for different stakeholders; examples include recruitment, compliance, etc. Interactive exercises allow participants to identify effective and ineffective practices in facilitation
- Facilitation Practice Tools: Many of the dozens of tools to support effective facilitation will be presented and applied in break-out sessions; ranking the value of the tools in certain settings will be accomplished
- Designing Project Communication to Support Effective Facilitation: Cross stakeholder application of core practices and tools within current best practices, including pre-study to termination activities
- Developing Research Team Members’ Skills for Facilitation: The multiple tools supplied in the course will be applied throughout for different roles in both sponsor, and site teams
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
• Time the meeting request
• Time the meeting package
• Organize the meeting package (using the traditional or Target Product Profile format)
• Manage meeting logistics (including who should attend)
• Manage meeting decorum
• Conduct meeting rehearsals
• Take meeting minutes and submit them to the agency
• Confirm agency meeting minute receipt
• Ask for 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.C.T.I., R.A.C., F.R.A.P.S.

Course Dates and Locations
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Accreditation
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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.
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
- Implement 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.
Global GCP Monitoring: Domestic and International Compliance

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

Learning Objectives
- Describe FDA Good Clinical Practice
- Define ICH Good Clinical Practice
- Discuss the European Union Directive and GCP
- Review other selected countries’ monitoring bodies and responsibilities
- Assess the cultural impacts on monitoring responsibilities OUS

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.

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

Interactive Exercises
- Shared Participants’ Good Monitoring Practices
- Examination of Real Life Scenarios
- Review of FDA Q&A Information Sheet

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 and Welcome
- Ethics in Clinical Research – An Overview
- FDA GCP
- ICH GCP
- European Union Directive and GCP
- Summary and Q&A
Day Two: 8:30 a.m. – 5:00 p.m.
- Specific Country Regulatory Bodies
- Culture Impacts on GCP
- GCP Exercises
- Wrap-up and Course Evaluation

What Participants Say About Barnett Seminars:
“Up-to-date teaching by an excellent presenter.”

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.
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
- Provide 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
Gary B. Freeman, M.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.
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
- Model 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

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

Course Dates and Locations

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<th>Course</th>
<th>Dates</th>
<th>Location</th>
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<td>May 3-4, 2016</td>
<td>Philadelphia, PA 19103</td>
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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#: 0778-0000-14-012-L01-P. Released: 2/14.
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 worst, 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 of 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: Conduct a Process Mapping Session
- Activity 2: Using the map and SOP template provided, draft an SOP. Provide your SOP to your neighbor and review each other’s SOPs
- Activity 3: Create a Work Instruction for Sending email from IntraLinks Microsoft Outlook Web App

Instructors

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

Holly J. DeIaco-Smith, MS Ed.
Kirsten Morasco

Course Dates and Locations

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<tr>
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Academic Discount

A $100 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 7 hours (0.7 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#: 0778-0000-16-012-L01-P. Released: 2/16.
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

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

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

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

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

In-Person Offerings
March 23, 2016
San Francisco, CA 94102
Hilton San Francisco
Course #: SIBF0316
$800 by February 19
$1,000 after February 19

Web-Based Offerings*
February 16, 2016 (10:30 a.m. – 2:15 p.m. Eastern)
February 18, 2016 (10:30 a.m. – 2:15 p.m. Eastern)
Course #: SIBO0216
$800 by January 15
$1,000 after January 15

May 23, 2016 (8:30 a.m. – 12:15 p.m. Eastern)
May 25, 2016 (8:30 a.m. – 12:15 p.m. Eastern)
Course #: SIBO0516
$800 by April 22
$1,000 after April 22

*See page 97 for system requirements
NOTE: Web-Based Offerings are for individual registrants only.

Academic Discount
A $100 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 7 hours (0.7 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#: 0778-0000-14-040-L01-P. Released: 3/14.
Inspection Readiness: Demystifying the FDA Inspection Process

Course Description
There is often fear and a mystique surrounding the process of an FDA site inspection. This workshop will include insights from a former FDA medical officer on the importance of Good Clinical Practices (GCPs) to help ensure sites are prepared for the FDA. Your instructor will show learners exactly what the FDA is looking for during a site inspection, and why these inspections are critical to both the drug/device approval process. This workshop will include presentations, discussions, and problem-solving using case studies applicable to both drug and device studies. Exercises are designed to prepare you for the FDA’s arrival, anticipate FDA issues and concerns, and ensure success. Learners are encouraged to bring their questions and join in interactive discussions. Together we will de-mystify the process of FDA audits and help you learn how to ready your site for the FDA.

Learning Objectives
• Ensure investigational sites are better prepared for GCP/FDA inspections
• Anticipate FDA GCP expectations for both drugs and medical devices
• Recognize sponsor/company/investigator responsibilities applicable to FDA submission
• Apply basic concepts to assess whether companies/sponsors follow current FDA risk-based monitoring/auditing guidances
• How to think like a regulator

Instructor
Jerri Barden Perkins, M.D.

Who Should Attend
• Clinical Research Professionals
• Clinical Research Coordinators
• Clinical Research Associates
• Investigators and Site Personnel
• IRB/Ethic Committee Members
• Project Managers
• Quality Assurance Personnel
• Regulatory Affairs Professionals
• Auditors/Monitors

Interactive Activities
• Team Review of Warning Letters with group discussion
• Team Role Play in Mock Audit
• Questions for each participant to be answered independently with group discussion on answers

Course Dates and Locations
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SIRD0216
$1,595 by January 22
$1,795 after January 22

May 4-5, 2016
Philadelphia, PA 19103
The Hub Meeting Center — CityView
Course #: SIRA0516
$1,595 by April 1
$1,795 after April 1

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.

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 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 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

Course Dates and Locations
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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 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
• Identify key resources and databases for information on clinical trials

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
• Protocol and Informed Consent Review
• Recruitment Advertisement Review
• Delineating Roles and Responsibilities
• Internet Search and Review

Instructor
Linda Carter, R.N., B.S.N.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• The Evolution of Research Ethics
• Good Clinical Practice
• Investigational Product Development
• Clinical Research Team

Day Two: 8:30 a.m. – 5:00 p.m.
• Elements of a Good Clinical Study
• Informed Consent and Confidentiality
• Clinical Trials and Safety Information
• Audits and Inspections

In-Person Offerings
May 10-11, 2016
Boston, MA 02110
Metro Meeting Centers
Course #: SC2B0516
$1,595 by April 8
$1,795 after April 8
June 1-2, 2016
Boston, MA 02110
Metro Meeting Centers
Course #: SC2B0616
$1,595 by April 29
$1,795 after April 29

Web-Based Offerings*
March 30, 2016 (8:30 a.m. – 12:15 p.m. Eastern)
April 1, 2016 (8:30 a.m. – 12:15 p.m. Eastern)
April 4, 2016 (8:30 a.m. – 12:15 p.m. Eastern)
April 8, 2016 (8:30 a.m. – 12:15 p.m. Eastern)
Course #: SC200316
$1,595 by February 26
$1,795 after February 26

*See page 97 for system requirements
NOTE: Web-Based Offerings are for individual registrants only.

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.

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
- Understand FDA responsibilities
- Describe the FDA centers
- Describe the FDA review process
- Summarize FDA compliance activities
- 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
Gary B. Freeman, M.S., C.C.R.A.

Course Dates and Locations
March 22-23, 2016
Philadelphia, PA 19103
The Hub Meeting Center - CityView
Course #: SFDA0316
$1,595 by February 19
$1,795 after February 19

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#: 0778-0000-15-046-L01-P. Released 10/15.

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
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
Gary B. Freeman, M.S., C.C.R.A.

Course Dates and Locations
March 10, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SIIID0316
$800 by February 9
$1,000 after February 9

May 18, 2016
Philadelphia, PA 19103
The Hub Meeting Center – Commerce Square
Course #: SIIA0516
$800 by April 18
$1,000 after April 18

Academic Discount
A $100 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 7 hours (0.7 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#: 0778-0000-16-013-L01-P. Released: 3/16.
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
Gary B. Freeman, M.S., C.C.R.A.

Course Dates and Locations
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: S9900216
$1,595 by January 22
$1,795 after January 22

June 7-8, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SD9A0616
$1,595 by May 5
$1,795 after May 5

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.


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

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 GCP Overview

Course Description
This course provides information across the full range of medical device clinical trial activities. 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
- Navigate the regulatory pathways for medical devices
- Explore practical aspects of investigator selection
- Discuss how to comply with the fundamentals of Good Clinical Practice (GCP)
- Explore practical aspects of conducting international clinical trials under ICH GCP

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 Outline
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

Course Dates and Locations
March 2-3, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SD8A0316
$1,595 by February 1
$1,795 after February 1

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.

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
• Overview of 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:
Nikki Christison, B.S., C.C.R.A.
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:
“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.
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

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)

Instructor
Cheryl Vitow

Course Dates and Locations
March 3, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SMWD0316
$800 by February 2
$1,000 after February 2

June 16, 2016
Boston, MA 02110
Metro Meeting Centers
Course #: SMWB0616
$800 by May 13
$1,000 after May 13

Academic Discount
A $100 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 7 hours (0.7 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 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 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
The course will be taught by one of the following instructors:
Linda Carter, R.N., B.S.N.
Elizabeth Ronk Nelson, M.P.H.
Nikki Christison, B.S., C.C.R.A.
Lily Romero, P.A., C.C.R.C.
Gary B. Freeman, M.S., C.C.R.A.

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
• Overview of Drug Development, FDA 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
• IRBs/IECs and the Protocol Approval Process: Membership requirements; documents and activities
• Study Subject Recruitment, and the Informed Consent Document & Process: FDA and ICH requirements; the role of the monitor in assuring appropriate consent
• Investigator’s Meetings & Study Initiation Visits: Purpose, preparation, and documentation
• Managing & Reporting Adverse Events: Terminology and examples; investigator and sponsor reporting requirements
• Investigational Product Accountability & Essential Documents: Regulatory and subject Documents; drug storage, documentation, and accountability requirements.
• Routine Monitoring Visits & 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

In-Person Offerings
February 2-4, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SSBA0216
$1,695 by December 31
$1,895 after December 31

Boston, MA 02110
Metro Meeting Centers
Course #: SSBB0616
$1,695 by May 13
$1,895 after May 13

July 19-21, 2016
Philadelphia, PA 19103
The Hub Meeting Center – Commerce Square
Course #: SSBA0716
$1,695 by June 17
$1,895 after June 17

Web-Based Offerings*
April 12, 2016 (8:30 a.m. – 5:00 p.m. Eastern)
April 13, 2016 (8:30 a.m. – 5:00 p.m. Eastern)
April 14, 2016 (8:30 a.m. – 5:00 p.m. Eastern)
Course #: SSBO0416
$1,595 by March 11
$1,795 after March 11

*See page 97 for system requirements
NOTE: Web-Based Offerings are for individual registrants only.

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.

ACPE#: 0778-0000-15-048-L01-P. Released 7/15.
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 ICH guidelines
- Evaluate and develop more efficient study tracking and management tools
- Participate more effectively in mentoring and co-monitoring assessments
- Effectively manage your sites, 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 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

Interactive Activities
- The experienced Monitor’s simulation exercise
- Case studies in motivation and site management
- How can I document this in a follow-up letter?
- CAPA documentation critique

Instructors
The course will be taught by one of the following instructors:
Linda Carter, R.N., B.S.N.
Nikki Christison, B.S., C.C.R.A.
Gary B. Freeman, M.S., C.C.R.A.
Elizabeth Ronk Nelson, M.P.H.
Lily Romero, P.A., C.C.R.C.

Course Dates and Locations

February 17-18, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SSIA0216
$1,595 by January 15
$1,795 after January 15

April 5-6, 2016
Boston, MA 02110
Metro Meeting Centers
Course #: SSIB0416
$1,595 by March 4
$1,795 after March 4

June 7-8, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SSID0616
$1,595 by May 6
$1,795 after May 6

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#: 0778-0000-15-049-L01-P. Released 8/15.
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
• Understand 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:
Linda Carter, R.N., B.S.N.
Gary B. Freeman, M.S., C.C.R.A.
Lily Romero, P.A., C.C.R.C.

Course Dates and Locations

<table>
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<tr>
<th>Course Dates</th>
<th>Location</th>
<th>Course #:</th>
<th>Hotel/Center</th>
<th>Rate</th>
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<td>January 27-28, 2016</td>
<td>San Diego, CA 92101</td>
<td>SSAD0116</td>
<td>Courtyard San Diego Downtown</td>
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<td>April 26-27, 2016</td>
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<td>SSAB0416</td>
<td>Metro Meeting Centers</td>
<td>$1,695 by March 25, $1,895 after March 25</td>
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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.


Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• Regulatory Update: The latest FDA Guidelines will be reviewed
• Monitoring Visits Update: Risk-Based Monitoring Approach
• Monitoring Plans: Writing, evaluating, implementing, and assessing effectiveness
• Mentoring, Communication, and Negotiating Skills: Tips for making the most of “mentoring” opportunities
• Co-Monitoring/Assessing Monitoring Skills: Techniques for assessing monitors in the Sponsor/CRO environment
• Managing Stakeholders: Developing and communicating realistic expectations; reaching stakeholder agreement

Day Two: 8:30 a.m. – 5:00 p.m.
• Site Management (Performance)
• Identifying, Reporting and Managing Study-Specific Issues/Corrective and Preventive Action Plans
• Managing Situations Involving Fraudulent Data
• Regulatory Compliance: Discussion of sponsor and investigational site inspections by FDA; current information regarding FDA and regulatory authority inspections/audits; practical tips for preparing your site for an audit

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! 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
• 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
• 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
March 22-23, 2016
San Francisco, CA 94102
Hilton San Francisco
Course #: SMOF0316
$1,595 by February 19
$1,795 after February 19
June 21-22, 2016
Boston, MA 02110
Metro Meeting Centers
Course #: SMOB0616
$1,595 by May 20
$1,795 after May 20

Web-Based Offerings*
April 4, 2016 (10:00 a.m. – 1:30 p.m. Eastern)
April 5, 2016 (10:00 a.m. – 1:30 p.m. Eastern)
April 6, 2016 (10:00 a.m. – 1:30 p.m. Eastern)
April 7, 2016 (10:00 a.m. – 1:30 p.m. Eastern)
Course #: SMOO0416
$1,595 by March 4
$1,795 after March 4

*See page 97 for system requirements
NOTE: Web-Based Offerings are for individual registrants only.

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#: 0778-0000-16-018-L01-P. Released: 3/16.

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
- Access 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

Course Dates and Locations
<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>Course #: SOPD0116</th>
<th>Course Fee</th>
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<tr>
<td>January 14-15, 2016</td>
<td>San Diego, CA 92101</td>
<td>$1,595 by December 23</td>
<td>$1,795 after December 23</td>
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<tr>
<td>May 3-4, 2016</td>
<td>San Diego, CA 92101</td>
<td>$1,595 by April 1</td>
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</tr>
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Academic Discount
A $400 academic discount is available to those who qualify.

Instructor
Marina Malikova, Ph.D., M.S., M.A., C.C.R.A.

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

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.
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
- Understand 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

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

Instructor
Anil D'Mello, Ph.D.

Course Dates and Locations
March 2-3, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SCKA0316
$1,595 by February 1
$1,795 after February 1

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.


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
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
- Assess 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
- Anticipate the challenges involved in global clinical trials
- Formulate strategies for meeting the challenges

Instructor

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

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

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?

Course Dates and Locations
April 11-12, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SMGA0416
$1,595 by March 11
$1,795 after March 11

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.

Preparing IND 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 on-going investigation, request and prepare for meetings with the Agency to discuss development plans, 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
• Find 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.C.T.I., R.A.C., F.R.A.P.S.

Course Dates & Locations
April 26-27, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SPDD0416
$1,595 by March 25
$1,795 after March 25

June 21-22, 2016
Boston, MA 02110
Metro Meeting Centers
Course #: SPDB0616
$1,595 by May 20
$1,795 after May 20

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#: 0778-0000-14-009-L01-P. Released: 4/14.
Quality System Management Approach in a GCP Environment

Course Description
The future of clinical trial conduct demands a Quality System approach. Recently, regulators have been recommending that a Quality System approach be used for the design, development, and execution of clinical studies. Newly released 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 is an integral component of a Quality System approach, and many researchers do not have the knowledge or experience to conduct clinical trial risk management. 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
• Describe a Quality System approach as it pertains to clinical trial conduct
• Apply the concepts of a risk management approach and how they relate to a Quality System approach
• Describe how Corrective and Preventive Action (CAPA) and Root Cause Analysis (RCA) pertain to a Quality System approach
• Define and demonstrate the application of Quality System approach tools to study conduct

Who Should Attend
• Clinical Quality Assurance Professionals
• 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
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SQSD0216
$1,595 by January 22
$1,795 after January 22

June 7-8, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SQSA0616
$1,595 by May 6
$1,795 after May 6

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#: 0000-0778-15-087-L01-P. Released: 8/15.

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• Principals of Quality Management System (QMS)
• Fitting Clinical into the QMS
• Developing a QMS Quality Manual Group Exercise
• Principals of Risk Management
• Risk Management Group Exercise

Day Two: 8:30 a.m. – 5:00 p.m.
• Recap Day 1
• Principals of RCA
• RCA Group Exercise
• Principals of a CAPA Program
• CAPA Group Exercise
• Questions and Answers

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.”

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.
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

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?

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.

