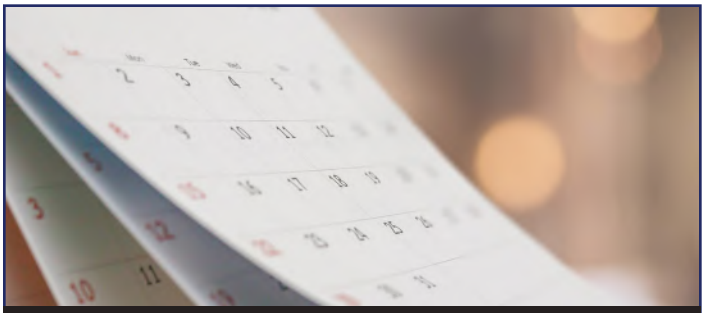
BARNETT INTERNATIONAL
Leaders in Clinical Research Training

Clinical Research Training & Professional Development

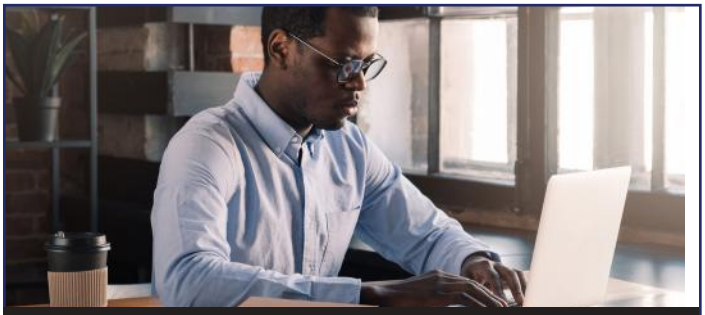
Advance Your Career with Accredited Industry Leading Training

Course & Publications Catalog: January – July 2025

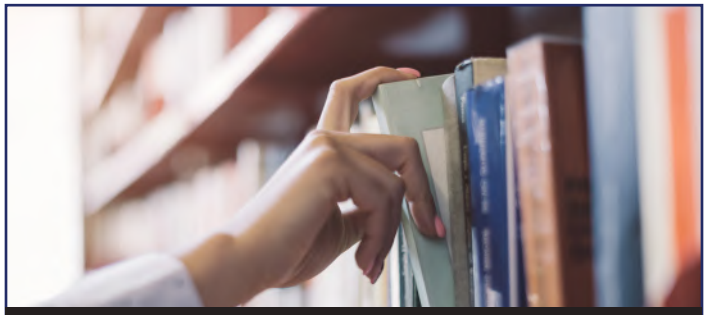


Upcoming Course Schedule

Training Strategy Consulting



Training Portal Subscription



Publications

Comprehensive Training and Resources for Clinical Research Professionals Covering Core Topic Areas:

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

Team Training
from Barnett International

Leverage Barnett's Resources for Your In-house Training Needs!

Comprehensive Training Programs:

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

Annual Training Program Development:

- Curriculum and content development tailored to your needs
- Gap analysis, needs assessment, and "hot spot" identification
- Mock audits with follow-up remediation training

Curriculum/Train-the-Trainer:

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

Accredited Content:

- Professional development CEUs are available from ACPE

Experienced Instructors:

- Courses are taught by industry subject matter experts with hands-on experience in their topic areas
- Barnett's Instructors can be brought to your site or deliver courses virtually that meet your exact training needs

Personalized Service:

- Contact Naila Ganatra at +1 215.413.2471 or nganatra@barnettinternational.com for more information about how to leverage Barnett's resources to meet your in-house training goals

November 2024

Dear Colleagues,

It is with continued pleasure that we present our January – July 2025 catalog. Included are details about all of Barnett's offerings, including our core curriculum courses, interactive web-based training, eLearning, and training consulting offerings. We hope you will find that our flexible training programs and our performance-based consulting offerings are all designed with practical, on-the-job focused content and the needs of our learners in mind.

Our content updates for this catalog continue to address the ICH E8 updates and ICH E6 (R3) status. We've also significantly updated our 30-Hour CRA curriculum to include many new application-based case studies, exercises, and practical implementation examples. With that in mind, there has never been a better time to ensure you are up to date on the latest industry developments through focused role-based training.

Following are some newly-developed courses for your consideration:

- 9-Hour Preparing IND Submissions: How to Organize, Write, Submit, and Track Submissions
- 9-Hour Regulatory Strategy Development
- 10-Week Comprehensive Monitoring for Medical Devices Certification Program
- 18-Hour Writing Clinical/Performance Evaluation Reports
- Agile Project Management for Clinical Research Data Managers
- Creating Impactful Audit Reports in Clinical Research
- Database Design Considerations in Clinical Trials
- Decoding FDA's Draft Guidance on Remote Regulatory Assessments: A Practical Guide
- FDA's Draft Guidance on Integrating Randomized Controlled Trials for Drug and Biological Products into Routine Clinical Practice
- Identifying Safety Signals in Clinical Trial Data
- Mastering Clinical Research Audits: Effective Responses and CAPA Development
- Navigating FDA's June 2024 BIMO Inspection Guidance: A Practical Approach
- The Quality Mindset and Risk-Based Thinking Connection
- "Statistical Intuition" for Clinical Research Data Managers
- Strategies for Assessing Risk Tolerance
- Understanding ICH E6 R3 (GCP) Updates: Key Changes from R2

We have also released a new edition of our Good Clinical Practice: A Question and Answer Reference Guide. The edition includes a number of new chapters and details about impending changes associated with the release of E6 (R3). Don't miss out on this important information!

And as you may know, Barnett has launched a new subscription-based learning portal that provides members with 24/7 access to our robust self-paced learning library. New courses are added on a weekly basis, so please visit our website for more details on this offering.

Finally, we would like to remind you that Barnett also provides a complete and up-to-date library of publications, regulatory reference guides, self-study manuals and job aids, and we regularly assist clients with in-house training needs in numerous content areas. These services include courses delivered at your location, customized content development, role-based training assessments, competency mapping, gap and needs analysis, content focused on the development of critical/executive thinking skills, as well as other types of training support.

Thank you again for the continued opportunity to serve you. We look forward to welcoming you to an upcoming course!

Yours truly,

Naila Ganatra, M.Ed.
Vice President, Learning and Development
Barnett International

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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

- Conducting Clinical Trials Under ICH GCP E6
- Monitoring Clinical Drug Studies: Beginner

Web Seminars (Choose 4)

- 10-Week Clinical Research Associate (CRA) On-Boarding Program*
- Adverse Event Monitoring for CRAs
- Building Relationships with Clinical Research Sites
- Essential Documentation in Clinical Trials at Research Sites
- Good Clinical Practice: Practical Application and Implementation
- Monitoring Medical Device Trials: An Introduction
- Preparing Clinical Research Sites for FDA Inspections
- Source Documentation: What is Adequate and Accurate?
- Use of Notes to File in Clinical Trial Essential Documentation

Level 2: Moderate Experience (2-4 Years)

Core Curriculum Training

- Auditing Techniques for Clinical Research Professionals
- Monitoring Clinical Drug Studies: Intermediate

Web Seminars (Choose 4)

- 10-Hour Clinical Trial Start-Up Series*
- Corrective Action Plans: Essential Documentation of a Site's Response to GCP Deficiencies
- Electronic Medical Records: Approaches for Ensuring Source Document and 21 CFR Part 11 Required Components
- FDA's Bioresearch Monitoring (BIMO) Program: Inspection of Sponsors, CROs, and Monitors
- Good Clinical Practice: Practical Application and Implementation
- Monitoring Visit Reports for Medical Device Studies
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- "Risk-Based Thinking": How Monitors Can Develop an Auditor's Perspective
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- Strategies for Managing Difficult Clinical Research Sites
- Use of Notes to File in Clinical Trial Essential Documentation
- Working with Clinical Research Sites: Strategic Planning and Operations for Sponsors and CROs

Level 3: Extended Experience (4+ Years)

Core Curriculum Training

- Clinical Project Management: Fundamentals of Project Management
- Monitoring Clinical Drug Studies: Advanced

Web Seminars (Choose 4)

- 10-Hour Clinical Research Manager Skills Development Series*
- 10-Week Conducting and Managing Oncology Clinical Trials*
- 10-Week ICH GCP E6: Risk-Based Monitoring Plan Development Series
- 12-Hour Clinical Trial Management Series*
- Cases in Advanced GCP: A Problem-Solving Practicum
- Corrective Action Plans: Essential Documentation of a Site's Response to GCP Deficiencies
- Current FDA and EMA Inspection Findings: Lessons Learned
- Electronic Informed Consent Guidance: Regulatory Updates
- FDA's Draft Guidance on Ethical Considerations for Clinical Investigations of Medical Products Involving Children
- FDA's Updated Informed Consent Guidance: What's New?
- ICH E6 (R3) and ICH E8 (R1) Updates: Impact on Sponsors
- ICH GCP E6 R3 Updates: Implementing Risk Management Approaches for Compliance
- Inspection Readiness: Understanding BIMO Inspection Requirements for Sponsors, CROs, Monitors and Investigators
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- Managing CRAs to Improve Performance and Study Outcomes
- Monitoring Plan Development
- Overseeing Teams and Projects
- Protocol Deviations: Documenting, Managing, and Reporting
- "Risk-Based Thinking": How Monitors Can Develop an Auditor's Perspective
- Root Cause Analysis: Applying the Concept for Better Study Compliance Management
- Sponsor Management of Investigator Non-Compliance
- Strategies for Active Listening
- Strategies for Having Difficult Conversations
- Strategies for Remote Auditing of Investigative Sites
- A Systematic Approach to Study Start-Up: Improving Site Activation

Included with All Levels:

eLearning:

Barnett's On-Demand
GCP for Sponsors and CROs

Recommended Reading:

Good Clinical Practice:
A Question & Answer Reference Guide

Cost: $5,000

*For selections including these courses, please add $500 per course (due to course duration).

To Register:

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

Barnett's Blended Curriculum Path: Clinical Research Coordinator

Background:

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

How it Works:

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

Level 1: Minimal Experience (0-2 Years)

Core Curriculum Training

- Conducting Clinical Trials Under ICH GCP E6
- CRA & CRC: Beginner Program

Web Seminars (Choose 4)

- 10-Week Clinical Research Coordinator (CRC) On-Boarding Program*
- 10-Week CRA & CRC Beginner Program*
- Adverse Events: Best Practices for Reporting and Communicating Safety Information to IRBs
- Drug Development and FDA Regulations
- Essential Documentation in Clinical Trials at Research Sites
- Good Clinical Practice: Practical Application and Implementation
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- Introduction to Clinical Research
- Introduction to Data Management
- Principal Investigator Oversight and the Appropriate Delegation of Tasks
- Source Documentation: What is Adequate and Accurate?
- Use of Notes to File in Clinical Trial Essential Documentation

Level 2: Moderate Experience (2-4 Years)

Core Curriculum Training

- Auditing Techniques for Clinical Research Professionals
- Clinical Project Management: Fundamentals of Project Management

Web Seminars (Choose 4)

- Corrective Action Plans: Essential Documentation of a Site's Response to GCP Deficiencies
- Developing and Negotiating Research Site Clinical Study Budgets and Contracts
- Electronic Medical Records: Approaches for Ensuring Source Document and 21 CFR Part 11 Required Components
- The GCPs of Essential Documents
- Good Clinical Practice: Practical Application and Implementation
- Informed Consent Procedure: Lessons Learned from Inspection Findings
- Investigational Product Accountability Best Practices
- Preparing Clinical Research Sites for FDA Inspections
- Root Cause Analysis: Applying the Concept for Better Study Compliance Management
- Subject Recruitment: Proactive Project Plans and Issues Management
- Use of Notes to File in Clinical Trial Essential Documentation

Level 3: Extended Experience (4+ Years)

Core Curriculum Training

- Clinical Project Management: Advanced Concepts in Project Management

Web Seminars (Choose 4)

- 10-Hour Clinical Research Manager Skills Development Series*
- 10-Hour Clinical Trial Start-Up Series*
- 10-Week Conducting and Managing Oncology Clinical Trials*
- Adverse Events: Best Practices for Reporting and Communicating Safety Information to IRBs
- Clinical Research Financial Management for Investigative Sites
- Corrective Action Plans: Essential Documentation of a Site's Response to GCP Deficiencies
- Developing and Negotiating Research Site Clinical Study Budgets and Contracts
- FDA Requirements for Electronic Source Data in Clinical Investigations
- FDA's Draft Guidance on Ethical Considerations for Clinical Investigations of Medical Products Involving Children
- ICH GCP E6 R3 Updates: Implementing Risk Management Approaches for Compliance
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- Overcoming Site Challenges: Managing Sponsor Payment Delays
- Preparing Clinical Research Sites for FDA Inspections
- Recent Trends in Noncompliance: Critical Review and Analysis of Recent Regulatory Letters and Communications from the FDA, EMA, and Health Canada
- Root Cause Analysis: Applying the Concept for Better Study Compliance Management
- Strategies for Active Listening
- Strategies for Having Difficult Conversations
- Subject Recruitment: Proactive Project Plans and Issues Management
- Use of Notes to File in Clinical Trial Essential Documentation

Included with All Levels:

eLearning:

Barnett's On-Demand
GCP for Study Coordinators

Recommended Reading:

Good Clinical Practice:
A Question & Answer Reference Guide

Cost: $5,000

*For selections including these courses, please add $500 per course (due to course duration).

To Register:

Simply select your courses and contact Barnett at +1 781.972.5400 or toll-free in the U.S. at 800 .856.2556. Course schedules can be viewed on our website at: barnettinternational.com.

Barnett's Blended Curriculum Path: Project Manager

Background:

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

How it Works:

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

Level 1: Minimal Experience (0-2 Years)

Core Curriculum Training

- Clinical Project Management: Fundamentals of Project Management
- Conducting Clinical Trials Under ICH GCP E6

Web Seminars (Choose 4)

- 30-Hour Clinical Project Management Fundamentals Certification Program*
- Auditing Sponsors and CROs: Deconstruction and Application of the FDA's Compliance Program Guidance Manual
- Building Relationships with Clinical Research Sites
- CRO Partnership Management
- Drug Development and FDA Regulations
- The GCPs of Essential Documents
- Introduction to Data Management
- Preparing Clinical Research Sites for FDA Inspections
- Recent Trends in Noncompliance: Critical Review and Analysis of Recent Regulatory Letters and Communications from the FDA, EMA, and Health Canada
- Trial Master File (TMF) for Sponsors: Set-Up and Maintenance

Level 2: Moderate Experience (2-4 Years)

Core Curriculum Training

- Auditing Techniques for Clinical Research Professionals
- Statistical Concepts for Non-Statisticians

Web Seminars (Choose 4)

- Clinical Trial Start-Up: Using a Work Breakdown Structure (WBS) for Effective Planning
- Corrective Action Plans: Essential Documentation of a Site's Response to GCP Deficiencies
- CRO Partnership Management
- Developing Clinical Study Budgets for Sponsors
- FDA's Bioresearch Monitoring (BIMO) Program: Inspection of Sponsors, CROs, and Monitors
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- Investigational Product Accountability Best Practices
- Overseeing Teams and Projects
- Preparing Clinical Research Sites for FDA Inspections
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- Risk-Based Monitoring and Quality Management of Clinical Trials: Recent Guidance Updates from the FDA and EMA
- 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

- Clinical Project Management: Advanced Concepts in Project Management
- Statistical Concepts for Non-Statisticians

Web Seminars (Choose 4)

- 10-Hour Advanced Clinical Project Management Skills Development*
- 10-Hour Clinical Research Manager Skills Development Series*
- 10-Week Conducting and Managing Oncology Clinical Trials*
- 10-Week Establishing a Vendor Qualification and Management Program*
- 12-Hour Clinical Trial Management Series*
- Approaches to Address Challenges in Vendor Management
- Cases in Advanced GCP: A Problem-Solving Practicum
- Clinical Trial Start-Up: Using a Work Breakdown Structure (WBS) for Effective Planning
- Corrective Action Plans: Essential Documentation of a Site's Response to GCP Deficiencies
- Current FDA and EMA Inspection Findings: Lessons Learned
- ICH E6 (R3) and ICH E8 (R1) Updates: Impact on Sponsors
- ICH GCP E6 R3 Updates: Implementing Risk Management Approaches for Compliance
- Inspection Readiness: Understanding BIMO Inspection Requirements for Sponsors, CROs, Monitors and Investigators
- Managing Risks in Outsourced Clinical Trials: Practical Approaches and Tools
- Risk-Based Auditing: Effective Compliance Strategies
- Root Cause Analysis: Applying the Concept for Better Study Compliance Management
- Sponsor Management of Investigator Non-Compliance
- Strategies for Active Listening
- Strategies for Having Difficult Conversations
- A Systematic Approach to Study Start-Up: Improving Site Activation

Included with All Levels:

eLearning:

Barnett's On-Demand
GCP for Sponsors and CROs

Recommended Reading:

Good Clinical Practice:
A Question & Answer Reference Guide

Cost: $5,000

*For selections including these courses, please add $500 per course (due to course duration).

To Register:

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BARNETT INTERNATIONAL

"Hands-On" 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 virtual learning environment. 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. To focus on the customized application of the exercises, ***registration for 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 emphasis. *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 Workshops:

WebEx offers cross-platform, unmatched support across a wide range of devices. Supported computer operating systems include Windows, Mac, Linux, and Solaris. Browser support includes Internet Explorer, Microsoft Edge, Google Chrome, Mozilla Firefox, and Safari. You can also download the free WebEx Meetings app to your Apple, Android, or Amazon smartphone or tablet. You can always test your system by going to http://www.webex.com/test-meeting.html and following the onscreen 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. You will also 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. 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 Good Clinical Practice E6 Guideline, identify the Case Report Form (CRF) as one of the essential documents for a clinical trial. Therefore, it is imperative to understand and implement the best practices of the CRF design process. That includes making sure all the protocol-required data are collected, ensuring the design of the CRF minimizes errors, and keeping the study coordinator in their normal workflow.

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

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

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

- CRF Definition, Purpose, Considerations
- Best Practices in CRF Design
- External Data Integration
- CDISC/CDASH

Interactive Activities

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

Who Should Attend

- Case Report Form Designers
- Clinical Data Managers
- Clinical Research Associates
- Project Managers

Instructor

Denise G. Redkar-Brown, MT

Course Dates and Times

March 20, 2025
Online via WebEx
Course #: BI16574
$850 by February 14, 2025
$1,050 after February 14, 2025

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#: 0778-0000-23-035-L99-P. Released: 3/23.

How to Write Effective Monitoring Reports and Communications

Course Description

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

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

Learning Objectives

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

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

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

Course Dates and Times

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.

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." R2 Guideline, Section 8.1 defines these essential documents as those that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements. They are all also eligible for inspection by the regulatory authorities at any time during and after the study is completed and submitted for product approval. This is the same regulation for drugs, biologics and devices. It is, therefore, paramount that these documents are filed in a way to make them immediately accessible for use by the study team and for regulatory inspection. This module will provide some practical solutions to meet these challenges.

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

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

In today's regulatory environment, the files must be "inspection ready" at all times. Regulatory authorities may conduct a regulatory inspection at any time throughout the life of the study. 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
- Recognize the importance of a well-organized Trial Master File
- Implement strategies for effective filing of required documents
- Identify processes that support the effective management of the Trial Master File
- Investigate common deficiencies in filing strategies
- 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
- Trial Master File Mapping and Content Review by Zone
- TMF Quality Oversight and Inspection Readiness
- Global Crisis Trial Master File Impact
- SOPs that Support Trial Master File Management
- 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
- Outline a Trial Master File Management Standard Operating Procedure
- Participate in filing sample documents using the Drug Information Association Trial Master File Reference Model
- Discuss the value of filing Trial Master File content appropriately
- 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.

Jim Markley

Laura Wiggins, M.B.A.

Course Dates

June 3, 2025
Online via WebEx
Course #: STMA0625
$850 by May 9
$1,050 after May 9

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#: 0778-0000-23-030-L99-P. Released: 6/23.

BARNETT INTERNATIONAL

Core Curriculum Courses

What Are Core Curriculum Courses?

Barnett International's Core Curriculum courses are 1, 2- and 3-day courses offered in a dynamic virtual setting. Courses are held quarterly during Barnett's "Clinical Research Training Weeks," and provide you with a unique combination of strategy development and practical, hands-on content and course materials, enabling you to get the most out of your training experience. Our experienced instructors offer application-focused instruction that is based on content that can be immediately applied on the job. The "Barnett Difference" is evident through our high-quality content, instructors who are not only trainers experienced in adult learning but are also subject matter experts working in the field, our deep organizational understanding of the clinical research process, and through the rapid and tangible performance improvements we deliver.

What Are the Benefits?

- Interaction with industry expert trainers
- 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 234) with payment to Barnett Customer Service.

After registering, you will receive an email confirmation that provides you with all of the login details you need for the course. One week 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). 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.

30-Hour Clinical Research Financial Certification Program: Setting Up Compliant Financial Operations and Budgets

Course Description

Many organizations struggle with incorporating federal and billing regulations with electronic systems. This 30-hr course takes learners through, step-by-step, the clinical research financial road map. We will examine the financial feasibility of considering clinical research study involvement, incorporating the study into the integrated systems, and managing patient and sponsor billing. This series focuses on the applicable regulations, operational efficiencies and risk mitigation through a compliant Clinical Research Billing (CRB) program. Participants will learn how to leverage study and patient data to maintain and enhance a comprehensive and compliant program.

Learning Objectives

- Discuss federal and billing regulations while building a compliant clinical research billing program
- Describe the financial feasibility process and deciding to conduct/participate in a clinical research study
- Describe the creation of the Medicare Coverage Analysis (MCA) process, determining coverage of items and services and incorporating MCA into the clinical trial budget
- Discuss integrating MCA into an electronic health record and managing patient billing
- Review sponsor billing and leverage system integrations to mitigate organizational risk

Interactive Activities

- Multiple budgeting and tracking exercises including provided templates and forms

Who Should Attend

- Clinical Research Coordinators
- Clinical Trial Managers
- Clinical Research Associates
- Clinical Research Managers/Directors
- Administrative Directors
- Financial Analysts

Instructor

Mary L. Veazie, M.B.A., CPA, CHC, CHRC

Course Dates and Times

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

- Module 1: Financial Feasibility and Decision to Participate in a Clinical Research Study
- Module 2: Creating a Medicare Coverage Analysis (MCA) – A Step-By-Step Approach; Billing Regulation Review
- Module 3: Creating a Clinical Trial Budget and Incorporating MCA
- Module 4: Negotiating a Clinical Trial Budget
- Module 5: Integrating MCA into an Electronic Health Record; Creating a Billing Grid
- Module 6: Consenting Patients, Creating Timelines, and Ordering Services
- Module 7: Patient Billing: Charge Review Process and Medical Documentation
- Module 8: Sponsor Billing: Milestone Payments
- Module 9: Leveraging Data: Using Patient and Study Data to Manage Current and Future Studies
- Module 10: Study Close Out: Reconciliation Process and Ensuring All Payments Are Received

Note: This course can be scheduled in a number of formats. Please contact Barnett for more details.

Advanced Good Clinical Practice: Practical Application and Implementation

Includes R3 Updates

Course Description

This course provides an advanced, in-depth review of the structural elements of Good Clinical Practice (GCP). Participants will learn practical application of GCP regulations and guidelines for critical components of the clinical research process. Incorporating the updates in ICH E6 R3, we will discuss how clinical research team members can implement systems to manage quality throughout the trial process.

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

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

Learning Objectives

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

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

- 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

Course Outline

Day One

- Principles of GCP: Different Perspectives: Examination; application; implementation
- New Developments and Emerging Trends in GCP
- The "Forgotten" Elements of GCP: Regulations; laws; guidelines
- Quality Systems: The Roadmap to GCP: Quality control; quality assurance; quality improvement

Day Two

- Quality Risk Management (QRM) in Clinical Trials: Application of risk assessment in the review of protocols
- The Role of Standard Operating Procedures in GCP: Rationale; development; training; implementation; maintenance
- GCP Across Investigational Products: Drugs; devices; biologics
- Are We There Yet? Recent non-compliance issues with discussion of Corrective and Preventive Action planning

Course Dates and Times

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 Post-Marketing Pharmacovigilance Auditing

Course Description

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

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

Learning Objectives

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

Who Should Attend

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

Instructors

Vaska Tone

Course Dates and Times

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

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

Day Two

- Auditor Preparation: PV Audit Questionnaires & Checklists
- PV Audit Conduct
- Hands-on Exercise:
  - Use of the pre-audit questionnaire – review of several examples
  - Use of PV Audit Checklists
  - Follow the AE: Review of PV tracker, source document(s), cases (MedWatch/ CIOMS), submissions
  - Role Playing

Adverse Events: Managing and Reporting for Medical Devices

Course Description

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

Learning Objectives

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

Instructors

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

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

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

Who Should Attend

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

Interactive Activities

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

Course Outline

Day One

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

Day Two

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

Course Dates and Times

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.

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

Instructors

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

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

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 Outline

Day One

- Introduction to AE Management and Reporting: Brief history of the FDA; pertinent historical/ethical perspectives; overview of pharmacovigilance
- Clinical Trials: Overview of Regulations: FDA, ICH, EU, ISO; causality, relatedness/ expectedness, serious; sponsor reporting variations; FDA and international expedited reporting; post-marketing clinical trial considerations; reporting into IND; reporting into NDA; review of warning letters
- Use of Electronic Records and Coding Concepts: Electronic records: regulations, considerations in your environment, storage, submissions; MedDRA; SNOMED

Day Two

- Post-Marketing: Overview of FDA and international regulations; FDA and international reporting requirements; labeling requirements; product complaints/quality control; review
- Combination Products: Introduction to device regulations, definitions, concepts; overview of Office of Combination Products; reporting considerations for combination products

Course Dates and Times

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.

Blended Curriculum Course

Auditing Techniques for Clinical Research Professionals

Course Description

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

Learning Objectives

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

Who Should Attend

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

Interactive Activities

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

Instructors

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

Elizabeth Ronk Nelson, M.P.H.

Shana Zink, B.S., C.C.R.A.

Course Dates and Times

March 20-21, 2025
9:00 a.m. – 4:00 p.m. Eastern
Online via WebEx
Course #: SFCA0325
$1,675 by February 21
$1,875 after February 21

June 5-6, 2025
12:00 p.m. – 7:00 p.m. Eastern
Online via WebEx
Course#: SFCD0625
$1,675 by May 9
$1,875 after May 9

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#: 0778-0000-25-016-L99-P. Released: 3/25.

Course Outline

Day One

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

Day Two

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

Basics of Post-Marketing Pharmacovigilance and the Beginner PV Auditor

Course Description

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

Instructors

Vaska Tone

Who Should Attend

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

Course Dates and Times

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

- EMA PV Modules and FDA Safety Reporting Basics
- Systems Used in PV Data Gathering and Individual Safety Case Reporting (ICSRs)
- Understanding Requirement to Periodic Safety Update Reports (PSURs)
- Eudravigilance & Signal Detection
- Hands-on Exercise: Reviewing "AE Source Documents" & Resulting ICSRs

Day Two

- PV Audit Plans, Scope, and Agendas
- PV Audit Questionnaires and Checklists
- Current EMA/FDA PV inspection findings
- Hands-on Exercise: Drafting the audit agendas and checklists for:
- System Audit
- Affiliate Audit
- Vendor Audit

Becoming a Clinical Research Investigator: Expectations and Responsibilities

Course Description

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

Learning Objectives

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

Who Should Attend

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

Interactive Activities

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

Course Outline

Day One

- GCP and Investigator Responsibilities
- New Developments and Emerging Trends in GCP
- Human Subject Protection
- Quality Systems and Investigational Product Management
- Adequate and Accurate Records and Safety Event Management
- Advanced Cases in GCP: Application of GCP, RCA and CAPA
- Recent Non-Compliance Issues with Discussion

Instructor

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

Course Dates and Times

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:

"You will not leave class uninformed."