Instructor
Denise G. Redkar-Brown, MT

Accreditation
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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 maximizing 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
• Monitor the constantly changing regulatory landscape
• Break down a regulatory research question into researchable units, and conduct the research using a Regulatory Intelligence Database
• Summarize and present Regulatory Intelligence findings back to a team
• 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.C.T.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
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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
• Find and use available tools that can aid in developing regulatory strategy
• How to summarize the data and perform strategic analysis once the data is identified
• Output and format of strategic information after analysis into a “playbook”

Who Should Attend
• Mid-level regulatory professionals who have 3-5 years 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.C.T.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.
• 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
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
• Locate 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 guidelines 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 is occurring 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 are both promoting 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
- Anticipate 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

Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
- Risk-Based Monitoring: Regulatory authority guidance, ICH GCP, and industry initiatives
- Risk Assessment: Identifying critical data and risks; evaluating and mitigating risks
- Monitoring Plans: Considerations, content, and associated quality management documents
- The Clinical Data Management Connection: Data management as monitoring; central monitoring techniques and reporting
- Remote Monitoring: Strategies, tools, and responding to findings
- Research Sites and Risk-Based Monitoring: Managing change, clarifying expectations, and supporting sites through transition

In-Person Offerings
March 3, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SRMD0316
$800 by February 2
$1,000 after February 2
June 9, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SRMA0616
$800 by May 9
$1,000 May 9

Web-Based Offerings*
March 15, 2016 (9:00 a.m. – 1:00 p.m. Eastern)
March 17, 2016 (9:00 a.m. – 1:00 p.m. Eastern)
Course #: SRMO0316
$1,595 by February 12
$1,795 after February 12
June 28, 2016 (10:30 a.m. – 2:30 p.m. Eastern)
June 30, 2016 (10:30 a.m. – 2:30 p.m. Eastern)
Course #: SRMO0616
$1,595 by May 27
$1,795 after May 27

*See page 97 for system requirements
NOTE: Web-Based Offerings are for individual registrants only.

Academic Discount
A $100 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 7 hours (0.7 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#: 0778-0000-14-010-L01-P. Released: 3/14.

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 non-compliance 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 non-compliance, compromised subject safety, poor data quality, and 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
- Describe performance management concepts and skills for effective site risk management
- Promote 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
The course will be taught by one of the following instructors:
Linda Carter, R.N., B.S.N.
Nikki Christison, B.S., C.C.R.A.
Lily Romero, P.A., C.C.R.C.

Course Dates and Locations

<table>
<thead>
<tr>
<th>Course #: SRCA0316</th>
<th>Philadelphia, PA 19103</th>
<th>March 1-2, 2016</th>
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<td>The Hub Meeting Center – CityView</td>
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<th>Course #: SRCB0516</th>
<th>Boston, MA 02110</th>
<th>May 17-18, 2016</th>
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<tr>
<td>Metro Meeting Centers</td>
<td>$1,595 by April 18</td>
<td>$1,795 after April 18</td>
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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#: 0778-0000-14-011-L01-P. Released: 3/14.

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

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

Instructors
The course will be taught by one of the following instructors:
Linda Carter, R.N., B.S.N.
Nikki Christison, 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.

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

What Participants Say About Barnett Seminars:

“Lots of good energy and ideas, kept it interesting the whole time.”
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
• Ascertain what information the statistician needs to determine the sample size
• Choose 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
• Become comfortable talking with 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

Interactive Exercises
• Drawing Random Samples
• Constructing Confidence Intervals
• Creating and Testing with Real Data Individual and Group Hypotheses

Course Dates and Locations

<table>
<thead>
<tr>
<th>Course Dates</th>
<th>Locations</th>
<th>Course #: Course Location</th>
<th>Initial Fee</th>
<th>Final Fee</th>
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<td>April 18-19, 2016</td>
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<td>SSTB0616</td>
<td>$1,595 by May 20</td>
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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#: 0778-0000-15-052-L01-P. Released 10/15.

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
March 22-23, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SSCD0316
$1,595 by February 19
$1,795 after February 19

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.


Course Outline
Day One: 8:30 a.m. – 5:00 p.m.
• Overview of Operational Planning: Charter; scope; work breakdown structure (WBS) and the network
• Strategic Planning in Clinical Research: Projections of expenditures and milestones; estimation of risks
• Contractors – Managing Outsourcing: Selection; scope; standards and expectations
• Project Communications Plan: Team building; conflict resolution; virtual teams; reporting and communications
• Timeline Management: Schedules and milestones completion; scope change
• Project Cost Estimation: PERT analysis, bottom-up and top-down cost estimation techniques

Day Two: 8:30 a.m. – 5:00 p.m.
• Development and Management of Project Budgets: Cost estimation techniques; ongoing financial management and costs monitoring
• Project Tracking: Tracking requirements; identifying and establishing project metrics
• Project Progress Monitoring Tools: Earned value; actual versus planned costs; schedule and cost; performance index
• Risk Management and Implementation of Strategic Project Management Concepts in Clinical Trials: Risk mitigation strategies; schedule; cost and change management
• Quality by Design (QbD) Principles and Risk-Based Monitoring: Applying a risk-based management approach in development of relevant Key Performance and Quality Indicators (KP-QIs)
• Close Out Phase: Plan and process; study documentation and record retention; laboratory records and specimen retention; study participant rights and notifications

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

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; 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
• Articulate 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

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

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

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

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

Who Should Attend
- Clinical Research Associates
- Clinical Research Associate Managers
- Clinical Research Professionals with responsibility for vendor selection and management
- Project Managers

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

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.

Course Dates and Locations
February 2-3, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SPF0216
$1,595 by December 31
$1,795 after December 31
May 3-4, 2016
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SPF0516
$1,595 by April 1
$1,795 after April 1
June 21-22, 2016
Philadelphia, PA 19103
The Hub Meeting Center – CityView
Course #: SPF0616
$1,595 by May 20
$1,795 after May 20

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.

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 a phone.

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? DVD archives are available and they will allow you to watch recordings of previous Interactive Web Seminars any time you want. Pricing is available for single users and site licenses. See page 203 for more details.

System Requirements:

WebEx offers cross platform support, so you do not have to worry about what operating system you use. WebEx provides unmatched support for Windows, Mac, Linux, and Solaris. Browser support includes Internet Explorer, Mozilla, Firefox, Netscape, and Safari. 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. Upon completion, Barnett will provide resume assistance so that you can position yourself for entry into this market.

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 CRA and CRC
- Describe the four types of monitoring visits, including the responsibilities of the CRA and CRC in preparation, activities, and follow-up
- Discuss the role of the Institutional Review Board in clinical trials, define informed consent requirements, and discuss the informed consent process
- Define safety definitions and reporting requirements for both drugs and devices
- 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 experience)
- College Students and New Graduates in a Scientific Field
- Nurses

Instructors
This course will be taught by one of the following instructors:
Linda Carter, R.N., B.S.N.
Janet Ellen Holwell, C.C.R.C., C.C.R.A.
Susan Torchio, R.N., B.S.N.

Course Length and Time
3 hours/week, 6:00 – 9:00 p.m. Eastern, 10 weeks
Wednesday Evenings

Course Dates
- January 13, 2016 – March 16, 2016
  $1,695 by December 16
  $1,895 after December 16
- April 6, 2016 – June 8, 2016
  $1,695 by March 4
  $1,895 after March 4
- July 20, 2016 – September 21, 2016
  $1,695 by June 17
  $1,895 after June 17

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 comprehensive course materials. 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#: 0778-0000-14-053-L01-P. Released: 10/14.

What Participants Say About The Course
“I have learned a lot that I will be able to use directly in my current role, and it has really reinforced the value of the work that I do. I have been able to get involved with a variety of different CROs and sponsors. It was extremely helpful seeing the clinical trial industry from their perspective.”

“I thought it was fantastic and it did help me land my job – a CRA I. 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.”

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.
10-Week Clinical Research Associate (CRA) On-Boarding Program

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. The course follows an ICH/ISO global GCP framework, and covers how to identify specific country requirements, making it appropriate for both U.S. and global audiences. 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, and the roles and responsibilities of the research team
• Define the regulatory requirements, explain the differences between ICH and FDA guidelines, and describe the elements of a protocol
• Outline required elements of the informed consent
• Grasp 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 complete source document verification
• Perform the steps involved in monitoring the study pre-visit, during the visit, and post-visit
• Create cohesive, well-written protocol deviations and action items, and accurately complete the monitor visit report and site follow-up letter
• Define the impact of quality assurance and audits in clinical research

Course Outline
• Module 1: Drug Development Process, 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 and Contact Reports
• Module 10: Regulatory Compliance and Quality Assurance: Audits and Inspections

Who Should Attend
• Clinical Research Associates with less than two years 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)

Instructors
This course will be taught by one of the following instructors:
Linda Carter, R.N., B.S.N.
Janet Ellen Holwell, C.C.R.C., C.C.R.A.

Course Length and Time
3 hours/week, 8:30 – 11:30 a.m. and 12:00 – 3:00 p.m. Eastern 10 weeks

Course Dates
March 4, 2016 – May 13, 2016
Friday Afternoons
No class: April 15
$1,695 by February 5
$1,895 after February 5

June 10, 2016 – August 19, 2016
Friday Mornings
No class: July 8
$1,695 by May 13
$1,895 after May 13

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 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 comprehensive course materials. 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#: 0778-0000-14-015-L01-P. Released: 3/14.

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. Thank you so much.”

“I have been given a solid framework on how to approach future studies from site selection, protocol development, and inclusion/exclusion importance to regulatory considerations (when to report what to whom). I plan to make use of all the monitoring tools provided to achieve success and utilize EDC for ease of CRF collection. When in doubt, I will always refer back to modules for guidance. Great course!”
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 and Device Development, 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 Inspection

Instructors
This course will be taught by one of the following instructors:
Linda Carter, R.N., B.S.N.
Janet Ellen Holwell, C.C.R.C., C.C.R.A.

Course Length and Time
3 hours/week, 8:30 – 11:30 a.m. and 12:00 – 3:00 p.m. Eastern
10 weeks

Course Dates
- **March 4, 2016 – May 13, 2016**
  - Friday Mornings
  - No class: April 15
  - $1,695 by February 5
  - $1,895 after February 5
- **June 10, 2016 – August 19, 2016**
  - Friday Afternoons
  - No class: July 8
  - $1,695 by May 13
  - $1,895 after May 13

**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 comprehensive course materials. 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#: 0778-0000-14-088-L01-P. Released: 8/14.

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!”
NEW! 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

Course Outline
- Module 1: FDA Guidances, 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

Instructor
Denise G. Redkar-Brown, MT

Course Length and Time
3 hours/week, 5:00 – 8:00 p.m. Eastern, 10 weeks Wednesday Evenings

Course Dates
January 27, 2016 – March 30, 2016
$1,695 by December 18
$1,895 after December 18
April 20, 2016 – June 22, 2016
$1,695 by March 18
$1,895 after March 18

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 comprehensive course materials. 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#: 0778-0000-16-016-L01-P. Released: 1/16.

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
- 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)
30-Hour Clinical Project Management Fundamentals Certification Program

Course Description
In today’s outsourcing environment, the need for strong project management skills is greater than ever. This comprehensive hands-on 30-hour course is designed to provide the tools necessary to become a strong project manager in clinical research. Whether you are looking to become a clinical research project manager, you are already in an entry-level project manager role or you have become an “accidental” project manager by assignment, this program will provide you with project management skills development 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. Discussions, exercises, and tools are practically oriented with an emphasis given to practical application of key concepts and principles.

Learning Objectives
- 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
- Use project management budgeting and tracking techniques
- Utilize appropriate communication skills and effectively motivate team members
- Apply strategies for seamless project closeout 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: Timeline 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
- Project Managers looking to gain experience in clinical research project management
- Project Leaders that are unfamiliar with project management tools and principles
- Clinical Research Personnel transitioning to project management roles/functions

Instructors
This course will be taught by one of the following instructors:
Véronique Lalevee, Pharm.D., P.M.P.
Eric Morfin, Ph.D., M.B.A., P.M.P.

Course Length and Time
3 hours/week, 9:00 a.m. – 12:00 p.m., 1:00 – 4:00 p.m., and 5:00 – 8:00 p.m. Eastern
10 weeks

Course Dates
February 5, 2016 – April 8, 2016
Friday Mornings
$1,695 by January 8
$1,895 after January 8
Thursday Evenings
No class: April 7, April 14, April 21, April 28, June 2
$1,695 by January 29
$1,895 after January 29
April 15, 2016 – June 17, 2016
Friday Afternoon
$1,695 by March 18
$1,895 after March 18

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 comprehensive course materials. 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#: 0778-0000-14-087-L01-P. Released: 8/14.
This 30-hour program will provide you with 30 Education Credit Hours toward taking your PMP certification with BioPharmaPM and PMI. Or if you are already PMP certified, this 30-hour program will provide you with 30 PDUs (Professional Development Units) toward your PMP re-certification.

What Participants Say About The Course
I’ve 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 am already using this material to re-engineer our research enterprise to plan, monitor, and to improve and streamline our processes for quality and efficiency. Thanks for a great course.

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.
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 14, 2016 – March 31, 2016
Thursday Mornings
No class: March 3, March 24
$1,695 by December 11
$1,895 after December 11

February 11, 2016 – April 21, 2016
Thursday Evenings
No class: March 24
$1,695 by January 8
$1,895 after January 8

April 28, 2016 – June 30, 2016
Thursday Evenings
$1,695 by March 25
$1,895 after March 25

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 comprehensive course materials. 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. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.


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
Gary B. Freeman, M.S., C.C.R.A.

Course Length and Time
2.5 hours 9:00 – 11:30 a.m. and 12:30 – 3:00 p.m. Eastern

ABCs of GCP and the 13 Principles of ICH

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 ICH Guidelines) 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 ICH GCP 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 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
Gary B. Freeman, M.S., 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

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.
Adequate Sponsor Monitoring Systems In Anticipation of FDA Sponsor GCP Inspections

Course Description
In the current regulatory climate, sponsors should anticipate more FDA sponsor GCP inspections and information requests regarding monitoring practices. Many monitoring systems lack components that ensure proper management of the research site without relying on the “star performer.” Monitoring systems should include specific components to ensure control of investigational product, data integrity, oversight of vendors, as well as other areas. The components of a quality monitoring system will be presented so that participants can assess their current practices for identifying gaps and risks, particularly in relation to preparing for regulatory inspections of sponsor monitoring programs.

Learning Objectives
• Discuss BIMO Sponsor/CROs and monitors program
• Identify components of a sponsor monitoring system: Beyond SOPs
• Distinguish each component’s suggested elements
• Define adequate oversight of non-employee performers
• Identify other measures to ensure quality monitoring
• Evaluate gaps in monitoring systems

Who Should Attend
• Sponsor Senior Management
• Project Managers
• Clinical Research Associate Managers
• Quality Assurance and Compliance Professionals
• Clinical Research Associates

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 12:30 – 2:30 p.m. Eastern

Course Dates
March 1, 2016

Archived Recording Available!

FEE: $695*
*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. 800.896.2556 for pricing.

This web seminar qualifies for a reduced individual participant fee of $149.

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


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. The safety, regulatory, and ICH definitions will be reviewed and applied to the monitoring process in this web seminar. 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
• Verify appropriate credentialing for site AE evaluation of event relationship
• Appreciate 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
Linda Carter, R.N., B.S.N.

Course Length and Time
2 hours 12:00 – 2:00 p.m. Eastern

Course Dates
February 4, 2016

Archived Recording Available!

FEE: $695*
*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. 800.896.2556 for pricing.

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

NEW! Annual GCP Training Update: MHRA Inspection Findings for 2015

Course Description
The UK's Medicines and Healthcare products Regulatory Agency (MHRA) is one 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, which areas cause the regulator 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
• Explain the main areas of concern to the MHRA
• Become aware of the most common and most significant findings being written by the MHRA
• Understand where the MHRA applies 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

Instructor
Paul Strickland, B.Sc., FRQA, DipRQA

Course Length and Time
3 hours 9:00 a.m. – 12:00 p.m. Eastern

Course Dates
February 29, 2016
May 27, 2016

FEE: $795*
*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#: 0778-0000-16-022-L01-P. Released: 2/16.

Applied Clinical Statistics in Centralized 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
• Subject Enrollment Managers
• Research Nurses and Scientists
• Clinical Project Managers

Instructor
Moe Alsumidaie, M.B.A., M.S.F.

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates
February 12, 2016 (1-2:30)
May 9, 2016 (9:30-11)

FEE: $695*
*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.

Blended Curriculum Course

Approaches to Address Challenges in Vendor Management

Course Description
Outsourcing in clinical development continues to grow and so do the challenges of ensuring quality outcomes. Managing a vendor vs. micro-managing a vendor will be discussed with some practices to improve the relationship. Recommendations for sponsor oversight practices are discussed with a review of helpful tools.

Learning Objectives
- Identify key approaches to planning and preparing to outsource to improve relationships
- Identify key components for formal study of vendor performance management
- Identify adequate oversight SOPs and other practices for the sponsor
- 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:
Nikki Christison, B.S., C.C.R.A.
Jeanne Morris, B.S., MT (ASCP)

Course Length and Time
2.5 hours 12:00 – 2:30 p.m. Eastern

Course Dates
March 14, 2016

Archived Recording Available!

FEE: $795*
*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#: 0778-0000-15-008-L01-P. Released: 2/15.

Interactive Web Seminars

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 Length and Time
2 hours 9:30 – 11:30 a.m. and 12:30 – 2:30 p.m. Eastern

Course Dates
March 2, 2016 (12:30-2:30)
June 14, 2016 (9:30-11:30)

Archived Recording Available!

FEE: $795*
*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.

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
- Incorporate 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
March 3, 2016

FEE: $695*

*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.

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
- 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 K. Westbrook, RQAP-GCP

Course Length and Time
2 hours 1:00 – 3:00 p.m. Eastern

Course Dates
May 3, 2016

FEE: $695*

*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#: 0778-0000-14-042-L01-P. Released: 3/14.
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 thru 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.