Best Practices to Become a Preferred Site

Course Description

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

Learning Objectives

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

Instructor

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Who Should Attend

- Clinical Research Coordinators
- Site Managers
- Investigators
- Site Selection Personnel
- Clinical Research Associates who wish to help develop sites
- Quality Personnel

Interactive Activities

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

Course Outline

Day One

- Quality in Clinical Trials: Key factors determining quality of sites
- Site/Study Selection: Questions to ask and tools to impress
- Study Documentation: Best practices for maintaining and archiving
- FDA Monitoring/Audits/Inspections: Best practices to be inspection ready
- Tips on Promoting Your Site

Course Dates and Times

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.

Biologics Development and Regulations

Course Description

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

Learning Objectives

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

Instructor

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

Who Should Attend

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

Interactive Activities

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

Course Dates and Times

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

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

Day Two

- How to design appropriate clinical trials for biologics
- The Biological License Application (BLA) and review process
- Regulations for regenerative products as medical devices, combination products
- Applicable Good Manufacturing and Good Laboratory Practices
- Product labeling, marketing, and advertising
- Post-licensure requirements
- Bioresearch Monitoring Program for biologics

Blended Curriculum Course

Clinical Project Management: Fundamentals of Project Management

Course Description

This introductory project management course covers concepts from the Project Management Institute, PMBOK® 6th and 7th editions, and how they specifically apply to clinical research. The course is designed for newly hired clinical project managers, clinical project managers without formal project management training, or those exploring the clinical project management role. Principles of clinical project management are covered, including project stakeholder and team engagement, project planning, scope and budget management, risk identification, risk management, and schedule management in the lifecycle of a clinical trial. Case studies and learner discussions are utilized throughout the modules to reinforce concepts covered during this two-day interactive, hands-on program.

Learning Objectives

- Describe project management as it applies to clinical research
- Explore stakeholder and team engagement in project lifecycle management
- Define scope management and tools utilized by project managers, including the work breakdown structure, process mapping, and schedule management
- Identify how project managers work with the clinical operations team and stakeholders in risk identification, risk planning, and risk management
- Define effective vendor management and sponsor oversight in clinical trial projects

Instructors

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

Shelley Marti, M.S.N., P.M.P.

Danny Nasmyth-Miller, B.A. (Hons), M.B.A.

Nazma M. Rosado, MAOL, P.M.P., CPLP, 6σ, CMQ/OE

Who Should Attend

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

Interactive Activities

- Case Study: Creation of Work Breakdown Structure (WBS)
- Case Study: Development of a Project WBS and Project Schedule
- Case Study: Investigational Product Risk
- Case Study: Risk Double Blind Study Design
- Case Study: Risk Dosing of Investigational Product
- Case Study: Using a Third-Party Vendor

Course Outline

Day One

- Module 1: Introduction to Clinical Project Management: Overview of project management as defined by PMI®; roles and responsibilities of the clinical project manager; establishment of project teams
- Module 2: Project Planning: Scope identification, planning, and schedule planning
- Module 3: Effective Schedule Management: Defining project scope; creation of a project schedule; identify critical path; effectively project scope changes and impact to project schedule

Day Two

- Module 4: Budget Planning: Introduction to budget estimates, development of a project budget, and budget tracking
- Module 5: Project Risk and Quality Management: Introduction to ICH GCP E6 (R3) and ICH E8 (R1) (risk identification, risk planning, risk register, and critical to quality)
- Module 6: Vendor Management: Vendor selection process, sponsor oversight and success factors

Course Dates and Times

March 18-19, 2025
12:00 p.m. – 7:00 p.m. Eastern
Online via WebEx
Course #: SPMD0325
$1,675 by February 21
$1,875 after February 21

June 9-10, 2025
9:00 a.m. – 4:00 p.m. Eastern
Online via WebEx
Course #: SPMB0625
$1,675 by May 16
$1,875 after May 16

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#: 0778-0000-24-002-L99-P. Released: 3/24.

Blended Curriculum Course

Clinical Project Management: Advanced Concepts in Project Management

Course Description

This two-day advanced course delves into advanced clinical research project management skills, mapped to the Project Management Institute, PMBOK® 6th and 7th editions. This course is recommended for the experienced clinical project manager with a minimum of three years of clinical project management experience. Advanced concepts are presented to explore how project managers effectively communicate and lead project teams to overcome complex issues, including prioritizing project needs, influencing and leading project teams and stakeholders. The course also covers challenges in vendor lifecycle management, project risk assessment (project, quality), and issues management. All concepts are presented in a dynamic, interactive manner to facilitate learning and retention.

Learning Objectives

- Explain project management tools and principles used in clinical trials
- Formulate project priorities and approaches to manage project needs effectively
- Develop effective communication and leadership skills for the project needs
- Identify critical to quality factors and risks in a clinical trial project
- Appraise effective stakeholder and vendor management in clinical trials
- Describe effective leadership skills in leading project teams

Instructors

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

Shelley Marti, M.S.N., P.M.P.

Danny Nasmyth-Miller, B.A. (Hons), M.B.A.

Nazma M. Rosado, MAOL, P.M.P., CPLP, 6σ, CMQ/OE

Who Should Attend

- Project Managers
- Clinical Research Coordinators, Associates, Monitors, and Managers
- Regulatory, Medical, and Clinical Affairs Professionals

Interactive Activities

- Case Study: Prioritization management for the clinical project manager and effective delegation
- Case Study: Stakeholder identification, interests, and considerations for effective management
- Discussion: Effective leadership skills, per the topic or the situation, encountered
- Case Study: Identify project risks and implement a treatment plan
- Case Study: Stakeholder and vendor management

Course Outline

Day One

- Introduction: Review of the clinical project charter, project plan, project risk analysis, and use of various tracking methods in project management
- Importance of the Project Team: The key to a successful project
- Prioritization Management: Priority setting to manage project schedule and workload
- Managing Projects: Stakeholder management and effectively leading/directing/influencing project teams

Day Two

- Project Risk and Critical to Quality Factors: ICH GCP E6 (R3) and ICH E8 (R1) in the conduct and management of a clinical trial
- Project Vendor Management and Oversight: Ensuring successful vendor oversight and issue management

Course Dates and Times

March 25-26, 2025
9:00 a.m. – 4:00 p.m. Eastern
Online via WebEx
Course #: SMYA0325
$1,675 by February 28
$1,875 after February 28

June 16-17, 2025
12:00 p.m. – 7:00 p.m. Eastern
Online via WebEx
Course #: SMYD0625
$1,675 by May 23
$1,875 after May 23

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#: 0778-0000-24-003-L99-P. Released: 3/24.

Clinical Trial Assistant Fundamentals

Includes R3 Updates

Course Description

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

Learning Objectives

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

Instructors

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

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

Sonja Cooper, Ph.D., M.B.A.

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Elizabeth Weeks-Rowe, LVN, C.C.R.A.

Who Should Attend

- Clinical Trial Associates
- Clinical Trial Assistants
- Clinical Coordinators at the sponsor or CRO

Interactive Activities

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

Course Outline

Day One

- Module 1: ICH GCP and FDA Regulations
- Module 2: Roles and Responsibilities of the Clinical Research Team
- Module 3: Investigational Product Development: Drug and Device Approval Process
- Module 4: Investigational Product: Accountability, Management, and Issue Management

Day Two

- Module 5: Trial Master File: Set up, Maintain, and Manage
- Module 6: Clinical Trial Start Up Process and Essential Documentation
- Module 7: Clinical Trial Maintenance and Essential Documentation
- Module 8: Clinical Trial Close Out and Essential Documentation

Course Dates and Times

March 31 – April 1, 2025
9:00 a.m. – 4:00 p.m. Eastern
Online via WebEx
Course #: STFA0325
$1,675 by March 7
$1,875 after March 7

June 16-17, 2025
12:00 p.m. – 7:00 p.m. Eastern
Online via WebEx
Course #: STFD0625
$1,675 by May 23
$1,875 after May 23

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#: 0778-0000-25-017-L99-P. Released: 3/25.

Clinical Trial Start-Up: Effective Planning for Sponsors, CROs, and Sponsor-Investigators

Course Description

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

Learning Objectives

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

Instructors

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

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

Elizabeth Weeks-Rowe, LVN, C.C.R.A.

Shana Zink, B.S., C.C.R.A.

Who Should Attend

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

Interactive Activities

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

Course Outline

Day One

- Module 1: Defining Protocol Requirements and Risks
- Module 2: Development of Protocol Specific Tools
- Module 3: Creation of Communication Plans

Day Two

- Module 4: Work Breakdown Structure: Effective planning tool for your team and investigative site
- Module 5: Application of the Start-Up Process: Development of a Work Breakdown Structure from time of site selection through IRB/IEC, budget/clinical trial agreement approval, and scheduling of site initiation visit
- Module 6: Lessons Learned: Discussion and review of application

Course Dates and Times

March 31 – April 1, 2025
9:00 a.m. – 4:00 p.m. Eastern
Online via WebEx
Course #: SWBA0325
$1,675 by March 7
$1,875 after March 7

June 26-27, 2025
12:00 p.m. – 7:00 p.m. Eastern
Online via WebEx
Course #: SWBD0625
$1,675 by May 30
$1,875 after May 30

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#: 0778-0000-23-037-L99-P. Released: 10/23.

Clinical Trials for Medical Devices: Design and Development

Course Description

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

Learning Objectives

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

Instructor

Elizabeth Ronk Nelson, M.P.H.

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

Interactive Activities

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

Course Dates and Times

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

- Historical Overview: Overview of the regulatory process and general ethical considerations
- Device Regulations Pertaining to Device Trial Design and Development: "Least Burdensome" approach in the USA; Europe; Japan; "Rest of World"
- Impact of ICH on Device Trials and Development: Principles of the ICH GCP E6 Guideline
- Investigational Plan: Strategic planning; risk analysis; clinical operations; regulatory planning: marketing considerations
- Trial Design Considerations: Definitions; types; randomizing; blinding or masking; outcomes

Day Two

- 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 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 FDA inspection process and what can be learned from issued warning letters

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
- Monitor Group Discussions – Includes Case Studies for Monitor Visits, Device Accountability, Informed Consent Review, and Monitoring Priorities
- The Device Approval Process – Classifying Devices and Determining Pathways to Marketing
- Assessing Adverse Events
- Warning Letter Lessons Learned

Instructors

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

Heather Marshall, M.S.N., B.S.N., R.N.

Shana Zink, B.S., C.C.R.A.

Course Dates and Times

March 25-27, 2025
12:00 p.m. – 7:00 p.m. Eastern
Online via WebEx
Course #: SDOD0325
$1,795 by February 28
$1,995 after February 28

June 11-13, 2025
9:00 a.m. – 4:00 p.m. Eastern
Online via WebEx
Course #: SDOB0625
$1,795 by May 16
$1,995 after May 16

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#: 0778-0000-23-028-L99-P. Released: 3/23.

Course Outline

Day One

- Introduction to the FDA and the Medical Device Approval Process: Introduction to the FDA; ICH overview; definitions; medical device regulatory processes
- US Good Clinical Practices: Concept of Good Clinical Practices; US GCP – sponsor, investigator and IRB obligations; overview of monitor's responsibilities
- IRB Approval & Informed Consent Process: IRB application for approval; approval process – initial and ongoing; informed consent process and documentation; HIPAA authorization
- Pre-Study Processes: Determining the sponsor's investigator/site needs; pre-investigation and confidentiality agreement; investigator/site selection; contracts/agreements; investigator's meeting; initiation visit; recruitment and advertising

Day Two

- Study Documentation: Sponsor files; investigator files; source documentation; case report forms; communication
- Monitoring: Roles and responsibilities of the monitor during periodic visits; source document verification; case report form review in EDC; data retrieval and correction; document retrieval; protocol, investigational plan and GCP deviations; monitoring documentation

Day Three

- Device Accountability: Sponsor responsibilities as they relate to device accountability; investigator responsibilities as they relate to device accountability
- Close-out Visits: Reasons for a closeout visit; roles and responsibilities of the monitor during a closeout visit; investigator responsibilities after closeout
- Managing and Reporting Adverse Events: Adverse event terminology; variations in adverse event reporting and documentation; sponsor obligations relating to adverse event reporting; investigator obligations relating to adverse event reporting
- FDA Inspections: Purpose, types and mechanics of FDA inspections; common audit findings; FDA actions following an inspection; review of warning letters

Blended Curriculum Course

Conducting Clinical Trials Under ICH GCP E6

Includes R3 Updates

Course Description

This course provides a comprehensive review of Good Clinical Practice (GCP) and FDA regulations and requirements. Participants receive a foundation of knowledge about GCP, practical examples, and the underlying scientific and regulatory principles involved. Guidelines for each aspect of research are provided, as well as information on the structuring and preparation of protocols, consent forms, and investigator brochure. Information on maintaining an ongoing relationship with the FDA will also be discussed. This course enables clinical professionals to prepare concise documents and provide their company and the FDA with necessary information for their clinical studies. The R2 changes as well as proposed R3 updates are covered in this course.

Learning Objectives

- Summarize Good Clinical Practice (GCP)
- Identify 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

Instructors

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

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

Elizabeth Weeks-Rowe, LVN, C.C.R.A.

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.

Course Outline

Day One

- Introduction to ICH and FDA GCPs: History; law; regulations; definitions; FDA organization; bioresearch monitoring group; evolution of GCP; ICH process
- Clinical Research Team Roles and Responsibilities: Sponsor, Investigator and IRB responsibility
- Informed Consent and Essential Documents: Elements of the Informed Consent, Essential Documentation Responsibilities of Sponsor and Investigator

Day Two

- Root Cause Analysis & Corrective and Preventive Actions for Quality Management
- Compliance, Audits, Inspections & Conclusions

Course Dates and Times

March 24-25, 2025
9:00 a.m. – 4:00 p.m. Eastern
Online via WebEx
Course #: SGCA0325
$1,675 by February 28
$1,875 after February 28

June 26-27, 2025
12:00 p.m. – 7:00 p.m. Eastern
Online via WebEx
Course #: SGCD0625
$1,675 by May 30
$1,875 after May 30

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#: 0778-0000-25-018-L99-P. Released: 3/25.

Blended Curriculum Course

CRA & CRC: Beginner Program

Course Description

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

Learning Objectives

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

Who Should Attend

- Aspiring Clinical Research Coordinators and Nurses
- Aspiring Clinical Research Associates – In-house or Field-based
- College Students and New Graduates in a Scientific Field

NOTE: This course is also appropriate for CRAs or CRCs with less than six months experience

Interactive Activities

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

Course Outline

Day One

- Introduction to Clinical Research
- Clinical Research Team: Roles & Responsibilities
- Investigational Product (IP) Development
- Good Clinical Practice: FDA Regulations, FDA Guidance, and ICH GCP E6 Guideline

Day Two

- 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

- IP Accountability, Essential Documents, and Routine Monitoring Visits
- Source Document Verification, Data Management, and the Trial Close-out Visit
- Interactive Exercises I and II: CRF completion and monitoring simulation exercise
- Regulatory Compliance & Quality Assurance: Audits & Inspections

Instructors

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

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

Sonja Cooper, Ph.D., M.B.A.

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

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

Elizabeth Weeks-Rowe, LVN, C.C.R.A.

Course Dates and Times

March 24-26, 2025
9:00 a.m. – 4:00 p.m. Eastern
Online via WebEx
Course #: SCOA0325
$1,795 by February 28
$1,995 after February 28

June 24-26, 2025
12:00 p.m. – 7:00 p.m. Eastern
Online via WebEx
Course #: SCOD0625
$1,795 by May 30
$1,995 after May 30

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#: 0778-0000-25-019-L99-P. Released: 3/25.

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)

Instructor

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

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

Course Dates and Times

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

- Overview of Drug/Device Development Process for FDA Regulated Studies
- An Introduction to Design and Conduct of Clinical Trials
- Research Ethics and Informed Consent
- Clinical Trial Protocol Requirements
- Types of Observational Studies
- The Basics of Prospective Design
- Selecting a Study Population
- Safety Monitoring for Clinical Trials

Day Two

- Statistical Considerations in Design and Analysis of Clinical Research Studies
- Systemic and Random Errors, Bias and Confounding, Test Qualities
- Fundamentals of Trials with Medical Devices
- Requirements for Biologics License Application (BLA)
- Special Designation Status (Multi-Center, Orphan Designation, Fast-Track)
- Post-Marketing Studies
- Quality by Design (QbD), Risk-Based Monitoring (RBM), Quality Risk Management (QRM), and Key Performance and Quality Indicators (KP-QIs)

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., T.I.A.C.R

Course Dates and Times

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Accreditation

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Course Outline

Day One

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

Developing Clinical Study Budgets

Course Description

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

Learning Objectives

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

Instructors

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

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

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

Who Should Attend

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

Interactive Activities

- Core Concepts
- Case Study

Course Dates and Times

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

- Protocol Dissection Techniques: Assessing protocol feasibility; determining resource needs
- Negotiation Considerations: Identifying negotiable items; performance-based contracts; payment schedules
- Developing the Study Budget: Identifying line items; accounting for the site's time; fee for service, fixed and fixed-unit pricing structures; case study
- Technology to Enhance the Budget Development Process
- Protocol Dissection Techniques: Using spreadsheets; clinical study software programs
- Tracking Payments and Financial Reports: Accounting systems; tracking and managing payments; financial reports

Developing CRAs as Site Study Managers

Course Description

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

Learning Objectives

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

Instructor

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

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

Course Dates and Times

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Accreditation

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Course Outline

Day One

- Introductions
- The CRA as a Study Manager
  - Regulatory Guidance Documents and Updates: Discussion, Overview and Knowledge Checks
  - Risk Based Monitoring: Discussion and Overview
  - Case Study on 1572: Hands on Activity
- Proactive Site Management: Managing Challenging Situations
  - "Red Flag" Identification: Hands on Activity
- Communicating Effectively with Investigators
  - Definition of Roles and Responsibilities: Hands on Activity
  - Conversation Techniques: Hands on Activity
- Adult Learning and Development Techniques
  - Techniques That Enhance Learning: Hands on Activity
  - Trainer Tips and Checklists: Tool review

Day Two

- Review of Building Blocks from Day One
- Root Cause Analysis and Corrective/ Preventive Action Planning (CAPA)
  - RCA Exercise: Team Exercise
- Recruitment and Retention
  - Enrollment Potential Evaluation: Discussion
  - Recruitment Action Plan Review and Discussion
- Monitoring Plans
  - Development and Prioritizing: Discussion
- Project Management: Tools, Techniques and Practice
  - Tool Review, Development Strategies and Discussion

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

Course Outline

Day One

- Training and facilitation in clinical research
- Adult learning principles and styles
- Successful training techniques
- Facilitation skills
- Optimizing the learning environment
- Methods to manage the learning environment and challenging situations

Instructor

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

Course Dates and Times

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

Accreditation

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

Drug 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

Instructor

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

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.

Course Dates and Times

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

- 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

- 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:

"The trainer is an exceptional instructor. He made training items practical and easy to learn and apply in real-life situations."

Drug Safety and Pharmacovigilance: Effective Drug Safety Reporting and Surveillance

Course Description

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

Learning Objectives

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

Instructor

Indu Kayarat

Course Dates and Times

March 17-18, 2025
12:00 p.m. – 7:00 p.m. Eastern
Online via WebEx
Course #: SSVD0325
$1,675 by February 21
$1,875 after February 21

June 2-3, 2025
9:00 a.m. – 4:00 p.m. Eastern
Online via WebEx
Course #: SSVB0625
$1,675 by May 9
$1,875 after May 9

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#: 0778-0000-24-056-L99-P. Released: 10/24.

Course Outline

Day One

- 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/EMA; serious ADR; unlabeled or unexpected ADR; expectedness "listed" vs. "unlisted"; severity/intensity; lack of efficacy; pharmacovigilance
- Global Regulatory References and Expectations: Global regulations addressing safety (ICH, CIOMS, FDA and EU)
- Regulatory Reporting: Expedited reporting timelines; aggregate reports and timelines

Day Two

- PV Audits and Audit Issues: Regulatory inspections; preparation, problems and issues; checklists; ADR; inspection principles; inspection results; potential regulatory actions
- Signaling: What is safety signal; safety signal generation; definition; pharmacovigilance process; risk/benefit; situations for signal detection; sources of signals; analysis and investigation of a signal; understanding safety signals; suspected signals, risk assessment
- Characteristics of a Good Case Report: How to do a narrative evaluation for follow-up; active query; investigator's brochure; safety; interim update for investigators; FDA time/report obligations; regulatory reporting and notification
- Risk Management: Understanding Risk Evaluation and Mitigation Strategy (REMS) and Risk Management Plans (RMP)

What Participants Say About Barnett Seminars:

"This seminar is a 'must' for anybody working in clinical development."

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

Instructor

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

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 Outline

Day One

- Writing Basics
- Overview of the Protocol Requirements
- Building the Protocol

Day Two

- Building the Protocol, cont.
- Past precedence and approved labels
- Constructing protocol based on research
- Informed Consent Form
- Case Report Forms
- Protocol Amendments

Course Dates and Times

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

Accreditation

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

Facilitation Skills for Clinical Research Team Leaders

Course Description

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

Learning Objectives

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

Instructors

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

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

Kirsten Morasco, B.S.

Who Should Attend

- Sponsor/CRO Team Leaders
- Clinical Research Associate Managers
- Project Managers

Interactive Activities

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

Course Outline

Day One

- Introduction to Facilitation
- The facilitative mindset
- The role of the facilitator
- Facilitator responsibilities
- The Facilitative Process
- Story Share: Pain points and facilitation war stories
- Plan the Meeting: Best practices techniques and tools
- Open the Meeting: Best practices techniques and tools
- Conduct the Meeting Using the
- Facilitation Framework: Best practices techniques and tools, managing the process, managing the participants
- Close the Meeting: Best practices techniques and tools

Course Dates and Times

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

Accreditation

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

FDA Meetings 101: How to Hold a Successful Meeting with Regulatory Agencies

Course Description

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

Learning Objectives

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

Instructor

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

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

Course Outline

Day One

- 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.

Course Dates and Times

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

Accreditation

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

FDA Inspection Readiness: Clinical Investigators

Includes R3 Updates

Course Description

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

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

Learning Objectives

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

Instructor

Elizabeth Ronk Nelson, M.P.H.

Who Should Attend

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

Interactive Activities

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

Course Outline

Day One

Regulatory Inspections of Clinical Investigators

- The standards
- Logistics and pre-inspection activities
- Clinical Investigator inspections
- Post inspection
- Case study

Course Dates and Times

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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.

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!"

FDA Inspection Readiness: Sponsors and CROs

Includes R3 Updates

Course Description

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

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

Learning Objectives

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

Instructor

Elizabeth Ronk Nelson, M.P.H.

Who Should Attend

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

Interactive Activities

- Inspect sample records from the sponsor/CRO using the same techniques as the FDA

Course Outline

Day One

Regulatory Inspections of Sponsors/CROs

- The standards
- Logistics and Pre-inspection activities
- Sponsor/CRO inspections
- Post inspection
- Case study

Course Dates and Times

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.

Fundamentals of Drug Development and the Conduct of Clinical Trials

Course Description

This course provides an introduction to the scientific, ethical and regulatory aspects of clinical research. Topics include basic principles and current methodologies used in the drug development field and the conduct 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. The recent ICH GCP E6 R3, and ICH E8 addendums and their impact on conduct of clinical trials are discussed, and all aspects of the development of a study protocol are addressed, including criteria for the selection of participants, assignment of study treatments, endpoints, randomization procedures, adverse event reporting, risk-based quality assurance approach and protocol compliance monitoring. The ethical issues that arise at each phase of new biomedical product development are also explored.

Learning Objectives

- Discuss the role of regulatory bodies in drug development
- Review recent revisions of ICH GCP E6 and E8 guidelines and their impact on the design and conduct of clinical trials
- Explain the logistics of the drug development process
- Provide an overview of regulations and guidance documents for drugs and biologics submissions
- Discuss content and requirements for the Investigational New Drug (IND) Application
- Review fundamentals of clinical trial structure and design, including Phases I-IV clinical studies
- Identify scientific and practical issues associated with the planning of a clinical research study

Instructor

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

Who Should Attend

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

Interactive Activities

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

Course Dates and Times

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

- Module 1: Drug Development Process, Requirements and GCP Compliance: The drug development process for FDA regulated studies; clinical trial regulatory requirements for drugs and biologics; overview of regulatory requirements to plan, initiate and execute a clinical trial; GCP compliance to ensure ethical and procedural conduct of clinical trials to produce high-quality data
- Module 2: Clinical Trial Design and Study Population Considerations: Developing clinical trial/fundamental principles of prospective design; selecting a study population and providing patient centric solutions in study protocol design
- Module 3: The Investigational New Drug Application: Transition from pre-clinical to clinical phase of drug development; review the Investigational New Drug (IND) content and application process for human testing of drugs and biologics

Day Two

- Module 4: Safety Monitoring, GCP Regulations, Ethics and Informed Consent: Data Safety monitoring committees (DSMBs), integrated safety summaries; safety reporting and requirements; Institutional Review Boards (IRBs); ethical considerations and responsibilities of the parties involved in clinical research; research ethics and informed consent implementation and the responsible conduct of research; overview of required and optional elements of the Informed Consent Form (ICF) according to current FDA, and recent GCP ICH E6 R3 and E8 regulations revisions
- Module 5: Transition from Clinical Research to Practice: Requirements for a New Drug Application (NDA) and Biologic License Application (BLA) content and regulatory process; key aspects of transition from clinical research to clinical practice; Biologics License Application (BLA) and regulatory requirements for safety and efficacy assessments to be addressed in the study design for biologics
- Module 6: Assurance of Compliance and Quality in Clinical Research: Review of Industry Gold Standards; Quality by Design (QbD) principles and Risk-Based Monitoring; applying a Quality Risk-Management (QRM) approach in development of relevant Key Performance and Quality Indicators (KP-QIs) based on recent ICH GCP revisions

Good Clinical Practice for the Laboratory Scientist

Includes R3 Updates

Course Description

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

Learning Objectives

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

Who Should Attend

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

Interactive Activities

- Group activities: Situational reviews of practical scenarios
- Critique of current FDA Warning Letters
- Group discussions

Course Outline

Day One

- Overview of the drug development process
  - Discovery through post-market
- Working in a regulated environment
  - Definitions of GLP, GCP, and GMP
  - Global regulatory authorities – mission and responsibilities
  - Regulations – U.S. (Code of Federal Regulation); ex-U.S. (International Council for Harmonization – ICH GCP E6 Guideline; EU Directive); forgotten elements
- Fundamentals of GLP, GCP and GMP
  - Non-clinical testing (GLP) – elements and examples of non-compliance
  - Clinical research (GCP) – elements, sponsor responsibilities, examples of non-compliance
  - Investigational product manufacture (GMP) – elements and examples of non-compliance
- Quality Management of GCP Laboratories
  - Laboratory Quality System identification
  - Qualifications
  - Outsourcing
  - Accreditation
  - Challenges with global studies

Instructor

Shelia Russell McCullers, M.S., D.M.

Course Dates and Times

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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.

What Participants Say About Barnett Seminars:

"Up-to-date teaching by an excellent presenter."

How to Write Great SOPs and Work Instructions

Course Description

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

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

Learning Objectives

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

Instructors

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

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

Kirsten Morasco, B.S.

Who Should Attend

- Authors and Reviewers of SOPs and Work Instructions

Interactive Activities

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

Course Outline

Day One

- What is an SOP?
- Methodology for Developing SOPs
- Components of an SOP
- Dos and Don'ts of SOP Writing
- What is a Work Instruction?
- Methodology for Developing Work Instructions
- Components of a Work Instruction
- Dos and Don'ts of Work Instruction Writing

Course Dates and Times

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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.

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

Instructor

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

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

Course Dates and Times

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Accreditation

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Course Outline

Day One

- 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

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

Instructor

Denise Redkar-Brown, MT

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

Course Dates and Times

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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Course Outline

Day One

- 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

- 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

Introduction to Clinical Research

Includes R3 Updates

Course Description

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

Learning Objectives

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

Instructors

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

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

Sonja Cooper, Ph.D., M.B.A.

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

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

Elizabeth Weeks-Rowe, LVN, C.C.R.A.