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
- Clarify 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.C.T.I., R.A.C., F.R.A.P.S.

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates
January 28, 2016 (9:30-11)
June 6, 2016 (1-2:30)

FEE: $695*
*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.

What Participants Say About Barnett Interactive Web Seminars:

“The seminar provided me new strategies and elements to empower my team.”
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
Nikki Christison, B.S., C.C.R.A.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
March 15, 2016

Archived Recording Available!

FEE: $695*
*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#: 0778-0000-15-054-L01-P. Released: 8/15.

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 Conference on 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
• Appropriately define and evaluate the critical data elements
• Clarify special situations and challenges
• Acquire and practice the skills necessary for generating well-written case narratives for reporting to regulatory authorities

Who Should Attend
• Drug Safety Professionals
• Pharmacovigilance Personnel
• Regulatory Affairs Professionals
• Clinical Development Personnel

Instructor
Azita Ahmadi, B.S.

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates
January 26, 2016 (1-2:30)
March 24, 2016 (9:30-11)
June 22, 2016 (1-2:30)

Archived Recording Available!

FEE: $695*
*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
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ACPE#: 0778-0000-14-069-L01-P. Released: 8/14.
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
June 1, 2016
Archived Recording Available!

FEE: $695*
*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

Instructors
This course will be taught by one of the following instructors:
Nikki Christison, B.S., C.C.R.A.
Jeanne Morris, B.S., MT (ASCP)

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 25, 2016 (12-3)
February 16, 2016 (9-12)
June 20, 2016 (12-3)

Archived Recording Available!

FEE: $795*
*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#: 0778-0000-14-050-L01-P. Released: 3/14.
NEW! 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 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.

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.C.T.I., R.A.C., F.R.A.P.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
March 8, 2016

FEE: $695*
*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.

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 of 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
• Consider 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 – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates
April 26, 2016 (9:30-11)
June 16, 2016 (1-2:30)

FEE: $695*
*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.

NEW! CMS-Medicare Coverage Analysis, Budgeting and Billing Compliance

Course Description
This web seminar is focused on processes and approaches to increase fiscal return and mitigate fiscal compliance risk for clinical trials. The ability to develop robust budgets, ensure billing compliance and adherence to CMS-Medicare regulations for clinical trials remains a challenge for many clinical sites, sponsors and Contract Research Organizations (CROs). A risk-based approach requires not only a strategy but tools to define key indicators to measure specific risks. In this web seminar, learners will come away with strategies for covering true costs related to clinical research and how to distinguish them from routine care charges. Methodologies to avoid false claims and/or wrongful billing will also be presented.

Learning Objectives
• Discuss budgeting considerations in clinical research
• Explain how to perform a Medicare Coverage Analysis
• Recognize device classifications and the applicable categories of devices for insurance reimbursement within a clinical trial
• Categorize different charges in clinical research (research-related versus routine care, “billable to insurance”)
• Identify fiscal and billing compliance risk mitigation strategies

Who Should Attend
• Clinical Research Coordinators
• Site Directors
• Clinical Research Associates
• Office of Research Compliance and Risk Management Personnel
• Study Managers/Trial Managers
• Billing Specialists
• Project Managers

Instructor
Marina Malikova, Ph.D., M.S., M.A., 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 8, 2016 (9:30-11)
June 6, 2016 (1-2:30)

FEE: $695*
*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
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ACPE#: 0778-0000-16-014-L01-P. Released: 2/16.
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:
Gary B. Freeman, M.S., C.C.R.A.
Jeanne Morris, B.S., MT (ASCP)

Course Length and Time
1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates
April 12, 2016

Archived Recording Available!

FEE: $795*
*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#: 0778-0000-14-054-L01-P. Released: 10/14.

CRA Current Practice Update: Impact of the FDA Bioresearch Monitoring (BIMO) Program

Course Description
The FDA announced in 2006 an initiative to modernize the regulation of clinical trials, including the BIMO inspections program. This includes conducting inspections and other assessments earlier in the development of a potential product to build quality into the clinical trial upfront rather than assessing it at trial completion. From this initiative, the FDA has generated new guidance and regulation that directly affect the performance of the sponsor monitor. The initiative is a dynamic process and this web seminar tracks the updates that directly affect monitoring. Examples of how to implement the agency requirements and recommendations into current practices and specific projects are also covered.

Learning Objectives
- Discuss the FDA BIMO initiative and the direct impact on sponsor monitoring
- Examine industry regulatory update impacting the role of the Clinical Research Associate
- Integrate strategies for determining appropriate role performance for earlier and more frequent sponsor monitoring inspections
- Apply tools and resources to implement the new required and recommended practices

Who Should Attend
- Clinical Research Associates (Pharma, Biologic, or Device)
- Contract Clinical Research Associates
- Sponsor Project Managers
- Clinical Research Associate Managers
- Recruiters

Instructors
This course will be taught by one of the following instructors:
Linda Carter, R.N., B.S.N.
Nikki Christison, B.S., C.C.R.A.

Course Length and Time
2 hours 1:00 – 3:00 p.m. Eastern

Course Dates
March 10, 2016

FEE: $695*
*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#: 0778-0000-16-001-L01-P. Released: 3/16.
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
Nikki Christison, B.S., C.C.R.A.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
March 16, 2016
Archived Recording Available!

FEE: $695*
*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 $149.

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

CRC Role/Responsibilities Training

Course Description
The Clinical Research Coordinator (CRC) can be a key liaison between the investigator, subject, Institutional Review Board (IRB), and sponsor. The CRC assists the investigator to ensure that the clinical trial is successfully implemented and completed. This web seminar presents the core skills and activities performed by the CRC and the documentation requirements that come along with clinical trials.

Learning Objectives
• Define the role of the CRC at the research site
• Identify appropriate delegation of study tasks to CRCs
• Identify required subject and non-subject documentation requirements
• Identify key activities performed by the CRC monitored by the sponsor

Who Should Attend
• Clinical Research Coordinators
• Site Managers
• Principal Investigators

Instructors
This course will be taught by one of the following instructors:
Linda Carter, R.N., B.S.N.
Nikki Christison, B.S., C.C.R.A.

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!

FEE:

This web seminar qualifies for a reduced individual participant fee of $149.

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

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
• Discuss techniques for building working teams through the application of adult learning and management skills application
• Determine communication and escalation pathways for outsourced providers
• Identify tools for managing and solving partnership problems through RCA and practical application of solutions
• 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
Nikki Christison, B.S., C.C.R.A.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
May 2, 2016

Archived Recording Available!

FEE: $695*
*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.


CRO Selection Criteria, Evaluation, and Establishing the Relationship

Course Description
Outsourcing to Contract Research Organizations (CROs) to complete studies has become a foundation for pharmaceutical and device companies. With the lengthy drug development and approval process, it is nearly impossible to have complete study teams kept as full-time employees as the workload continually ebbs and flows. One of the challenges of outsourcing is selecting the right partner and then maintaining a team atmosphere where everyone takes ownership of the study. Key considerations when collaborating successfully with a CRO are selecting the right partner by knowing what questions to ask; establishing a foundation for the partnership with clear expectations, goals, and communication; and maintaining a sense of ownership in the work that has been outsourced. This web seminar will address the key criteria in selecting a partner, as well as review the necessary processes to foster positive relationships and allow for high quality performance of the CRO.

Learning Objectives
• Review key questions and selection criteria during the CRO evaluation and the Request for Proposal (RFP) review process
• Explain the importance and various tools necessary for establishing clear expectations, communication, and objectives for the collaboration
• Address techniques and oversight requirements to allow for a high performance alliance

Who Should Attend
• Project Managers
• Clinical Research Associates
• Clinical Research Associate Managers
• Contract and Budget Management Personnel
• Directors in Clinical Operations
• Site Managers

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

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
March 21, 2016

Archived Recording Available!

FEE: $695*
*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.

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
• Regulatory Affairs Professionals
• Trainers and Educators
• Investigators
• Auditors and Inspectors

Instructor
Janet Ellen Holwell, C.C.R.C., C.C.R.A.

Data Management in the Electronic Data Capture Arena

Course Description
This web seminar will explore the evolution of Clinical Data Management from a paper Case Report Form (CRF) process to the "real time" data review capable in the world of electronic data capture (EDC). We will review the specific regulations governing EDC and electronic signature requirements. Participants will examine the changing role of the Clinical Data Manager (CDM) as the technology drives the process, thereby allowing today’s CDM to move forward in the discipline and ensure their place as a viable member of the clinical study team. The EDC technology is enabling the data management component of clinical trial activities to advance and it is important that the CDM is aware of the capabilities the applications have to offer.

Learning Objectives
• Describe the regulations as they impact data management
• Discuss the rationale and perceived enhancements leading to greater utilization of EDC
• Examine the changing role of the Clinical Data Manager
• Describe the data management documentation required in clinical trial conduct

Who Should Attend
• Clinical Data Managers who are involved in the transition from a paper CRF process to EDC
• Clinical Data Managers new to the EDC process
• Electronic Data Capture Developers who require a better understanding of the CDM process and role

Instructor
Denise G. Redkar-Brown, MT

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
February 22, 2016

Archived Recording Available!

FEE: $695*
*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.


This web seminar qualifies for a reduced individual participant fee of $149.

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#: 0778-0000-14-072-L01-P. Released: 8/14.
Data Management: Key Regulations Impacting the Role of the Clinical Data Manager

Course Description
In conducting clinical research, there are some specific regulations that directly impact the discipline of Clinical Data Management (CDM). 21 CFR Part 11 includes mandatory regulations that govern clinical trials data. It requires a system in which electronic records and signatures are trustworthy, reliable, and secure; electronic signatures that are equivalent to paper records and handwritten signatures executed on paper; a system that discerns invalid or altered records; and signatures that are linked to an electronic record. The “Guidance for Industry—Computerized Systems Used in Clinical Trials,” builds on the importance of information inclusion when utilizing computerized systems. In addition, the recently finalized “Guidance for Industry: Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring” specifically mentions the role that Clinical Data Management is expected to have in assisting in a risk-based monitoring approach. In this web seminar, we will explore the information in these regulations/guidances that will further the understanding of their impact on our current way of working.

Learning Objectives
• Define the 21 CFR Part 11 regulations as they impact Clinical Data Management
• Describe what is meant by an electronic signature
• List components defining “computerized systems”
• Identify the Clinical Data Manager’s role in risk-based monitoring

Who Should Attend
• Clinical Data Managers
• Clinical Research Professionals

Instructor
Denise G. Redkar-Brown, MT

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
January 12, 2016
April 19, 2016

Archived Recording Available!

FEE: $695*
*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
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ACPE#: 0778-0000-14-071-L01-P. Released: 9/14.
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 webinar, 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
February 23, 2016

Archived Recording Available!

FEE: $695*
*Includes up to 30 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.


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 webinar 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

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!

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:

“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

Detected 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 guidelines, 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.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
July 19, 2016

FEE: $695*

*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.


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
- Go from study protocols 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
- Site Managers
- Project Managers
- Contracts and Budget Department Representatives
- Clinical Research Coordinators
- Research Nurses
- Investigators
- Sponsor Representatives working with sites on study start-up

Instructor
Lily Romero, P.A., C.C.R.C.

Course Length and Time
3 hours 8:30 – 11:30 a.m. and 12:00 – 3:00 p.m. Eastern

Course Dates
March 17, 2016 (8:30-11:30)
July 21, 2016 (12-3)

Archived Recording Available!

FEE: $795*

*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#: 0778-0000-14-018-L01-P. Released: 3/14.
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
- Address 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

Instructors
This course will be taught by one of the following instructors:
Nikki Christison, B.S., C.C.R.A.
Lily Romero, P.A., C.C.R.C.

Course Length and Time
2 hours 12:30 – 2:30 p.m. Eastern

Course Dates
March 22, 2016

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.C.T.I., R.A.C., F.R.A.P.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
March 28, 2016

FEE: $695*
*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#: 0778-0000-15-080-L01-P. Released: 8/15.
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
Gary B. Freeman, M.S., C.C.R.A.

Course Length and Time
3 hours 12:30 – 3:30 p.m. Eastern

Course Dates
April 4, 2016
Archived Recording Available!

FEE: $695*
*Includes up to 20 participants at one site. All participants 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.


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 and 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. The FDA's final guidance document for 21 CFR Part 11 supports certain characteristics that EMRs should include, but many site electronic records do not meet the requirements. This web seminar will discuss assessment of EMRs, ideal monitoring vs. contingency planning, and risk management.

Learning Objectives
• Define source documents (FDA & ICH)
• 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
Nikki Christison, B.S., C.C.R.A.

Course Length and Time
2.5 hours 8:30 – 11:00 a.m. and 12:00 – 2:30 p.m. Eastern

Course Dates
March 23, 2016 (12-2-30)
July 19, 2016 (6-30-11)
Archived Recording Available!

FEE: $795*
*Includes up to 20 participants at one site. All participants 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 $349.

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#: 0778-0000-16-004-L01-P. Released: 4/16.

This web seminar qualifies for a reduced individual participant fee of $349.

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#: 0778-0000-14-025-L01-P. Released: 2/14.
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 12:30 – 2:30 p.m. Eastern

EMA and FDA Inspections: Key Differences and Similarities

Course Description
The European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA) collaborated and performed official joint Good Clinical Practice (GCP) inspections of sponsors, CROs, and investigational sites between 2009 through 2011. Those collaborations have continued into 2014. In this web seminar, we will review the Report on the Pilot EMA-FDA GCP Initiative, and discuss the similarities and differences between EMA and FDA inspectors and inspection processes conducted over the last five years using recent examples of joint inspections. Clarification will also be provided for reporting of Serious Breaches in the UK along with a review of common inspection findings.

Learning Objectives
- Describe the EMA and FDA inspection processes
- Clarify reporting of Serious Breaches Requirements
- Review inspection findings

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 and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
April 5, 2016

Archived Recording Available!

FEE: $695*
*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.

NEW! 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
• Know 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

Instructor
Paul Strickland, B.Sc., FRQA, DipRQA

Course Length and Time
4 hours 9:00 a.m. – 1:00 p.m. Eastern

Course Dates
March 7, 2016
June 27, 2016

FEE: $895*
*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#: 0778-0000-16-023-L01-P. Released: 3/16.

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
Janet Ellen Holwell, C.C.R.C., C.C.R.A.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
January 14, 2016
June 7, 2016

Archived Recording Available!

FEE: $695*
*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#: 0778-0000-14-073-L01-P. Released: 8/14.
Essential Documentation in Clinical Trials at Research Sites

Course Description
Essential documentation serves to demonstrate the compliance of the investigator, sponsor and monitor, and IRB with the standards of GCP, best practice, and all applicable regulatory requirements. This course will discuss various types of essential documentation, subject specific and non-subject specific, for both drug and device trial research sites. The course will help define what should be maintained at a research site to promote adequate and accurate documentation of site, monitor, and IRB performance.

Learning Objectives
- Define clinical research essential documentation
- Determine essential subject and non-subject specific documentation requirements per trial
- Discuss essential documentation for drug vs. device vs. combination products
- Prepare for regulatory inspection: Proactive and reactive use of essential documentation

Who Should Attend
- Clinical Research Coordinators
- Principal Investigators
- Research Site Managers
- Clinical Research Associates
- Quality Assurance Personnel
- Project Managers
- Clinical Research Associate Managers

Instructors
This course will be taught by one of the following instructors:
Linda Carter, R.N., B.S.N.
Nikki Christison, B.S., C.C.R.A.

Course Length and Time
2 hours 1:00 – 3:00 p.m. Eastern

Course Dates
March 29, 2016

FEE: $695*
*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#: 0778-0000-14-056-L01-P. Released: 11/14.

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

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
February 10, 2016

FEE: $695*
*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#: 0778-0000-14-089-L01-P. Released: 9/14.

What Participants Say About Barnett Interactive Web Seminars:
“Kudos again for a nicely paced, interactive presentation!”
NEW! eTMF Implementation Strategies

Course Description
Across the industry, organizations are moving towards an electronic Trial Master File (eTMF). Moving from a paper TMF to an eTMF is a large undertaking for any organization. The right approach to the project is critical to the implementation. In this web seminar, we will discuss the key activities including vendor selection, developing eTMF management processes that ensure a high quality TMF, implications of eTMF within your organization, and working with Contract Research Organizations (CROs) and sponsor partners during the implementation process. Successful planning and implementation will result in a high quality eTMF system that ensures the organization is inspection and audit ready.

Learning Objectives
- Identify the key processes impacted by an eTMF implementation
- Describe three techniques for addressing the functional area impact of eTMF implementation
- Develop a list of user requirements to assist in the selection of an eTMF vendor
- Discuss the strategies for communicating with business partners in the implementation of an eTMF

Who Should Attend
- Trial Master File Directors
- Trial Master File Managers
- 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
February 12, 2016 (1-3)
April 22, 2016 (9:30-11:30)

FEE: $795*
*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#: 0778-0000-16-028-L01-P. Released: 2/16.

NEW! 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
- 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
February 26, 2016 (9:30-11:30)
June 3, 2016 (1-3)

FEE: $795*
*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#: 0778-0000-16-024-L01-P. Released: 2/16.
European Pharmacovigilance Modules: What Are They and Why They Are Important

Course Description
Since 2012, 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

NEW! 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 ICH E-6 GCP 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
- Understand 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

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


**FDA Drug Approval Process**

**Course Description**

This web seminar provides an overview of what is required to take a new drug from research to market. 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**
Gary B. Freeman, M.S., C.C.R.A.

**Course Length and Time**
3 hours 12:30 – 3:30 p.m. Eastern

**Course Dates**
April 5, 2016

**Archived Recording Available!**

**FEE:** $695*

*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#: 0778-0000-14-020-L01-P. Released: 5/14.

**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 21 CFR 812
- 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
- Define 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**
Gary B. Freeman, M.S., C.C.R.A.

**Course Length and Time**
1.5 hours 9:30 – 11:00 a.m. and 3:00 – 4:30 p.m. Eastern

**Course Dates**
January 18, 2016 (3-4:30)
May 12, 2016 (9:30-11)

**FEE:** $695*

*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#: 0778-0000-15-075-L01-P. Released: 8/15.
FDA’s Bioresearch Monitoring (BIMO) Program: Inspection of Sponsors, CROs, and Monitors

Course Description
This web seminar includes a detailed review of the FDA’s Compliance Program Guidance Manual (CPGM) on how agency investigators are trained to conduct inspections of sponsors, Contract Research Organizations (CROs), and monitors involved in the conduct of clinical research. The course will look at the FDA’s current focus during inspections and the factors driving these changes. Assessment and discussion of the standard operating procedures that are expected for sponsors and CROs, including registration of trials and informed consent document issues, will be highlighted.

Learning Objectives
• Review how new regulatory requirements are being incorporated into inspections
• Discuss the CPGM and rules that support changes in inspection focus
• Assess the FDA’s application of the inspection manual contents 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
• Sponsor-Investigators
• Sponsor and CRO Representatives

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
2 hours 12:30 – 2:30 p.m. Eastern

Course Dates
April 26, 2016

Archived Recording Available!

FEE: $695*
*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 $149.

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.


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
Gary B. Freeman, M.S., C.C.R.A.

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 3:00 – 4:30 p.m. Eastern

Course Dates
February 22, 2016 (9:30-11)
May 12, 2016 (3-4:30)

FEE: $695*
*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.

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

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates
April 27, 2016

Archived Recording Available!

FEE: $595*
*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.


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

Instructors
This course will be taught by one of the following instructors:
Linda Carter, R.N., B.S.N.
Gary B. Freeman, M.S., C.C.R.A

Course Length and Time
2 hours 1:00 – 3:00 p.m. Eastern

Course Dates
March 24, 2016

Archived Recording Available!

FEE: $595*
*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#: 0778-0000-14-057-L01-P. Released: 11/14.
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.

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
- Landmark and recent cases of fraud in clinical research
- Group discussion of best practices

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:
Elizabeth Ronk Nelson, M.P.H.
Jeanne Morris B.S., MT (ASCP)

Course Dates
June 15, 2016

Course Length and Time
2 hours 12:30 – 2:30 p.m. Eastern

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 Dates
February 24, 2016

Course Length and Time
1.5 hours 12:00 – 1:30 p.m. Eastern

FEE: $695*
*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.

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 Conference on 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 ICH GCP 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

Instructors
This course will be taught by one of the following instructors:
Gary B. Freeman, M.S., C.C.R.A.
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.

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 ICH GCP E6 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
Nikki Christison, B.S., C.C.R.A.

Course Dates
March 24, 2016

FEE: $695*
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:
“’The webinar was very easy to navigate and allowed for questions, comments and active participation of the learners.’”
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

Instructors
This course will be taught by one of the following instructors:
Gary B. Freeman, M.S., C.C.R.A.
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 16, 2016 (9:30-11:30)
May 18, 2016 (12:30-2:30)
June 16, 2016 (12:30-2:30)

Archived Recording Available!

FEE: $795*
*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.


Good Clinical Practice (GCP) for Medical Devices: ICH GCP and ISO 14155

Course Description
Both ICH E6 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 ICH 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 1:00 – 2:30 p.m. Eastern

Course Dates
March 1, 2016 (9:30-11)
May 16, 2016 (1-2:30)

Archived Recording Available!

FEE: $695*
*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.

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
3 hours 12:00 – 3:00 p.m. Eastern

Course Dates
May 17, 2016

NEW! ICH E-6 GCP Proposed Revisions 2016 Review: Impact on Sites, Sponsors, and CROs

Course Description
For the first time in 20 years, the International Conference for Harmonization (ICH) E-6 Good Clinical Practice (GCP) Guideline is being updated. The proposed revisions are intended to modernize and encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, documentation, and reporting, as well as human subject protections. But, the proposed changes have resounding effects and impact on Sponsors and Investigators, requiring a complete and systematic analysis to ensure adherence to these proposed clinical trial standards. This web seminar not only informs learners of the proposed changes, but also provides information and techniques for a constructive and systematic approach in assessing organizational practices and designing any modifications.

Learning Objectives
- Identify three changes impacting Investigator and Sponsor responsibilities
- Explain the impact of the proposed revisions to three organizational practices
- Evaluate presented solutions for applicability, use, modification for proactive assessments of organizational practices, processes, procedures, and staff training

Who Should Attend
- Study Managers and Monitors (Centralized, On-site)
- Clinical Research Associates and Project Managers
- Quality Assurance Personnel
- Investigators and Study Coordinators
- Directors: Clinical Trial Unit, Clinical Trial Offices
- Office of Research Compliance and Risk Management Personnel

Instructor

Course Length and Time
2 hours 3:00 – 5:00 p.m. Eastern

Course Dates
February 10, 2016
June 15, 2016

FEE: $795*
*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#: 0778-0000-16-020-L01. Released: 2/16.
Implications of the FDA Guidance for a Risk-Based Approach to Monitoring

Course Description
The FDA’s Guidance for the Monitoring of Clinical Investigations (1988-2010) has been removed from the FDA list of guidance documents. Instead, the FDA has released an updated version of the Bioresearch Monitoring (BIMO) Compliance Program Guidance Manual for Sponsor/CRO and Monitoring. In August 2013, the agency issued a final guidance to reflect their expectations and recommendations related to monitoring investigation sites, monitoring systems, and investigative site oversight. In this web seminar, the content and the implications to sponsor monitoring and clinical investigation sites will be discussed.

Learning Objectives
• Discuss the content of the guidance in relation to traditional monitoring plans
• Assess the implications of the guidance to current monitoring practices and relationships with oversight of Clinical Investigator
• Explain ways in which the regulatory climate is reflected in the monitoring guidance

Who Should Attend
• Clinical Investigators and Staff
• Clinical Research Associates
• Study and Clinical Research Associate Managers
• Sponsors/CRO Clinical Operations
• Clinical Quality Compliance and Quality Assurance Professionals

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

Course Length and Time
1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates
May 23, 2016

Archived Recording Available!

FEE: $149*
*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 $149.

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#: 0778-0000-14-058-L01-P. Released: 8/14.

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 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
Cheryl Vitow

Course Length and Time
1.5 hours 2:30 – 4:00 p.m. Eastern

Course Dates
January 20, 2016
April 12, 2016

Archived Recording Available!

FEE: $695*
*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 $349.

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#: 0778-0000-14-017-L01-P. Released: 3/14.
Informed Consent: Execution, Documentation, and Monitoring the Dynamic Process

Course Description
This web seminar presents the elements of the informed consent document and the components of the process. Industry specific scenarios are presented to reinforce important concepts, for example: Evaluating and documenting capacity to consent, voluntariness, when a HIPAA authorization is required, withdrawal of consent, and more. Discussions also include reported poor regulatory performance regarding informed consent, and successful solutions for practices that increase the protection of human subjects in clinical research.

Learning Objectives
• Examine required content of the Informed Consent Form (ICF): Are all stakeholders checking?
• Define the informed consent process per regulations and best practices
• Clearly define who and what determines if consent has been adequately executed
• Evaluate exceptions for obtaining consent, and the role of the research site, Institutional Review Board (IRB), and sponsor in the process
• Apply clear documentation of the informed consent process, including withdrawal of consent
• Review elements that must be included in an authorization for use and disclosure of protected health information
• Compare and contrast HIPAA authorization and the informed consent process

Who Should Attend
• Clinical Research Coordinators
• Site Research Managers
• Clinical Research Monitors
• Sponsor Project Managers
• Investigators

Instructors
This course will be taught by one of the following instructors:
Gary B. Freeman, M.S., C.C.R.A.
Jeanne Morris B.S., MT (ASCP)
Elizabeth Ronk Nelson, M.P.H.

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 language in the consent form and that their rights, safety, and welfare are not jeopardized. In this web seminar, we’ll look at the essential language in the informed consent document through review of the FDA regulations and guidance documents, including the March 2015 draft guidance, “Use of Electronic Informed Consent in Clinical Investigations: Questions and Answers,” the September 2011 “Guidance on Exculpatory Language in Informed Consent,” and additional regulatory updates.

Learning Objectives
• Discuss the content of the recent guidances related to informed consent: What do you need to know?
• Present the implications of the guidances on current practices and policy: How will the changes impact how you conduct clinical trials?
• Explore 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
• Clinical Research Associate Managers
• Project Managers
• Sponsor/CRO Staff
• Clinical Quality Compliance and Quality Assurance Professionals

Instructor
Nikki Christison, B.S., C.C.R.A.
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 webinar, 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. Tools will also be provided to assist in compliance.

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
Janet Ellen Holwell, C.C.R.C., 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 9, 2016 (1-2:30)
June 7, 2016 (9:30-11)

FEE: $695*
*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.

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 11, 2016 (12:30-2:30)
February 23, 2016 (9:30-11:30)
June 2, 2016 (12:30-2:30)

Archived Recording Available!

FEE: $695*
*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#: 0778-0000-14-059-L01-P. Released: 9/14.

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
- Become more 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
Bart Harvey, M.D., Ph.D., M.Ed.

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 21, 2016 (12-3)
April 21, 2016 (9-12)
June 23, 2016 (12-3)

Archived Recording Available!

FEE: $795*
*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#: 0778-0000-14-086-L01-P. Released: 9/14.
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
Nikki Christison, B.S., C.C.R.A.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
July 20, 2016

FEE: $695*
*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.

Instructor
Gary B. Freeman, M.S., C.C.R.A.

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
- Review the applicable federal regulations for Investigator Initiated Trials, including sponsor and investigator responsibilities
- Review the steps involved in initiating an Investigator Initiated Trial and review regulatory reporting requirement of investigators and sponsors
- Identify essential documentation for the Sponsor-Investigator: Remaining audit ready
- Minimize risks associated with IITs by avoiding common pitfalls associated with IITs
- Review examples of regulatory deficiencies to Sponsor-Investigators

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

Instructor
Gary B. Freeman, M.S., C.C.R.A.

Course Length and Time
2 hours 9:30 – 11:30 a.m. and 12:00 – 2:00 p.m. Eastern

Course Dates
February 9, 2016 (9:30-11:30)
May 10, 2016 (12-2)

FEE: $695*
*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.

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!"
Key Components of Strategic Clinical Research Operational Planning

Course Description
This web seminar will examine the concepts and applied techniques for cost estimation (PERT analysis, bottom-up, top-down, etc.), budget development, risk management, and quality assurance for clinical research projects. Project management principles and methodology are provided with a focus on planning, controlling, and coordinating individual and group efforts. Topics include organization strategy and project selection, defining a project, developing a project plan, scheduling resources, risk analysis, work breakdown structures, project networks, process mapping, and building high performance teams. The needs of project managers who aren’t familiar with the technical tasks involved in clinical trial management will be discussed.

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 and develop schedule for completion of milestones
- Establish systems for quality control and monitoring of clinical trials
- Identify resources needed to complete projects and reasons to outsource
- Assign roles and responsibilities for a clinical trial and develop a communication plan
- Gather performance metrics and use them to improve project success
- Identify and manage risks of clinical trials

Who Should Attend
- Project Managers with little or no drug development-clinical trial experience
- Sponsor and CRO Personnel involved with the management of clinical trials
- Clinical, Regulatory, and Department Staff who design clinical trial programs
- Clinical Research Associates
- Data Managers
- Team Leaders

Instructor
Marina Malikova, Ph.D., M.S., M.A., C.C.R.A.

Course Length and Time
2 hours 3:00 – 5:00 p.m. Eastern

Course Dates
May 25, 2016

FEE: $695*
*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.


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:
Nikki Christison, B.S., C.C.R.A.
Holly J. Delaco-Smith, M.S.

Course Length and Time
2 hours 12:30 – 2:30 p.m. Eastern

Course Dates
May 24, 2016

Archived Recording Available!

FEE: $695*
*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 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
May 25, 2016

Archived Recording Available!

FEE: $595*

*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#: 0778-0000-14-060-L01-P. Released: 10/14.

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.”
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
- Describe the areas for risk management when partnering with the CRO/clinical vendor
- 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

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
January 27, 2016
March 9, 2016

Archived Recording Available!

FEE:
$695*

*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#: 0778-0000-14-090-L01-P . Released: 10/14.

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 webinar 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
- Navigate 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
Cheryl Vitow

Course Length and Time
1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates
January 20, 2016
April 12, 2016

Archived Recording Available!

FEE:
$695*

*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.

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 of 2013, 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
Gary B. Freeman, M.S., C.C.R.A.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
May 13, 2016

Archived Recording Available!

FEE: $695*
*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#: 0778-0000-14-067-L01-P. Released: 10/14.

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
- Address 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

Instructors
This course will be taught by one of the following instructors:
Karen L. Gilbert, B.S., C.C.R.A.
Lily Romero, P.A., C.C.R.C.

Course Length and Time
2 hours 1:00 – 3:00 p.m. Eastern

Course Dates
March 14, 2016
May 2, 2016

Archived Recording Available!

FEE: $695*
*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#: 0778-0000-14-027-L01-P. Released: 2/14.

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."
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 web seminar 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 Filoramo, R.N., B.S.

Course Length and Time
2 hours 12:00 – 2:00 p.m. Eastern

Course Dates
April 29, 2016

Archived Recording Available!

FEE: $795*
*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.

Monitoring Plan Development

Course Description
Although monitoring plans are not defined or specifically required by FDA regulations or the ICH Guideline for Good Clinical Practice, both organizations endorse 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 web seminar provides participants with concepts and templates to set up a monitoring plan that supports unique project risks and links to valuable data regarding investigative site and Clinical Research Associate (CRA) performance. Suggestions for development of monitoring plans for a risk-based approach to monitoring are also provided in this session.

Learning Objectives
• Develop a monitoring plan to meet the unique needs of a project and protocol
• Identify factors to consider when developing a monitoring plan for a risk-based monitoring approach
• Link the plan to CRA and site performance to meet project goals and promote continuous improvement

Who Should Attend
• Clinical Research Associates
• Project Managers
• Clinical Research Associate Managers

Instructors
This course will be taught by one of the following instructors:
Linda Carter, R.N., B.S.N.
Nikki Christison, B.S., C.C.R.A.

Course Length and Time
2 hours 8:30 – 10:30 a.m. and 1:00 – 3:00 p.m. Eastern

Course Dates
January 12, 2016 (8:30-10:30)
April 7, 2016 (8:30-10:30)
July 25, 2016 (1-3)

Archived Recording Available!

FEE: $695*
*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#: 0778-0000-14-024-L01-P. Released: 4/14.
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
- Appreciate 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
Gary B. Freeman, M.S., C.C.R.A.

Course Length and Time
3 hours 8:30 – 11:30 a.m. and 12:00 – 3:00 p.m. Eastern

Course Dates
February 9, 2016 (12-3)
May 10, 2016 (8:30-11:30)

Archived Recording Available!

FEE: $795*
*Includes up to 20 participants at one site. All participants 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. 800.896.2556 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#: 0778-0000-16-005-L01-P. Released: 2/16.

What Participants Say About Barnett Interactive Web Seminars:
“I will use the techniques presented to help in site issue resolution.”

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

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 International Conference on Harmonization Guidelines, 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
- Effectively manage site and sponsor activities and document them appropriately

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
Gary B. Freeman, M.S., C.C.R.A.

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 3:00 – 4:30 p.m. Eastern

Course Dates
February 29, 2016 (9:30-11)
May 10, 2016 (3-4:30)

FEE: $695*
*Includes up to 20 participants at one site. All participants 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. 800.896.2556 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.

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
- Confidently influence without authority
- Persuasively communicate and negotiate in face-to-face and virtual settings
- Complete and analyze a negotiation matrix
- Conduct effective negotiations
- 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.

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NEW! Overseeing Teams and Projects

Course Description
According to a survey by Ernst & Young, 80% of the issues surrounding project failure are people issues. Project success requires that project managers not only manage projects, but lead people. To do so effectively, they must gain the knowledge, skills, tools, and experiences of other leaders to enable them to manage and lead both the technical and the people side of project management. In this web seminar, participants will review key components of effective communication skills to achieve peak team performance. Team leadership and management, negotiation and influencing skills will also be covered through the examination of different leadership styles and qualities that are required for successful project delivery.

Learning Objectives
- Develop effective communication skills and master relationships within project teams
- Design a performance environment that motivates all team members through clear expectations and consequences
- Understand the differences between project management and leadership
- Develop effective team leadership skills, including interpersonal communication skills, negotiation skills and influencing skills

Who Should Attend
- Clinical Research Associates
- Clinical Research Project Managers
- Managers, Directors, and Leadership Professionals
- Personnel responsible for team oversight

Instructor
Eric Morfin, Ph.D., M.B.A., P.M.P.

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Course Length and Time
2 hours 9:00 – 11:00 a.m. and 1:00 – 3:00 p.m. Eastern

Course Dates
February 16, 2016 (1-3)
July 19, 2016 (9-11)

FEE: $795*
*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, re-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-16-015-L01-P Released: 2/16.

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.”

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.
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 Filoramo, R.N., B.S.

Course Length and Time
1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates
May 6, 2016

Archived Recording Available!

FEE: $595*
*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.

NEW! 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

Instructor
Janet Ellen Holwell, C.C.R.C., C.C.R.A.