Who Should Attend

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

Interactive Activities

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

Course Outline

Day One

- The Evolution of Research Ethics
- Good Clinical Practice
- Investigational Product Development
- Clinical Research Team

Day Two

- Elements of a Good Clinical Study
- Informed Consent and Confidentiality
- Clinical Trials and Safety Information
- Audits and Inspections

Course Dates and Times

March 27-28, 2025
9:00 a.m. – 4:00 p.m. Eastern
Online via WebEx
Course #: SC2A0325
$1,675 by February 28
$1,875 after February 28

June 4-5, 2025
12:00 p.m. – 7:00 p.m. Eastern
Online via WebEx
Course #: SC2D0625
$1,675 by May 9
$1,875 after May 9

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#: 0778-0000-24-004-L99-P. Released: 3/24.

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

Course Outline

Day One

- Federal Regulations for Investigator-Initiated Trials (IITs)
- GCPs and the Principles Involved in Quality Research
- Steps Involved in Initiating an IIT
- Regulatory Reporting, including Safety and Investigational Product Accountability
- Protocol Development and Compliance
- Informed Consent Development and HIPAA Authorization
- Essential Documentation
- Adequate Monitoring
- Ways to Minimize Risks Associated with IITs
- Regulatory Deficiencies – FDA Warning Letters
- Principles of Ethics and Quality Control Process

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Dates and Times

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

Accreditation

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

In Vitro Diagnostic Devices: Study Design, Conduct, Regulatory Requirements and Submissions for Approval

Course Description

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

Learning Objectives

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

Instructor

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

Who Should Attend

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

Interactive Activities

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

Course Dates and Times

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

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

Day Two

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

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

Instructor

Elizabeth Ronk Nelson, M.P.H.

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.

Course Dates and Times

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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.

Course Outline

Day One

- 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

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

Medical Device GCP Overview

Includes R3 Updates

Course Description

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

Learning Objectives

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

Instructor

Elizabeth Ronk Nelson, M.P.H.

Who Should Attend

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

Interactive Exercises

- Clinical and Data Management Discussions
- Review of Regulatory Documents

Course Outline

Day One

- Medical Device and Good Clinical Practices
- Medical Device and Regulatory Requirements
- Clinical Research Team: Roles and Responsibilities

Day Two

- 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 Times

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.

Medical Terminology for Clinical Research Professionals

Course Description

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

Learning Objectives

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

Instructors

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

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

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.

Course Outline

Day One

- Overview of medical terminology from a body system approach
- Break down medical terms into the core elements: prefix, suffix, and root words
- Combining forms: Learn to take a root word and a prefix or suffix with a combining vowel to form a medical term
- Discussion of body systems, basic anatomy, and disease states

Day Two

- Continue the discussion of body systems, basic anatomy, and disease states
- Simulation: review of sample patient records to determine subject eligibility for a trial, and identify adverse events and serious adverse events

Course Dates and Times

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.

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

Instructor

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

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)

Course Outline

Day One

- Basic Skills: Industry standards for formatting, abbreviations, tables, figures, captioning, linking, fonts
- Styles and Templates: How to make styles work for you, template generation and use
- Style Guides: What are they? Why have one?
- Literature Searches: Practical methods for completing a literature search, understanding when to do it
- Communication: Keys to successful document review and finalization

Course Dates and Times

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.

Blended Curriculum Course

Monitoring Clinical Drug Studies: Beginner

Course Description

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

Learning Objectives

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

Instructors

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

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

Sonja Cooper, Ph.D., M.B.A.

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

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

Elizabeth Weeks-Rowe, LVN, 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

Course Outline

Day One

- Overview of Drug Development and ICH GCP: Terminology; the drug approval process
- The Clinical Research Team: Roles and responsibilities
- The Site Selection Process and Site Qualification Visits: Locating, screening, and evaluating prospective investigators; selection criteria

Day Two

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

Day Three

- Routine Monitoring Visits and Source Data Verification: Preparing for, during the visit, and post visit activities; process for reviewing source documents and identifying discrepancies
- Clinical Data Management Overview, Trip Reports, and Study Close-out Visits: Paper-based and electronic case report forms, queries, and conducting close-out visits
- Monitoring Simulation Exercise: Regulatory Binder and Source Data Verification

Course Dates and Times

March 17-19, 2025
12:00 p.m. – 7:00 p.m. Eastern
Online via WebEx
Course #: SSBD0325
$1,795 by February 21
$1,995 after February 21

June 4-6, 2025
9:00 a.m. – 4:00 p.m. Eastern
Online via WebEx
Course #: SSBB0625
$1,675 by May 9
$1,875 after May 9

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#: 0778-0000-23-029-L99-P. Released: 3/23.

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.

Blended Curriculum Course

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, monitoring plan development best practices, and successful time management. Discussion will include how sponsors/CROs interpret and implement various aspects of clinical trials and GCP principles.

Learning Objectives

- Describe various sponsor interpretations of FDA regulations and practical application of the ICH GCP E6 Guideline
- Discuss current trends in clinical research
- Evaluate and develop more efficient study tracking and management tools
- Identify more effective mentoring and CRA assessments
- Manage your sites more effectively and ensure their optimum performance
- Identify strategies for managing issues including root cause analysis and corrective and preventive action plans (CAPA)
- Develop effective monitoring plans and best practices
- Prepare sites for an FDA/Regulatory Authority inspection
- Describe how FDA/Regulatory Authority assess sponsor monitoring during inspections

Who Should Attend

- Experienced Clinical Research Associates and Medical Research Associates with more than two years of experience seeking to update their knowledge of the GCP regulations and guidelines and fine tune their site management and monitoring skills
- Clinical Research Professionals involved in the management of Clinical Research Associates, and/or study/project management

Interactive Exercises

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

Course Outline

Day One

- Regulatory Recap and Update: Application of GCP: FDA regulations, guidance documents and the ICH GCP E6 Guideline
- Monitoring and CRA Assessment, Monitoring Tools and Tracking Systems: Best Practices
- Successful Site Management: Influencing without authority, analyzing site performance problems; exploring root causes; corrective and preventive action plans (CAPA)

Day Two

- Monitoring Plan Development and Best Practices
- Problem Solving and Prioritizing Monitoring Challenges: Monitoring simulation
- FDA Inspections and Site Preparation: Mechanics of an FDA inspection, FDA classifications, common deficiencies, possible restrictions, tips for helping sites prepare for an FDA inspection

Instructors

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

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

Sonja Cooper, Ph.D., M.B.A.

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

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

Elizabeth Weeks-Rowe, LVN, C.C.R.A.

Course Dates and Times

March 20-21, 2025
9:00 a.m. – 4:00 p.m. Eastern
Online via WebEx
Course #: SSIA0325
$1,675 by February 21
$1,875 after February 21

June 11-12, 2025
12:00 p.m. – 7:00 p.m. Eastern
Online via WebEx
Course #: SSID0625
$1,675 by May 16
$1,875 after May 16

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#: 0778-0000-24-005-L99-P. Released: 3/24.

Monitoring Clinical Drug Studies: Advanced

Course Description

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

Learning Objectives

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

Instructors

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

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

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

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

Elizabeth Weeks-Rowe, LVN, C.C.R.A.

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

Course Outline

Day One

- Regulatory Update: The latest FDA Guidances 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

Day Two

- Managing Stakeholders: Developing and communicating realistic expectations; reaching stakeholder agreement
- 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

Course Dates and Times

March 31- April 1, 2025
12:00 p.m. – 7:00 p.m. Eastern
Online via WebEx
Course #: SSAD0325
$1,675 by March 7
$1,875 after March 7

June 17-18, 2025
9:00 a.m. – 4:00 p.m. Eastern
Online via WebEx
Course #: SSAB0625
$1,675 by May 23
$1,875 after May 23

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#: 0778-0000-24-006-L99-P. Released: 3/24.

Monitoring Oncology Clinical Trials

Course Description

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

Learning Objectives

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

Who Should Attend

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

Interactive Activities

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

Course Outline

Day One

- Oncology Sites and Infrastructure for Monitors
- Ethical Considerations in Oncology Clinical Trial Monitoring
- Managing Investigational Products and Dosing in Oncology Clinical Trials
- Adverse Event Management and Reporting in Oncology Clinical Trials

Day Two

- Tumor and Disease Progression Assessments for Monitors
- Laboratory and Biomarker Management for Monitors
- Source Data Verification in Oncology Clinical Trials
- Monitoring Tools and Best Practices in Oncology Clinical Trials

Instructor

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

Course Dates and Times

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.

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

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

Who Should Attend

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

Instructor

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

Course Dates and Times

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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.

Course Outline

Day One

FDA Division Information

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

Publishing the Submission

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

Tracking the Submissions

- Creating the index history
- Creating an issues log

Day Two

- Common Technical Document Format

Pre-Market

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

Marketing Application

- NDA in a CTD Format

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

Instructor

Denise G. Redkar-Brown, MT

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

Course Dates and Times

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

- Protocol review, CRFs. and the DMP.
- Activity Discussion: Queries Gone Wrong
- Examine the DMP for the edit checks and output messages.
- Activity
- Examine whether there is a CRF for each item listed on the Schedule of Events (purposely some will be missing)
- Identify any items you consider missing. How do the CRFs for this study differ from those used in your company?
- Queries to definition, elements of a good query, examples of queries.
- Discussion
- Using self-evident corrections is not always self evident. Does your company use self-evident corrections? What are some examples of self-evident corrections? How do you manage self-evident corrections with the investigator?
- Query Resolution and Database Updates
- Part 1: From previous activity, for each discrepancy not matched to the edit check appendices, create a query based on the elements of a "good query."
- Part 2: Review your partner's queries as if you are at the study site. Are these queries easy to understand? Identify whether each is clear, ambiguous, or impossible? Describe the data you would send based on each query. Propose rewording ambiguous or impossible queries.

Regulatory Intelligence 101

Course Description

The regulatory environment is constantly shifting and changing. This dynamism necessitates keeping abreast of current information from a variety of sources. Regulatory Intelligence (RI) is the act of gathering and analyzing regulatory information for impact or changes in laws, regulations, directives, guidance documents, etc. There is more to regulatory intelligence than keeping up with the latest regulations and guidelines. Regulatory precedence, industry practices, regulatory agency opinions, and competitor information are just a few of the valuable sources of information that can help regulatory affairs professionals to develop successful regulatory strategies.

The monitoring and gathering of RI will ultimately culminate in developing a regulatory strategy which can result in decreased time to approval; potentially decreased cost of product development through strategizing risk based on current information; and maximization of target market(s). As more companies are conducting trials and filing marketing applications worldwide, the need to keep abreast of worldwide regulatory information is crucial as a change in the global landscape can affect the global regulatory strategy. RI allows a regulatory professional to determine requirements for conducting global clinical trials, meet manufacturing requirements, advise personnel, answer strategic regulatory questions, and write or construct a global marketing application.

This class examines the scope of regulatory intelligence which encompasses: identifying information sources; monitoring the regulatory landscape (periodic versus ongoing); using an RI database and other sources to research the regulatory question; summarizing, analyzing, integrating, and presenting RI; and discussing implementation choices – with in-house staff, consultants, information services, or a mixture thereof – and the advantages/disadvantages of each choice. Hands-on class exercises help participants gain experience using a regulatory intelligence database to search and summarize regulatory intelligence information.

Learning Objectives

- Discuss what Regulatory Intelligence is and why it is important to companies
- Identify multiple sources of Regulatory Intelligence
- Evaluate the constantly changing regulatory landscape
- Evaluate a regulatory research question into researchable units, and conduct the research using a Regulatory Intelligence Database
- Summarize and present Regulatory Intelligence findings back to a team
- Describe how to archive and store RI
- Apply and integrate Regulatory Intelligence to current company practices and global regulatory strategy

Instructor

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

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

Course Outline

Day One

- What is Regulatory Intelligence (RI), regulatory information and sources of RI
- How RI is conducted at large, medium, and small drug, biologic, and medical device companies
- How RI differs at each stage of product development
- Using Regulatory consultants to conduct RI and what to expect
- How to break down regulatory research questions down into researchable components
- How to conduct regulatory research using the internet and an RI database
- How to compile, analyze, and summarize regulatory information
- Storage and archiving RI

Course Dates and Times

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.

Regulatory Strategy 101

Course Description

Drug development is getting more expensive by the year and a sound regulatory strategy can make or break a drug or biologic's ability to initiate and support clinical trials or obtain marketing approval. Knowing what to research, review, negotiate and include in the regulatory strategy differs by company; however, basic requirements include:

- Target product profile/draft package insert
- Past precedence review
- Clinical endpoints
- Competitor label analysis
- FDA interactions planning

As a regulatory professional develops their skill set, knowing how to create and implement a regulatory strategy is critical to career advancement. This session will walk participants through a case study for a hypothetical Type 2 Diabetes drug that has just been developed and the process of creating a regulatory strategy. The session will:

- Define regulatory strategy
- Provide an overview of regulatory strategy elements, by phase of development and discipline
- Illustrate how to research and pull together a strategy
- Planning regulatory strategy in Phase 1, Phase 2 and Phase 3
- How to adapt and update a strategy as information changes

Participants will walk away with a strategy toolbox they can immediately apply to their jobs.

Learning Objectives

- Identify the elements of regulatory strategy
- Understand the questions that need to be addressed when developing a regulatory strategy, by phase and discipline
- Locate and use available tools that can aid in developing regulatory strategy
- Summarize the data and perform strategic analysis once the data is identified
- Determine the output and format of strategic information after analysis into a "playbook"

Instructor

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

Who Should Attend

- Mid-level regulatory professionals who have 3-5 years of regulatory experience and are looking to learn the "next level" of regulatory, beyond submission preparation
- Any other drug development team member that would like to learn more about regulatory strategy

Interactive Activities

- Using a mock indication and regulatory intelligence tools, research sections of the regulatory strategy
- How to use templates to summarize components of the strategy
- How to formalize regulatory's portion of the strategy into a "playbook"

Course Dates and Times

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

- 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

- Identify and become familiar with industry regulations and guidelines relating to report writing
- List the rules for writing an effective report
- Identify the steps in effective report writing
- List the essential content of the four major types of monitoring visit reports
- Define the report mapping process relating to action item identification, documentation and 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

Instructor

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

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

Course Dates and Times

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Accreditation

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Course Outline

Day One

- Report Writing Roots and Mandates: FDA requirements regarding monitoring, record and report keeping; ICH GCP E6 Guideline for monitoring visit reports and non-compliance
- 10 Rules of Effective Report Writing: Application of good report writing practices; steps in report writing: before, during, after
- Approaches to Report Writing: Objective vs. subjective, choice of tense & voice, use of abbreviations, fragments vs. full sentences, proper use of bullets, etc.
- Remember Who Your Audience Is: Who reviews and has access to monitoring reports
- Always Be Ready if Abducted by Aliens: Designing reports to be independent of author to smoothly handle staffing changes and/or temporary stand-ins
- The Mapping and Flow of Reports: Each report depends on one another; reports and follow-up letters correlation; contact reports; mapping to action item resolution
- The Major Types of Monitoring Reports: Evaluation, initiation, interim, closeout, combos and abbreviated
- Use of References to Support Report Claims: Documentation of protocol sections and past correspondence, etc.
- Answering the Question Right and Answering the Right Question: Comment when needed; make it mean something; document teaching and re-instruction; document what was accomplished and what was not
- Compliance Plans: Development, agreement, and success!
- Industry Standards: Best practice; goals and content of industry monitoring reports; regulatory authority use of report content

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."

Risk-Based Monitoring: Successful Planning and Implementation

Course Description

A fundamental shift has occurred in the clinical research industry related to how sponsors satisfy their regulatory and GCP requirements for the adequate monitoring of clinical trials. Recent regulatory authority guidance and industry initiatives have promoted a modern approach to clinical trial monitoring based upon program and study-specific risk assessments and mitigation plans. In order for clinical research professionals to embrace this industry shift, it is critical that they understand the rationale, concepts, and actual work practices inherent in risk-based monitoring.

This course is designed for clinical research professionals across the spectrum of research organizations, investigational product types, and experience levels. Participants will acquire a deeper understanding of the philosophy of risk-based monitoring and be able to apply this understanding to operational activities including the following:

- Performing program and study-level risk assessments and managing risks
- Writing a risk-based Monitoring Plan
- Designing reports and metrics for central monitoring activities
- Supporting Clinical Research Associates for success in the new monitoring environment
- Preparing Investigators and site personnel for risk-based monitoring

Learning Objectives

- Compare and contrast risk-based monitoring with a traditional monitoring approach
- Identify program and study-level monitoring risks
- Develop a monitoring plan which focuses on mitigating risks at both the program and study levels
- List the activities, responsibilities, and outputs of Clinical Data Management in risk-based monitoring
- Describe approaches and techniques for central/remote monitoring and data review
- Predict changes for Investigators/sites as a result of wider adoption of risk-based monitoring

Instructors

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

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

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

- Risk-Based Monitoring: Regulatory authority guidance, ICH GCP E6 Guideline, 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

Course Dates and Times

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

Accreditation

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

Risk Management/Risk-Based Quality Management for Clinical Trials Certification Program

Course Description

Are you prepared for Quality Risk Management (QRM), Risk Management (RM), Risk-Based Quality Management (RBQM)? With the finalization of ICH GCP E6 (R3) in January 2025, risk-based approaches to managing quality in clinical trials is a requirement. This course takes you through how to execute the requirements in Section 3.10 (Quality Management) and how to review tools while discussing hands-on experience with various risk management programs.

This course focuses on all the critical elements for clinical trial sponsors and CROs included in the final version of ICH GCP E6 (R3) , while highlighting key points from other regulatory bodies such as ISO 31000 Risk Management. Further, this course reviews each step of risk identification, assessment, control, review, reporting, management, and communication. Having an effective Risk Management program not only ensures compliance with ICH GCP E6 (R3) requirements, but also ensures continuous improvement strategies for your clinical trials.

Learning Objectives

- Describe the expectations of QRM in relation to the ICH E6 (R3) updates
- Discuss how to analyze risks and develop a risk register
- Describe how to use multiple risk analysis tools
- Describe how to formulate risk mitigation strategies

Instructor

Susan M. Leister, M.B.A., Ph.D., CQA, CSSBB

Who Should Attend

- Quality Control/Assurance Professionals
- Regulatory Affairs Professionals
- Clinical Research/Operations Personnel
- Information Technology/Security Personnel
- Data Managers
- Study Managers
- Project Physicians/Medical Monitors
- Pharmacovigilance Professionals
- Biostatisticians

Interactive Activities

- Knowledge Checks
- Group Discussions
- Case Studies
- Group Exercises

Course Dates and Times

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Accreditation

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Course Outline

Day One

- Quality Risk Management: Describe Quality Risk Management/Risk Management (ICH GCP E6 (R3) & ISO 31000); Discuss establishing a Risk Management Policy/ Program and Accountability considerations
- Risk Management Plan and Culture: Describe the framework for communicating risk within an organization/program; Discuss communication strategies and challenges for risk stakeholders
- Risk Identification: Describe how to identify risks and when to start; Describe protocol level risks; Discuss the use of a risk register (risk log) for tracking risks
- Risk Evaluation: Describe the likelihood, impact, extent and detection of error; Discuss risk priority number values

Day Two

- Risk Analysis Tools: SWOT (Strength, Weakness, Opportunities, Threats); Root Cause Analysis and affinity diagrams
- Risk Control: Discuss developing risk mitigation strategies, options and priority rankings; Discuss internal and external stakeholders and their impact; Describe escalation processes and plans

Day Three

- Risk Communication: Discuss how to document risk mitigation plans in the risk register/log
- Risk Review: Describe the need for periodic review and when a risk is closed or when it needs further mitigation; Discuss how to detect change and emerging risks (what clinical data to look at)
- Risk Reporting: Discuss risks, deviations, and predefined quality tolerance limits; Requirements for the Clinical Study Report, Discuss access to risk management documents, retention and the value of lessons learned/ continuous learning approach

Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) in Site Management

Course Description

Managing investigator noncompliance in the research industry is critical to successful clinical trials. Regulatory authorities expect that all stakeholders identify noncompliance, correct the noncompliance through intervention, and evaluate the effectiveness of the intervention. Root cause analysis provides a process through which issues can be accurately identified and interventions can be effectively designed. The corrective action process including, when appropriate, preventive action planning, should be implemented when RCA has been completed. An effective CAPA process can lead to improved human subject protections and confidence in the integrity of the data. Lack of effective corrective action management can lead to repeated noncompliance, compromised subject safety, poor data quality, and/ or unacceptable inspection findings with subsequent negative impact on the final submission. This course focuses specifically on the management of noncompliance issues occurring at investigative sites.

Learning Objectives

- Define investigator and site noncompliance
- Describe performance management concepts and skills for effective site risk management
- Integrate prevention of performance issues and ensure adequate site issues management
- Implement Gilbert's Behavioral Engineering Model for a diagnostic root cause analysis process
- Apply performance management concepts in case studies with a focus on prevention and issues management
- Recognize components of effective corrective action planning and documentation
- Identify examples of corrective action planning for different site noncompliance case scenarios
- Discuss successful preventive action planning and implementation

Instructors

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

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

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

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

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

Course Outline

Day One

- 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

- 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

Course Dates and Times

March 18-19, 2025
9:00 a.m. – 4:00 p.m. Eastern
Online via WebEx
Course #: SRCA0325
$1,675 by February 21
$1,875 after February 21

June 12-13, 2025
12:00 p.m. – 7:00 p.m. Eastern
Online via WebEx
Course #: SRCD0625
$1,675 by May 16
$1,875 after May 16

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#: 0778-0000-24-057-L99-P. Released: 10/24.

Soft Skills Development for Clinical Research Professionals

Course Description

In an environment that is ever changing with organizational mergers, role revisions, and an emphasis on risk-based oversight approaches, the need for better communication skills and comfort with change is essential. It is during these times of change that leaders emerge. What are the skills that differentiate a leader? The aim of this course is to present the concept of the Highly Effective Clinical Research Professional as a model for transforming the way you work. In this two-day course that is jam-packed with interactive activities, knowledge sharing and practical tips you can start doing right away, you will identify and utilize soft skill techniques which will increase your effectiveness with key stakeholders and advance and develop your skills as Clinical Research Professionals.

This course also includes a Myers-Briggs Type Indicator component, enabling participants to increase their self-awareness and reduce instances where they might take things personally.

Learning Objectives

- Identify best practices planning strategies and evaluate my priorities
- Utilize active listening techniques to build relationships and increase my effectiveness at work
- Increase self-awareness through discovery of my communication preferences and use that knowledge to increase my interpersonal communication effectiveness
- Utilize conflict management techniques
- Identify professional behaviors and explain why they are considered "professional"
- Describe the mindset and behaviors of professionals who demonstrate accountability
- Describe the Positive Change Curve
- Identify the 4 People Needs of change management
- Identify why a clinical research team may not be collaborating and employ techniques to foster collaboration and alignment

Instructor

Holly J. Deiaco-Smith, MS

Who Should Attend

- Investigators
- Study Coordinators
- Site Managers
- Project Managers
- General Managers
- Project and Department Leads
- Clinical Research Associates
- Regulatory Managers
- Clinical Trial Assistants

Interactive Activities

- Your True North
- Proactive or Reactive?
- A Day in Your Life as a Clinical Research Professional
- What's Going On?
- MBTI Refresh
- Increasing Awareness of Communication Preferences
- Sticky Situations
- Accountable Behavior? You be the Judge.
- Professional Behavior? You be the Judge.
- Discovering My Change Needs

Course Outline

Day One

- Introduction: The Imperative for Soft Skills
- Module 1: Great Planner
  - Your True North
    - Being Deliberate
    - Prioritization
    - Time Management
    - Proactive Language
- Module 2: Great Communicator
  - Active Listening – a Leader's Most Powerful Tool
  - Increasing Self-Awareness
  - Addressing Conflict

Day Two

- Day 1 Refresher
- Module 3: Great Professional
  - Pride & Professionalism
- Module 4: Great Leader
  - Accountability – Mindset & Behaviors
  - Change Management
  - Team Development

Course Dates and Times

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.

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

Instructor

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

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

Course Dates and Times

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

- 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

Blended Curriculum Course

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 advanced statistical formulas or computations. An understanding of basic algebra is required as application of some basic statistical formulas will be conducted.

Learning Objectives

- Determine what information the statistician needs to determine the sample size
- Identify the appropriate sample statistical designs for a study
- Employ statistical terms used in clinical research
- Define the role of the statistician in the study design
- Determine the approach to become comfortable talking to statisticians

Instructor

Misha Eliasziw, Ph.D.

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

- Constructing Confidence Intervals
- Creating and Testing with Real Data Individual and Group Hypotheses
- Calculating Sample Sizes and Study Power

Course Outline

Day One

- Elements in Choice of Statistical Method Descriptive Statistics: Distributions; mean, median, mode, standard deviation
- Methods for Preserving Objectivity: Blinding; randomization; consequences of violations
- Inference, Generalizing to a Population: Standard error; confidence interval; estimation and prediction
- Study Design: Uncontrolled studies; parallel groups; crossover designs (patient as own control); block designs

Day Two

- Hypothesis Testing: Creating hypothesis from objectives; level of significance, p-values; one-sided versus two-sided; types of errors
- Power and Sample Size: Accuracy of estimates; confidence intervals; testing (effect size and variability)
- Choice of Statistical Method
- Specialized Topics
- Interpreting the Statistical Report

Course Dates and Times

March 20-21, 2025
12:00 p.m. – 7:00 p.m. Eastern
Online via WebEx
Course #: SSTD0325
$1,675 by February 21
$1,875 after February 21

June 2-3, 2025
9:00 a.m. – 4:00 p.m. Eastern
Online via WebEx
Course #: SSTB0625
$1,675 by May 9
$1,875 after May 9

Academic Discount

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

Accreditation

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ACPE#: 0778-0000-24-007-L99-P. Released: 3/24.

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 Times

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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Course Outline

Day One

- Demonstrated Keys to Success for Research Sites: Benchmarking successful site practices; case scenario of the successful research site
- Business Planning: Stakeholder buy-in and support; incorporating; liability insurance; vision and mission statements; objectives and goals
- Site GCP Responsibilities: ICH GCP E6 Guideline; FDA regulations 21 CFR Parts 11, 50, 54, 56; drug/biologic 21 CFR Part 312; device and combinations 21 CFR Parts 3 & 812; other GCPs, state laws and HIPAA; NIH studies, The Common Rule 45 CFR Part 46 Human Subject Protections Government Funded Research; other best practices
- Content of Clinical Research SOPs: Components; training and implementation; measuring compliance
- Staffing: Design of department: facilities and management models; key players; credentialing; national average salaries
- Marketing a Research Site: How; to whom: customers (sponsors, participants and FDA); when; healing a bruised reputation; PR
- Contracts & Budget: Negotiating; contract language; budget components; essentials to include; legal review
- Project Feasibility: What it takes to run a successful study; completing a study feasibility; risk factor analysis and management
- Subject Recruitment: Identifying accurate potential subject numbers; methods and strategies; formal recruitment plans
- Quality Systems and Audit Readiness: FDA inspection program and site deficiencies; quality system components; establishing audit readiness
- Performance Improvement: How to keep your site on top; evaluation and improving never ends; conflict resolution; root cause analysis and effective interventions; changing with the times

What Participants Say About Barnett Seminars:

"Lots of good energy and ideas, kept it interesting the whole time."

Understanding Clinical Data Management for the Non-CDM Professional

Course Description

This course will review Clinical Data Management (CDM) operations as they relate to the conduct of clinical trials. The seminar will begin with an introduction to the regulations that directly impact CDM. From there, it will provide a high level overview of CDM processes and the stages of their execution, allowing clinical research professionals to understand the interconnectivity of CDM with other trial procedures. Study start-up, timeline considerations, metrics generation, and a description of the differences between electronic data capture vs. paper-based studies will also be introduced.