Course Length and Time
4 hours 10:00 a.m. – 2:00 p.m. Eastern

Course Dates
March 3, 2016
May 12, 2016

FEE: $995*
*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#: 0778-0000-16-017-L01-P. Released: 3/16.
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:
Gary B. Freeman, M.S., C.C.R.A.
Jeanne Morris, B.S., MT (ASCP)

Course Length and Time
2.5 hours 12:00 – 2:30 p.m. Eastern

Course Dates
May 4, 2016

Archived Recording Available!

FEE: $595*
*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 $149.

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#: 0778-0000-14-026-L01-P. Released: 4/14.

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:
Nikki Christison, B.S., C.C.R.A.
Gary B. Freeman, M.S., C.C.R.A.,
Jeanne Morris B.S., MT (ASCP)

Course Length and Time
1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates
May 26, 2016

Archived Recording Available!

FEE: $695*
*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#: 0778-0000-14-061-L01-P. Released: 9/14.
NEW! Principal Investigator/Site GCP Compliance and Performance: What it Really Takes to Be GCP Compliant

Course Description
FDA inspections in today’s regulatory climate go beyond checking for a signed consent form and source data verification of the case report form. Today, inspections focus on how the cycle of quality is implemented for all aspects of the sponsor’s investigational plan. This includes Clinical Investigator supervision of the protocol’s execution in alignment with state statute/regulatory requirements. When there is an error/deficiency identified during the trial execution — what is done to address and correct this finding? And, if the same problem occurred again in the clinical trial do you know how to respond? In this webinar, these questions will be further examined and examples will be reviewed on how sites implement ‘quality practices’ for trial execution that includes the health care standards/statutes for the site location.

Learning Objectives
• Understand that clinical trial execution requirements in 2016 is more than being compliant — it is about the prospective cycle of quality
• Distinguish attributes of patient care/health care standards/clinical care and scope of practice that apply to the execution of clinical trials
• Translate regulatory agency expectations regarding Clinical Investigator supervision, oversight and control of the clinical investigation

Who Should Attend
• Principal Investigators
• Clinical Research Coordinators
• Directors: Clinical Trial Unit and Clinical Trial Offices
• Office of Research Compliance and Risk Management Personnel
• Managers/Directors: Clinical Operations
• Study Managers and Monitors/Clinical Research Associates (Centralized, On-site)
• Quality Assurance Professionals

Instructor

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. and 3:00 – 4:30 p.m. Eastern

Course Dates
February 3, 2016 (3-4:30)
June 15, 2016 (1-2:30)

FEE: $695*
*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. 800.896.2556 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#: 0778-0000-16-021-L01-P. Released: 2/16.

Interactive Web Seminars
Protocol Deviations: Documenting, Managing, and Reporting

Course Description
According to both U.S. regulations and the ICH Good Clinical Practice: Consolidated 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
• Utilize 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

Instructors
This course will be taught by one of the following instructors:
Linda Carter, R.N., B.S.N.
Nikki Christison, B.S., C.C.R.A.

Course Length and Time
2 hours 9:00 – 11:00 a.m. and 1:00 – 3:00 p.m. Eastern

Course Dates
March 31, 2016 (9-11)
July 26, 2016 (1-3)

Archived Recording Available!

FEE: $695*
*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. 800.896.2556 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.
Quality by Design: A Lean Six Sigma Approach to Risk-Based Monitoring

Course Description
Monitoring consumes 30-60% of an operational budget for clinical trials or clinical programs. To sustain growth and reinvest in innovation, sponsors must find viable alternatives to reduce the resource burn, as well as create efficient and effective solutions to increase regulatory compliance, data integrity, and patient safety. By utilizing the combined toolboxes of Lean Six Sigma (LSS) + Quality by Design (QbD), sponsors can continue to invest in innovative products while producing customer-centric/efficient operational processes that are highly adaptable, constantly reproducible, and consume fewer resources. LSS + QbD provides CRAs and other risk-based monitoring staff with an arsenal of analytical tools to conduct fewer on site monitoring visits yet monitor the site more effectively and in real-time.

Learning Objectives
• Review the current regulatory environment and identify internal and external risks in clinical trials, at sites and with the sponsor
• Define the Quality by Design (QbD) step-by-step method for implementing risk-based monitoring
• Identify Lean Six Sigma tools (LSS) to mitigate, monitor, and control risk in a clinical trial

Who Should Attend
• Clinical Research Associates
• Clinical Research Associate Managers
• Sponsor Certified Quality Auditors
• Clinical Development/Operations Managers/Directors
• Site Quality Compliance Monitors
• Site Quality Assurance Auditors

Instructor
Christina Eberhart, B.S.

Course Length and Time
1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates
January 28, 2016
June 13, 2016

Archived Recording Available!

FEE: $695*
*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.

ACPE#: 0778-0000-14-079-L01-P. Released: 9/14.

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 webinar 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 Research Associate Managers
• Project Managers
• Quality Assurance and Compliance Personnel
• Business Process Owners
• Risk Management Specialists

Instructor

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. and 3:00 – 4:30 p.m. Eastern

Course Dates
February 3, 2016 (1-2:30)
May 4, 2016 (3-4:30)

FEE: $695*
*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.

Quality Risk Management in Clinical Trials and Pharmacovigilance

Course Description
The ICH Q9 Quality Risk Management (QRM) guideline has become an accepted standard, facilitating the development and implementation of a systematic risk-based approach to quality management of clinical trials and pharmacovigilance. Industry and regulatory bodies, including the EMA and FDA, have recognized the need and benefits of implementing a risk-based approach to quality management.

This web seminar is designed to provide a strong conceptual foundation of the principles of quality risk management with a clear focus on the application of these principles. We will address applying QRM to support decision-making throughout the clinical trial management and pharmacovigilance process, allocating limited resources effectively to areas of high risk, and preparing the participant to become an active contributor towards risk-based quality management at his/her organization.

Learning Objectives:
- Define Quality Management System (QMS) levels for applicable areas in clinical trials and pharmacovigilance
- Build quality at key points in the process
- Apply QRM principles: Identification and quantification of key risk indicators
- Implement a quality by design approach to overcome shortcomings in quality and compliance
- Leverage existing information to support decision-making in resource allocation within clinical trials
- Create a governance model to support mitigation strategies and the overall QMS infrastructure

Who Should Attend
- Clinical Research, Operations, and Development Professionals
- Medical Affairs Personnel
- Safety and Risk Management/Operations Personnel
- Compliance, Regulatory Affairs, and Clinical Quality Assurance Personnel

Instructor
Randy Ramin-Wright, M.Sc.

Course Length and Time
1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates
April 7, 2016

Archived Recording Available!

FEE: $695*
*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.

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 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 19, 2016

Archived Recording Available!

FEE: $695*
*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.
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:
Linda Carter, R.N., B.S.N.
Nikki Christison, B.S., C.C.R.A.
Gary B. Freeman, M.S., C.C.R.A.

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.

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, 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.
RECEIST 1.0 and 1.1: Overview and Data Challenges in Oncology Clinical Trials

Course Description
RECEIST stands for Response Evaluation Criteria in Solid Tumors. The National Cancer Institute is the best resource for information, and defines RECEIST 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." RECEIST criteria provide a way to standardize measurement of solid tumors worldwide for any clinical trials that include this data to define study endpoints. RECEIST defines and standardizes how and when subjects are seen to progress, respond or remain stable in terms of their metastatic disease burden during a course of therapy. When these criteria are not well understood at the site level or consistently followed during a trial, it can put the study endpoint data in jeopardy.

Learning Objectives
- Differentiate between RECEIST 1.0 and 1.1
- Describe the components of RECEIST/tumor data
- Correctly calculate TRG 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

Instructors
This course will be taught by one of the following instructors:
Karen L. Gilbert, B.S., C.C.R.A.
Lily Romero, P.A., C.C.R.C.

Course Length and Time
2 hours 1:00 – 3:00 p.m. Eastern

Course Dates
March 7, 2016
May 9, 2016

Archived Recording Available!

FEE: $695*
*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#: 0778-0000-14-029-L01-P. Released: 3/14.

Re-Engineering the RFP and Bid Defense Meeting to Effectively Manage Risk and Quality

Course Description
In this web seminar, we will review the re-engineering of the Request for Proposal (RFP) and bid defense meeting to target identification of risks for the potential services to be awarded to your CRO, vendor, or supplier, whether a preferred partnership model, a “company approved list,” or based solely on project needs. This approach also gives the provider the opportunity to communicate their ability and willingness to adjust their approach and methods beyond the RFP, thus beginning a dialogue regarding management and quality oversight methods early on in the partnership. This improved process drives business efficiencies and cost savings now, rather than later during trial execution, and helps identify impact on protocol and data integrity if performance is inadequate.

Learning Objectives
- Explain the role of all stakeholders in the CRO, vendor, or supplier selection process for identification, selection, and ongoing work
- Identify strengths and opportunities for improvement in current RFP process
- Discuss approaches to utilize for identification of risks in the RFP and RFP process

Who Should Attend
- Vendor Contracting Specialists who evaluate and select external service providers
- Clinical Operations Personnel involved in the vendor contracting process
- Personnel responsible for quality and compliance of third-party vendors

Instructor

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. and 3:00 – 4:30 p.m. Eastern

Course Dates
January 27, 2016 (3-4:30)
May 4, 2016 (1-2:30)

FEE: $695*
*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.
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
- Monitor the constantly changing regulatory landscape
- Break down 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

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

Course Length and Time
1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates
June 1, 2016

Archived Recording Available!

FEE: $695*
*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#: 0778-0000-14-031-L01-P. Released: 4/14.

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
April 28, 2016

Archived Recording Available!

FEE: $695*
*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#: 0778-0000-14-046-L01-P. Released: 2/14.

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.
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
February 24, 2016

Archived Recording Available!

FEE: $695*
*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#: 0778-0000-16-006-L01-P. Released: 2/16.

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.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
June 27, 2016

Archived Recording Available!

FEE: $695*
*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 $149.

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#: 0778-0000-14-047-L01-P. Released: 3/14.

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.”
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
Nikki Christison, B.S., C.C.R.A.

Course Dates
June 28, 2016

Archived Recording Available!

FEE: $695*
*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 $149.

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#: 0778-0000-14-064-L01-P. Released: 9/14.

“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 these 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 Dates
June 13, 2016

Archived Recording Available!

FEE: $695*
*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#: 0778-0000-14-074-L01-P. Released: 8/14.
## 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.

### 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.

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## 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
- Proactively use 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:
Gary B. Freeman, M.S., C.C.R.A.
Jeanne Morris, B.S., MT (ASCP)

### Course Length and Time
2.5 hours 12:00 – 2:30 p.m. Eastern

### Course Dates
May 5, 2016

**Archived Recording Available!**

**FEE:** $595*
*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#:** 0778-0000-14-032-L01-P Released: 4/14.
SDTM and CDASH: What’s the Connection?

Course Description
Currently, the FDA requires that clinical trial data be electronically submitted in the Clinical Data Interchange Standards Consortium (CDISC) format for consideration for a new drug/biological approval. A significant element in this submission is the Study Data Tabulation Model (SDTM). This web seminar will examine the information defining the concepts of the SDTM as presented in the documentation Version 1.4. The purpose of data standards, benefits of applying these standards, and the relationship between datasets and records will be examined. The relationship between the standard for data collection instruments — also known as Clinical Data Acquisition Standards Harmonization (CDASH) standards — and the standard data format in which the data will be presented will also be discussed.

Learning Objectives
• Review SDTM concepts and terms
• Discuss Model fundamentals
• Demonstrate the Trial Design Model
• Identify relationships among datasets and records
• Examine Model fundamentals application to Associated Persons
• Describe the connection between CDASH and CDISC for data capture

Who Should Attend
• Clinical Data Managers
• Clinical/Statistical Programmers
• Statisticians

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 12, 2016 (9:30-11)
April 21, 2016 (1-2:30)

FEE: $695*
*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.

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 and Time
2 hours 9:00 – 11:00 a.m. and 1:00 – 3:00 p.m. Eastern

Course Dates
January 21, 2016 (9-11)
June 21, 2016 (1-3)

FEE: $695*
*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!

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#: 0778-0000-14-049-L01-P. Released: 3/14.
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
- Incorporate 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.C.T.I., R.A.C., F.R.A.P.S.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
January 28, 2016
July 27, 2016

FEE: $695*
*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.

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. There is significant variability between stakeholder requirements regarding source documentation per study, including sponsor to sponsor, sponsor to site, etc. The creation and use of source document worksheets and the use of the Case Report Form (CRF) as the original source have raised a lot of industry debate. These issues and more regarding adequate and accurate source documentation to meet the requirements of regulatory agencies essential documentation standards will be presented and discussed.

Learning Objectives
- Define source documents
- Identify regulatory authorities required characteristics of source data
- Analyze source document worksheets: The love-hate relationship
- Discuss the CRF as source data
- Evaluate best practices

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:
Linda Carter, R.N., C.C.R.A.
Nikki Christison, B.S., C.C.R.A.

Course Length and Time
2 hours 9:30 – 11:30 a.m. and 1:00 – 3:00 p.m. Eastern

Course Dates
January 13, 2016 (1-3)
April 28, 2016 (9:30-11:30)
July 27, 2016 (1-3)

Archived Recording Available!

FEE: $795*
*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#: 0778-0000-14-033-L01-P. Released: 3/14.
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:
Nikki Christison, B.S., C.C.R.A.
Jeanne Morris, B.S., MT (ASCP)

Course Length and Time
2 hours 12:00 – 2:00 p.m. Eastern

Course Dates
June 29, 2016

Archived Recording Available!

FEE: $695*
*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#: 0778-0000-16-007-L01-P. Released: 6/16.

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 Conference on 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 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 Research Associates
- 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
Gary B. Freeman, M.S., C.C.R.A.
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
- Consider 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.

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.

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

Rules and regulations vary from state to state. Contact your state’s regulatory agency for the latest information regarding state laws governing clinical trial regulatory compliance.
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.

Archived Recording Available!

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#: 0778-0000-14-082-L01-P. Released: 9/14.
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 naive 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 trends techniques to anticipate site issues
• Apply 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:
Gary B. Freeman, M.S., C.C.R.A.
Jeanne Morris, B.S., MT (ASCP)

Course Length and Time
2 hours 8:30 – 10:30 a.m. and 12:00 – 2:00 p.m. Eastern

Course Dates
March 21, 2016 (8:30-10:30)
June 9, 2016 (12-2)

Archived Recording Available!

FEE: $795*
*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 +1 781.972.5406 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#: 0778-0000-16-008-L01-P. Released: 3/16.

Strategies for Protocol Operationalization and Adherence

Course Description
Protocols are rising in complexity, length, and numbers of procedures. Protocol training is trending toward webinars vs. live meetings where questions are more limited and less likely to be asked. With more to do and less time and instruction, taking on new and challenging protocols can be daunting. This webinar will focus on some introductory steps to taking a protocol apart and making it operational and executable without deviations at a site. Topics to be addressed include how to get the most out of the initial protocol review, understanding and putting into practice the patient flow, and how to ensure protocol adherence in a busy, ever-changing site environment.

Learning Objectives
• Describe approaches to the protocol review, understanding, and planning process
• Explain techniques for planning study patient flow and timing of visits
• Discuss tools and checkpoints to avoid protocol deviations

Who Should Attend
• Study Coordinators
• Site Managers
• Clinical Research Associates
• Project Managers

Instructor
Nikki Christison, B.S., C.C.R.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!

FEE: $795*
*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 +1 215.413.2471 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.

ACPE#: 0778-0000-16-008-L01-P. Released: 3/16.
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
- Re-define the concepts of study feasibility at the protocol, country, site level
- Discuss and objective 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 and Time
2 hours 12:30 – 2:30 p.m. Eastern

Course Dates
June 22, 2016

Archived Recording Available!

FEE: $595*
*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 $349.

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

Course 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.

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!

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#: 0778-0000-14-034-L01-P. Released: 4/14.
Blended Curriculum Course

Subject Enrollment: Creating Effective Enrollment Models

Course Description
Although clinical trial subject enrollment has been debated, analyzed, and implemented in many forms, study teams still face ongoing challenges. Although study sites are often blamed for sluggish enrollment, the challenges are study-specific and can be sponsor-related. Moreover, some sponsors are going global in order to recruit subjects, while failing to access the many untapped patient populations in native western countries, such as the U.S., Canada, and Europe. This web seminar provides an overview of the changes driven by globalization of clinical research, looks at subject enrollment challenges, and addresses patient engagement issues. Innovative tools for improving clinical trial subject enrollment will be provided.

Learning Objectives
• Meet subject enrollment challenges and patient engagement issues
• Employ effective models for clinical trial subject enrollment
• Develop, manage, and measure enrollment campaigns
• Develop subject enrollment business infrastructures
• Leverage pharmacies and IT for subject enrollment

Who Should Attend
• Clinical Operations Personnel
• Clinical Affairs Professionals
• Clinical Research Associates
• Principal Investigators
• Clinical Research Coordinators
• Clinical Project Managers
• Subject Enrollment Managers

Instructor
Moe Alsumidaie, M.B.A., M.S.F.

Course Length and Time
1.5 hours 9:30 – 11:00 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates
February 8, 2016 (9:30-11)
May 11, 2016 (1-2:30)

FEE: $695*
*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.

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
- 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
Nikki Christison, B.S., C.C.R.A.

NEW! 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 completeness of the entire TMF. This web seminar will present a strategy for conducting a TMF audit that identifies gaps that have potential impact on the quality of the TMF. 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.

What Participants Say About Barnett Interactive Web Seminars:

“I learned a lot of new information from this course and the materials are all relevant!”