Learning Objectives

- Identify regulatory issues specific to CDM
- Outline the overall CDM study procedures and where they impact other research disciplines
- Explain the considerations for CDM study "start-up"
- Discuss the rationale regarding timeline differences between a paper vs. EDC study
- Describe the Data Management documentation required in clinical trial conduct

Instructor

Denise G. Redkar-Brown, MT

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

Course Dates and Times

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Accreditation

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Course Outline

Day One

- The Regulatory Environment: Overall review of the 21 CFR Part 11 regulations, e-signature requirements for FDA, EU, and Japan as they pertain to CDM
- CDM Processes: Identifying the overall CDM process within clinical trial conduct, and mapping the points of interaction with other clinical trials professionals
- CDM Documentation: What are all of those CDM documents anyway? Examine the documentation required for proper CDM conduct and understand the rationale behind document development
- Study Start-Up, Protocol Synopsis Review, eCRF Development: Examine the CDM activities associated with the study start-up in an EDC or paper CRF environment

Day Two

- CDISC/CDASH: What is it? Why is it important? How does it impact CDM?
- User Acceptance Testing (UAT): How does the application work? How do we test it or try to "break" it?
- Database Lock: Is it really just a push of the button?
- Outsourcing EDC DM Issues: Vendor outsourcing, the evaluation of vendors for total CDM projects or vendor development of eCRFs

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

Treena Jackson, M.S., M.A., C.Q.A., R.A.C., C.S.S.G.B.

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 Dates and Times

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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.

Course Outline

Day One

- 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

- 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

What Participants Say About Barnett Seminars:

"The learning activities were very helpful toward reinforcing concepts in a practical way."

Writing Clinical Evaluation Reports

Course Description

This course will include a review of the Medical Devices (MEDDEV) 2.7.1, Rev 4 guideline issued in June 2016 and a discussion of the Therapeutic Goods Administration (TGA) guideline. In this interactive program, participants will also have the opportunity to share their experiences with Clinical Evaluation Reports (CERs) in general. All devices are required to have a CER for products marketed in the EU and globally. This course will explore good writing skills and techniques needed to create a CER and to respond to reviewer comments.

Learning Objectives

- Summarize the MEDDEV 2.7.1, Rev 4 guideline
- Create a work plan for CER development
- Summarize key CER features evaluated by Notified Bodies
- Use CER template (provided) to complete a CER
- Engage and respond to a critique from an experienced CER reviewer to complete CER

Instructor

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

Who Should Attend

- Project Managers
- Clinical Data Specialists/Analysts/Managers
- Technical Communication Specialists/Medical Writers
- Clinical Affairs Directors
- Clinical Program Managers
- Clinical Nurse Specialists
- Post Market Surveillance Managers
- Clinical Evaluation Report/Reporting Specialists
- Evaluation and Research Directors
- Clinical Education Specialists
- Corporate Librarians
- Regulatory Specialists/Managers

Interactive Activities

- SOP Template and Examples (Review, identify questions or concerns, report to group)
- Current CER/SOP Review (Review, identify questions or concerns, report to group)
- CER Checklist (Review, identify questions or concerns, report to group)
- Notified Body Activities (Review, identify questions or concerns, report to group)
- Literature Searches (Review databases, identify questions or concerns, report to group)

Course Outline

Day One

- Course Materials and Background
- Regulatory Requirements and Guidelines
- Evaluating Data and Telling the Story
- Literature Searching
- Appraising and Selecting Clinical Data - Inclusion/Exclusion Coding

Day Two

- Analyzing Clinical Data
- Writing CER – Technical Components
- Drawing Conclusions – Team/Medical Review
- Notified Body (NB) Review
- Conclusions

Course Dates and Times

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.

BARNETT INTERNATIONAL
Interactive Web Seminars

What Is an Interactive Web Seminar?

Barnett International teams with WebEx™ meeting services to provide you with Interactive Web Seminars. Ask questions, chat, learn from industry leaders, and network with your fellow attendees all from the convenience of your own office. No travel, no travel expenses, and no time away from the office! The resources required are already at your fingertips – an Internet connection and an audio connection (via phone or VoIP).

A Barnett Interactive Web Seminar offers you a seamless, secure, multimedia learning experience. After registering, you will receive an email confirmation that provides you with the web seminar link and audio connection information. You can then participate in the Web Seminar individually or, with most web seminars, as a team. For team training, simply put your phone or headset on speaker and either gather around your computer, or project the seminar to a screen. The live Interactive Web Seminar will enable you to ask questions, provide feedback, and learn the information critical to your business needs. Upon completion, attendance certificates will be provided to all participants.

NOTE: The only exceptions to the web seminar team training are: The Web Seminar Workshop and the online 30-Hour/10-Week, 20-Hour, 18-Hour, 15-Hour, 12-Hour, 10-Hour, and 9-Hour series which are for individual registrants only.

Enjoy the convenience of interactive training without the hassle of travel. Real-time learning at an affordable price — Barnett Interactive Web Seminars!

What Are the Benefits?

- A seamless, secure, real-time multimedia learning experience
- No travel, no travel expenses, and no time away from the office
- Resources required are already at your fingertips — an Internet connection and a phone or headset
- You can ask questions, chat, learn from industry leaders, and network with your fellow attendees, all from the convenience of your own office
- Convenient, customizable learning environment where you will have your specific questions answered
- Learn the information critical to your business needs, when you need it

The Barnett Difference

- Engagement-focused instructional format designed for online learning
- Direct interaction with experienced trainers and subject matter experts
- Learning activities focused on application and information retention
- Availability of course and reference materials
- Accredited content and cost-effective group training

Web Seminar Archives

Unable to attend an Interactive Web Seminar? Archived recordings are available and they will allow you to watch previous Interactive Web Seminars any time you want. Pricing is available for single users and site licenses. See page 203 for more details.

System Requirements:

WebEx offers cross-platform, unmatched support across a wide range of devices. Supported computer operating systems include Windows, Mac, Linux, and Solaris. Browser support includes Internet Explorer, Microsoft Edge, Google Chrome, Mozilla Firefox, and Safari. You can also download the free WebEx Meetings app to your Apple, Android, or Amazon smartphone or tablet. You can always test your system by going to http://www.webex.com/test-meeting.html and following the onscreen prompts.

Registration:

Registration for Web Seminars can be accessed online at www.barnettinternational.com or by calling +1 781.972.5400 or toll-free in the U.S. at 800.856.2556. After registering, you will receive an email confirmation of your purchase, and course access information will be sent prior to the start of class. 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.

NEW! 9-Hour 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 involves more than just writing. It entails strategy, editing, publishing and systematic tracking of key information. Through a blend of lectures, case studies, and hands-on exercises new and experienced regulatory professionals will learn how to navigate the regulations, guidance documents, and style guides to produce submissions that comply with the requirements and are clear to the reviewers.

Approved drug labels and summary basis of approvals are also used to help learners acquire the knowledge and insight needed to understand and construct core U.S. drug and biologics submissions, including pre-marketing (IND), and marketing (NDA/CTD) applications. In addition, learners will gain experience using tools that help manage timelines and sections needed from contributors.

Learning Objectives

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

Course Outline

- Module 1: FDA Division Information
- Module 2: Publishing the Submission
- Module 3: Tracking the Submissions
- Module 4: Common Technical Document Format
- Module 5: Pre-Market
- Module 6: Marketing Application

Who Should Attend

- Any Member of the Drug Development Team who wishes to know more about the IND submission and amendment process
- Regulatory Associates
- Quality Assurance, Manufacturing, Clinical, Project Management, and Pre-Clinical Personnel

Instructor

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

Course Length and Time

1.5 hours/week 12:00 – 1:30 p.m. Eastern
6 weeks

Course Dates

January 16, 2025 - February 20, 2025
Thursday Afternoons
$1,595 by December 13
$1,795 after December 13

April 10, 2025 – May 15, 2025
Thursday Afternoons
$1,595 by March 7
$1,795 after March 7

NOTE: This course is for individual registrants only.

Logistical Details

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. 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 9 hours (0.9 CEUs)** of continuing education credit for full participation, including the completion of a mid-term, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-24-066-L99-P. Released: 10/24.

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!"

NEW! 9-Hour Regulatory Strategy Development

Medical Device Coverage

Course Description

The cost of drug and device development is getting more expensive, underscoring the importance of a sound regulatory strategy. Such a strategy can determine if a drug, device or biologic has the ability to initiate and support a clinical trial 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 program will walk learners through a case study focusing on a newly developed product and the step-by-step process of creating a regulatory strategy. In this session, you will learn:

- The definition of regulatory strategy
- Regulatory strategy elements, by phase of development and discipline
- How to research and pull together a strategy
- How to plan and modify the regulatory strategy in Phase 1, Phase 2 and Phase 3
- Ways to adapt and update a strategy as information changes

Participants will walk away with a strategy toolbox that can be immediately applied on the job.

Learning Objectives

- Identify the elements of regulatory strategy
- Understand the questions that need to be addressed when developing a regulatory strategy, by phase and discipline
- Locate and use available tools that can aid in developing regulatory strategy
- Summarize the data and perform strategic analysis once the data is identified
- Determine the output and format of strategic information after analysis into a "playbook"

Course Outline

- Module 1: What is regulatory strategy?
- Module 2: What makes good strategic qualities?
- Module 3: How to perform strategic analysis
- Module 4: Landmines (how to plan for them or mitigate as much risk as possible)
- Module 5: Updates and monitoring the regulatory landscape
- Module 6: Performing strategy at different phases of investigation and how it differs

Available by individual module! Contact Barnett to learn more.

Who Should Attend

- Mid-Level Regulatory Professionals who have 3-5 years of regulatory experience and are looking to learn the "next level" of regulatory, beyond submission preparation
- Drug Development Team Members that would like to learn more about regulatory strategy

Instructor

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

Course Length and Time

1.5 hours/week, 12:00 – 1:30 p.m. Eastern
6 weeks

Course Dates

March 4, 2025 – April 8, 2025
Tuesday Afternoons
$1,595 by January 31
$1,795 after January 31

June 10, 2025 – July 22, 2025
No Class: July 1
Tuesday Afternoons
$1,595 by May 9
$1,795 after May 9

NOTE: This course is for individual registrants only. Course is available on an individual module basis. Contact Barnett to learn more.

LOGISTICAL DETAILS

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. 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 9 hours (0.9 CEUs)** of continuing education credit for full participation, including the completion of a mid-term, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-24-065-L99-P. Released: 8/24.

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!"

Blended Curriculum Course

10-Hour Advanced Clinical Project Management Skills Development

Medical Device Coverage

Course Description

This 10-Hour Advanced Clinical Project Management Skills Development program delves into advanced clinical research project management skills, mapped to the Project Management Institute, PMBOK® 6th and 7th editions. This course is recommended for the experienced clinical project manager with a minimum of three years of experience seeking advanced project management skills. Advanced concepts are presented to explore how project managers effectively communicate and lead project teams to overcome complex issues, including prioritizing project needs, influencing and leading project teams and stakeholders. The course also covers challenges in vendor lifecycle management, project risk assessment (project, quality), using a root cause analysis (RCA), and corrective and preventive action (CAPA) plan for effective issue management. All concepts are presented in a dynamic, interactive manner to facilitate learning and retention.

Learning Objectives

- Describe effective leadership skills in leading project teams
- Appraise communication and leadership skills for the project needs
- Formulate project priorities and approaches to manage project needs effectively
- Identify critical to quality factors and risks in a clinical trial project
- Appraise effective stakeholder and vendor management in clinical trials
- Apply RCA and CAPA in the management of projects

Course Outline

- Module 1: Leadership in Project Management
- Module 2: Project Risk and Critical to Quality Factors: ICH GCP E6 (R3) and ICH E8 (R1) in the conduct and management of a clinical trial
- Module 3: Project Risk: Risk Management Plan Implementation and Procedures
- Module 4: Project Vendor Management Part 1: Successful Vendor Relationship Management
- Module 5: Project Vendor Management Part 2: Ensuring Continued Project Success with Vendors

Who Should Attend

- Clinical Project Managers/Leaders
- Clinical Research Associates
- Clinical Operational Managers/Leaders

Instructors

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

Shelley Marti, M.S.N., P.M.P.

Danny Nasmyth-Miller, B.A. (Hons), M.B.A.

Nazma M. Rosado, MAOL, P.M.P., CPLP, 6σ, CMQ/OE

Shana Zink, B.S., C.C.R.A.

Course Length and Time

2 hours/week, 6:00 – 8:00 p.m. Eastern
5 weeks

Course Dates

January 15, 2025 - February 12, 2025
Wednesday Evenings
$1,595 by December 13
$1,795 after December 13

May 14, 2025 – June 11, 2025
Wednesday Evenings
$1,595 by April 11
$1,795 after April 11

July 16, 2025 - August 13, 2025
Wednesday Evenings
$1,595 by June 13
$1,795 after June 13

NOTE: This course is for individual registrants only.

LOGISTICAL DETAILS

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. 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 10 hours (1.0 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#: 0778-0000-23-038-L99-P. Released: 7/23.

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!"

Blended Curriculum Course

10-Hour Clinical Research Manager Skills Development Series

Medical Device Coverage

Course Description

Barnett International developed this five-module, 10-hour series for clinical research managers seeking to enhance their management and leadership skills to successfully support clinical research professionals and projects. This course will sharpen your management skills by focusing on the various soft-skill topic areas effective leaders and managers must master. Topics include: Management versus leadership, communication, delegation, conflict resolution, and performance management. Tools and techniques for successful remote management as well as Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) are also discussed. Each module will include core content followed by interactive exercises and case studies to reinforce practical application and learning.

Learning Objectives

- Describe effective leadership skills required to lead a team
- Demonstrate effective communication and listening skills required
- Define communication barriers and obstacles
- Apply effective delegation skills
- Describe the objective of performance management
- Develop coaching skills to improve performance
- Recognize effective usage of coaching and praise
- Develop a more engaged team that contributes to quality performance
- Describe methods for managing clinical research projects more effectively
- Identify challenges and tools for leading cross-culturally
- Discuss tools and techniques for successful remote management
- Apply RCA and practical applications of CAPAs to everyday research activities for problem solving

Course Outline

- Module 1: Introduction to Management: Defining Effective Leadership of Teams, Challenges New Managers and Leaders Encounter in their Role, Team Development
- Module 2: Communication: Effective Communication and Listening Skills, Barriers and Obstacles in Communication, Effective Delegation, and Conflict Resolution
- Module 3: Performance Management, Appraisal Management and Coaching
- Module 4: Building Effective Teams: Expectation Setting, Key Performance Indicators and Motivation
- Module 5: Change Management and Problem Solving: Managing Teams Through Changing Environments, Cross-Cultural Considerations and Remote Management

Who Should Attend

- Clinical Research Professionals with Direct Reports: Clinical Research Managers at Investigative Sites, Clinical Research Associates Managing CRAs, and Clinical Project Managers
- Newly promoted Clinical Research Managers
- Experienced Clinical Research Professionals interested in becoming Team Leaders and Managers
- Technically Trained Staff with little or no management experience seeking leadership and management skills

Instructors

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

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

Nazma M. Rosado, MAOL, P.M.P., CPLP, 6σ, CMQ/OE

Course Length and Time

2 hours/week, 9:30 – 11:30 a.m. and 2:00 – 4:00 p.m. Eastern
5 weeks

Course Dates

February 18, 2025 – March 18, 2025
Tuesday Mornings
$1,595 by January 17
$1,795 after January 17

May 1, 2025 – May 29, 2025
Thursday Afternoons
$1,595 by March 28
$1,795 after March 28

NOTE: This course is for individual registrants only.

LOGISTICAL DETAILS

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. 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 10 hours (1.0 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#: 0778-0000-23-039-L99-P. Released: 9/23.

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!"

Blended Curriculum Course

10-Hour Clinical Trial Start-Up Series

Medical Device Coverage

Course Description

Successful and timely clinical trial start-up is for key sponsors, CROs and investigative sites. Too often, clinical trial start-up is challenged by delays in investigator selection, Institutional Review Board (IRB)/Ethics Committee (EC) budget approvals, or the discovery that once a site is initiated, the investigator/site indicates the protocol is not feasible due to lack of subjects. This online 10-Hour Clinical Trial Start-Up Series will address how to overcome challenges encountered in clinical trial start-up from understanding protocol requirements and risks, exploring methods to improve the investigator/site understanding of eligibility criteria, use of a Work Breakdown Structure (WBS) to help drive timely IRB/EC and Clinical Trial Agreement (CTA)/budget approvals, and tools and techniques for more engaging/interactive site qualification and initiation visits. Case studies, handouts, and tools will be provided for immediate implementation to address your start-up needs.

Learning Objectives

- Identify protocol requirements and risks
- Create tools and templates for clinical trial start-up planning
- Examine best practices to improve Investigator/site selection
- Create engaging interactions with Investigator/site personnel during site interactions
- Identify situations where a Work Breakdown Structure (WBS) would have a positive impact on clinical trial start-up

Course Outline

- Module 1: The Clinical Protocol: Evaluation of Requirements and Risks
- Module 2: Development of the Investigator/Site Feasibility Questionnaire: Asking the Right Questions for Your Protocol
- Module 3: Investigator/Site Selection Visit: Matching Protocol Needs to Your Investigator/Site
- Module 4: Tools to Support Clinical Teams for Timely Start-Up: Trackers, Questionnaires, and Communication Practices that Yield Results
- Module 5: The Site Initiation Visit: Engaging and Interactive Gets Results

Who Should Attend

- Clinical Project Managers/Leaders
- Clinical Trial Managers
- Clinical Research Associates
- Clinical Trial Assistants
- Other Team Members from sponsors/CROs working in clinical trial start-up
- Clinical research Team Members from Investigative Sites seeking to improve their start-up practices

Instructors

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

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

Nazma M. Rosado, MAOL, P.M.P., CPLP, 6σ, CMQ/OE

Elizabeth Weeks-Rowe, LVN, C.C.R.A.

Course Length and Time

2 hours/week, 9:30 – 11:30 a.m. and 2:00 – 4:00 p.m. Eastern
5 weeks

Course Dates

January 21, 2025 - February 18, 2025
Tuesday Afternoons
$1,595 by December 20
$1,795 after December 20

March 7, 2025 – April 4, 2025
Friday Mornings
$1,595 by February 7
$1,795 after February 7

June 9, 2025 – July 7, 2025
Monday Afternoons
$1,595 by May 9
$1,795 after May 9

NOTE: This course is for individual registrants only.

LOGISTICAL DETAILS

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. 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 10 hours (1.0 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#: 0778-0000-23-040-L99-P. Released: 8/23.

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!"

Blended Curriculum Course

NEW FORMAT! 10-Week Clinical Research Associate (CRA) On-Boarding Program

Medical Device Coverage

Course Description

This newly updated online 10-Week program 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 is built on Barnett's deep in-person CRA training experience and is designed to engage participants actively, making the learning experience truly dynamic. Here's what participants can expect from this revamped, highly interactive training program:

Enhanced Skills Development: Good Clinical Practice (GCP) skills are reinforced through a combination of activities, including lecture, case studies, in class breakout sessions, interactive web-based knowledge applications, information and support.

Experts in the Field: Instructor-led weekly classes by an experienced subject matter expert who is passionate about creating interactive learning environments, ensuring participants get the most out of every session.

Technology Integration: Delivered through Barnett's Learning Management System (LMS) this course leverages cutting-edge technology to facilitate an interactive learning experience, making complex concepts easier to grasp.

Application-based Homework Assignments and Final Project: Designed to help gauge progress and allow participants to apply their knowledge in a practical context, fostering a deeper understanding of the material.

The course 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 application and intention of GCPs
- Differentiate the roles of the Sponsor and Investigator
- Review the drug and device development process
- Discuss the roles and responsibilities of a CRA within clinical research drug and device trials in relation to other roles within an organization
- Discuss protocol design and areas of protocol focus for CRAs
- Discuss the role of Institutional Review Boards (IRBs)/Ethics Committees (ECs)
- Evaluate the Informed Consent Document, process, and monitoring expectations
- Review key essential documents and the CRAs responsibilities in reviewing the Site Master File (SMF) and document collection
- Apply skills in monitoring essential documents and Investigational Product Accountability
- Define Adverse Event monitoring expectations and reporting
- Identify and apply requirements for types of monitoring visits (qualification, initiation, routine monitoring, remote monitoring, closeout visits)
- Discuss key CRA responsibilities during monitoring visits (on-site and remote) including source document verification and source document review
- Apply monitoring skills
- Discuss writing monitoring reports, queries, and visit follow up expectations
- Discuss elements of a study audit, preparation, and common findings

Course Outline

- Module 1: Applications of GCPs in Drug and Device Development Process and Sponsor and Investigator Responsibilities
- Module 2: Drug and Device Development, Roles and Responsibilities of CRAs, and Navigating Protocols
- Module 3: Role of IRBs/ECs and Informed Consents
- Module 4: Essential Documents and Investigational Product Accountability
- Module 5: Safety Definitions and Reporting Requirements
- Module 6: Monitoring Visit Types and Monitoring Expectations
- Module 7: Source Document Verification
- Module 8: Monitoring Visit Reports, Follow-Up Letters, Contact Reports
- Module 9: Regulatory Compliance and Quality Assurance: Audits and Inspections
- Module 10: Final Project and Course Review

Who Should Attend

- CRAs with less than two years of experience – in-house or remote
- 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:

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

Sonja Cooper, Ph.D, M.B.A.

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

3 hours/week, 9:30 a.m. – 12:30 p.m., 1:00 – 4:00 p.m. and 6:00 – 9:00 p.m. Eastern, 10 weeks

Course Dates

March 7, 2025 – May 9, 2025	**May 9, 2025 – July 25, 2025**	**July 16, 2025 - September 17, 2025**
Friday Mornings	*No Class:*	Wednesday Evenings
$1,795 by February 7	May 23, July 4	**$1,795** by June 13
$1,995 after February 7	Friday Afternoons	**$1,995** after June 13
	$1,795 by April 11	
	$1,995 by April 11	

Resume support is available as an add-on option!

NOTE: This course is for individual registrants only.

Logistical Details

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. 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#: 0778-0000-23-003-L99-P. Released: 3/23.

Blended Curriculum Course

10-Week Clinical Research Coordinator (CRC) On-Boarding Program

Medical Device Coverage

Course Description

The Clinical Research Coordinator (CRC) has a vital role in the conduct of a clinical trial and is a key liaison between the investigator, subject, IRB, and sponsor. The online 10-Week Clinical Research Coordinator (CRC) On-Boarding Program will provide a comprehensive introduction to clinical research and the job functions of the CRC for both drug/biologic and device trials. This program will provide core skills and encourage critical thinking to those individuals looking to support, facilitate, and coordinate the daily activities of clinical trials.

Case studies and industry best practices will be presented to underscore how the learning objectives apply directly to the responsibilities of the CRC.

Learning Objectives

- Understand the roles and responsibilities of the Clinical Research Coordinator
- Prepare for what a pharmaceutical or device sponsor is looking for in a research site during a pre-study evaluation or site selection visit
- Understand the requirements for source documentation, case report forms, study tool development, and standard operating procedures (SOPs)
- Define informed consent requirements and learn the process of conducting informed consent
- Define safety reporting: Definitions and reporting requirements
- Discuss regulatory compliance and quality assurance as it relates to audits and inspections

Course Outline

- Module 1: Introduction to Clinical Research, Investigational Product Development: Drug and Device, Regulatory Oversight, and Good Clinical Practice Guidelines
- Module 2: The Clinical Research Team: Roles and Responsibilities
- Module 3: The Principal Investigator and Site Selection
- Module 4: Clinical Study Protocol Breakdown and Feasibility Evaluation
- Module 5: Source Documentation, Case-Report Forms, Study Tool Development, and Standard Operating Procedures
- Module 6: Informed Consent Requirements and Process
- Module 7: Study Initiation, Start-up, and Ongoing Management Activities and Sponsor Expectations
- Module 8: Safety Reporting: Definitions and Reporting Requirements
- Module 9: Accountability for the Test Article and the Trial Termination Visit
- Module 10: Regulatory Compliance and Quality Assurance: Audits and Inspection

Who Should Attend

- Aspiring CRCs (This course is also appropriate for CRCs with less than six months of experience)
- College Students and New Graduates in a Scientific Field
- Nurses interested in developing skills in clinical research

Too Busy To Attend?

This course is also available as a self-paced course. See page 231 for more details!

Instructor

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Course Length and Time

3 hours/week, 9:30 a.m. – 12:30 p.m. and 1:00 – 4:00 p.m. Eastern
10 weeks

Course Dates

March 7, 2025 – May 16, 2025
No Class: April 25
Friday Afternoons
$1,795 by February 7
$1,995 after February 7

May 16, 2025 – July 25, 2025
No Class: July 4
Friday Mornings
$1,795 by April 18
$1,995 after April 18

Resume support is available as an add-on option!

NOTE: This course is for individual registrants only.

Logistical Details

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. 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#: 0778-0000-23-004-L99-P. Released: 3/23.

What Participants Say About The Course

"The course provided useful tools. It was easy to ask questions and the weekly online course format allowed time for the new material to be absorbed, before adding new content. It was manageable, even with a full time job."

"Lessons learned in this seminar are already being put to practice in my day-to-day Oncology Research Coordinator position. This course has given me a clear picture and understanding of the drug development process to the time study closes and the drug is marketed. This is a great wealth of knowledge and the course was very informative. Thank you!"

"I am already using almost everything that we went over in class in my day-to-day activities! Thank you so much for a wonderful class!"

NEW! 10-Week Comprehensive Monitoring for Medical Devices Certification Program

Course Description

This online 10-Week program 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 devices 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 close-out 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 FDA inspection process and what can be learned from issues warning letters

Course Outline

- Module 1: Introduction to the FDA and the Medical Device Approval Process: Introduction to the FDA; ICH overview; definitions; medical device regulatory processes
- Module 2: US Good Clinical Practices: Concept of Good Clinical Practices; US GCP – sponsor, investigator and IRB obligations; overview of monitor's responsibilities
- Module 3: IRB Approval & Informed Consent Process: IRB application for approval; approval process – initial and ongoing; informed consent process and documentation; HIPAA authorization
- Module 4: Pre-Study Processes: Determining the sponsor's investigator/site needs; pre-investigation and confidentiality agreement; investigator/site selection; contracts/ agreements; investigator's meeting; initiation visit; recruitment and advertising
- Module 5: Study Documentation: Sponsor files; investigator files; source documentation; case report forms; communication
- Module 6: Monitoring: Roles and responsibilities of the monitor during periodic visits; source document verification; case report form review in EDC; data retrieval and correction; document retrieval; protocol, investigational plan and GCP deviations; monitoring documentation
- Module 7: Device Accountability: Sponsor responsibilities as they relate to device accountability; investigator responsibilities as they relate to device accountability
- Module 8: Close-out Visits: Reasons for a closeout visit; roles and responsibilities of the monitor during a closeout visit; investigator responsibilities after closeout
- Module 9: Managing and Reporting Adverse Events: Adverse event terminology; variations in adverse event reporting and documentation; sponsor obligations relating to adverse event reporting; investigator obligations relating to adverse event reporting
- Module 10: FDA Inspections: Purpose, types and mechanics of FDA inspections; common audit findings; FDA actions following an inspection; review of warning letters

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 GCP

Instructor

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

Heather Marshall, M.S.N., B.S.N., R.N.

Shana Zink, B.S.,

Course Length and Time

3 hours/week, 6:00 – 9:00 p.m. Eastern
10 weeks

Course Dates

February 11, 2025 – April 29, 2025
No Class: March 25, April 1
Tuesday Evenings
$1,795 by January 17
$1,995 after January 17

May 6, 2025 – July 15, 2025
No Class: July 1
Tuesday Evenings
$1,795 by April 11
$1,995 after April 11

Resume support is available as an add-on option!

NOTE: This course is for individual registrants only.

Logistical Details

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. Upon course completion, participants will be provided training certificates. In order to receive accreditation CEUs, participants are required to pass both a mid-term and final exam. Upon completion of the exams, CEU certificates will be provided.

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 30 hours (3.0 CEUs)** of continuing education credit for full participation, including the completion of a mid-term, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-25-025-L99-P. Released: 2/25.

What Participants Say About Barnett›s 10-Week Courses

"Treat 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!"

Blended Curriculum Course

10-Week Conducting and Managing Oncology Clinical Trials

Course Description

This 10-week series provides an in-depth look at how oncology trials are conducted and how they differ from other clinical trials. For example, oncology can be more difficult due to the complexity of the disease and its treatments, number of prior therapies, or proper staging of the disease and other criteria for trial eligibility. Each module will address a specific oncology knowledge area to improve the clinical researcher's knowledge. This course is for the clinical research professional who is either in oncology clinical research seeking education to improve their understanding of oncology trials or for those who would like to enter the field or who are assigned to these trials but who have little or no experience in oncology trials.

Learning Objectives

- Define best practices for understanding the oncology trial, including the basics of phase I, phase II, and phase III trials
- Identify the parts of an oncology protocol and types of therapies used in oncology trials
- Define the future new agent therapies in cancer research and the role of traditional therapies
- Define and compare RECIST 1.1, iRECIST, and PERCIST
- Examine why adjudication of tumor assessment is used in oncology clinical trials
- Examine challenges in adverse event reporting: Common Terminology Criteria for Adverse Events (CTCAE)
- Identify how the clinical researcher plays a significant role in the field of oncology research

Course Outline

- Module 1: Design and Conduct of Oncology Trials: From Non-Clinical Through Pivotal Trial Phases
- Module 2: The Oncology Protocol: Dissection of the Protocol for Better Understanding, Training, and Compliance/Adherence By Research Teams
- Module 3: Defining Types of Therapies: Adjuvant, Neoadjuvant, Maintenance, and the Rationale for Combination Therapy; Use of Surgical or Radiation Therapy in the Treatment of Cancers
- Module 4: Understanding Future New Agent Therapies in Cancer Research and Some that are Already Here: The Future of Immunotherapy and Beyond While Maintaining the Role of Traditional Therapies
- Module 5: Oncology Endpoints: Making Sure Everyone Understands How, When, and Why Endpoints Matter, What the Path to Approval Is, and What the New Approval Designations Mean
- Module 6: Understanding Why RECIST 1.1, iRECIST, or PERCIST is Being Used in the Clinical Trial You Are Assigned/Manage
- Module 7: Adverse Event Reporting in Oncology Clinical Trials: Considerations for Successful Adverse Event Reporting the Importance of CTCAE
- Module 8: Understand Oncologic Emergencies, Supportive Care, and Alternative/Complementary Medicine and How These Contribute to or Cause Adverse Events
- Module 9: Recruitment Challenges: Define the Challenges and Methods for Improvement, Including the Role and Effect of Expanded Access Programs and Investigator-Initiated Trials
- Module 10: Putting It All Together and the Role of the Clinical Researcher. How Your Role Impacts the Outcome of Clinical Trials and What Can You Do to Improve the Outcome

Who Should Attend

- Clinical Project Managers/Clinical Project Leaders
- Clinical Trial Managers
- Clinical Operations Managers
- Clinical Safety Team Personnel
- Clinical Research Associates
- Clinical Research Coordinators
- Clinical Trial Assistants
- Data Managers
- Clinical Research Personnel seeking to learn about oncology clinical trials

Instructors

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

Denis R. Miller, M.D.

Linda Patricia Miller, M.D.

Course Length and Time

3 hours/week, 1:00 – 4:00 p.m. Eastern
10 weeks

Course Dates

March 6, 2025 – May 8, 2025
Thursday Afternoons
$2,295 by January 31
$2,495 after January 31

NOTE: This course is for individual registrants only.

Logistical Details

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. 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#: 0778-0000-23-041-L99-P. Released: 9/23.

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!"

Blended Curriculum Course

10-Week CRA & CRC Beginner Program

Medical Device Coverage

Course Description

The online 10-Week CRA & CRC Beginner Program provides a comprehensive introduction to clinical research and the job functions of the Clinical Research Associate (CRA) and Clinical Research Coordinator (CRC) for drug, biologic, and device trials. This program is geared toward individuals seeking a new career or career change into clinical research, but haven't decided which job track to pursue. Case studies and industry best practices are presented to emphasize how the learning objectives apply directly to the responsibilities of the CRA and CRC.

Learning Objectives

- Describe and discuss the investigational product development process, including FDA regulations, ICH guidelines, and Good Clinical Practice (GCP)
- Explain the roles and responsibilities of a CRA and CRC
- Describe the four types of monitoring visits, including the responsibilities of the CRA and CRC in preparation, activities, and follow-up
- Explain the Key Pre-Study Concepts: Role of the Principal Investigator, Site Selection, Clinical Trial Agreement and Budget Negotiation
- Discuss the role of the Institutional Review Board in clinical trials, define informed consent requirements, and discuss the informed consent process
- Discuss the study site initiation, interim monitoring activities, and data management
- Define safety definitions and reporting requirements for both drugs and devices
- Examine accountability for the investigational product and study closeout visits
- Discuss regulatory compliance and quality assurance as it relates to audits and inspections

Course Outline

- Module 1: Investigational Product Development, the FDA, and Good Clinical Practice Guidelines
- Module 2: Clinical Research Team: Roles and Responsibilities
- Module 3: The Principal Investigator, Site Selection, and Budget Negotiation
- Module 4: Clinical Study Protocol Elements
- Module 5: Institutional Review Boards, the Consent of Human Volunteers, and HIPAA
- Module 6: Study Monitoring, Data Management, and Study Initiation Visit
- Module 7: Safety Reporting: Definitions and Reporting Requirements
- Module 8: Accountability for the Test Article and Trial Termination Visits
- Module 9: Regulatory Compliance and Quality Assurance: Audits and Inspections
- Module 10: Managing Your Time and Preparing for the Interview

Who Should Attend

- Aspiring Clinical Research Associates and Clinical Research Coordinators (This course is also appropriate for Clinical Research Associates and Clinical Research Coordinators with less than six months of experience)
- College Students and New Graduates in a Scientific Field
- Nurses

Instructors

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

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

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

Susan Torchio, R.N., B.S.N.

Elizabeth Weeks-Rowe, LVN, C.C.R.A.

Course Length and Time

3 hours/week, 1:00 – 4:00 p.m. and 6:00 – 9:00 p.m. Eastern
10 weeks

Course Dates

January 23, 2025 - March 27, 2025
Thursday Afternoons
$1,795 by December 27
$1,995 after December 27

March 12, 2025 – May 14, 2025
Wednesday Evenings
$1,795 by February 7
$1,995 after February 7

May 12, 2025 – July 28, 2025
No Class: May 26, June 30
Monday Afternoons
$1,795 by April 11
$1,995 after April 11

July 30, 2025 – October 1, 2025
Wednesday Evenings
$1,795 by June 27
$1,995 after June 27

Resume support is available as an add-on option!

NOTE: This course is for individual registrants only.

Logistical Details

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. 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#: 0778-0000-23-002-L99-P. Released: 1/23.

What Participants Say About The Course

"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."

Blended Curriculum Course

10-Week Establishing a Vendor Qualification and Management Program

Medical Device Coverage

Course Description

This 10-week program will provide a comprehensive review of what is required to establish and maintain a robust and compliant vendor qualification and management program. Participants will come away with practical tools, checklists and templates to help ensure that vendor oversight is well-executed and performed in accordance with regulatory expectations. In addition to a review of vendor management processes and maintenance of the key components, participants will also develop techniques, including soft skills, needed to maintain ongoing communication, effective meeting management and conflict resolution often required in the oversight of vendors.

Learning Objectives

- Describe the components of an effective vendor qualification program
- Understand how to use tools for vendor identification, qualification, and selection
- Describe skills required for effective communication and ongoing relationship management
- Demonstrate understanding of how to successfully audit and measure performance of vendors
- Understand risk mitigation and management techniques used in vendor management

Course Outline

- Module 1: Establishing Vendor Expectations Based on Regulatory Requirements
- Module 2: Strategies for Identifying Potential Vendors
- Module 3: Procedures for Vendor Evaluation and Qualification
- Module 4: Establishing a Vendor Selection Process
- Module 5: Vendor Contracts and Budgets
- Module 6: Performing Vendor Audits
- Module 7: Vendor Relationship Building Techniques
- Module 8: Ongoing Vendor Management and Oversight
- Module 9: Vendor Risk Mitigation and Management
- Module 10: Vendor Re-Evaluation

Who Should Attend

- Clinical Researchers responsible for the oversight of vendor relationships
- Vendor Managers/Oversight Personnel
- Directors, Operations Managers
- Project Managers/Leads

Instructor

Treena Jackson, M.S., M.A., C.Q.A., R.A.C., C.S.S.G.B.

Course Length and Time

2 hours/week, 9:30 – 11:30 a.m. and 12:00 – 2:00 p.m. Eastern
10 weeks

Course Dates

April 1, 2025 – June 10, 2025
No Class: April 18
Tuesday Afternoons
$1,695 by February 28
$1,895 after February 28

June 17, 2025 – August 26, 2025
No Class: July 1
Tuesday Mornings
$1,695 by May 16
$1,895 after May 16

NOTE: This course is for individual registrants only.

Logistical Details

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. Upon course completion, participants will be provided training certificates. In order to receive accreditation CEUs, participants are required to pass both a mid-term and final exam. Upon completion of the exams, CEU certificates will be provided.

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 20 hours (2.0 CEUs)** of continuing education credit for full participation, including the completion of a mid-term exam, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-24-037-L99-P. Released: 9/24.

What Participants Say About Barnett's 10-Week Courses

"Great course! Instruction is expertly led and engaging. I will recommend Barnett to any colleague and will seek out topics for my own future training and professional development needs."

"The course has been so incredibly helpful thus far...I look forward to Thursday evenings!"

"This class exceeded my expectations of an online learning experience. The instructor was knowledgeable, came equipped with great examples to keep the class interesting and is a strong presenter. Thank you!"

10-Week Fundamentals of Drug Development Series

Course Description

The 10-Week Fundamentals of Drug Development Series will provide an introduction to the scientific, ethical, and regulatory aspects of the drug discovery and development process throughout the product life cycle and the issues that arise at each phase of new biomedical product development will be explored. Topics will include basic principles and current methodologies used in the drug discovery and development field, conduct 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, and endpoints, randomization procedures, adverse event reporting, and protocol compliance monitoring. Current trends influencing the pharmaceutic field such as targeted therapy approach in precision medicine, decentralization of clinical trials, digitalization, patient centricity, and changing regulatory landscape will be discussed.

Learning Objectives

- Discuss the FDA's role in drug development
- Explain the logistics of the drug development process for small and large molecule drugs
- Provide an overview of current trends and changing regulatory landscape
- Provide an overview of regulations and guidance documents for drugs and biologics submissions
- Discuss content and requirements for Investigational New Drug (IND) applications
- Review fundamentals of clinical trial structure and design, including Phase I, Phase II, and Phase III clinical studies
- Identify scientific and practical issues associated with the planning of a clinical research study
- Describe the overall structure of a protocol and regulatory requirements

Course Outline

- Module 1: Overview of the Drug Development Process for FDA Regulated Studies
- Module 2: Drug Discovery for Small and Large Molecules. Drug Development and Pre-Clinical Studies
- Module 3: Strategic Planning and Operations in the Drug Development Process
- Module 4: Regulatory Requirements for Clinical Development of Drugs and Biologics; Good Clinical Practice Regulations and Recent ICH GCP E6 and E8 Revisions and Their Impact of Drug Development
- Module 5: Regulatory Requirements to Plan, Initiate and Execute a Clinical Trial
- Module 6: Developing Clinical Trials/Fundamental Principles of Prospective Design
- Module 7: Investigational New Drug Application
- Module 8: Safety Monitoring, Risk Signal Detection and Communications in Clinical Trials
- Module 9: Transition from Clinical Research to Clinical Practice, Factors of Success for Post-Market Launch and Adoption of New Therapies.
- Module 10: Assurance of Compliance and Quality in Clinical Research

Who Should Attend

- Clinical, Regulatory, and Department Staff
- Clinical Research Associates, Data Managers or others interested in transitioning into clinical trial management
- Project Team Leaders with limited direct clinical trial experience who will be managing drug development programs and supervising project managers
- Grant Administrators
- Medical Directors
- Medical Writers
- Regulatory Affairs Professionals

Instructor

Marina Malikova, Ph.D., MSci, MA, CCRA., RAC

Course Length and Time

3 hours/week, 12:00 – 3:00 p.m. and 5:00 – 8:00 p.m. Eastern
10 weeks

Course Dates

February 3, 2025 – April 14, 2025
No Class: February 17
Monday Afternoons
$1,795 by January 3
$1,995 after January 3

May 5, 2025 – July 21, 2025
No Class: May 26, June 30
Monday Evenings
$1,795 by April 4
$1,995 after April 4

NOTE: This course is for individual registrants only.

Logistical Details

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. 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#: 0778-0000-23-042-L99-P. Released: 10/23.

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."

Blended Curriculum Course

10-Week ICH GCP E6: Risk-Based Monitoring Plan Development Series

Includes R3 Updates

Course Description

Risk-based approaches to clinical trials and risk-based monitoring are now required for clinical trial sponsors under ICH GCP E6 R3 Addendum. This comprehensive 10-week series provides a step-by-step approach for developing the content of the clinical trial monitoring plan. Specific attention is given to translating the Trial Risk Assessment (TRA) output and Integrated Quality Risk Management Plan (IQRMP) into a well-orchestrated document that is concise, comprehensive, and clearly articulates the complete strategy for all aspects of the monitoring to be undertaken and how risks will be mitigated.

Learning Objectives

- Describe the monitoring responsibilities of a risk-based quality management trial and the key areas to focus on and include in the monitoring plan
- Explain how the TRA and IQRMP outputs are integrated into the monitoring plan
- Explain the importance of proactive risk-based monitoring that allows for real-time identification and management of potential risks
- Identify the stakeholders necessary for monitoring plan development
- Explain inclusion of roles, responsibilities, and communication strategies in the monitoring plan
- Identify content and the components needed for developing a clear and concise risk-based monitoring plan
- Discuss how critical and non-critical data are to be incorporated into the monitoring framework while remaining focused on critical processes and data and ensuring monitoring efforts are proportionate to the identified risks
- Define centralized monitoring activities based on a case study and how to include these activities in the monitoring plan

Course Outline

- Module 1: Monitoring Plan Overview, Stakeholders, and Planning for Success
- Module 2: Deriving Input: Risks, Critical Data/Processes, Mitigation Plans
- Module 3: Case Study: Let's Get Started
- Module 4: On-Site Visit and Site Management
- Module 5: Off-Site (Remote) Site Monitoring
- Module 6: Centralized/Statistical Monitoring
- Module 7: Escalation and De-escalation/Management of Noncompliance
- Module 8: End of Study Activities and Other Monitoring Plan Components
- Module 9: Drivers for Revisions and Updates
- Module 10: Regulatory Agency Inspections: Helpful Tips

Who Should Attend

- Clinical Trial Managers/Study Leads
- Project Managers
- Clinical Trial Management/Clinical Operations Directors
- Quality Compliance Professionals
- Data Managers and Statisticians

Instructors

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

Treena Jackson, M.S., M.A., C.Q.A., R.A.C., C.S.S.G.B.

Heather Marshall, M.S.N., B.S.N., R.N.

Shana Zink, B.S., C.C.R.A.

Course Length and Time

2 hours/week, 12:00 – 2:00 p.m. and 6:00 – 8:00 p.m. Eastern, 10 weeks

Course Dates

March 6, 2025 – May 22, 2025
No Class: March 20, March 27
Thursday Afternoons
$1,695 by January 31
$1,895 after January 31

May 14, 2025 – July 30, 2025
No Class: June 11, July 2
Wednesday Evenings
$1,695 by April 11
$1,895 after April 11

NOTE: This course is for individual registrants only.

Logistical Details

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. Upon course completion, participants will be provided training certificates. In order to receive accreditation CEUs, participants are required to pass both a mid-term and final exam. Upon completion of the exams, CEU certificates will be provided.

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 20 hours (2.0 CEUs)** of continuing education credit for full participation, including the completion of a mid-term exam, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-22-035-L99-P. Released: 10/22.

What Participants Say About The Course

"I now have more tools and guidance when writing my next monitoring plan for upcoming trials to account for expectations from E6 R2 changes."

"Very helpful guidance to monitoring and data management."

"I enjoyed the class and can apply it immediately."

"This series clarified a lot of the questions I had regarding risk-based monitoring and also confirmed that we are on our way to having a great risk-based monitoring plan. The risk assessment lessons were key for me."

10-Week In Vitro Diagnostic Devices Fundamentals: Study Design, Conduct, Regulatory Requirements and Submissions for Approval

Course Description

The online 10-Week In Vitro Diagnostic Devices Fundamentals program covers the different regulatory pathways for medical devices, and how each impact the regulations to which they are subjected. Specifically, we will focus on in vitro diagnostic devices (IVDs), and discuss how the determination is made for those to be exempt from most of the requirements of the Investigational Device Exemption (IDE) regulations. We will also discuss how the determination of significant and non-significant risk for the device is made, and how it affects the submissions and review process by the IRB. Study design and conduct basic considerations, and quality control (QC) requirements for IVDs and laboratory-developed tests will be covered.

Learning Objectives

- Discuss the FDA's role in device development
- Explain the logistics of the device development process
- Understand regulatory pathways for devices, specifically in vitro diagnostic tests
- Review the pre-submission process for IVDs
- Understand considerations required for laboratory-developed tests
- Learn what documentation to submit to the IRB, depending upon the device category
- Identify scientific and practical issues associated with the planning of a clinical research study for medical devices
- Explain the post-approval responsibilities of sponsors and device reporting requirements

Course Outline

- Module 1: A Brief Overview of the Device Development Process
- Module 2: Investigational Device Exemptions (IDEs) and Types of IDEs
- Module 3: Regulatory Requirements for Planning, Initiating and Executing a Clinical Trial for Medical Devices
- Module 4: Transition From Pre-Clinical Phase of Development to Clinical Phases; Feasibility and Pivotal Study Requirements and Basic Considerations for Study Design and Conduct ; IDE Exempt Studies; Documentation Required for IRB Submissions
- Module 5: Sponsor Responsibilities for Significant and Non-Significant Risk Devices
- Module 6: Classification of In Vitro Diagnostic Products (IVDs); Regulatory Requirements for IVDs; Review of Pre-Submission Process for IVDs
- Module 7: Investigational IVDs Used in Clinical Investigations of Therapeutic Products; the Difference Between IVDs and Companion Diagnostic Trials and Classifications; Overview of IVD Study Designs with Predictive and Prognostic Biomarkers
- Module 8: Emergency Use of IVDs Outside of Study Protocol; De Novo Classification for IVD Devices;, Labelling and Pre-Market Approval Requirements for IVDs
- Module 9: FDA Requirements for Quality Control (QC) for Medical Devices and IVDs; Laboratory- Developed Tests and Applicable FDA Regulations; Current Good Manufacturing Practices (CGMPs) and Quality System Regulation (QSR Regulation) Requirements for Medical Devices; CLIA-Waiver Requirements
- Module 10: Medical Device Reporting Requirements

Who Should Attend

- New Clinical, Regulatory, and Department Staff who will design clinical trial programs for medical devices
- Project Team Leaders with limited direct clinical trial experience who will be managing device development programs and supervising project managers
- Medical Directors involved in the development and conduct of device research
- Medical Writers involved in device trials
- Clinical Research Associates working with organizations that sponsor device research
- Regulatory Affairs Professionals involved in research with IVDs
- Research professionals involved in submitting material for IRB review
- IRB members and support staff involved in review of device research

Instructor

Marina Malikova, Ph.D., MSci, MA, CCRA., RAC

Course Length and Time

3 hours/week, 5:00 – 8:00 p.m. Eastern
10 weeks

Course Dates

May 1, 2025 – July 17, 2025
No Class: June 19, July 3
Thursday Evenings
$1,795 by March 28
$1,995 after March 28

NOTE: This course is for individual registrants only.

Logistical Details

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. 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#: 0778-0000-23-043-L99-P. Released: 9/23.

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."

10-Week Risk Management/Risk-Based Quality Management for Clinical Trials Certification Program

Medical Device Coverage

Course Description

Are you prepared for Quality Risk Management (QRM), Risk Management (RM), Risk-Based Quality Management (RBQM)? The finalization of ICH GCP E6 R3 in January 2025 revealed that the guideline still requires risk-based approaches to managing quality in clinical trials. This 10-Week series takes you through, step-by-step, how to execute these requirements. We will focus on the critical elements for clinical trial sponsors and CROs included in the ICH GCP E6 R3 expectations, while highlighting key points from other regulatory bodies such as ISO 31000 Risk Management. Each step of risk identification, assessment, control, review, reporting, management, and communication are also reviewed along with what is to be documented in the clinical study report.

Learning Objectives

- Describe the expectations of QRM in relation to the ICH E6 R3 updates
- Discuss how to analyze risks and develop a risk register
- Describe how to use multiple risk analysis tools including: Failure Mode Effect Analysis (FMEA), Bow Tie, and Affinity Diagram
- Describe how to formulate risk mitigation strategies

Course Outline

- Module 1: Quality Risk Management: Quality Risk Management/ Risk Management (ICH GCP E6 R3 and ISO 31000), Risk Management Policy/ Program, Accountability and Resources
- Module 2: Risk Management Plan and Culture: Framework for Communicating Risk Within an Organization/Program, Strategies and Challenges for Risk Stakeholders, Required Commitment and Mandate
- Module 3: Risk Identification: Risk Identification and When to Start, Protocol Risks, Risk Register (Risk Log) for Tracking Risks
- Module 4: Risk Evaluation: Impact of Error, Detection of the Error, Risk Priority Number (RPN) Values
- Module 5: Risk Analysis Tools Part I: FMEA, Bow Tie, and Delphi technique
- Module 6: Risk Analysis Tools Part II: SWOT (Strengths, Weakness, Opportunities, Threats), Affinity Diagram, Cause and Effect Analysis
- Module 7: Risk Control: Risk Mitigation Strategies, Risk Mitigation Options, Priority Rankings of Risk Mitigation Plans
- Module 8: Risk Communication: Risk Mitigation Plans in the Risk Register/Log, Impact of Internal and External Stakeholders, Escalation Processes and Plans
- Module 9: Risk Review: Periodic Review, Risk Assessment, and Risk Detection
- Module 10: Risk Reporting: Risks, Deviations, Predefined Quality Tolerance Limits, Lessons Learned/Continuous Learning, Required Documentation in the Clinical Study Report

Who Should Attend

- Quality Control/Assurance Professionals
- Regulatory Affairs Professionals
- Clinical Research/Operations Personnel
- Information Technology/Security Personnel
- Data Managers
- Study Managers
- Project Physicians/Medical Monitors
- Pharmacovigilance Professionals
- Biostatisticians

Instructors

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

Susan M. Leister, M.B.A., Ph.D., CQA, CSSBB

Shelia Russell McCullers, M.S., D.M.

Course Length and Time

2 hours/week, 9:00 – 11:00 a.m. and 1:00 – 3:00 p.m. Eastern
10 weeks

Course Dates

April 4, 2025 – June 6, 2025
Friday Mornings
$1,695 by March 7
$1,895 after March 7

June 6, 2025 – August 15, 2025
No Class: July 4
Friday Afternoons
$1,695 by May 9
$1,895 after May 9

NOTE: This course is for individual registrants only.

Logistical Details

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. Upon course completion, participants will be provided training certificates. In order to receive accreditation CEUs, participants are required to pass both a mid-term and final exam. Upon completion of the exams, CEU certificates will be provided.

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 20 hours (2.0 CEUs)** of continuing education credit for full participation, including the completion of a mid-term, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-23-005-L99-P. Released: 4/23.

What Participants Say About The Course

"This course is beyond my expectation with very practical examples and tools. Both instructors are excellent with great attention to address participants' questions."

"Thanks a lot for this interesting and helpful course."

"The course was well designed. These lessons were valuable in seeing the big picture of clinical research."

"The tools provided were great. I hope to use the risk log and risk analysis tools."

Blended Curriculum Course

12-Hour Clinical Trial Management Series

Medical Device Coverage

Course Description

The 12-Hour Clinical Trial Management Series will focus on the critical skills needed for successful clinical trial management. This series is geared toward clinical trial managers, clinical project managers, and other key trial personnel seeking to improve their trial management expertise. Each module will focus on a comprehensive competency for clinical trial managers and project managers, as described in the learning objectives and course modules. Clinical trial management skills are reinforced through a combination of activities, including case studies and scenario review.

Learning Objectives

- Understanding risk and risk analysis for clinical trials
- Identify effective vendor selection, oversight and risk management techniques
- Apply risk management techniques in protocol development, site selection, and vendor selection
- Develop effective budgets for clinical trials
- Describe useful metrics and forecasting techniques used in clinical trials
- Describe strategies for effective communications and meetings

Course Outline

- Module 1: Risk Management Part 1: How Clinical Trial Managers are Risk Managers Throughout the Project Lifecycle
- Module 2: Vendor Management and Selection: Effective Selection, Oversight and Risk Management of Clinical Trial Vendors
- Module 3: Risk Management Part 2: Application of Risk Management
- Module 4: Budget Management: Successful Budget Planning and Management
- Module 5: Metrics and Forecasting: Why Metrics and Forecasting Matter in Clinical Trials
- Module 6: Effective Communication and Meetings

Who Should Attend

- Clinical Trial Managers
- Clinical Project Managers
- Clinical Research Department/Team Managers
- Clinical Research Associates and others seeking a better understanding of clinical trial management

Instructor

Shana Zink, B.S., C.C.R.A.

Course Length and Time

2 hours/week, 6:00 – 8:00 p.m. Eastern
6 weeks

Course Dates

February 3, 2025 – March 17, 2025
No Class: February 17
Monday Evenings
$1,595 by January 3
$1,795 after January 3

April 7, 2025 – May 12, 2025
Monday Evenings
$1,595 by March 7
$1,795 after March 7

NOTE: This course is for individual registrants only.

LOGISTICAL DETAILS

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. Upon course completion, participants will be provided training certificates. In order to receive accreditation CEUs, participants are required to pass a 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 12 hours (1.2 CEUs)** of continuing education credit for full participation, including the completion of a final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-23-044-L99-P. Released: 7/23.

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!"

15-Hour Clinical Trial Assistant Fundamentals Training Program

Medical Device Coverage

Course Description

The 15-hour Clinical Trial Assistant Fundamentals Program focuses on the responsibilities of the Clinical Trial Assistant or Associate (CTA), a key administrative member of a project team at the sponsor or CRO. This course provides CTAs information regarding the drug and medical device development and approval process. Best practice techniques for collecting and managing essential documentation stored in the sponsor's Trial Master File are covered in detail. Activities such as knowledge checks, case scenarios, and simulation exercises reviewing essential documentation for correctness and completeness provide the learner with a hands-on opportunity to apply knowledge gained from the course in their daily roles.

Learning Objectives

- Review FDA regulations and the ICH GCP E6 Guideline for Good Clinical Practice (GCP)
- Describe the role of the Clinical Trial Assistant and other team members in clinical research
- Describe the investigational product development process: Drug and device
- List essential documentation required in the conduct of clinical research
- Describe the Trial Master File
- Develop tracking tools used in clinical research
- Define investigational product management and accountability in clinical research
- Explain how FDA inspections are conducted at the sponsor and investigative sites

Course Outline

- Module 1: FDA Regulations and ICH GCP
- Module 2: Roles and Responsibilities of the Clinical Research Team
- Module 3: Investigational Product Development: Drug and Medical Device Approval Process, Importance of Investigational Accountability and Issue Management
- Module 4: Essential Documentation and the Trial Master File: Set Up, Maintenance, and Management
- Module 5: Simulation Exercise Case Study: Review of Essential Documentation Forms for Completeness and Acceptance
- Module 6: Review of Simulation Exercise Study and FDA Inspections and Preparedness

Who Should Attend

- Clinical Trial Associates
- Clinical Trial Assistants
- Clinical Coordinators at the sponsor or CRO

Instructors

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

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

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Elizabeth Weeks-Rowe, LVN, C.C.R.A.

Course Length and Time

Two 2.5 hour classes/week, 9:00 – 11:30 a.m. and 2:00 – 4:30 p.m. Eastern
3 weeks

Course Dates

April 8, 2025 – April 29, 2025
No Class: April 24
Tuesday and Thursday Mornings
$1,695 by March 7
$1,895 after March 7

July 8, 2025 – July 24, 2025
Tuesday and Thursday Afternoons
$1,695 by June 6
$1,895 after June 6

Resume support is available as an add-on option!

NOTE: This course is for individual registrants only.

LOGISTICAL DETAILS

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. 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 15 hours (1.5 CEUs)** of continuing education credit for full participation, including the completion of a mid-term, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-24-008-L99-P. Released: 4/24.

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!"