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! TMF/eTMF Regulatory Agency Expectations, Inspections, and Findings

Course Description
On April 24, 2014, the United Kingdom’s Medicines and Healthcare products Regulatory Agency (MHRA) issued a press release indicating that the definition of a critical Good Clinical Practice (GCP) inspection finding had been changed. It now includes ‘Where provision of the Trial Master File (TMF) does not comply with Regulation 31A 1-3, as the TMF is not readily available or accessible, or the TMF is incomplete to such an extent that it cannot form the basis of inspection and therefore impedes or obstructs inspectors carrying out their duties in verifying compliance with the regulations’. Recently, the European Medicines Agency (EMA) released a reflection paper on GCP compliance in relation to TMFs. Currently, the FDA has not released regulatory guidance that directly addresses TMF expectations. 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 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

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 Length and Time
2.5 hours 11:00 a.m. – 1:30 p.m. Eastern

Course Dates
March 11, 2016
June 17, 2016

FEE: $795* 
*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#: 0778-0000-16-025-L01-P. Released: 3/16.

Tools for Trainers: Clinical Research Job-Aids and Checklists

Course Description
As adult learners, clinical research professionals are motivated by an understanding of how training interactions directly impact their work lives. The use of job aids and checklists can serve to satisfy this need by providing a resource to someone performing a task exactly when and where they need it. These tools can also serve to reinforce the training as participants return to the workplace, resulting in a greater likelihood that the organization’s performance goals will be met. In some cases, a job aid alone can replace unnecessary training expenses.

This web seminar includes a decision-making framework about the use of job aids as stand-alone training objects versus a complementary tool to existing training programs. Sample tools that may be appropriate for various clinical research audiences will be discussed.

Learning Objectives
- Discuss the considerations for determining when a job aid is appropriate to incorporate into a training presentation and when it can stand alone to accomplish the desired training objective
- Identify strategies for using tools and checklists in training programs across various audiences and venues
- Describe the elements of an effective job aid

Who Should Attend
- Clinical Research Training Professionals
- Pharma/Device Professionals with responsibility for internal and/or investigator training
- Clinical Research Site Professionals
- Clinical Research Associates
- Clinical Research Associate Managers

Instructors
This course will be taught by one of the following instructors:
Linda Carter, R.N., B.S.N.
Nikki Christison, B.S., C.C.R.A.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
March 30, 2016

Archived Recording Available!

FEE: $695* 
*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.

Understanding Global Requirements for Trial Registration and Disclosure of Results

Course Description
Since its inception in 2000, the clinical trials registry has served as a source of information for the general public, academia, and industry. In 2007, the U.S. Congress passed FDAAA, which required additional trial registration information, more types of trials to be registered, and the submission of summary results for applicable clinical trials. The following year, sponsors and Principal Investigators began submitting the results of clinical studies on ClinicalTrials.gov. Although submission of Adverse Event information was optional when the results database was released, it became required in September 2009.

Despite these requirements, recent studies indicate that not all required information is submitted. In late 2012, the U.S. DHHS transferred authority to the FDA to oversee ClinicalTrials.gov and seek out those who do not file, or file misleading or false data.

Learning Objectives
• Discuss the purpose and procedures for registration and the requirements for submission of results
• Explore who is responsible for registration and reporting, who benefits and how, and which entities require compliance
• Explain an “applicable clinical trial” and exceptions to registration and reporting
• Examine timelines for reporting and exceptions and penalties for noncompliance
• Review procedures for editing and updating submissions

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)
• Sponsor-Investigators
• Clinical Quality Assurance Auditors and Compliance Professionals
• Clinical Research Associates
• Regulatory Affairs Professionals

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.

Archived Recording Available!

Accreditation
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Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.
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
- Write an effective NTF, when applicable
- 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
Gary B. Freeman, M.S., C.C.R.A.

Course Length and Time
1.5 hours 8:30 – 10:00 a.m. and 12:00 – 1:30 p.m. Eastern

Course Dates
January 18, 2016 (8:30-10)
May 12, 2016 (12-1:30)
Archived Recording Available!

FEE: $795*
*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
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ACPE#: 0778-0000-15-017-L01-P. Released: 2/15.

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
- Describe best practice approaches to warning letter response
- 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.C.T.I., R.A.C., F.R.A.P.S.

Course Length and Time
1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates
January 27, 2016
June 8, 2016

FEE: $695*
*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 $349.

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#: 0778-0000-14-081-L01-P. Released: 10/14.
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
Cheryl Vitow

Course Length and Time
3 hours 12:00 – 3:00 p.m. Eastern

Course Dates
May 11, 2016

Archived Recording Available!

FEE: $795*
*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#: 0778-0000-14-036-L01-P. Released: 3/14.

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. While ICH E6 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
- Detail IB requirements per ICH E6 and effectively implement these requirements
- Research literature 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
- Get a physician to read an 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
Cheryl Vitow

Course Length and Time
2 hours 1:00 – 3:00 p.m. Eastern

Course Dates
May 12, 2016

Archived Recording Available!

FEE: $795*
*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.

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)
  - Types of studies
  - Design (single blind, double blind, randomized, etc.)
  - Establishing the hypothesis
  - What is safety and efficacy and how do you establish either or both
  - Determining inclusion/exclusion criteria
  - Determining the Schedule of Events
  - Adverse and Serious Adverse Event reporting

Who Should Attend
- Medical Directors
- Medical Writers
- Clinical Research Associates
- Regulatory Affairs Professionals
- Research and Development Personnel

Instructor
Cheryl Vitow

Course Length and Time
3 hours 12:00 – 3:00 p.m. Eastern

Course Dates
January 14, 2016
April 13, 2016
July 20, 2016

Archived Recording Available!

FEE: $795*
*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#: 0778-0000-14-038-L01-P. Released: 4/14.

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 basic 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
- Turn the 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
Cheryl Vitow

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!

FEE:

Accreditation
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Accreditation available upon request.
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
• Link 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 Mangers
• Personnel planning a change from the pharma sector to the diagnostic sector

Instructor
Janet Ellen Holwell, C.C.R.C., C.C.R.A.

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.

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
Cheryl Vitow

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!

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.”

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 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
- Turn the 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
Cheryl Vitow

Course Length and Time
3 hours 12:00 – 3:00 p.m. Eastern

Course Dates
January 19, 2016
April 14, 2016
July 21, 2016

Archived Recording Available!

FEE: $695*
*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#: 0778-0000-14-084-L01-P. Released: 7/14.

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. ””
Consulting and Support Services

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.

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**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: http://www.barnettinternational.com/On-Demand-Courses/On-Demand-GCP-Training-Courses/
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 Refresher Training

Too Busy To Attend A Course?
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:
• 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 Conference on Harmonisation 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 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 and to try our demo, visit:
http://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. The structure includes two assessment and completion options, depending on experience level. Upon 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 and to try our demo, visit:
http://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. The structure includes two assessment and completion options, depending on experience level. Upon 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 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 and to try our demo, visit: http://www.barnettinternational.com/On-Demand-Courses/GCP-Training-for-Study-Coordinators/

Barnett’s On-Demand Foundations 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.

Course Learning Objectives:
• Describe core principles of GCP and the application of these concepts in clinical research
• Apply the basics of the International Conference on Harmonization Good Clinical Practice (ICH GCP) including the 13 core principles
• Describe the roles and responsibilities of sponsors and investigators in conducting research
• Evaluate informed consent and subject data management to ensure the protection of trial subjects and that data are credible, reliable, and accurate

Key Features Include:
• Comprehensive ICH GCP E6 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 and to try our demo, visit: http://www.barnettinternational.com/on-demand-courses/GCP-Training/
What Makes Barnett’s Publications Unique?

Unparalleled in industry, Barnett’s comprehensive reference guides, publications, self-study tools, and job aides 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. Three of our most popular publications, the Good Clinical Practice: A Question & Answer Reference Guide, the State-by-State Clinical Trial Requirements Reference Guide, 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, the CFR/ICH GCP Requirements Reference Guides (Drug and Device), the Glossary & Acronyms for Clinical Research Professionals, and the Study Day Estimator Wheel job aide. Custom cover books are great for new hires, clinical research sites, and exhibition giveaways!

How Do I Order Barnett Publications?

Online: barnettinternational.com

Telephone: +1 781.972.5400 or toll-free in the U.S. 800.856.2556

Mail Check to*: Barnett International 250 First Avenue, Suite 300 Needham, MA 02494

*To mail in your order, please complete the order form on page 207.
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, editing, 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.

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

Publication Code: IND09 ............................. Price: $295.00

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.
**Medical Device Development: Regulation and Law**

“This is one of the best books written on the subject of regulatory affairs for the medical device industry. The book is a great tool whether you are a seasoned regulatory professional or a front line supervisor. Kahan is in my opinion on his way to becoming the Juran of the regulatory field.” - Scott Baker, CQT, CSE, CQA, Supplier Quality Engineer II, Smith & Nephew, Inc.

The all-new **Medical Device Development: Regulation and Law, 2014 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 FDA device legislation and over a dozen important new guidances, and addresses how emerging developments and trends are reshaping medical device and combination product regulations in the U.S.

- Update on all the new provisions of the Food and Drug Administration Safety and Improvement Act of 2012 (FDASIA).
- New statutory provisions and guidances related to device reclassification, humanitarian devices, the CDRH appeal process, Section 522 postmarket surveillance, and custom devices.
- Updates on the new organizational structure of CDRH.
- Changes to the 510(k) premarket notification process.
- Changes to the pre-submission process, including the end of the pre-IDE process and the birth of the “Q-sub.”
- New guidances on FDA’s “Refusal to Accept” policies relating to 510(k)s, PMAs, and pre-submissions.
- Update on the investigational device exemption process.
- Changes to the premarket approval application process, including birth of the e-copy and modifications to the advisory panel process.
- New policies and guidances concerning *in vitro* diagnostic products, including the new guidances on Research Use Only (RUO)/Investigational Use Only (IUO) products, and *in vitro* “companion” diagnostics.
- Update on device compliance issues, including the 2013 draft medical device reporting guidance and recall procedures relating to product enhancements.
- New guidances and cases relating to combination products incorporating medical devices.

Publication Code: MEDDEV3 ......................... Price:$195.00

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**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

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: CT12......................... Price:$99.95
Electronic Version: CT12E...................... Price:$89.95

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Instructor Biographies

Azita Ahmadi, B.S., received her Bachelor of Science in Biology from the University of the Pacific along with a certificate in Clinical Trial Design and Management from the University of Santa Cruz. She eventually earned her position as a senior Drug Safety Associate at InterMune Inc. Her professional experience has provided exposure to drug safety, drug development process, clinical monitoring processes, collaborative opportunities, compliance, training, data collection, source documentation, and validation. She recently developed a comprehensive narrative writing training program to help others acquire and practice the skills necessary for generating well-written case narratives for reporting to regulatory authorities. Azita is currently working toward her M.S. in Public Health Economics at the Johns Hopkins Bloomberg School of Public Health.

Moe Alsumidaie, M.B.A., M.S.F., is a business strategist who specializes in predictive modeling and clinical trial technologies. Moe has extensive experience in Phase I-IV, IDE, and 510(k) clinical research and healthcare business operations. Moe has worked in-house for Stanford Medical Center, Abbott Vascular, Genentech, and Roche, and is currently affiliated with The Mount Sinai Hospital. Moe holds a Bachelor of Science in Physiology and Neuroscience from UC San Diego, an M.B.A. in Marketing, and an MS in Investment Finance and Technical Analysis from Northeastern University’s D’Amore-McKim School of Business.

Jerri Barden Perkins, M.D., spent eight years at FDA as a Medical Officer. She was an Acting Division Director for medical devices, involved in policy decisions in the Office of the Commissioner, and a Reviewing Medical Officer for drugs. She made recommendations to the FDA Commissioner on whether or not unsafe products should be recalled from the market. She also made recommendations on whether or not devices and drugs were safe and effective for the US market. Dr. Perkins has assisted both pharmaceutical and medical device industries with regulatory and clinical trials. She has given numerous presentations in the US and Europe, and was an invited speaker in China and India. She has published both research and articles regarding FDA issues such as, “How Does a Medical Officer Review an NDA Submission?” and “Tips on PMA Preparation/Presentation.” Dr. Perkins did her post-doctoral training at the National Institutes of Health, and received her M.D. degree from the Medical College of Virginia.

Elizabeth Buchanan, Ph.D., is Endowed Chair in Ethics and Director of the Center for Applied Ethics at the University of Wisconsin-Stout. She is a scholar in the fields of research ethics, information/communication technology ethics, and research methods. Her work is particularly focused on the intersections of research regulation, Internet or online venues and tools, and the subsequent ethical challenges that arise for researchers and research board reviewers. She is professionally active in Public Responsibility in Medicine and Research, the International Society for Ethics and Information Technology (Co-Director), and the Association of Internet Researchers. Elizabeth serves as an Associate Editor for the Journal of Research on Human Research Ethics (JERHRE), on the Editorial Board of Philosophy and Technology, and reviews for many other scholarly journals and granting agencies. Elizabeth is Vice-Chair of the UW Stout’s Institutional Review Board, and has served on both social science and medical school research ethics boards. She has presented her National Science Foundation-funded research on IRBs and Internet research to the Secretary’s Advisory Committee to the Office for Human Research Protections in 2010, 2012, and 2013. She has also presented at the OHRP Community Research Forums, and has done professional development work with many IRBs. She has been on the Faculty of the Public Responsibility in Medicine and Research roster since 2008, and has participated in pre-conference workshops and many didactic sessions at PRIM&R. As of 2012, she is a member of the PRIM&R Conference Planning Committee and a member of the American Association for the Advancement of Science Committee on Scientific Freedom and Responsibility. Elizabeth holds BA degrees in Philosophy and English from Rutgers University and her M.S. and Ph.D. from University of Wisconsin-Milwaukee.

Linda Carter, R.N., B.S.N., has been working in clinical research for over 10 years. Her roles have included working as a study coordinator for investigator initiated trials, a clinical research associate for CRO, biomedical, and vaccine companies, as well as a clinical trial manager for international vaccine trials. Linda has provided training to her colleagues within the industry and clinical site personnel on protocols, EDC, IP management, and data listing review. She has also worked within the pharmaceutical industry as a training manager where she collaborated with subject matter experts to develop curricula that would engage participants, leverage best practices, meet regulatory requirements, address knowledge gaps, and support professional growth. Before working in clinical research, Linda began her career as a nurse in the United States Army Nurse Corp, followed by over ten years as a civilian nurse in critical care and in the emergency room. Linda applies her unique insight into the training needs of the teams that run and monitor clinical trials, drawing on her diverse experience, foundation for critical thinking, and practical understanding of the compliance issues found throughout clinical operations.

Nikki Christison, B.S., C.C.R.A., 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 and Johnson), participated on international project teams for pivotal Phase III studies, and led Canadian Phase Illb-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 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.
Holly Delaco-Smith, M.S., 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 Vice President of Pharmacovigilance Sciences for the Drug Safety Alliance. Prior to her current role, Ms. Donatucci was responsible for overseeing DSA’s case management function and ensuring that resources were properly allocated for optimal operating capacity and effective, efficient delivery of services. A member of DSA since its inception in 2000, Ms. Donatucci previously served as Senior Director of Training and Quality Control, overseeing the quality aspects of case processing 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.

Christina Eberhart, B.S., has over 13 years of clinical research experience, contributing in such roles as director of clinical operations, director of quality assurance, manager of quality assurance, clinical research associate, and as the principle of an investigator trial network. Christina has conducted quality control monitoring and auditing for sponsors and CROs. She has contributed to the development of on-boarding and training systems for clinical research departments, academic medical centers, and the division of acquired immunodeficiency syndrome (DAIDS) within the National Institutes of Health (NIH). Christina is a national speaker on several clinical research topics for the Association of Clinical Research Professionals (ACRP), Drug Information Association (DIA), Society of Clinical Research Associates (SoCRA), and MAGI. She is a member of ACRP and ASQ. She is a member of the bioresearch central advisory board, and is past-president for the Greater Kansas City Chapter of ACRP.

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.

Gary B. Freeman, M.S., C.C.R.A., provides quality clinical monitoring, auditing, training, project management, and consulting services internationally. He has personally worked in these areas with pharmaceutical, device, healthcare, and contract research organizations for over 30 years. Mr. Freeman has been a credentialed clinical research trainer through ACRP since its inception in 2003. Mr. Freeman holds a B.S. in Biology (pre-med program) from the University at Albany and an M.S. in Science Education from Russell Sage College. He has been actively involved in various clinical capacities for multiple therapeutic areas (Phase I-IV) for the following indications, as well as devices: allergy, anti-infective, cardiovascular, critical care, dental, dermatology, endocrinology, eye care, GI, imaging/diagnostics, immunology, infectious disease, oncology, organ transplant, OTC medications, psychiatric disorders, pulmonary, sleep disorders, and STDs. This experience includes pre-clinical laboratory work, data management, protocol writing and CRF design, clinical monitoring, clinical trial management, GCP auditing, developing and presenting clinical training programs, regulatory affairs management and overall responsibility for clinical operations in several settings, including presentations at FDA Advisory meetings. Mr. Freeman has also participated as a trainer for ACRP’s CRA and CRC Certification Exam Review courses and other clinical offerings, and is an active instructor for several drug and device courses for Barnett International for public and on-site offerings. He lectures routinely worldwide and presents training workshops for drug and device companies, as well as investigator sites. He also conducts GCP audits at investigational sites and vendors for pharmaceutical and device studies. Mr. Freeman is currently an active member of ACRP (Association of Clinical Research Professionals), DIA (Drug Information Association) and SQA (Society of Quality Assurance).

Joy Frestedt, Ph.D., C.C.T.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 pathology from the University of Minnesota Medical School. Dr. Frestedt is a member of American Society of Clinical Oncology (ASCO), American Association of Pharmaceutical Scientists (AAP), Association of Clinical Research Professionals (ACRP), and Society of Clinical Research Associates (SoCRA), and is a Fellow of Regulatory Affairs Professionals Society (FRAPS). Dr. Frestedt was honored in 2011 as one of the “101 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.

Susan Gordon, R.N., M.S.N., is an experienced drug safety professional with over 20 years of experience. In addition to her training work, she serves as CEO of the Drug Safety Alliance. Prior to her current role, Susan served as Senior Vice President of Global Case Processing, overseeing the company’s case management function and ensuring the proper allocation of resources for optimal operating capacity and efficient delivery of services. Ms. Gordon has also served in senior leadership roles, including providing strategic
direction and leadership for all project management, clinical operations and R&D sourcing and procurement activities within King Pharmaceutical’s scientific operations. Before her tenure with King, Ms. Gordon spent 19 years in positions of increasing responsibility for GlaxoSmithKline and its parent companies, working within the full range of pharmaceutical clinical development including drug safety, clinical operations and project management. A licensed Registered Nurse, Ms. Gordon received both her Bachelor of Science degree and her Master’s degree in Nursing from the University of North Carolina at Chapel Hill.

Glenda Guest, C.C.R.A., ROAP-GCP, 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.

Elkan Halpern, Ph.D., is the chief statistician for the Department of Radiology and the Director of Statistics for the Decision Analysis and Technology Assessment Group, Massachusetts General Hospital. Formerly holding positions of Principal Statistician and Vice President, Dr. Halpern has had over 30 years of experience in all phases of clinical and statistical research for FDA submissions and post-marketing studies.

Bart 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, Bart 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.

Bart Harvey, M.D., Ph.D., M.Ed., is a Public Health Physician-Epidemiologist and Associate Professor in the University of Toronto’s Dalla Lana School of Public Health where he teaches courses in public health, epidemiology, and statistics. He has been the principal or co-author of nearly 50 peer-reviewed publications, and has presented invited and peer-reviewed papers at national and international professional conferences. In addition, Bart has authored a self-study text, Statistics for Medical Writers and Editors (2009) and was the lead editor of The Research Guide: A Primer for Residents, Other Health Trainees and Practitioners (2011). He is a Fellow of the American College of Preventive Medicine (ACPM) and the American Medical Writers Association (AMWA). Bart was the recipient of the Eric Martin Award for Excellence in Medical Writing in 2011 and an AMWA Book Award for The Research Guide in 2012. Bart also serves as an investigating coroner in Toronto.

Janet Ellen Holwell, C.C.R.C., C.C.R.A., is an independent consultant specializing in maximizing excellence in GCP quality, compliance, and training for both sites and industry. She works contractually with sponsors, CROs, academic medical centers, and site investigators and their personnel to provide training in the clinical research process, specializing in ICH GCP compliance and quality oversight. Janet began her career as a clinical research coordinator in academia over 30 years ago. Prior to transitioning to industry, she managed a clinical pharmacology unit at Columbia Presbyterian Medical Center in New York City, overseeing all operations. She was an instructor in GCP and helped develop the first GCP program in an academic institution. She was an invited lecturer for Columbia University School of Nursing’s post-graduate Course for Clinical Research Coordinators. Prior to her position in quality management with Pfizer, she held positions as a clinical research associate, site selection specialist, study manager with oversight of vendor CRAs, and trainer for several pharmaceutical companies. Janet 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. She is also an approved trainer for the ACRP Certification Examination Prep Course and Fundamentals in Clinical Research.

Treena Jackson, M.S., C.G.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.

Véronique Lalvee, Pharm.D., P.M.P., is a proven leader with extensive experience assisting companies with their product development. Véronique has a wealth of experience in portfolio and project management for drugs, medical devices and cosmetics. During her career, Véronique has led international teams in pharmaceutical R&D coordination, planning and regulatory dossiers development, and project and portfolio management. She is recognized for successfully and consistently developing and implementing processes, procedures, and tools to enhance R&D performances and streamline the organization. One of Véronique’s key strengths is building engaged teams that execute and deliver as promised. Using her experience as both a portfolio manager and a scientist, she applies project management best practices to the pharmaceutical, biotech, and life sciences industries.

Marina Malikova, Ph.D., M.S., M.A., C.C.R.A., has over 10 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 vascular surgery, neurosurgery, cancer diagnostics, and interventional radiology. In her current role, she is responsible for clinical trials and basic biomedical research operations, quality assurance, risk management, strategic planning, and macro-management of research programs. She provides guidance and oversight to all clinical research personnel, and advises faculty/staff on protocol and informed consent writing; assists with applications and submissions; and ensures compliance. She also provides oversight for data user agreements; cost coverage analysis and budgets development; and contracts and licensing for clinical research. Dr. Malikova has a Ph.D. in Biochemistry, a Master’s Degree in Clinical Investigation, and Project Management Certification from Boston University. She has seven years of teaching experience, and has developed several clinical research related courses. She is a member of Association for Clinical Research Professionals (ACRP), Drug Information Association (DIA), Regulatory Affairs Professionals Society (RAPS), and European Society of Radiology (ESR).

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,
Instructor Biographies

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.

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.

Eric Morfin, Ph.D., M.B.A., P.M.P., has been a project manager since 1987. A sought-after speaker on the subject of project management, portfolio management, and resource management at North American and European symposiums and conferences, Mr. Morfin has been published many times in project management magazines and pharmaceutical publications. Currently the co-author of several project management books, Mr. Morfin is an active member of several professional societies and has developed several unique seminars on project management in drug development, such as “Project Management in Discovery and Preclinical” and “Project Management for Global Clinical Trials.” He has consulted with clients in a variety of industry settings throughout North America, Europe, and Asia. He has worked with the World Bank, Merck Frost, Hewlett Packard, GlaxoSmithKline, Aventis, Novartis, Bristol Myers-Squibb, and AstraZeneca to name only a few. For 10 years, Mr. Morfin managed the project management practice of a worldwide training and consulting organization headquartered in the USA. Previously, he worked with a leading consulting group in the strategic field. In Europe, besides managing his own computer firm dealing in digital animation, he created and managed an entire new division for Apple Computer. Mr. Morfin is bilingual in French and English, has traveled extensively in Europe and Asia, and earned his M.B.A. in International Business in San Francisco. He currently lives in San Francisco with his wife and daughter.

Jeanne Morris, B.S., MT (ASCP), is an ASQ Certified Manager of Quality/Organizational Excellence. Ms. Morris provides GMP, GCP, GxP, and GMS 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.

Randy Ramin-Wright, M.Sc., is a Program Manager and ORM Consultant with more than 20 years of experience in IT consulting, modeling, designing, and implementing information management systems. This expertise draws on project experience from a wide range of industries: pharmaceutical R&D, pharmaceutical finance, pharmaceutical informatics, systems biology research, material sciences, banking, and national security. His current focus is on the development and commercialization of Quality Risk Management products and services, and the development of industry standard risk metrics to help pharmaceutical companies optimize the use of their drug development resources. Randy has an M.Sc. in Physics and B.Sc. in Astro-Physics from Michigan State University.

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 Celero Research, and is serving as a member of the Board of Trustees for the Society of Clinical Data Management (SCDM).

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).

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 Educational Services, 2012; “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).

David M. Stier, M.D., provides study design and data analysis for outcomes studies, clinical trials, and patient registry programs. Prior to his consulting work, he was Vice President with The Lewin Group, an international health policy and research consulting firm. Dr. Stier has worked closely with pharmaceutical, biotechnology, and medical device company executives to create research platforms that blend clinical medical research, health outcomes research, and product commercialization objectives into comprehensive research programs executed during the peri-launch and post-product-launch periods.

Paul Strickland, B.Sc., FRQA, DipRQA, has over 23 years of experience in Clinical Quality Assurance. As a consultant he has audited across the world, in both GCP and PV areas. He has also given GCP training and refresher courses, inspection preparation guidance, and has spoken at numerous conferences. Paul previously worked for 12 years at Amgen Ltd, most recently as Director of Intelligence and Inspections, and Regional Head of Clinical Auditing. In former years, Paul worked in a GCP auditing capacity with the Wellcome Foundation and with Glaxo. From the beginning, he has led the facilitation of many regulatory inspections, both in-house and in the field in Europe, the U.S., and Africa. He also has several years’ previous experience in QA of manufacturing with Serono Diagnostics. His first healthcare role was in 1979 with Amersham International. Paul has been course principal for the RQA GCP auditing course for 15 years, and was a tutor on the course for a number of years prior to that. He is chair of the Audit Working Party, a subgroup of the EFGCP, and has held this role since 2005. He is a member of the EFGCP Board and an invited member of the MHRA Stakeholder Engagement Meeting. He gained RQA’s Diploma in Research Quality Assurance in 1998 and is a Fellow of the Association.

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 development. She is a Society of Quality Assurance (SQA) committee member, and a pre-test writer for the ROA-GCP annual certification test. She is a participant on developing comprehensive auditing standards within QA Societies, namely joint projects with RQA, SQA, and JSQA. She is an American Society of Quality certified auditor with experience in lean-sigma standards, and a guest lecturer at the University of Southern California (USC) School of Pharmacy.

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.

Lee Trux-Bellows, M.S., FNP, C.C.R.A., ROQA-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 (SQA). Lee is ACRP certified as a Certified Clinical Research Associate (CCRA) and registered through SQA as a Registered Quality Assurance Professional in Good Clinical Practices (ROQA-GCP).

Cheryl Vitow is a medical writer and clinical management consultant with over 25 years in the pharmaceutical, biotechnology, and device industries. She has a degree in Medical Technology, Biochemistry (Rutgers), and her Masters work is in Clinical Pharmacology (Jefferson). She began her career as a bench chemist. She has been involved in the design, conduct, and reporting of clinical studies from Phase 1 through Phase 4 and has worked for Johnson and Johnson, Aventis, Squibb (before BMS), Etsai, Lippincott, and many others. She has run a successful medical writing and clinical project management consulting firm for 15 years.

Tabitha Westbrook, ROQA-GCP, has nearly 17 years experience in the pharmaceutical industry, 12 of which have been in quality assurance. Currently, as the Quality Assurance Manager for the Americas of a major CRO, Ms. Westbrook oversees most types of audits and regulatory inspections. Ms. Westbrook received her undergraduate degree in Psychology from North Carolina Central University and is currently seeking her Master’s degree in Professional Counseling from Liberty University. Tabitha is passionate about people living full and authentic lives, including in the workplace, and speaks regularly on such topics.

Liz Wool, R.N., B.S.N., C.C.R.A., CMT, has 37 years of experience in healthcare and 25 in clinical research, and is a recognized industry expert, consultant, and international speaker with a focus on solutions and added value results for her clients. Her expertise is in the areas of clinical research, trial management, clinical quality management systems, vendor management and oversight, compliance, operations, personnel training and development, and, performance management methods. Liz’s services and solutions produce results in both organizational effectiveness and efficiencies (design, re-design, modifications for growing companies, and post-mergers and acquisitions) in support of the organization’s goals. Liz’s strategic, operational, leadership, and facilitation expertise combined with her spirit of teamwork brings the ability to swiftly identify the organizational challenges. She draws on her experience working with the full range of national and international stakeholders in clinical research for the design, development, and deployment of enterprise solutions. Liz provides solutions focused services and recommendations that are a “right fit” for the organizational size, scope of business, business plan, business goals, and culture. Liz has provided consulting services to 6 of the 21 TransCelerate Biopharma, Inc. companies during her consulting tenure in the areas of department level strategic support, SOPs and performance management (post-merge/acquisitions), vendor program gap analyses, enterprise-wide training strategy, and framework gap analyses, training courses, and metrics.
**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 800.856.2556

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**Hotel Information**

Following are contact details for each of Barnett’s seminar venues, which are located in centrally located hotels or state-of-the-art corporate meeting centers. To make hotel reservations, please 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**

**Metro Meeting Centers – Boston**

(please note: meeting facility only; not a hotel)

101 Federal Street, 4th Floor,
Boston, MA 02110
Tel: +1 617-737-1200

**Club Quarters Boston 1**

161 Devonshire Street (Between Milk & Franklin Streets),
Boston, MA 02110
Tel: +1 617-357-6400
Fax: +1 617-357-6462

**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
Fax: +1 617-451-2198

**The Park Plaza Hotel & Towers**

50 Park Plaza
Boston, MA 02116
Tel: +1 617-426-2000

**The Westin Philadelphia**

99 South 17th Street at Liberty Place
Philadelphia, PA 19103
Tel: +1 215-563-1600

**The Latham Hotel**

(mention The Hub 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

**San Diego, CA**

**Courtyard San Diego Downtown**

530 Broadway Street
San Diego, CA 92101
Tel: +1 619-446-3000
Fax: +1 619-446-3010

**San Francisco, CA**

**Hilton San Francisco**

333 O’Farrell Street
San Francisco, CA 94102
Tel: +1 415-771-1400
Fax: +1 415-771-6807

1 For Boston meetings being held at Metro Meeting Center, attendees are encouraged to make hotel arrangements at the Club Quarters, The Langham or Hilton Boston Downtown/Financial District.

2 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.

3 For Philadelphia meetings being held at The Hub Meeting Center, 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 The Hub Meeting Center.

4 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.
### Courses Listed by Location and Month

#### January

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<tr>
<th>Course</th>
<th>Location</th>
<th>Date</th>
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<tr>
<td>Introduction to Data Management</td>
<td>On the Web</td>
<td>January 11, 2016</td>
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<tr>
<td>Introduction to Clinical Research</td>
<td>On the Web</td>
<td>January 12, 2016</td>
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<tr>
<td>Data Management: Key Regulations Impacting the Role of the Clinical Data Manager</td>
<td>On the Web</td>
<td>January 12, 2016</td>
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<tr>
<td>Writing Clinical Study Protocols</td>
<td>On the Web</td>
<td>January 14, 2016</td>
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<td>Ensuring Success Through Smarter Site Selection and Study Feasibility</td>
<td>On the Web</td>
<td>January 14, 2016</td>
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<tr>
<td>30-Hour Clinical Research Auditing Certification Program</td>
<td>On the Web</td>
<td>January 14 - March 31, 2016</td>
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<tr>
<td>Use of Notes to File in Clinical Trial Essential Documentation</td>
<td>On the Web</td>
<td>January 18, 2016</td>
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<tr>
<td>Trial Master File (TMF) for Sponsors: Set-Up and Maintenance</td>
<td>On the Web</td>
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<tr>
<td>FDA Medical Device Approval Process</td>
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<tr>
<td>WORKSHOP: Trial Master Files: Why They Are Important and How to Organize Them</td>
<td>On the Web</td>
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<tr>
<td>Writing the Clinical Study Report</td>
<td>On the Web</td>
<td>January 19, 2016</td>
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<tr>
<td>Medical Writing Fundamentals: How to Write Regulatory Documents</td>
<td>On the Web</td>
<td>January 20, 2016</td>
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<td>The IND in a CTD/eCTD Format</td>
<td>On the Web</td>
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<td>WORKSHOP: How to Write Effective Monitoring Reports and Communications</td>
<td>On the Web</td>
<td>January 21, 2016</td>
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<tr>
<td>Negotiation Skills for Clinical Research Professionals</td>
<td>On the Web</td>
<td>January 22, 2016</td>
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<tr>
<td>Cases in Advanced GCP: A Problem-Solving Practicum</td>
<td>On the Web</td>
<td>January 25, 2016</td>
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<tr>
<td>Case Narrative Writing for Reporting Adverse Events</td>
<td>On the Web</td>
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<tr>
<td>Re-Engineering the RFP and Bid Defense Meeting to Effectively Manage Risk and Quality</td>
<td>On the Web</td>
<td>January 27, 2016</td>
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<tr>
<td>Conducting Clinical Trials Under ICH GCP</td>
<td>San Diego, CA</td>
<td>January 27-28, 2016</td>
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<tr>
<td>Bringing the Clinical Perspective into ISO 14971 Risk Management Discussions</td>
<td>On the Web</td>
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<tr>
<td>Software as a Medical Device: Clinical Considerations</td>
<td>On the Web</td>
<td>January 28, 2016</td>
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<tr>
<td>Developing Clinical Study Budgets</td>
<td>San Diego, CA</td>
<td>January 29, 2016</td>
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#### February

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<thead>
<tr>
<th>Course</th>
<th>Location</th>
<th>Date</th>
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<tbody>
<tr>
<td>Principal Investigator/Site GCP Compliance and Performance: What it Really Takes to Be GCP Compliant</td>
<td>On the Web</td>
<td>February 3, 2016</td>
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<tr>
<td>Adverse Event Monitoring for CRAs</td>
<td>On the Web</td>
<td>February 4, 2016</td>
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<tr>
<td>30-Hour Clinical Project Management Fundamentals Certification Program</td>
<td>On the Web</td>
<td>February 5 - April 8, 2016</td>
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<td>ABCs of Clinical Research for Clinical Administrative Support Staff</td>
<td>On the Web</td>
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<td>Subject Enrollment: Creating Effective Enrollment Models</td>
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<td>CMS-Medicare Coverage Analysis, Budgeting and Billing Compliance</td>
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<td>ABCs of GCP and the 13 Principles of ICH</td>
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<td>Informed Consent Procedure: Lessons Learned from Inspection Findings</td>
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<td>Clinical Project Management: Advanced</td>
<td>Boston, MA</td>
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<td>Auditing Techniques for Clinical Research Professionals</td>
<td>Boston, MA</td>
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Courses Listed by Location and Month