NEW! 18-Hour Writing Clinical/Performance Evaluation Reports

Medical Device Coverage

Course Description

This series includes a review of the Clinical/Performance Evaluation Reports (CER/PER) requirements in the EU MDR and IVDR (EU Reg 2017/745 and 746, respectively) and associated guidelines along with a discussion of the CER/PER regulations outside the US. All devices are required to have a CER/PER for products marketed in the EU and globally. Good writing skills and techniques needed to create a CER/PER and to respond to reviewer comments will be explored. This highly interactive program will be based on the included course textbook, and learners will have the opportunity to share their experiences and ask specific questions about CERs and PERs.

Learning Objectives

- Describe the history of CER/PER development
- Summarize the Clinical/Performance Evaluation Reports (CER) requirements in the EU MDR (EU Reg 2017/745 and 746) and associated guidelines
- Create a work plan for CER/PER development
- Summarize key CER/PER features evaluated by Notified Bodies
- Use CEP/PEP template (provided) to complete a CEP/PEP
- Use CER/PER template (provided) to complete a CER/PER
- Use PMCFP/PMPFP template (provided) to complete a PMCFP/PMPFP
- Engage and respond to a critique from an experienced CER/PER reviewer

Course Outline

- Module 1: Introduction and CER/PER Requirements
- Module 2: Planning Clinical/Performance Evaluations
- Module 3: Identifying Clinical/Performance Data
- Module 4: Appraising Clinical/Performance Data
- Module 5: Analyzing Clinical/Performance Data
- Module 6: Establishing Clinical Benefit-Risk Ratios
- Module 7: Writing Clinical/Performance Evaluation Documents
- Module 8: Writing SSCPs/SSPs
- Module 9: Reviewing CE/PE Documents
- Module 10: Integrating CE/PE, PMS and RM Systems
- Module 11: Understanding CER/PER Regulations Outside of Europe
- Module 12: Forecasting CER/PER Future Directions

Available by individual module! Contact Barnett to learn more.

Who Should Attend

- Project Managers
- Clinical Data Specialists/Analysts/Managers
- Technical Communication Specialists/Medical Writers
- Clinical Affairs Directors
- Clinical Program Managers
- Clinical Nurse Specialists
- Post Market Surveillance Managers
- Clinical Evaluation Report/Reporting Specialists
- Evaluation and Research Directors
- Clinical Education Specialists
- Corporate Librarians
- Regulatory Specialists/Managers

Instructor

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

Course Length and Time

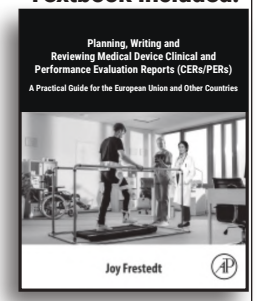
1.5 hours/week, 12:00 – 1:30 p.m. Eastern
12 weeks

Course Dates

March 12, 2025 – May 28, 2025
Wednesday Afternoons
$1,795 by February 7
$1,995 after February 7

June 4, 2025 – August 27, 2025
No Class: July 2
Wednesday Afternoons
$1,795 by May 2
$1,995 after May 2

Textbook Included!



NOTE: This course is for individual registrants only. Course is available on an individual module basis. Contact Barnett to learn more.

Logistical Details

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. 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 18 hours (1.8 CEUs)** of continuing education credit for full participation, including the completion of a mid-term, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-24-064-L99-P. Released: 9/24.

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!"

20-Hour Fundamentals of Clinical Research Series: Getting Started in Clinical Research

Medical Device Coverage

Course Description

The 20-Hour Fundamentals of Clinical Research Series provides a comprehensive introduction to clinical research for newly hired clinical research professionals or individuals interested in working in the pharmaceutical and medical device industry. Participants will learn about the basics of clinical research. The series covers core sponsor and investigator site activities to help learners understand the key considerations in the real-life work of clinical researchers. This course covers FDA regulations, the importance of ICH GCP, protocol development, monitoring in clinical research, and the identification and reporting of adverse events. Activities in the course include interactive discussions, knowledge checks, and a final course practicum exercise.

Learning Objectives

- Define clinical research and discuss how preclinical development leads to clinical development
- Explain the roles and responsibilities of all members of the clinical team: Sponsor, vendor, CRO, investigator, Institutional Review Board, subject and regulatory authority
- Describe the investigational product development process, including study design and the logic involved
- Define the regulatory requirements, including principles of Good Clinical Practice from the International Council for Harmonization, FDA regulations (Code of Federal Regulations), ethical considerations for a study and the need for Standard Operating Procedures
- Define the steps involved in proceeding with the study: Sponsor development of protocol, case report form, informed consent document, budget, database and identifying an investigational site
- Describe the conduct of the study, including monitoring visits to the site and site performance management and communication
- Describe the management of adverse events and completion of study reporting and retention of documents
- Identify career opportunities and reference materials available

Course Outline

- Module 1: Clinical Research: Protection of the Human Research Subject and ICH GCP
- Module 2: The Clinical Research Team: Roles and Responsibilities of the FDA, Sponsor, CRO, Clinical Investigator, CRA, CRC, and IRB/IEC
- Module 3: Development of New Products: How are new drugs and medical devices developed?
- Module 4: The Protocol: Understanding the Contents and Purpose of the Protocol in Clinical Research
- Module 5: Selection of the Clinical Investigator: Process and Procedures, Informed Consent, and Monitoring Visits
- Module 6: Safety in Clinical Trials: Understanding Adverse Events and Reporting Requirements
- Module 7: Clinical Research: Recruitment of Subjects, Good Documentation Practices, Essential Documents, and Source Documentation
- Module 8: Submission to Regulatory Authorities: Process for Approval of New Drugs and New Medical Devices
- Module 9: FDA Inspections: Understanding Purpose and Procedures
- Module 10: Course Practicum and Overview of Career Pathways

Who Should Attend

- Those who are new to clinical research
- Aspiring Clinical Research Coordinators and Clinical Research Associates
- Nurses interested in clinical research
- Aspiring and Entry Level Project Managers (looking to gain experience in clinical research)
- College Students and New Graduates in a Scientific Field

Instructors

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

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

Sonja Cooper, Ph.D., M.B.A.

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Elizabeth Weeks-Rowe, LVN, C.C.R.A.

Course Length and Time

Two 2-hour classes/week, 9:30 – 11:30 a.m. and 1:00 – 3:00 p.m. Eastern
5 weeks

Course Dates

January 7, 2025 - February 11, 2025
No Class: January 21
Tuesday and Thursday Mornings
$1,695 by December 6
$1,895 after December 6

April 7, 2025 – May 7, 2025
Monday and Wednesday Afternoons
$1,695 by March 7
$1,895 after March 7

July 22, 2025 – August 21, 2025
Tuesday and Thursday Mornings
$1,695 by June 20
$1,895 after June 20

Resume support is available as an add-on option!

NOTE: This course is for individual registrants only.

LOGISTICAL DETAILS

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. Upon course completion, participants will be provided training certificates. In order to receive accreditation CEUs, participants are required to pass both a mid-term and final exam. Upon completion of the exams, CEU certificates will be provided.

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 20 hours (2.0 CEUs)** of continuing education credit for full participation, including the completion of a mid-term, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-24-009-L99-P. Released: 1/24.

30-Hour Clinical Data Management On-Boarding Program

Medical Device Coverage

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 Risk-Based Monitoring, Risk Assessment and Quality by Design

Who Should Attend

- New or aspiring Clinical Data Managers
- Clinical Data Managers
- Data Coordinators
- Project Managers
- College Students and New Graduates in a Scientific Field
- This course is also ideal for "on-boarding" of individual new hires or entire teams (individual registrations required)

Instructor

Denise G. Redkar-Brown, MT

Course Length and Time

3 hours/week, 8:30 – 11:30 a.m. and 5:00 – 8:00 p.m. Eastern
10 weeks

Course Dates

February 12, 2025 – April 16, 2025
Wednesday Mornings
$1,795 by January 10
$1,995 after January 10

April 23, 2025 – June 25, 2025
Wednesday Evenings
$1,795 by March 21
$1,995 after March 21

Resume support is available as an add-on option!

NOTE: This course is for individual registrants only.

LOGISTICAL DETAILS

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. 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#: 0778-0000-24-038-L99-P. Released: 8/24.

What Participants Say About The Course

"I have thoroughly enjoyed this course and I sincerely believe that the information I learned will serve me well as a designer of the EDC system for studies. The presenter was an absolute delight! Thank you."

"This course is relevant to my day-to-day activities, particularly on CRF design, EDC maintenance, and data cleaning. I really appreciated the content of the materials that were provided, which helped me broaden my understanding of data management."

"The program was an excellent refresher for me and re-familiarized me with the state of the industry. Module 3 – Electronic Data Capture was particularly helpful."

Blended Curriculum Course

30-Hour Clinical Project Management Fundamentals Certification Program

Medical Device Coverage

Course Description

Theoretical concepts from the Project Management Institute, PMBOK® 6th and 7th editions and how they specifically apply to clinical research are introduced in this comprehensive introductory project management course. Whether you are looking to become a clinical research project manager, are a newly hired clinical project manager, or a clinical project manager without formal project management training, this hands-on program will provide you with project management skills, tools and processes required to successfully manage projects in clinical research settings. The course includes an emphasis on the need to anticipate, understand, and implement detailed project management activities in a proactive manner. Case studies, discussions, and interactive exercises are used to aid the learner in the application of clinical project management concepts and principles.

Learning Objectives

- Describe project management as it applies to clinical research
- Define scope management and tools utilized by project managers, including the work breakdown structure, process mapping, and schedule management
- Describe the fundamentals of process maps, flow charts and other project management tools
- Explain project management technical terminology
- Identify clinical trial project budgeting and tracking techniques
- Describe quality and risk management per ICH GCP E6 (R3) and ICH E8 (R1)
- Define effective vendor management and sponsor oversight in clinical trial projects
- Explore project tracking methods utilized in tracking clinical trial projects
- Utilize appropriate communication skills and effectively motivate team members
- Apply strategies for seamless project close out and continuous improvement

Course Outline

- Module 1: Introduction to Clinical Project Management
- Module 2: Project Planning Fundamentals
- Module 3: Process Mapping and Project Schedule Management
- Module 4: Project Management Technical Knowledge
- Module 5: Project Budget Planning
- Module 6: Project Quality and Risk Management
- Module 7: Project Tracking
- Module 8: Introduction to Project Vendor Management
- Module 9: Communication and Team Building for Project Managers
- Module 10: Project Closing, Audits, and Inspections

Who Should Attend

- Aspiring and Entry-Level Project Managers and Clinical Trial Managers
- Project Managers looking to gain experience in clinical research project management
- Project Leaders that are unfamiliar with project management tools and principles
- Clinical Research Members and Leaders at investigative sites seeking project management skills to aid in the execution of clinical research projects within their organization
- Clinical Research Professionals transitioning to project management roles/functions

Instructors

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

Shelley Marti, M.S.N., P.M.P.

Danny Nasmyth-Miller, B.A. (Hons), M.B.A.

Nazma M. Rosado, MAOL, P.M.P., CPLP, 6σ, CMQ/OE

Course Length and Time

3 hours/week, 9:00 a.m. – 12:00 p.m., 11:00 a.m. – 2:00 p.m., and 6:00 – 9:00 p.m. Eastern
10 weeks

Course Dates

January 23, 2025 - March 27, 2025
Thursday Afternoons
$1,795 by December 20
$1,995 after December 20

April 16, 2025 – June 18, 2025
Wednesday Mornings
$1,795 by March 14
$1,995 after March 14

June 25, 2025 – September 3, 2025
No Class: July 2
Wednesday Evenings
$1,795 by May 23
$1,995 after May 23

Resume support is available as an add-on option!

NOTE: This course is for individual registrants only.

LOGISTICAL DETAILS

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. 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#: 0778-0000-23-006-L99-P. Released: 1/23.

What Participants Say About The Course

"I have gained very valuable information regarding Clinical Project Management and have learned procedural and knowledge-based processes to execute various stages of clinical trials. I will take these learnings and implement them in day-to-day professional practice towards success of my present and future studies. This is very valuable."

30-Hour Clinical Research Auditing Certification Program

Medical Device Coverage

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., 12:00 – 3:00 p.m., and 6:00 – 9:00 p.m. Eastern
10 weeks

Course Dates

January 23, 2025 - April 10, 2025
No Class: February 20, April 3
Thursday Evenings
$1,795 by December 20
$1,995 after December 20

April 9, 2025 – July 16, 2025
No Class: April 23, May 14, June 25, July 2, July 9
Wednesday Mornings
$1,795 by March 7
$1,995 after March 7

June 3, 2025 – September 9, 2025
No Class: June 24, July 1, July 8, August 12, September 2
Tuesday Evenings
$1,795 by May 2
$1,995 after May 2

July 17, 2025 – October 2, 2025
No Class: August 14, September 4
Thursday Afternoons
$1,795 by June 13
$1,995 after June 13

Resume support is available as an add-on option!

NOTE: This course is for individual registrants only.

LOGISTICAL DETAILS

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. Upon course completion, participants will be provided training certificates. In order to receive accreditation CEUs, participants are required to pass both a mid-term and final exam. Upon completion of the exams, CEU certificates will be provided.

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 30 hours (3.0 CEUs)** of continuing education credit for full participation, including the completion of a mid-term, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-23-046-L99-P. Released: 7/23.

What Participants Say About The Course

"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!"

"I will apply the knowledge gained from this extremely informative course in all aspects of my day-to-day activities as an Audit Specialist."

30-Hour Design and Conduct of Clinical Trials: Requirements, Statistical Issues, and Clinical Protocols

Course Description

Clinical trials play a pivotal role in evidence-based medicine. This 30-Hour Design and Conduct of Clinical Trials Program will provide important epidemiological and basic statistical principles necessary for designing clinical research studies. Topics include bias, confounding, developing the research question, defining an appropriate study population, choosing outcome measures, clinical research ethics and regulation, sample size determination, and statistical analysis issues. All aspects of the development and writing informed consent form and study protocol will be addressed, including criteria for the selection of participants, assignment of study treatments, and endpoints, randomization procedures, adverse event reporting, and protocol compliance monitoring. The ethical issues that arise at each phase of new biomedical product development will be explored. Practical exercises will include critical analysis of the informed consent form and development of a preliminary Investigational New Drug (IND) submission strategy to the FDA.

Learning Objectives

- Discuss the FDA's role in biomedical product development process and provide overview of regulations/guidance for submissions
- Discuss content and requirements for IND and Investigational New Device (IDE) applications
- Review the fundamentals of clinical trial structure and design
- Identify scientific and practical issues associated with the planning of clinical research study
- Describe the overall structure of a study protocol and regulatory requirements, including overview of regulatory guidelines to incorporate biomarkers, patient centricity, diversity into clinical study designs and protocol.
- Manage the timeline for protocols and amendments, including key opinion leader input, patients feedback at pre-launch of the study, revisions, Quality Control (QC) process
- Discuss requirements for protection of human research subjects and their applications in responsible conduct of clinical research studies
- Discuss the requirements for pre-market New Drug Application (NDA) and Biologic License Application (BLA) and Pre-Market Application (PMA) content and regulatory process
- Explain the post-approval responsibilities of sponsors, including Phase 4 clinical studies

Course Outline

- Module 1: Overview of Drug/Device/Biologic Development Process for FDA Regulated Studies
- Module 2: Fundamentals of Study Designs: Types of Observational Studies and the Basics of Prospective Design
- Module 3: IRB Regulations and Process, Informed Consent and the Regulations
- Module 4: INDs, the IND Process
- Module 5: Safety Monitoring for Clinical Trials
- Module 6: Basic Statistical Considerations in Design and Analysis of Clinical Research Studies, Random and Systemic Error in Clinical Study Designs: Controlling for Bias and Confounders
- Module 7: Fundamentals of Trials with Medical Devices
- Module 8: Pre-Marketing Applications for Investigational Drugs and Biologics (NDA, BLA, PMA)
- Module 9: Review of Protocol Types, Special Designation Status (Multi-Center, Orphan Designation, Fast-Track), Post-Marketing Studies
- Module 10: Bioequivalence Studies for Development of Generic Drugs and Biosimilars for Biologics

Who Should Attend

- New Clinical, Regulatory, and Department Staff who will design clinical trial programs
- Clinical Research Associates, Data Managers, or others interested in transitioning into clinical trial management
- Project Team Leaders with limited direct clinical trial experience who will be managing drug development programs and supervising project managers
- Grant Administrators
- Medical Directors
- Medical Writers
- Regulatory Affairs Professionals
- Research and Development Personnel

Instructor

Marina Malikova, PhD, MSci, MA, CCRA, RAC

Course Length and Time

3 hours/week, 5:00 – 8:00 p.m. Eastern
10 weeks

Course Dates

March 11, 2025 – May 20, 2025
No Class: March 18
Tuesday Evenings
$1,795 by February 7
$1,995 after February 7

June 3, 2025 – August 12, 2025
No Class: July 1
Tuesday Evenings
$1,795 by May 2
$1,995 after May 2

NOTE: This course is for individual registrants only.

LOGISTICAL DETAILS

Prior to the start of the course, participants will receive their login credentials and links to access and download the many class resources and class meeting links. 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

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ACPE#: 0778-0000-23-047-L99-P. Released: 8/23.

ABCs of Clinical Research for Clinical Administrative Support Staff

Medical Device Coverage

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

Instructors

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

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

Elizabeth Weeks-Rowe, LVN, 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

Course Dates

March 4, 2025 (9-11:30) June 12, 2025 (12:30-3)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-24-040-L99-P. Released: 9/24.

ABCs of GCP and the Principles of ICH GCP E6

Includes R3 Updates

Course Description

This web seminar provides the basic concept of Good Clinical Practice (GCP). Participants will learn the goals of GCP and its common elements (FDA regulations and the ICH GCP E6 Guideline, including R3 updates) defining the quality system of mutual accountability between the sponsor, investigator, IRB/IEC, and the regulatory authority. The basic roles and responsibilities of each stakeholder will be discussed in relation to these criteria. The new principles of the ICH GCP E6 R3 Guideline will be discussed in a practical manner to ensure compliance with all regulatory requirements.

Learning Objectives

- Describe the goals of GCP
- Discuss the various regulations affecting drug, device, and biologic investigational products related to GCP
- Recognize the mutual accountability and responsibilities for each of the stakeholders: Sponsor, investigator, IRB/IEC, and regulatory authority
- Apply the principles of ICH GCP E6 to quality research studies to ensure compliance

Who Should Attend

- Clinical Research Associates
- Project Managers
- Study Coordinators
- Investigators
- Regulatory Affairs Professionals
- Institutional Review Board Professionals
- All other personnel responsible for ensuring compliance with GCP regulations

Instructors

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

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

Elizabeth Weeks-Rowe, LVN, 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

March 4, 2025 (1-2:30)

June 12, 2025 (9:30-11)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-23-048-L99-P. Released: 9/23.

Blended Curriculum Course

Adverse Event Monitoring for CRAs

Course Description

During monitoring visits, one of the most important and impacting activities that a Clinical Research Associate (CRA) performs is the source document verification of Adverse Events (AEs). The CRA serves as the eyes for the research sponsor when it comes to proper collection and documentation of subject safety information. Incorrect and inadequate monitoring of AEs can lead to inaccurate labeling for clinical trials and impact market application inspectional reviews, as well as post-marketing labeling. This includes causality, expectedness/unanticipated, and other important concepts. Case scenarios will be used to apply the information for better learning.

Learning Objectives

- Define safety concepts and reporting requirements
- Recognize the importance of verifying the subject baseline history
- Determine when to start and stop monitoring AEs
- Apply a detailed presentation of the source document verification process of AEs
- Manage challenges in monitoring AEs
- Determine appropriate credentialing for site AE evaluation of event relationship
- Describe the impact of monitoring on future product labeling
- Discuss reporting trends

Who Should Attend

- Device and Drug Study Clinical Research Associates
- Contract Clinical Research Associates
- Clinical Research Associate Managers
- Project Managers

Instructor

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

Course Length and Time

2 hours 10:00 a.m. – 12:00 p.m. and 12:00 – 2:00 p.m. Eastern

Course Dates

January 16, 2025 (12-2)

April 9, 2025 (10-12)

July 15, 2025 (12-2)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 2 hours (0.2 CEUs)** of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-23-007-L99-P. Released: 1/23.

Blended Curriculum Course

Adverse Events: Best Practices for Reporting and Communicating Safety Information to IRBs

Course Description

This web seminar presents content and impact discussion of the FDA and Office of Human Research Protections (OHRP) Adverse Event reporting guidance documents. The guidance documents address issues of Adverse Event information exchange between stakeholders and propose solutions to the issues of the quality of information being sent to the IRBs. The guidance impacts the activities of the research site, IRB, and sponsor/CRO's role in compiling and/or communicating Adverse Event information during a research study, changing the industry's current practices.

Learning Objectives

- Appreciate the changing regulatory climate and the impact on safety reporting in clinical trials
- Explain the global response and recommendations for more meaningful safety reporting between stakeholders
- Describe the FDA's response: January 2009 Final Guidance
- Describe the OHRP's response: January 2007 Final Guidance
- Recognize implications for current practices
- Examine case scenarios

Who Should Attend

- Sites: Principal Investigators, Clinical Research Coordinators, Managers
- Sponsors: Clinical Research Associates, Sponsor Clinical Operations, Safety Information Specialists, Regulatory Professionals

Instructors

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

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

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

1.5 hours 9:30 – 11:00 a.m. Eastern

Course Dates

January 13, 2025

July 8, 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-24-041-L99-P. Released: 7/24.

NEW! Agile Project Management for Clinical Research Data Managers

Course Description

Agile Project Management is an iterative and flexible approach to managing projects, primarily used in software development but is also applicable to various other industries and project types. It focuses on collaboration, customer feedback, and continuous improvement. Agile methodologies promote adaptive planning and emphasize customer satisfaction by delivering functional and valuable product increments in short development cycles, known as iterations or sprints. Clinical Data Managers and Clinical Programmers will find this web seminar valuable in understanding the Agile approach to software development.

Learning Objectives

- Define Agile Project Management
- Expand the developmental steps for this process
- Compare/Contrast Agile vs. Waterfall project management
- Discuss advantages that may be realized in using the Agile approach

Who Should Attend

- Clinical Programmers
- Clinical Data Managers

Instructor

Denise G. Redkar-Brown, MT

Course Length and Time

1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates

February 24**,** 2025

May 29**,** 2025

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-24-058-L99-P. Released: 8/24.

Applied Clinical Statistics in Risk-Based Monitoring

Course Description

With the release of FDA's guidance on risk-based monitoring (RBM), the FDA is requiring centralized monitors to have adequate training to perform centralized monitoring activities. Moreover, with the increase in the availability of clinical operational data, and with more biopharmaceutical and medical device enterprises outsourcing, clinical operations teams need to have the necessary skills to centrally and efficiently monitor and manage their clinical trials. This web seminar will provide a brief background as to how the industry is changing, address why centralized and RBM is gaining importance, and offer applied clinical statistical training and tools that can be utilized towards centralized clinical trial monitoring applications and identifying site underperformance. These tools are also flexible towards clinical business operations. Attendees will learn to interpret and graph histograms, quantify risk in histograms and datasets, identify clinical trial underperformance, and utilize minimum random sampling for RBM in histograms and datasets.

Learning Objectives

- Describe the role of centralized monitoring
- Interpret P-values, histograms, and confidence intervals and distribution
- Identify risk and clinical trial underperformance

Who Should Attend

- Clinical Operations Personnel
- Clinical Affairs Professionals
- Clinical Research Associates
- Principal Investigators
- Clinical Research Coordinators
- Subject Enrollment Managers
- Research Nurses and Scientists
- Clinical Project Managers

Instructor

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

Course Length

1.5 hours

Course Dates

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

Accreditation

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

What Participants Say About Barnett Interactive Web Seminars:

"I will use the techniques presented to help in site issue resolution."

Blended Curriculum Course

Approaches to Address Challenges in Vendor Management

Course Description

The stipulation of taking a more proactive approach to managing risk in clinical trials is a major component of ICH GCP E6. As outsourcing in clinical development continues to grow, so do the challenges of ensuring quality outcomes. In this web seminar, recommendations for sponsor oversight practices are discussed, as well as tools and best practices for managing vendor relationships. Managing a vendor vs. micro-managing a vendor will also be discussed.

Learning Objectives

- Identify key approaches to planning and preparing to outsource while managing clinical trial risk
- Identify key components for formal study of vendor performance management
- Identify adequate oversight SOPs and other practices
- Employ end of project analysis to pave the way for improvement in future relationships

Who Should Attend

- Sponsors
- CROs/Vendors
- Those that choose, manage, or evaluate external service providers

Instructors

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

Treena Jackson, M.S., M.A., C.Q.A., R.A.C., C.S.S.G.B.

Heather Marshall, M.S.N., B.S.N., R.N.

Shana Zink, B.S., C.C.R.A.

Course Length and Time

2.5 hours 9:00 – 11:30 a.m. Eastern

Course Dates

March 11, 2025

June 9, 2025

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-24-010-L99-P. Released: 3/24.

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 8:30 – 10:30 a.m. and 12:30 – 2:30 p.m. Eastern

Course Dates

February 24, 2025 (12:30-2:30)

May 6, 2025 (8:30-10:30)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-23-049-L99-P. Released: 8/23.

Blended Curriculum Course

Auditing Sponsors and CROs: Deconstruction and Application of the FDA's Compliance Program Guidance Manual

Course Description

As scrutiny of sponsors, Contract Research Organizations (CROs), and monitors involved in the conduct of clinical research intensifies, companies are using their quality assurance resources to review internal (and vendor) systems to ensure compliance within a changing regulatory environment. A systematic application of the Compliance Program Guidance Manual (CPGM) permits identification of regulatory risks during qualification and in-process audits. This web seminar will review the FDA's current guideline for conducting inspections and how to apply them to assess Quality Systems. Assessment of the SOPs that are expected for sponsors and CROs, including registration of trials and informed consent document issues, will also be discussed.

Learning Objectives

- Integrate new regulatory requirements and processes into audits
- Translate inspection criteria to Quality Systems that support changes in inspection focus
- Assess the FDA's application of the CPGM as reflected in regulatory communication
- Examine steps for preparation of an inspection

Who Should Attend

- Professionals from Academia whose institutions or investigators hold INDs or IDEs, or whose institutions support clinical research with Site Management Organizations (SMOs)
- Clinical Quality Assurance Auditors
- Clinical Quality and Compliance Professionals
- Clinical Research Associates
- Project Managers
- Medical Monitors
- Regulatory Affairs Professionals
- Clinical Research Coordinators

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

2 hours 9:00 – 11:00 a.m. and 2:00 – 4:00 p.m. Eastern

Course Dates

March 12, 2025 (9-11) June 4, 2025 (2-4)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 2 hours (0.2 CEUs)** of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-24-042-L99-P. Released: 9/24.

Auditing Techniques: A Problem-Solving Practicum

Course Description

An audit is defined as a systematic and independent examination of trial-related activities and documents. Beyond the review of documents and interviews, auditors are tasked with using factual, objective evidence to support conclusions regarding compliance and assessing whether proposed interventions are acceptable to effectively address the underlying concerns. Utilizing real-life examples and information, participants will work individually and within a group of their peers to review material, assess significance of findings, determine whether or not compliance issues exist, and develop plans for efficient compliance solutions. This interactive web seminar will allow participants to further develop auditing skills.

Learning Objectives

- Discuss current Good Clinical Practice (GCP) compliance issues
- Assess patterns in data using data trend analysis
- Review information for accuracy and validity
- Perform root cause analysis for a study scenario and develop a corrective and preventive action plan (CAPA), including impact assessment to facilitate review of intervention

Who Should Attend

- Clinical Quality Assurance Professionals
- Auditors
- Project Managers
- Clinical Investigators
- Clinical Operations Professionals
- Personnel responsible for ensuring compliance with Good Clinical Practice (GCP) regulations

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

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

Course Dates

January 8, 2025 (12-3)

April 18, 2025 (9-12)

July 23, 2025 (12-3)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-25-001-L99-P. Released: 1/25.