**March**

Good Clinical Practice (GCP) for Medical Devices: ICH GCP and ISO 14155 .................................................. On the Web .................................................. March 1, 2016
Adequate Sponsor Monitoring Systems In Anticipation of FDA Sponsor GCP Inspections .................................. On the Web .................................................. March 1, 2016
WORKSHOP: How to Write Effective Monitoring Reports and Communications ........................................... Philadelphia, PA .................................................. March 1, 2016
Developing CRAs as Site Study Managers. .......................................................................................................... San Diego, CA .................................................. March 1-2, 2016
Effectively Writing Clinical Trial Protocols .................................................................San Diego, CA .................................................. March 1-2, 2016
Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) in Site Management .......................... Philadelphia, PA .................................................. March 1-2, 2016
Data Management in the Electronic Data Capture Arena: Regulatory Considerations and Practical Applications for eCDM ................................................................. On the Web .................................................. March 1-10, 2016
Negotiation Skills for Clinical Research Professionals .......................................................................................... On the Web .................................................. March 2, 2016
Good Clinical Practice: Practical Application and Implementation ................................................................. On the Web .................................................. March 3, 2016
Preparation, Management, and Response to Inspections and Audits ................................................................. On the Web .................................................. March 3, 2016
Medical Writing Fundamentals: How to Write Regulatory Documents .............................................................. San Diego, CA .................................................. March 3, 2016
Risk-Based Monitoring: Successful Planning and Implementation ........................................................................ San Diego, CA .................................................. March 3, 2016
30-Hour Clinical Project Management Fundamentals Certification Program ............................................................. On the Web .................................................. March 3 - June 9, 2016
10-Week Clinical Research Coordinator (CRC) On-Boarding Program ................................................................. On the Web .................................................. March 4 - May 13, 2016
10-Week Clinical Research Associate (CRA) On-Boarding Program ........................................................................ On the Web .................................................. March 4 - May 13, 2016
EMA and MHRA Inspections: Successful Planning and Execution Tips and Techniques ...................................... On the Web .................................................. March 7, 2016
RECON 1.0 and 1.1: Overview and Data Challenges in Oncology Clinical Trials ............................................. On the Web .................................................. March 7, 2016
Comprehensive Monitoring for Medical Devices .................................................................................................. On the Web .................................................. March 7-19, 2016
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Clinical Evidence Writing for Medical Device Regulatory Submissions ................................................................. On the Web .................................................................................. March 8, 2016
WORKSHOP: How to Write Effective Monitoring Reports and Communications ........................................ San Diego, CA .................................................................................. March 8, 2016
Adverse Events: Managing and Reporting for Pharmaceuticals ........................................................................... Philadelphia, PA .................................................................................. March 8-9, 2016
Managing Risks in Outsourced Clinical Trials: Practical Approaches and Tools .................................................. On the Web .................................................................................. March 9, 2016
EU Clinical Trial Regulation 536/2014: Are You Ready? ...................................................................................... On the Web .................................................................................. March 9, 2016
Detecting Risk Signals in Protocols, Data, and Monitoring .................................................................................... San Diego, CA .................................................................................. March 9, 2016
WORKSHOP: Trial Master Files: Why They Are Important and How to Organize Them ................................ San Diego, CA .................................................................................. March 9, 2016
Investigator-Initiated Trials (IITs) and the Role and Responsibilities of the Investigator ..................................... San Diego, CA .................................................................................. March 10, 2016
Approaches to Address Challenges in Vendor Management ................................................................................. On the Web .................................................................................. March 14, 2016
Monitoring Oncology Clinical Trials ....................................................................................................................... On the Web .................................................................................. March 14, 2016
Building Relationships with Clinical Research Sites ......................................................................................... On the Web .................................................................................. March 15, 2016
Clinical Project Management: Introduction to Practical Clinical Trial Planning for Project Managers .............. San Diego, CA .................................................................................. March 15-16, 2016
Risk-Based Monitoring: Successful Planning and Implementation ................................................................. On the Web .................................................................................. March 15-17, 2016
The CRA Role in Risk-Based Monitoring: Strategies for Effective Remote Monitoring ........................................... On the Web .................................................................................. March 16, 2016
Developing and Negotiating Research Site Clinical Study Budgets and Contracts .............................................. On the Web .................................................................................. March 17, 2016
Developing Clinical Study Budgets for Sponsors ............................................................................................... On the Web .................................................................................. March 22, 2016
Effective Recruitment Planning and Management for Sponsors and CROs ......................................................... San Francisco, CA .............................................................................. March 22, 2016
Introduction to the FDA ...................................................................................................................................... Philadelphia, PA .................................................................................. March 22-23, 2016
Monitoring Oncology Clinical Trials ...................................................................................................................... San Francisco, CA .............................................................................. March 22-23, 2016
Conducting Clinical Trials Under ICH GCP ........................................................................................................ On the Web .................................................................................. March 22-31, 2016
Case Narrative Writing for Reporting Adverse Events ....................................................................................... On the Web .................................................................................. March 24, 2016
The GCPs of Essential Documents .................................................................................................................... On the Web .................................................................................. March 24, 2016
Final FDA Guidance: How to Complete the Form FDA 1572, Adequately and Accurately ................................. On the Web .................................................................................. March 24, 2016
Essential Documentation in Clinical Trials at Research Sites ............................................................................ On the Web .................................................................................. March 29, 2016
Introduction to Clinical Research ..................................................................................................................... On the Web .................................................................................. March 30 - April 8, 2016
WORKSHOP: Trial Master Files: Why They Are Important and How to Organize Them ................................ On the Web .................................................................................. March 31, 2016
Protocol Deviations: Documenting, Managing, and Reporting ........................................................................... On the Web .................................................................................. March 31, 2016

April

Drug Development and FDA Regulations ........................................................................................................... On the Web .................................................................................. April 4, 2016
Monitoring Oncology Clinical Trials ..................................................................................................................... On the Web .................................................................................. April 4-7, 2016
EMA and FDA Inspections: Key Differences and Similarities ............................................................................. On the Web .................................................................................. April 5, 2016
FDA Drug Approval Process ............................................................................................................................... On the Web .................................................................................. April 5, 2016
Clinical Project Management: Intermediate ......................................................................................................... San Diego, CA .................................................................................. April 5-6, 2016
Monitoring Clinical Drug Studies: Intermediate ................................................................................................ Boston, MA .................................................................................. April 5-6, 2016
Advanced Good Clinical Practice: Practical Application and Implementation .................................................. On the Web .................................................................................. April 6-15, 2016
10-Week CRA & CRC Beginner Program ........................................................................................................... On the Web .................................................................................. April 6 - June 8, 2016
Monitoring Plan Development ........................................................................................................................... On the Web .................................................................................. April 7, 2016
WORKSHOP: How to Write Effective Monitoring Reports and Communications ........................................... On the Web .................................................................................. April 7, 2016
Quality Risk Management in Clinical Trials and Pharmacovigilance ................................................................ On the Web .................................................................................. April 7, 2016
Trial Master File (TMF) for Sponsors: Set-Up and Maintenance ........................................................................... On the Web .................................................................................. April 11, 2016
Planning and Conducting Global Clinical Trials ............................................................................................. Philadelphia, PA .................................................................................. April 11-12, 2016
Corrective Action Plans: Essential Documentation of a Site’s Response to GCP Deficiencies ............................ On the Web .................................................................................. April 12, 2016
Medical Writing Fundamentals: How to Write Regulatory Documents ........................................................... On the Web .................................................................................. April 12, 2016
The IND in a CTD/eCTD Format .......................................................................................................................... On the Web .................................................................................. April 12, 2016
Courses Listed by Location and Month

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<tr>
<th>Course</th>
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<tr>
<td>Auditing Techniques for Clinical Research Professionals</td>
<td>On the Web</td>
<td>April 12-13, 2016</td>
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<tr>
<td>Monitoring Clinical Drug Studies: Beginner</td>
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<td>April 14-12, 2016</td>
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<tr>
<td>Writing Clinical Study Protocols</td>
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<tr>
<td>Comprehensive CRC Training</td>
<td>Philadelphia, PA</td>
<td>April 13-14, 2016</td>
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<tr>
<td>Writing the Clinical Study Report</td>
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<tr>
<td>30-Hour Clinical Project Management Fundamentals Certification Program</td>
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<td>April 15 - June 17, 2016</td>
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<td>Data Management: Key Regulations Impacting the Role of the Clinical Data Manager</td>
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<td>Data Management Plan Creation: Content and Rationale</td>
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<td>30-Hour Clinical Data Management On-Boarding Program</td>
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<td>April 20 - June 22, 2016</td>
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<td>Introduction to Clinical Research</td>
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<td>Introduction to Statistics for Non-Statisticians</td>
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<td>SDTM and CDASH: What’s the Connection?</td>
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<td>eTMF Implementation Strategies</td>
<td>On the Web</td>
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<td>Centralized TMF Management: The CRO Sponsor Partnership</td>
<td>On the Web</td>
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<tr>
<td>Clinical Trials and the “Sunshine Act”: The Effect on the Clinical Research Industry</td>
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<tr>
<td>FDA's Bioresearch Monitoring (BIMO) Program: Inspection of Sponsors, CROs, and Monitors</td>
<td>On the Web</td>
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<td>Basics of Post-Marketing Pharmacovigilance and the Beginner PV Auditor</td>
<td>Boston, MA</td>
<td>April 26-27, 2016</td>
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<td>Clinical Project Management: Advanced</td>
<td>San Diego, CA</td>
<td>April 26-27, 2016</td>
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<tr>
<td>Preparing IND Submissions: How to Organize, Write, Submit, and Track Submissions</td>
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<td>April 26-27, 2016</td>
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<td>Comprehensive Monitoring for Medical Devices</td>
<td>San Francisco, CA</td>
<td>April 26-28, 2016</td>
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<td>Final AE Regulatory Guidance: Reporting/Communication of Safety Information from Clinical Trials to IRBs</td>
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<td>Risk-Based Auditing: Effective Compliance Strategies</td>
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<td>Current FDA and EMA Inspection Findings: Lessons Learned</td>
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<td>30-Hour Clinical Research Auditing Certification Program</td>
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<td>Monitoring Phase I Clinical Trials</td>
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May

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<td>CR0 Partnership Management</td>
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<td>Monitoring Oncology Clinical Trials</td>
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<td>Advanced Good Clinical Practice: Practical Application and Implementation</td>
<td>San Diego, CA</td>
<td>May 2-3, 2016</td>
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<td>Auditor Emotional Intelligence</td>
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<td>Optimizing Protocol Design and Strategies to Achieve Efficient, Lower Cost Trial Execution</td>
<td>San Diego, CA</td>
<td>May 3-4, 2016</td>
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<td>Working with CROs: Building a Partnership for Project Success</td>
<td>San Diego, CA</td>
<td>May 3-4, 2016</td>
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<td>CRA &amp; CRC Beginner: Program</td>
<td>San Diego, CA</td>
<td>May 3-5, 2016</td>
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<td>Preparing Clinical Research Sites for FDA Inspections</td>
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<td>May 4, 2016</td>
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<td>Re-Engineering the RFP and Bid Defense Meeting to Effectively Manage Risk and Quality</td>
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<td>Inspection Readiness: Demystifying the FDA Inspection Process</td>
<td>Philadelphia, PA</td>
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<td>How to Write Great SOPs and Work Instructions</td>
<td>Philadelphia, PA</td>
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<td>Developing Effective Training and Facilitation Skills in Clinical Research: An Application-Based Course</td>
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<td>Phase I Study Management</td>
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<td>ABCs of GCP and the 13 Principles of ICH</td>
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<td>Applied Clinical Statistics in Centralized Monitoring</td>
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<td>ABCs of Clinical Research for Clinical Administrative Support Staff</td>
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<td>RECIST 1.0 and 1.1: Overview and Data Challenges in Oncology Clinical Trials</td>
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<td>Investigator Initiated Trials: Roles and Responsibilities</td>
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<td>Monitoring Visit Reports for Medical Device Studies</td>
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<td>Conducting Clinical Trials Under ICH GCP</td>
<td>Boston, MA</td>
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<td>Introduction to Clinical Research</td>
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<td>Clinical Project Management: Introduction to Practical Clinical Trial Planning for Project Managers</td>
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<td>Drug Discovery: The Path from Development to Marketing Approval</td>
<td>Boston, MA</td>
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<td>Developing Clinical Study Budgets</td>
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<td>Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) in Site Management</td>
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<td>Good Clinical Practice: Practical Application and Implementation</td>
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<td>Investigator-Initiated Trials (IITs) and the Role and Responsibilities of the Investigator</td>
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<td>Implications of the FDA Guidance for a Risk-Based Approach to Monitoring</td>
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<td>State Laws Governing Clinical Trial Regulatory Compliance</td>
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<td>Informed Consent: Beyond the Basics</td>
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<td>Managing CRAs to Improve Performance and Study Outcomes</td>
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<td>Key Components of Strategic Clinical Research Operational Planning</td>
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<td>Principal Investigator Oversight and the Appropriate Delegation of Tasks</td>
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<td>Regulatory Intelligence</td>
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<td>Case Report Form Design, Strategy, and Standards</td>
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<td>Best Practices for Writing Clinical Evaluation Reports for Medical Devices</td>
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<td>Introduction to Clinical Research</td>
<td>Boston, MA</td>
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<td>The CRA Manager Course</td>
<td>Boston, MA</td>
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<td>Adverse Events: Managing and Reporting for Medical Devices</td>
<td>San Francisco, CA</td>
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<td>Introduction to Data Management</td>
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<td>TMF/eTMF Audit Strategies</td>
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<td>eTMF Quality Oversight: A Risk-Based Approach</td>
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<td>Becoming a Preferred Site: Quality and Documentation Tips for Compliance</td>
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<td>WORKSHOP: Trial Master Files: Why They Are Important and How to Organize Them</td>
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<td>Bringing the Clinical Perspective into ISO 14971 Risk Management Discussions</td>
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<td>Advanced Good Clinical Practice: Practical Application and Implementation</td>
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<td>Informed Consent Procedure: Lessons Learned from Inspection Findings</td>
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<td>Ensuring Success Through Smarter Site Selection and Study Feasibility</td>
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<td>Basics of Post-Marketing Pharmacovigilance and the Beginner PV Auditor</td>
<td>San Diego, CA</td>
<td>June 7-8, 2016</td>
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<td>Medical Device Approval Process: Preparation and Processing of 510(k)s, IDEs, and PMAs</td>
<td>Philadelphia, PA</td>
<td>June 7-8, 2016</td>
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<tr>
<td>Developing CRAs as Site Study Managers</td>
<td>Philadelphia, PA</td>
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<td>Data Management in the Electronic Data Capture Arena: Regulatory Considerations and Practical Applications for eCDM</td>
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<td>Warning Letters: Applying Lessons Learned from Misbranding and Adulteration Noncompliance Findings</td>
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<td>Advanced Good Clinical Practice: Practical Application and Implementation</td>
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<td>Trial Master File (TMF) for Sponsors: Set-Up and Maintenance</td>
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<td>Risk-Based Monitoring: Successful Planning and Implementation</td>
<td>Philadelphia, PA</td>
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<td>10-Week Clinical Research Associate (CRA) On-Boarding Program</td>
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<td>June 10 - August 19, 2016</td>
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<tr>
<th>Course</th>
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<td>“Risk-Based Thinking”: How Monitors Can Develop an Auditor’s Perspective</td>
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<td>Clinical Trials and the “Sunshine Act”: The Effect on the Clinical Research Industry</td>
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<td>Effectively Writing Clinical Trial Protocols</td>
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<td>June 14-15, 2016</td>
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<td>Comprehensive Monitoring for Medical Devices</td>
<td>Boston, MA</td>
<td>June 14-16, 2016</td>
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<td>Principal Investigator/Site GCP Compliance and Performance: What it Really Takes to Be GCP Compliant</td>
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<td>Good Clinical Practice: Practical Application and Implementation</td>
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<td>Medical Writing Fundamentals: How to Write Regulatory Documents</td>
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<td>TMF/eTMF Regulatory Agency Expectations, Inspections, and Findings</td>
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<td>Cases in Advanced GCP: A Problem-Solving Practicum</td>
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<td>Conducting Clinical Trials Under ICH GCP</td>
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<td>June 20-29, 2016</td>
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<td>Clinical Trials for Medical Devices: Design and Development</td>
<td>San Francisco, CA</td>
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<td>Monitoring Oncology Clinical Trials</td>
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<td>Preparing IND Submissions: How to Organize, Write, Submit, and Track Submissions</td>
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<td>Study Feasibility: Eliminating Low and Late Enrollment</td>
<td>On the Web</td>
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<tr>
<td>Case Narrative Writing for Reporting Adverse Events</td>
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<td>EMA and MHRA Inspections: Successful Planning and Execution Tips and Techniques</td>
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<td>Risk-Based Monitoring for Sites: Prepare Your Site for Success</td>
<td>On the Web</td>
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<td>Risk-Based Site Monitoring</td>
<td>On the Web</td>
<td>June 28, 2016</td>
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<td>Clinical Project Management: Introduction to Practical Clinical Trial Planning for Project Managers</td>
<td>Philadelphia, PA</td>
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<td>Risk-Based Monitoring: Successful Planning and Implementation</td>
<td>On the Web</td>
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<td>Sponsor Management of Investigator Non-Compliance</td>
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### July

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<tr>
<td>Sponsor Responsibilities for Global Drug Studies</td>
<td>On the Web</td>
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<tr>
<td>Subject Recruitment: Proactive Project Plans and Issues Management</td>
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<td>Overseeing Teams and Projects</td>
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<td>Clinical Trials for Medical Devices: Design and Development</td>
<td>Philadelphia, PA</td>
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<td>Writing Clinical Study Protocols</td>
<td>Philadelphia, PA</td>
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<td>10-Week CRA &amp; CRC Beginner Program</td>
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<td>Writing the Clinical Study Report</td>
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<tr>
<td>Developing and Negotiating Research Site Clinical Study Budgets and Contracts</td>
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<td>Auditing Techniques for Clinical Research Professionals</td>
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<td>Software as a Medical Device: Clinical Considerations</td>
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<td>Introduction to Clinical Research</td>
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