Becoming a Clinical Research Investigator: Roles, Responsibilities and Successful Clinical Trial Management

Course Description

This web seminar has been designed for the clinical investigator seeking an understanding of their role and responsibilities in the conduct of clinical trials. We will focus on the investigator's responsibility to ensure human subject protection and data integrity in the conduct of clinical trials. Specific topic areas include: Delegation to and oversight of clinical research teams, FDA regulations and appliable guidance documents, Good Clinical Practice (GCP), ICH GCP E6 R3 requirements, adverse events, and FDA inspections and sponsor audits.

Learning Objectives

- Describe the clinical investigator roles and responsibilities in the conduct of human clinical trials
- Identify appropriate investigator delegation and oversight
- Define GCP and ICH GCP E6 R3 requirements for clinical investigators
- Recognize adverse events and reporting requirements in clinical trials
- Define types of FDA inspections and sponsor audits

Who Should Attend

- Clinical Investigators
- Sub-Investigators
- Clinical Research Team Members wanting to better understand the clinical investigator role and responsibilities in clinical research

Instructor

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

Course Length and Time

1.5 hours 9:30 – 11:00 a.m. Eastern

Course Dates

May 20**,** 2025

Fee: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-23-050-L99-P. Released: 9/23.

Best Practices for Hosting a Client Audit

Course Description

Hosting a client audit can be a stressful experience for all involved when there is a lack of preparation, communication, and understanding of expectations for the audit. As the audit host, there are ways to gain a sense of control in your work environment while providing the auditor(s) with the best audit experience possible. Meeting their audit needs while reducing unnecessary lost work time and increased stress by the company being audited can be accomplished by way of audit preparation efficiencies. In this web seminar, we will discuss preparation techniques for hosting a client audit including room staging, strategies for responding to audit requests, and the audit follow-up process. During the course, learners will walk through the process for hosting a client audit, discuss the various roles and responsibilities, as well as review strategies for successful audit results.

Learning Objectives

- Describe the potential roles involved in hosting a client audit
- Utilize preparation techniques for hosting a client audit and how to prepare the group/person(s) being audited
- List typical documentation requested during client audits
- Explore options in staging at the host facility
- Implement strategies for responding to audit requests
- Utilize best practices in audit follow-up that will result in reduced audit observations

Who Should Attend

- Quality Assurance Managers and Auditors
- Functional Group Members
- Personnel participating in an audit

Instructor

Treena Jackson, M.S., M.A., C.Q.A., R.A.C., C.S.S.G.B.

Course Length

1.5 hours

Course Dates

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

Accreditation

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

What Participants Say About Barnett Interactive Web Seminars:

"The course presenter was excellent. I have attended many online courses and this class was one of the best. The speaker was to the point and she made the seminar interactive. We were provided tips and hints of how to be a better leader."

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.

Bringing the Clinical Perspective into ISO 14971 Risk Management Discussions

Course Description

The clinical perspective is crucial to understanding risk and implementing effective decision-making in the risk management of medical devices. ISO 14971 is an international standard used by companies around the world as a basis for developing a risk management process for analyzing the risk associated with a medical device. Risk management for medical devices is typically handled by engineers responsible for designing and building a product and can have a tendency to focus on the mechanical risks instead of the clinical risks. A clinician needs to be available to discuss those risks in ways that are understandable to those outside of patient care, while understanding how the engineers discuss and view the device.

Learning Objectives

- Explain the requirements of ISO 14971
- Discuss how to predict severity and probability of risks based on clinical data
- Describe the product lifecycle and how to use clinical data to guide risk mitigation

Who Should Attend

- Clinical Data Specialists/Analysts
- Clinical Data Managers
- Clinical Operations Professionals
- Clinical Project Managers
- Clinical Safety Experts
- Production, Quality, and Safety Engineers

Instructor

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

Course Length

1.5 hours

Course Dates

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Accreditation

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Building Quality by Design (QbD) and Risk-Based Quality Management (RBQM) Systems into Clinical Operations

Course Description

The premise behind RBQM is that monitoring quality can be improved by leveraging existing data. The development of quality and risk management metrics involves identifying the values of an organization, and this web seminar will focus on developing measures to assess meeting those goals, building infrastructure to capture data to support the metrics, and establishing adequate and timely responses to drive improvement. As the industry's utilization of risk-based monitoring continues to increase along with the development and expansion of RBQM, the need for integrating these two concepts is necessary.

Learning Objectives

- Describe the principles of QbD and new regulatory requirements for risk-based monitoring
- Provide an overview of GCP regulations and recent ICH GCP E6 and E8 revisions and their impact on QC/QA process and RBQM systems
- Develop relevant metrics as quality and performance indicators for RBQM systems and effective Corrective and Preventive Action (CAPA) Plans
- Review recent noncompliance trends and regulatory focus for Sites, Sponsors, and IRBs
- Identify and manage risks of clinical trials
- Perform cause-effect analysis for risks and develop mitigation strategies

Who Should Attend

- Clinical Quality Assurance Auditors
- Clinical Quality and Compliance Professionals
- Clinical Research Associates
- Project Managers and Medical Monitors
- Regulatory Affairs Professionals
- Clinical Principal Investigators and Research Coordinators
- IRB Administrators and Members

Instructor

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

Course Length and Time

2 hours 10:00 a.m. – 12:00 p.m. and 1:00 - 3:00 p.m. Eastern

Course Dates

March 19, 2025 (10-12) June 17, 2025 (1-3)

Archived Recording Available in Multiple Formats!

Fee: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-24-043-L99-P. Released: 9/24.

Blended Curriculum Course

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

Instructors

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

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Elizabeth Weeks-Rowe, LVN, C.C.R.A.

Course Length and Time

1.5 hours 9:30 – 11:00 a.m. and 1:00 – 2:30 p.m.

Course Dates

February 13, 2025 (1-2:30)

May 6, 2025 (9:30-11)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-24-044-L99-P. Released: 8/24.

CAP and CLIA Requirements for Clinical Research Laboratories

Course Description

This web seminar will provide an introduction to the College of American Pathologists (CAP) and Clinical Laboratory Improvements Amendments (CLIA) requirements for laboratories that perform routine and non-routine testing of clinical samples for clinical trials. We will review the laboratory requirements for patient care and the requirements for clinical research. Similarities and differences of CAP requirements from ISO 15189 Medical Laboratories Requirements for Quality and Compliance, as applicable, will be discussed. This web seminar is an introductory course and not intended for experienced users.

Learning Objectives

- Describe CAP/CLIA's goals to patient safety and privacy
- Describe the general CAP/CLIA requirements
- Distinguish similarities and differences of laboratory requirements from CAP and ISO 15189
- Identify inspection and/or audit a laboratory's compliance to CAP/CLIA

Who Should Attend

- Laboratory Staff new to CAP and CLIA
- Auditors
- Regulatory Agency Inspectors
- Laboratory Managers/Directors
- Laboratory Quality Professionals

Instructor

Shelia Russell McCullers, M.S., D.M.

Course Length and Time

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

Course Dates

February 11, 2025 (9-11)

May 29, 2025 (1-3)

Archived Recording Available in Multiple Formats!

FEE: $835*

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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#: 0778-0000-23-051-L99-P. Released: 5/23.

Case Narrative Writing for Reporting Adverse Events

Course Description

A narrative is a short document that is required by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) to briefly describe the events in the life of a patient. These narratives are required when a patient enrolled in a study, after taking the study medication or approved drugs (post-marketing), has discontinued the study because of an adverse event, had one or more serious adverse events, or died. FDA, EMA, and International Council for Harmonization (ICH) guidance documents call for the submission of a study subject's experience in narrative form for those who meet these specific criteria. This web seminar will provide a set of guidelines, instructions, and templates for the writing of clinical and post-marketing case narratives for reporting adverse events.

Learning Objectives

- Describe relevant regulatory requirements in producing good quality case narratives
- Define and evaluate the critical data elements
- Examine special situations and challenges
- Describe and practice the skills necessary for generating well-written case narratives for reporting to regulatory authorities

Who Should Attend

- Drug Safety Professionals
- Pharmacovigilance Personnel
- Regulatory Affairs Professionals
- Clinical Development Personnel

Instructor

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

Course Length

1.5 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

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

Course Dates

February 7, 2025 (9:30-11:30)

May 19, 2025 (12:30-2:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

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ACPE#: 0778-0000-24-013-L99-P. Released: 2/24.

Blended Curriculum Course

Cases in Advanced GCP: A Problem-Solving Practicum

Includes R3 Updates

Course Description

This application-based web seminar covers advanced concepts and challenges encountered in the application of Good Clinical Practice (GCP). During this highly interactive course, participants will review and discuss cases that include GCP challenges in topic areas such as IRB/IEC approval, informed consent, drug accountability and reconciliation, SUSAR submissions, communications with ethics committees and health authorities, as well as the management of investigational product. Cases are based on actual industry examples, and participants are expected to solve cases by applying Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) principles, which are briefly reviewed.

Learning Objectives

- Apply your understanding of the GCP standards most critical to core clinical research job functions
- Explain the role of Quality Systems in the GCP environment
- Apply GCP through critical thinking in the context of real-world clinical research scenarios and simulations
- Explain the concepts of RCA and CAPA to improve site and sponsor performance and compliance

Who Should Attend

- Clinical Quality Assurance Professionals
- Clinical Research Associates
- Project Managers
- Investigators
- Study Coordinators
- GCP-focused Regulatory Affairs Professionals
- Clinical Operations Professionals

Instructor

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Course Length and Time

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

Course Dates

April 29, 2025 (12-3)

May 12, 2025 (9-12)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-23-008-L99-P. Released: 3/23.

Centralized TMF Management: The CRO Sponsor Partnership

Course Description

Many sponsor organizations transfer responsibility for Trial Master File (TMF) management to their Contract Research Organization (CRO) partners. However, the CRO maintains TMF content for those activities for which they have been delegated. Generally, a TMF is comprised of sponsor, CRO, and vendor content. The relationship between the CRO and the sponsor is critical in ensuring a quality inspection-ready TMF. This web seminar will explore critical activities and responsibilities on the part of the CRO and the sponsor. A successful partnership between these two groups is critical to ensuring an inspection ready file during and at the conclusion of the study. Both partners must understand the activities of each other to ensure that all artifacts within the TMF have been collected and are available within the TMF. A key tool in centralized TMF Management is the TMF Study Map. We will explore the process of developing and managing the TMF Study Map in tracking the content of the TMF during the active phase of the study and at completion. Use of a TMF Plan by the sponsor and the CRO will also be discussed.

Learning Objectives

- Identify the responsibilities of the sponsor and CRO for TMF Management
- Discuss the key components of the TMF Plan
- Demonstrate understanding of the key components of a TMF Study Map
- Identify strategies for managing the CRO and Sponsor relationship as it relates to the TMF

Who Should Attend

- Trial Master File Directors
- Trial Master File Managers
- Trial Master File Coordinators
- Clinical Operations Directors
- Trial Managers
- Records Management Team Members

Instructor

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

Course Length

1.5 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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cGMP for the Quality Control Laboratory

Course Description

This web seminar will provide a general overview of the cGMP regulations that are applicable to a quality control (QC) laboratory following ICH guidelines and 21 CFR 211. We will discuss the requirements for lab equipment, such as calibration, maintenance, and validation, as well as review analytical method validation, reference standard qualification, and documentation practices. This web seminar will also cover regulatory requirements for stability testing per 21 CFR 211.166 and ICH Q1. The session will conclude with a discussion around the requirements of proper Out of Specification (OOS) investigation.

Learning Objectives

- Review the requirements of laboratory equipment, including calibration, preventative maintenance, and validation
- Review the requirements of analytical method validation, reference standard qualification, and general documentation practices
- Describe the regulatory requirements of stability testing
- Describe the requirements of investigating OOS test results

Who Should Attend

- Quality Control Staff
- Lab Management
- Lab Analysts
- Quality Assurance Staff
- Production Personnel

Instructor

Susan M. Leister, M.B.A., Ph.D., CQA, CSSBB

Course Length

3 hours

Course Dates

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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.

Clinical Evidence Writing for Medical Device Regulatory Submissions

Course Description

Data used to support regulatory submissions comes from many sources. Clinical evidence can be found in the published literature, company complaints, and in publicly available databases like the U.S. Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database. In this web seminar, we will review how to gather and extract pertinent data from these sources to develop an appropriate analysis for your product and submission. Attendees will learn how to identify quality clinical evidence and utilize it in regulatory submissions.

Learning Objectives

- Discuss the different types of clinical evidence available
- Identify the limitations of clinical evidence
- Describe the content of clinical evidence analysis

Who Should Attend

- Regulatory Affairs Professionals
- Medical Writers

Instructor

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

Course Length

1.5 hours

Course Dates

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Blended Curriculum Course

Clinical Research Financial Management for Investigative Sites

Course Description

Frequently, clinical research financial regulations, the budget process, clinical trial revenue cycle, and patient remuneration are obscure topics to not only the investigator, but also to the study team delegates. This web seminar describes the significance of ensuring that the investigator and study team are integrated into the financial components of the study to mitigate the risks associated with non-compliance with federal research billing regulations. Strategies for developing operational efficiencies and establishing communication channels to enhance sponsor reimbursements while reducing insurance denials will also be discussed.

Learning Objectives

- Describe the significance of incorporating the investigator and study team into the financial phases of a clinical study
- Discuss the importance of integrating the development and approval of the protocol with the budget/contract process
- Discuss the impact of sponsor data capture systems, vendors, monitors, and auditors on clinical trial financial milestones
- Describe standard operating procedures and communication channels required for compliant clinical study financial billing (sponsor /patient), insurance authorizations, and participant remuneration

Who Should Attend

- Clinical Research Coordinators
- Clinical Trial Managers
- Clinical Research Associates
- Clinical Research Managers/Directors
- Administrative Directors
- Financial Analysts
- Research Nurses/Research Nurse Manager

Instructor

Mary L. Veazie, M.B.A., CPA, CHC, CHRC

Course Length and Time

1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates

March 20**,** 2025

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-24-045-L99-P Released: 9/24.

Blended Curriculum Course

Clinical Trial Start-Up: Using a Work Breakdown Structure (WBS) for Effective Planning

Course Description

A Work Breakdown Structure (WBS) defines the work, tasks, assignments, and timelines for work to be completed. This web seminar identifies how WBS aids team members involved in study start-up from the sponsor/CRO and investigative site to address clinical trial start-up challenges once an investigative site has been selected. Recommendations on how sponsors/CROs and investigative sites work collectively to improve turnaround times in clinical trial start-up are addressed, including IRB/IEC approval, clinical trial agreements, and how site initiation visits are mapped out using a WBS. Case studies, schematics, handouts, and tools will be provided.

Learning Objectives

- Identify three benefits of a communication plan during clinical trial start-up
- Examine a WBS in clinical trial start-up
- Identify situations where a WBS would have a positive impact on clinical trial start-up planning

Who Should Attend

- Clinical Project Managers
- Clinical Trial Managers
- Clinical Research Associates
- Clinical Trial Assistants
- Other team members from Sponsor/CROs who are responsible for clinical trial start-up activities with investigative sites
- Clinical Research Coordinators
- Clinical Research Team Leaders/Managers
- Other team members at the investigative site who are responsible for clinical trial start-up activities

Instructor

Nazma M. Rosado, MAOL, P.M.P., CPLP, 6σ, CMQ/OE

Course Length and Time

3 hours 9:00 a.m. – 12:00 p.m. and 1:00 – 4:00 p.m. Eastern

Course Dates

January 13, 2025 (9-12)

April 17, 2025 (1-4)

July 10, 2025 (9-12)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-24-014-L99-P. Released: 1/24.

ClinicalTrials.Gov Requirements: Clinical Trial Registration and Trial Results Reporting, Expanded Registry and Results Data Bank

Course Description

The purpose of the U.S. Department of Health and Human Services (HHS) final rule is to clarify and expand the requirements for the submission of clinical trial registration and results information to the ClinicalTrials.gov database.

This web seminar reviews the new requirements published in September 2016, under FDAAA 801 and 42 CFR Part 11, with an implementation date of January 2017, for applicable clinical trials: Submitting registration and clinical trial summary results information, including adverse event information, of drug products (including biological products) and device products to ClinicalTrials.gov. Discussion of the expanded registry and results data bank will be provided along with a summary of all trial registration and results reporting requirements.

Learning Objectives

- Explain the role and expectations of the responsible party
- List clinical trial registration requirements
- Identify two trial documents that are required to be submitted with the clinical trial results information
- Describe the trial results reporting requirements for unapproved/unlicensed/uncleared products and approved products

Who Should Attend

- Trial Managers
- Project Managers/Directors
- Clinical Quality Assurance/Compliance Personnel
- Principal Investigators
- Regulatory Professionals
- Clinical Operations Professionals

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

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

Course Dates

February 25, 2025 (12:30-2:30)

May 29, 2025 (9:30-11:30)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-23-009-L99-P. Released: 2/23.

Coaching Skills for Leaders

Course Description

The notion of managers coaching their employees is now well-entrenched in best business practices. As leaders, we know we need to engage in coach-like conversations to help our teams and direct reports achieve both personal and professional goals. Coaching skills, however, are different from mentorship, supportive management, and simple feedback. They look very different from other conversations and for leaders, are situational by nature. This web seminar will explore the various competencies required to develop coaching skills to help lead from a place of influence rather than top-down authority. Participants will learn about active listening and inquiry-based advocacy, appropriate coaching moments, and will be provided a tool to help navigate these generative conversations in the workplace.

Learning Objectives

- Identify and define specific coaching skills
- Distinguish between managing and coaching
- Describe and practice coaching skills in group scenarios
- Distinguish appropriate timing to employ coaching skills
- Combine authentic leadership style with coach-like presence

Who Should Attend

- Site Managers
- Sponsor Managers
- Project Managers
- Project Leads
- Principal Investigators
- Clinical Research Associates

Instructors

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

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

Nazma M. Rosado, MAOL, P.M.P., CPLP, 6σ, CMQ/OE

Course Length and Time

1.5 hours 11:00 a.m. – 12:30 p.m. and 1:30 – 3:00 p.m. Eastern

Course Dates

March 11, 2025 (11-12:30)

June 25, 2025 (1:30-3)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-24-046-L99-P. Released: 7/24.

Blended Curriculum Course

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:

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

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

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

Shana Zink, B.S., C.C.R.A.

Course Length and Time

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

Course Dates

February 24, 2025 (12:30-2:30) May 1, 2025 (9:30-11:30)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 2 hours (0.2 CEUs)** of continuing education credit for full participation, including the completion of a mid-term, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-24-069-L99-P. Released: 8/24.

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

Instructors

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

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Elizabeth Weeks-Rowe, LVN, C.C.R.A.

Course Length and Time

1.5 hours 9:30 – 11:00 a.m. and 12:00 – 1:30 p.m. Eastern

Course Dates

February 13, 2025 (9:30-11)

May 13, 2025 (12-1:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-24-015-L99-P. Released: 2/24.

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 the CRC
- 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:

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

Course Length

2 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

NEW! Creating Impactful Audit Reports in Clinical Research

Course Description

This interactive two-part, 4-hour web seminar provides participants with the essential skills needed to create effective and actionable audit reports in clinical research settings. Drawing from ICH E6 guidelines and FDA standards, this web seminar will focus on developing clear, concise, and impactful audit documentation that not only identifies compliance issues but also outlines actionable steps for resolution.

Learning Objectives

- Construct factual and objective observations
- Organize information for maximum impact
- Navigate common challenges in report writing and review
- Apply FDA Investigations Operations Manual (IOM) 2024 principles
- Develop practical skills through peer-based exercises
- Implement effective report distribution and response review strategies

Who Should Attend

- Clinical Quality Assurance and Compliance Professionals
- Project Managers
- Regulatory Affairs Specialists
- Clinical Investigators
- IRB Administrators and Members

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

4 hours, two days 9:00 – 11:00 a.m. Eastern each day and
1:00 – 3:00 p.m. Eastern each day

Course Dates

Offering #1:

February 28 & March 7, 2025 (9-11)

Offering #2:

April 30 & May 7, 2025 (1-3)

Offering #3:

June 16 & June 30, 2025 (9-11)

FEE: $1,195*

**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 4.0 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#: 0778-0000-25-024-L99-P. Released 2/25.

Blended Curriculum Course

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 considerations and techniques for building sponsor and CRO relationships
- Identify sponsor oversight requirements included in ICH GCP E6 R2 and the R3 draft
- Determine accountability structures, communication and escalation pathways for outsourced providers
- Identify tools for managing and solving partnership problems through root cause analysis (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

Instructors

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

Treena Jackson, M.S., M.A., C.Q.A., R.A.C., C.S.S.G.B.

Heather Marshall, M.S.N., B.S.N., R.N.

Shana Zink, B.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

Course Dates

February 18, 2025 (9:30-11)

May 12, 2025 (1-2:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-24-016-L99-P. Released: 2/24.

Blended Curriculum Course

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

Course Length and Time

2 hours 9:30 – 11:30 a.m. Eastern

Course Dates

May 7**,** 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-011-L99-P. Released: 5/23.

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
- Examine eSource Implementation from a CDM perspective

Who Should Attend

- Clinical Data Managers
- Clinical Research Professionals

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 in Multiple Formats!

Accreditation

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

Data Management Plan Creation: Content and Rationale

Course Description

A well-designed Data Management Plan (DMP) provides a detailed description of how to handle data under any foreseeable circumstances and establishes processes for how to deal with unplanned issues. The DMP is study specific, is considered a "living document," and is subject to audit; therefore, it is important to understand the content requirements and rationale for its creation.

In this web seminar, we will focus on the importance of the creation of a DMP and the expected content that this document should contain. Attendees will be provided with a sample template for review.

Learning Objectives

- Identify the rationale for creation of a robust DMP
- Describe the documentation required for a DMP when utilizing both paper and Electronic Data Capture (EDC) applications
- List the components of a DMP as defined in the Society for Clinical Data Management (SCDM) Good Clinical Data Management Practices (GCDMP) document
- Apply standards for creating, approving, and maintaining DMPs

Who Should Attend

- Clinical Data Managers
- Project Managers
- Clinical Research Personnel

Instructor

Denise G. Redkar-Brown, MT

Course Length and Time

1.5 hours 9:30 – 11:00 a.m. Eastern

Course Dates

May 8**,** 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-052-L99-P. Released: 8/23.

Data Quality in Clinical Trials: Rationale and Impact

Course Description

Good Clinical Practice (GCP) is the universal ethical and scientific quality standard for conducting clinical trials. The GCP standard applies to all aspects of the clinical trial process. Adherence to the GCP quality standard during the clinical trial process provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of the trial subjects are protected.

In this web seminar, we will explore the data quality definitions, processes involved in determination of quality, and the rationale utilized in ensuring data quality. It's not about the individual data point anymore.

Learning Objectives

- Describe a quality system approach for assuring appropriate data quality
- Identify data discrepancies, errors, outliers and bias and how to assess their importance
- Describe how poor data quality may or may not impact study operations or analysis
- Compare and contrast common approaches to discrepancy identification and resolution

Who Should Attend

- Clinical Data Managers
- Quality Assurance Personnel

Instructor

Denise G. Redkar-Brown, MT

Course Length and Time

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

Course Dates

March 18, 2025 (9:30-11:30)

June 2, 2025 (12:30-2:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

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Accreditation

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ACPE#: 0778-0000-23-053-L99-P. Released: 10/23.

NEW! Database Design Considerations in Clinical Trials

Course Description

This web seminar will identify the nine steps necessary to plan the data collection required as contained in the study protocol and other aspects of the clinical trial. Prioritizing the data and recognition of the risk assessment process will be covered in detail, as well as the identification of data standards. Data standards will be discussed and the relationship between CDASH and CDISC will be introduced. Database design considerations, including the elements to be included along with the most advantageous formation of the data capture for database elements (database questions, database answers, and the different element types) are also covered. Additionally, some examples of physical database design will be featured.

Learning Objectives

- Determine data collection requirements based on the protocol
- Evaluate the priority of data required/risk assessment
- Identify data standards
- Discuss the relationship between CDASH and CDISC

Who Should Attend

- Clinical Database Programmers
- Clinical Data Managers

Instructor

Denise G. Redkar-Brown, MT

Course Length and Time

1.5 hours 9:30 - 11:00 a.m. Eastern

Course Dates

February 24, 2025

May 28**,** 2025

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-24-059-L99-P. Released: 8/24.

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."

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! Decoding FDA's Draft Guidance on Remote Regulatory Assessments: A Practical Guide

Course Description

This web seminar provides a comprehensive overview of the FDA's recently released draft guidance on Conducting Remote Regulatory Assessments (RRAs). Learners will gain a thorough understanding of RRAs, their implementation, and their impact on FDA-regulated industries. We will explore the key aspects of the guidance, including the types of RRAs, FDA's expectations, and the potential consequences for regulated entities. By the end of the web seminar, attendees will be equipped with practical knowledge to navigate the evolving landscape of remote regulatory oversight.

Learning Objectives

- Define RRAs and differentiate them from traditional inspections
- Identify the circumstances under which FDA may initiate or request an RRA
- Review the difference between a Mandatory and Voluntary RRA
- Describe the expectations and technological requirements for participating in an RRA
- Explain the potential consequences of declining to participate in mandatory RRAs
- Develop effective strategies for preparing and responding to RRA requests

Who Should Attend

- Quality Assurance Managers
- Regulatory Affairs Professionals
- Compliance Officers
- Clinical Trial Managers
- Clinical Operations Directors
- CRO Project Managers

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

1.5 hours 9:00 – 10:30 a.m. and 1:30 – 3:00 p.m. Eastern

Course Dates

January 16, 2025 (9-10:30)

March 12, 2025 (1:30-3)

May 20, 2025 (9-10:30)

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-25-021-L99-P. Released 1/25.

Design Considerations for GCP Training Programs

Includes R3 Updates

Course Description

Regulatory authority inspection trends are identifying a need for truly effective Good Clinical Practice (GCP) training. GCP training should ensure that clinical research stakeholders not only "know GCP" but know how to apply the principles of GCP in their work lives. The decision to develop and implement a GCP Training Program is a time-consuming and expensive project for any clinical research organization. How can you maximize the effectiveness of the training to ensure return on this investment in both financial and compliance terms? By designing GCP training with a focus on engaging adult learners, which is critical to ensuring both acceptance by the learners and the transfer of knowledge into everyday professional practice. This web seminar will identify key elements to consider throughout the phases of program development and design, training deployment, and post-course assessment.

Learning Objectives

- Describe the training elements that effectively "connect" with adult learners
- Compare and contrast the pros and cons of face-to-face, web-based, and eLearning venues for GCP training
- Identify strategies for assessing training outcomes such as short-term knowledge transfer and long-term impact on the organization

Who Should Attend

- Clinical Research Training Professionals and/or Subject Matter Experts
- Pharma/Device Professionals with responsibility for internal and/or investigator GCP training
- Clinical Research Site Professionals

Instructor

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

Course Length

2 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

Detecting Risk Signals in Protocols, Data, and Monitoring

Course Description

In an environment where remote monitoring and management techniques are becoming the daily practice, preventive measures need to be implemented to identify risks. You need to be able to identify protocol data thresholds and parameters for risks to establish management and escalation triggers. As data becomes available in real time, you should not be waiting to intervene until deviations become a "trend" before intervention is implemented; you need to know how to look for outliers and "red flags" on a daily basis. With the increasing use of CROs and vendors, it is essential that best practices are established for identifying risk signals in management and monitoring practices. In this web seminar, we will discuss how to detect risk signals in protocols, data, and monitoring based on risk-based quality management, industry guidances, and practical application.

Learning Objectives

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

Who Should Attend

- Clinical Research Associates
- Project Managers

Instructor

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

Course Length

1.5 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

Blended Curriculum Course

Developing and Negotiating Research Site Clinical Study Budgets and Contracts

Course Description

Negotiating study contracts and budgets is critical for the future success of the clinical research site. This web seminar provides strategic skills and best practices for contract negotiations and budget development. Learners will also review and practice the art of negotiation.

Learning Objectives

- Prepare for negotiations: Define steps in the negotiation process; integrate strategies for effective negotiating; review success factors and risks in negotiations; discuss ethical considerations
- Review industry study start-up basic contract content: Discuss state law, institutional vs. sponsor required language; "boilerplate" terms; indemnification; other agreements including data use, confidentiality, HIPAA, master agreements
- Develop study budget presentations: Based on objective market data; subject vs. visit based
- Assess protocol feasibility and resource needs: Look for hidden costs; study start-up to final query resolution
- Translate information in a study protocol to successful study budgets: Plan for protocol amendments and procedure changes; financial checks and balances

Who Should Attend

- Research Site Representatives that have some direct and/or indirect responsibility in contract and budget negotiations
- Project Managers and Site Managers
- Contracts and Budget Department Representatives
- Clinical Research Coordinators and Research Nurses
- Investigators
- Sponsor Representatives working with sites on study start-up

Instructor

Mary L. Veazie, M.B.A., CPA, CHC, CHRC

Course Length and Time

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

Course Dates

February 11, 2025 (8:30-11:30)

May 13, 2025 (12-3)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 3 hours (0.3 CEUs)** of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-23-012-L99-P. Released: 2/23.

Blended Curriculum Course

Developing Clinical Study Budgets for Sponsors

Course Description

In an environment where studies are becoming more challenging to execute and taking more resources and time than anticipated, it is key to develop a solid and flexible budget to allow for study execution challenges. In developing a budget it is critical to address all standard line items such as reimbursement for procedures, but how can the oversight and follow-up time be accurately calculated? How does Fair Market Value (FMV) criteria factor into budget development? What questions should be asked to determine additional, unwritten, study expectations? What are some key elements leading to delayed budget negotiation and approval? This web seminar will address the fundamentals of budget development and considerations for ensuring that budgets are developed fairly to ensure that sites are appropriately reimbursed for study expectations.

Learning Objectives

- Discuss the elements of Fair Market Value (FMV)
- Review key questions and items to address prior to developing the budget
- Review techniques and tools for use in budget development at the sponsor and site level

Who Should Attend

Sponsor and CRO representatives in the following roles:

- Project Managers
- Clinical Research Associates
- Clinical Research Associate Managers
- Contract and Budget Management Personnel
- Directors in Clinical Operations
- Site Managers
- Principal Investigators
- Study Coordinators
- Site Budget and Contract Representatives

Instructor

Mary L. Veazie, M.B.A., CPA, CHC, CHRC

Course Length and Time

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

Course Dates

February 11, 2025 (12:30-2:30)

May 15, 2025 (9:30-11:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 2 hours (0.2 CEUs)** of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-24-047-L99-P. Released: 8/24.

Drug and Device Regulatory Submissions: A Comparison

Course Description

This web seminar is designed to provide details on what goes into FDA regulatory submissions for drugs and devices, and highlight the differences between the programs and Centers (CDER and CDRH) dealing with these products. Drug submissions may include an Investigational New Drug Application (IND), a New Drug Application (NDA), 505(b)(2) application, an Abbreviated New Drug Application (ANDA) for generic drugs, orphan drugs and supplemental filings, and contain information on manufacturing controls and clinical trial outcomes. Device submissions may include 510(k), PMA and PDPs, and de novo applications. Requirements for device submissions will depend on the device type and classification, as well as the available performance and safety information. The decision pathways needed to ensure the necessary information has been provided will be presented.

Learning Objectives

- Differentiate between drug and device FDA submissions
- Identify information and decisions needed to complete submissions
- Discuss the purpose of submission sections
- Discuss the impact of clinical data in submissions

Who Should Attend

- Regulatory Affairs Professionals who require an understanding of the pharmaceutical and medical device approval systems
- Management, Legal, and other personnel who must be familiar with the various approval process systems and submissions of related documents

Instructor

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

Course Length

1.5 hours

Course Dates

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

Accreditation

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

Blended Curriculum Course

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

Instructors

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

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

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

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

Course Length and Time

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

Course Dates

March 5, 2025 (9-12)

June 3, 2025 (12-3)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-25-002-L99-P. Released: 3/25.

Effective Use of Tools, Job Aids, Process Maps, and Checklists for Project Managers and Clinical Research Teams

Course Description

The clinical protocol is a complex document that must be understood by the clinical research sponsor, vendors and clinical research sites for successful implementation. Effective use of job aids, process maps and checklists can improve team members' understanding of what is being requested. This web seminar will explore how various tools can be utilized to improve project team members' understanding of tasks, and to enhance the training of internal teams, vendors, and investigational sites. We will explore the best use of flow charts, checklists, and job aids to enhance team performance, as well as provide examples to aid in eligibility requirements, exclusionary criteria, and safety and efficacy endpoint collection.

Learning Objectives

- Define a job aid and the benefits of using them
- Define types of job aids, formatting and when to use: Step-by-Step Job Aid, Form or Worksheet, Checklist, Decision Table, Flow Chart, Process Map, and Reference Source Job Aid
- Identify effective design methods for creation of job aids
- Describe how job aids can improve clinical project tasks

Who Should Attend

- Project Managers
- Clinical Trial Managers
- Clinical Research Associates
- Clinical Training Managers

Instructor

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

Course Length

1.5 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

What Participants Say About Barnett Interactive Web Seminars:

"The seminar provided me new strategies and elements to empower my team."

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

Blended Curriculum Course

Electronic Informed Consent Guidance: Regulatory Updates

Course Description

Conducting the informed consent process is one of the most critical tasks to be completed by a research site. It's essential that a subject clearly understands the information and language in the consent form and that their rights, safety, and welfare are not jeopardized. This web seminar will review the essential language in the informed consent document through review of the FDA regulations and guidance documents, including the December 2016 final guidance, "Use of Electronic Informed Consent in Clinical Investigations: Questions and Answers." Additionally, there will be discussion of some of the challenges faced in consenting pediatric subjects in trials of greater than minimal risk, the use of translators, and review of the use of electronic informed consent and electronic signatures.

Learning Objectives

- Explain the content of the recent guidances related to informed consent
- Discuss the implications of the guidances on current practices and policy
- Analyze the use of electronic media and processes to obtain electronic informed consent (eIC)
- Discuss implications and best practices of electronic signatures on consent documents

Who Should Attend

- Research Site Managers
- Investigators
- Clinical Research Coordinators
- Clinical Research Associates
- Clinical Research Associate Managers
- Project Managers
- Sponsor/CRO Staff
- Clinical Quality Compliance and Quality Assurance Professionals

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates

June 16**,** 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-23-055-L99-P. Released: 12/23.

Blended Curriculum Course

Electronic Medical Records: Approaches for Ensuring Source Document and 21 CFR Part 11 Required Components

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 and ICH GCP E6 Guideline)
- Explain required characteristics for source documents in any form
- Describe requirements of electronic source documents (21 CFR Part 11)
- Apply these concepts to electronic medical records at research sites
- Apply contingency planning for electronic source document deficiencies
- Manage site and sponsor activities regarding electronic medical records

Who Should Attend

- Investigators
- Clinical Research Coordinators
- Device and Drug Study Clinical Research Associates and Managers
- Project Managers
- Quality Assurance Personnel

Instructor

Denise Redkar-Brown, MT

Course Length and Time

2.5 hours 8:30 – 11:00 a.m. and 12:30 – 3:00 p.m. Eastern

Course Dates

January 21, 2025 (12:30-3)

April 4, 2025 (8:30-11)

July 24, 2025 (12:30-3)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-056-L99-P. Released: 7/23.

EMA and MHRA Inspections: Successful Planning and Execution Tips and Techniques

Course Description

In recent years, the European Medicines Agency (EMA) and the UK's Medicines and Healthcare products Regulatory Agency (MHRA) have increased the frequency and reach of their inspections. The outcome of the inspection can determine whether a product will be granted a marketing authorization in Europe or the UK, and good preparation will enable the research to be shown in the most favorable light. This web seminar will help learners to know how best to prepare their organizations for inspections by the EMA and MHRA inspectorates, to know what the inspectors are looking for, to understand what to expect during the inspection and to learn from real inspection experiences.

Learning Objectives

- Describe how to be inspection ready at all times
- Explain the differences between EMA and MHRA inspections, and their significance
- Identify tools to prepare the organization to perform at its best during the inspection
- Describe how to mitigate inspection findings
- Identify which records should be made available for the inspection

Who Should Attend

- Clinical Operations Staff
- Facilitators of the inspection
- Senior Management Personnel who have a role in the inspection

Instructors

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

Elizabeth Ronk Nelson, M.P.H.

Vaska Tone

Course Length

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.

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

Course Length

1.5 hours

Course Dates

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Archived Recording Available in Multiple Formats!

Accreditation

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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."

Blended Curriculum Course

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:

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

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Course Length and Time

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

Course Dates

January 7, 2025 (1-3)

April 3, 2025 (9-11)

July 14, 2025 (1-3)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-013-L99-P. Released: 1/23.

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 model for use that has been adopted by other industries and is referenced in current regulatory guidance documents.

Learning Objectives

- Describe important guiding principles when implementing a risk management framework
- Describe the attributes of a risk management framework
- Explain the rationale for knowing an organization's definition for risk

Who Should Attend

- Sponsor and Vendor Personnel responsible for trial oversight
- Clinical Research, Operations, and Development Professionals

Instructor

Debbie Harper, B.Sc., P.M.P.

Course Length

1.5 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

Establishing Quality Tolerance Limits (E6 R2 and E6 R3)

Course Description

The ICH GCP E6 R3 update builds on the foundation set by E6 R2, particularly with regard to risk management in clinical trials. While E6 R2 introduced the concept of Quality Tolerance Limits (QTLs) to address risk control, the R3 revision enhances the QTL concept at the trial level as well as adding in "Acceptable Ranges". QTLs are intended to ensure that clinical trials maintain data integrity, subject safety, and reliable results while adapting to the complexities of modern trial designs. This web seminar will explore the methodology for establishing, evaluating, and maintaining appropriate ranges, their relationship to Critical to Quality (CTQ) factors, and their role in Quality by Design (ICH E8 R1), Continuous Quality Improvement (CQI) and the move towards defined quality. Participants will learn how to implement QTLs effectively in the context of clinical trials and decision-making.

Learning Objectives

- Understand the background of QTLs and their relationship to CTQ factors, as well as their role in clinical trials
- Learn how to develop and establish ranges in line with ICH E6 R3, including identifying critical processes that impact subject protection and data integrity
- Understand the methodology for monitoring QTLs, tracking data, and responding when ranges are exceeded, as well as documenting any necessary adjustments
- Gain insights into how to study, report, and act on breaches of established Ranges, including conducting root cause analysis and documenting findings in the Clinical Study Report (CSR)
- Integrate QTLs into the Quality Management System (QMS) to ensure ongoing compliance and effective risk management
- Understand the changes in QTLs from ICH E6 R2 to ICH E6 R3 and how to effectively apply the concepts in trial management

Who Should Attend

- Managers/Directors in Clinical Operations, Quality Management, and Compliance
- Clinical Quality Assurance Professionals

Instructor

Andy Lawton

Course Length and Time

2 hours 9:00 – 11:00 a.m. Eastern

Course Dates

February 5**,** 2025

May 30**,** 2025

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-25-029-L99. Released: 2/25.

eTMF Implementation Strategies

Course Description

Across the industry, organizations are moving towards an electronic Trial Master File (eTMF). Moving from a paper TMF or CRO-held TMF to a sponsor-held 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, system validation, and working with business 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
- Discuss the validation requirements when implementing an eTMF

Who Should Attend

- Trial Master File Directors
- Trial Master File Managers
- Trial Master File Coordinators
- Clinical Operations Directors
- Trial Managers
- Records Management Team Members

Instructors

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

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

Jim Markley

Laura Wiggins, M.B.A.

Course Length and Time

2 hours 9:30-11:30 a.m. Eastern

Course Dates

April 15**,** 2025

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-24-048-L99-P. Released: 11/24.

eTMF Quality Oversight: A Risk-Based Approach

Course Description

When applied to electronic Trial Master File (eTMF) oversight, risk-based management is the combination of the potential of quality issues occurring and the impact these deficiencies may have on the integrity of the TMF and the overall Good Clinical Practice (GCP) impact on the study. The TMF is comprised of many records and documents, and a quality TMF is defined as a collection of records, which is complete, collected in a timely manner and comprised of quality records. In the past several years, regulatory agencies have been very clear in their expectation that a sponsor presents a quality TMF during an inspection. This web seminar will examine the concept of a risk-based approach to TMF management and oversight, and, its application to TMF oversight. Included are processes for conducting and documenting quality control (QC) activities that will ensure a high quality eTMF. Quality review findings can then drive the need for additional quality review activities, and by applying these concepts, the sponsor ensures TMF inspection readiness.

Learning Objectives

- Discuss the application of risk-based assessment to establish a plan for conducting eTMF QC activities
- Explain various QC activities to ensure a high quality eTMF
- Identify key TMF artifacts with significant risk for quality issues

Who Should Attend

- Trial Master File Directors
- Trial Master File Managers
- Trial Master File Coordinators
- Clinical Operations Directors
- Trial Managers
- Records Management Team Members

Instructors

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

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

Jim Markley

Laura Wiggins, M.B.A.

Course Length and Time

2 hours 9:30 – 11:30 a.m. Eastern

Course Dates

April 8, 2025

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-24-049-L99-P. Released: 9/24.

EU Clinical Trial Regulation (EU-CTR) Requirements

Course Description

The EU Clinical Trial Regulation (Regulation (EU) No. 536/2014) has ushered in a transformative era for clinical trials within the European Union and is built on three fundamental pillars: Enhancing the efficiency of clinical trials in Member States Concerned (MSCs) to foster innovation and reduce duplication, increasing the transparency of clinical trials across Europe, and prioritizing participant safety. At the core of this regulatory shift is the Clinical Trial Information System (CTIS), which serves as the central hub for all submissions to the EU. This comprehensive web seminar is designed to provide participants with a thorough understanding of the EU-CTR, its objectives, and its practical implications for clinical trial conduct in the EU.

Learning Objectives

- Understand the rationale and requirements for the regulation
- Become proficient in identifying and comprehending the different types of submissions within CTIS
- Explore the critical roles and responsibilities of key stakeholders involved
- Gain a comprehensive understanding of the submission process through the CTIS, from initial registration to ongoing updates and amendments

Who Should Attend

- Clinical Trial Management, Monitors and Leads
- Regulatory Affairs
- Executive Management

Instructor

Andy Lawton

Course Length and Time

1 hour, 9:00 – 10:00 a.m. and 1:00 – 2:00 p.m. Eastern

Course Dates

February 27, 2025 (9-10)

May 30, 2025 (1-2)

July 16, 2025 (9-10)

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 1 hours (0.1 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#: 0778-0000-24-034-L99-P. Released: 2/24.

EU Guideline on Computerised Systems and Electronic Data in Clinical Trials

Course Description

The EU Guideline on computerised systems and electronic data in clinical trials represents a unique perspective on computer system validation (CSV). Unlike conventional CSV guidance, which primarily focuses on system validation, this guideline offers a holistic framework deeply rooted in the context of clinical trials. Notably, it is crafted by EU GCP Inspectors, placing a strong emphasis on the clinical trial setting. While a substantial portion of the guideline aligns with traditional CSV principles, this web seminar is designed to shed light on the areas where it diverges from mainstream CSV methodologies such as Good Automated Manufacturing Practice (GAMP). Participants will delve into these distinctive aspects, gaining valuable insights into electronic data management in clinical trials.

Learning Objectives

- Explore the distinctions between the EU Guideline and other computer systems validation guidances and methods
- Recognize the role of metadata in ensuring the integrity and traceability of electronic data
- Grasp the significance of ALCOA++ in maintaining data reliability
- Describe risk management methods outlined in ICH E6
- Differentiate between investigator and sponsor systems, understanding their respective roles and responsibilities within the guideline's framework

Who Should Attend

- Quality Assurance Professionals
- Clinical Research Associates
- Clinical Trial Leads, Managers, Coordinators, and Investigators
- Data Managers/Data Scientists/Statisticians
- Information technology/Information Systems (IT/IS)
- Regulatory Affairs and Compliance Officers

Instructor

Andy Lawton

Course Length and Time

1.5 hours, 10:30 a.m. – 12:00.p.m. and 2:00 – 3:30 p.m. Eastern

Course Dates

February 27, 2025 (2-3:30)

May 22, 2025 (10:30-12)

July 16, 2025 (2-3:30)

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-24-035-L99-P. Released: 2/24.

FDA and MHRA: Annual GCP Inspection Findings

Includes R3 Updates

Course Description

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) and the U.S. Food and Drug Administration (FDA) are two of the most exacting regulatory authorities in the world. Their specialist inspectors are highly trained to identify problems, deviations and discrepancies in clinical research. One of the best ways to learn about the inspectorate and its areas of focus is to consider the inspection findings which they have made. This web seminar will bring learners up-to-date on the current findings of the MHRA and FDA, which areas cause the regulators the most concern, and how they interpret the regulations and guidance to which they hold researchers accountable.

Learning Objectives

- Describe the remit of the MHRA and FDA
- Explain the main areas of concern to the MHRA and FDA
- Identify the most common and most significant findings being written by the MHRA and FDA
- Describe where the MHRA and FDA apply enforcement discretion

Who Should Attend

- Clinical Researchers from Industry, Academia and CROs
- Quality Assurance Professionals from Industry, Academia and CROs
- Personnel with an interest in the quality of clinical research

Instructors

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

Elizabeth Ronk Nelson, M.P.H.

Vaska Tone

Course Length

3 hours

Course Dates

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

Accreditation

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

FDA Drug Approval Process

Course Description

This web seminar provides an overview of the drug development process and how the FDA approves new drugs. The Investigative New Drug (IND) contents and the New Drug Application (NDA) are described with reference to applicable FDA regulations and the phases of clinical trials required by the FDA.

Learning Objectives

- Describe the FDA's role in drug development
- Describe the basics of the clinical trial process
- Describe the FDA review process for IND/NDA submissions

Who Should Attend

- Clinical Research Coordinators
- Clinical Research Associates
- Clinical Trial Managers
- Clinical Project Managers
- Regulatory Affairs Personnel
- Quality Assurance Personnel
- Manufacturing Personnel
- Personnel that have to understand the FDA new drug approval process

Instructor

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

Course Length and Time

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

Course Dates

January 9, 2025 (12:30-2:30)

April 18, 2025 (9:30-11:30)

July 15, 2025 (12:30-2:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-24-050-L99-P. Released: 9/24.

FDA Medical Device Approval Process

Course Description

This web seminar provides an overview of the regulations and obligations of a sponsor and investigator in the development of a new device using FDA and ICH guidance — Investigational Device Exemption (IDE) and abbreviated IDE processes. This is done by reviewing sponsor and investigator obligations, along with the principles of Good Clinical Practice (GCP). Definitions used by sponsors and regulatory authorities for device development will be reviewed. Participants will become familiar with the regulatory decision-making process used by the FDA and learn to navigate the approval pathways to market.

Learning Objectives

- Discuss the FDA regulations and practical application of sponsor and investigator obligations defined in 21CFR812
- Describe the structure, purpose, and practical application of the ICH Guideline and its principles of GCP
- Describe the technical standards defined in ISO
- Define common terms used in device research
- Describe the three decisions in device development (classification, equivalence, and risk)
- Define the two pathways to market (PMA and 510(k))
- Navigate the FDA approval process
- Describe what an IDE and PMA are, identify their contents, and discuss the FDA review process

Who Should Attend

- Clinical Research Managers
- Principal Investigators
- Regulatory Associates
- Quality Assurance Personnel
- All other personnel responsible for the device approval process

Instructor

Shana Zink, B.S., C.C.R.A.

Course Length and Time

1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates

February 20**,** 2025

June 16**,** 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-24-051-L99-P. Released: 8/24.

Blended Curriculum Course

FDA Requirements for Electronic Source Data in Clinical Investigations

Course Description

As the use of electronic source documentation (eSource) increases, so does the scrutiny for ensuring the integrity of the systems used to generate and retain electronic source data. In late 2010, the FDA issued a draft guidance regarding the use of eSource, providing direction on capturing, using, and archiving electronic data. A final FDA guidance was released in September 2013 focusing on identification and specification of authorized source data originators, the creation of data element identifiers to facilitate examination of the data audit trail, capture of source data into the eCRF, and Investigator responsibilities. This web seminar will review how the requirements for paper source documentation translate to the electronic source document as well as examine real-world examples of the FDA's review of eSource.

Learning Objectives

- Navigate initiatives in the regulatory climate leading to the eSource guidance
- Examine the three tiers of data management
- Discuss the Clinical Investigator's responsibilities for eSource data origination, integrity, review, release for processing and retention
- Assess the implications of the guidance on source documentation practices and policy
- Review the FDA's expectations and inspection processes for eSource

Who Should Attend

- Clinical Research Associates and Managers
- Project Managers
- Clinical Investigators and Staff
- Personnel involved in site and IRB assessment and/or selection
- Academia Professionals involved in oversight, documentation, and conduct of clinical research
- Quality Assurance and Compliance Professionals
- Data Management Professionals

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

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

Course Dates

February 26, 2025 (9:30-11:30)

June 20, 2025 (12:30-2:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

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ACPE#: 0778-0000-25-003-L99-P. Released: 2/25.

Blended Curriculum Course

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 9:30 – 11:30 a.m. and 2:30 – 4:30 p.m. Eastern

Course Dates

February 14, 2025 (9:30-11:30)

May 20, 2025 (2:30-4:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-24-018-L99-P. Released: 2/24.

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Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.

Blended Curriculum Course

FDA's Draft Guidance on Ethical Considerations for Clinical Investigations of Medical Products Involving Children

Course Description

Historically, information regarding therapeutic interventions for children has been extrapolated from clinical research conducted on adults; however, there are circumstances under which use of this data is less than ideal. Although children represent over one quarter of the world's population, fewer than twenty percent of the applicable studies registered on clinicaltrials.gov are focused on understanding the medical needs of children. This web seminar will focus on the FDA's new draft guidance for the safe and controlled inclusion of children in clinical trials where their unique needs are the primary consideration.

Learning Objectives

- Review the ethical framework for inclusion of children in clinical trials
- Determine pediatric risk categories and potential interventions
- Assess risk associated with clinical trials in a vulnerable population
- Examine clinical trial design interventions to mitigate risk

Who Should Attend

- Directors of Clinical Operations
- Clinical Principal Investigators
- Clinical Research Coordinators
- Clinical Research Associates
- Project Managers
- Professionals from Academia whose institutions conduct research in the pediatric population
- Clinical Quality and Compliance Professionals
- Institutional Review Board Administrators and Members
- Medical Monitors and Safety Team Members
- Regulatory Affairs Professionals

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

1.5 hours 9:00 – 10:30 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates

February 25, 2025 (9-10:30)

June 10, 2025 (1-2:30)

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-23-033-L99-P. Released: 1/23.

NEW! FDA's Draft Guidance on Integrating Randomized Controlled Trials for Drug and Biological Products into Routine Clinical Practice

Course Description

The FDA is exploring the integration of randomized controlled drug trials (RCTs) into routine clinical practice. These "point of care trials" aim to streamline protocols, focusing on essential data collection. This approach could improve accessibility and diversity in enrollment. This web seminar will review the FDA's initiative on bridging the gap between clinical research and everyday patient care.

Learning Objectives

- Discuss Sponsors' role in engaging healthcare institutions
- Assess Clinical Investigators' and local healthcare providers' roles
- Examine processes for aligning trials with clinical practice
- Review quality by design elements in clinical trials
- Explain guidance on informed consent, data privacy, and ethics
- Describe leveraging real-world data sources in trial conduct

Who Should Attend

- Clinical Research Coordinators and Managers
- Principal Investigators and Sub-Investigators
- Regulatory Affairs Professionals
- Quality Assurance Specialists
- Clinical Trial Sponsors
- IRB/Ethics Committee Members
- Medical Affairs Professionals
- Clinical Operations Team Members

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

1.5 hours 9:00 - 10:30 a.m. Eastern and 1:30 - 3:00 p.m. Eastern

Course Dates

February 24, 2025 (9-10:30) June 10, 2025 (9-10:30)

April 14, 2025 (1:30-3:00)

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-25-026-L99-P. Released 2/25.

FDA's Role in Device Safety Inspections

Course Description

The primary role of the FDA or other regulatory authority is to protect public health and ensure that devices are safe and effective. This is done by systematically reviewing all data to ensure it is valid and obtained under proper conditions. The FDA has authority to conduct inspections according to the Code of Federal Regulations. This web seminar examines the types of inspections conducted by the FDA and the mechanics of the inspection of a device sponsor as well as an investigational site. Participants will learn the most common audit findings and possible regulatory actions. Several FDA Warning Letters will be reviewed to demonstrate the thoroughness of a regulatory review. Tips will be provided for the management of the inspection activities both during and after the inspection.

Learning Objectives

- Describe the purpose, types, and mechanics of a regulatory inspection at a device company and an investigational site
- Recognize the Compliance Program Guidance Manual used by the Inspectors
- Discuss common audit findings of sponsors and investigational sites and possible FDA actions
- Recognize common 'dos' and 'don'ts' in the event of a regulatory inspection

Who Should Attend

- Clinical Research Managers
- Clinical Research Associates
- Regulatory Associates
- Quality Assurance Personnel
- Clinical Study Coordinators
- Principal Investigators

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length

1.5 hours

Course Dates

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Accreditation

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Blended Curriculum Course

FDA's Updated Informed Consent Guidance: What's New?

Course Description

This web seminar will review the updated FDA Guidance Document titled "Informed Consent Guidance for IRBs, Clinical investigators and Sponsors" dated August 2023. This guidance is intended to assist institutional review boards (IRBs), clinical investigators, and sponsors in complying with FDA's informed consent regulations for clinical investigations. The revisions include significant changes to the provisions regarding informed consent and provide guidance related to the requirements described in 21 CFR part 50; as well as regulations pertaining to informed consent found in FDA's regulations on Investigational New Drug Applications (21 CFR part 312) and Investigational Device Exemptions (21 CFR part 812). An overview of the guidance will include general consent requirements and exceptions, review of the basic elements, documentation requirements, and responsibilities of each party. Additional questions to be addressed include consideration in pediatrics, non-English speakers, considerations for Legally Authorized Representatives (LARs), and electronic informed consent.

Learning Objectives

- Review contents and key elements in the new Guidance Document
- Discuss responsibilities for informed consent for IRBs, clinical investigators, sponsors, and FDA
- Evaluate applications in pediatrics, non-English speakers, LARs, and electronic informed consent

Who Should Attend

- Clinical Trial Investigators and Coordinators
- Regulatory Affairs Professionals/Compliance Officers
- Ethics Committee Members
- Institution Review Board (IRB) Members
- Clinical Research Associates (CRAs)
- Quality Assurance Professionals
- Research Ethics Professionals/Legal Counsel

Instructor

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

Course Length and Time

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

Course Dates

February 24, 2025 (9:30-11)

May 19, 2025 (1-2:30)

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-24-036-L99-P. Released: 1/24.

Fraud in Clinical Research: An Overview

Course Description

Fraudulent activities in clinical research undermine clinical research professionals' ability to meet their obligations for ensuring credible data is obtained from protected participants. This web seminar provides an overview of fraud in clinical research and its potential impact on the industry and the public's health. It also includes a group discussion of best practices.

Learning Objectives

- Discuss significant and current examples of fraud in clinical research
- Describe the current focus of regulatory and Congressional bodies and their findings
- Explain the Sponsor/CRO, IRB, Clinical Investigator, and Study Staff role in detection and prevention
- Recognize the impact and consequences of fraud in clinical research
- Examine landmark and recent cases of fraud in clinical research

Who Should Attend

- Clinical Quality Assurance Professionals
- Clinical Research Associates
- Project Managers
- Clinical Investigators
- Study Coordinators
- Institutional Review Board Professionals
- Institutional Officials involved in oversight of clinical research
- Data Management Professionals
- Regulatory Affairs Professionals

Instructors

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

Jeanne Morris B.S., MT (ASCP)

Elizabeth Ronk Nelson, M.P.H.

Course Length

2 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

The Fundamentals of Clinical Research Project Management

Course Description

Participants will explore the principles of project management and apply project management tools to ensure the success of their clinical research projects. Participants will learn to develop a project charter, a work breakdown structure, a risk assessment and contingency plan, a process improvement plan, as well as how to lead without authority. Each participant will leave the session with tools and checklists to apply to their projects.

Learning Objectives

- Develop a project charter
- Develop a work breakdown structure
- Determine your project's critical path
- Evaluate risk and develop contingency plans

Who Should Attend

- New Project Managers and Project Leaders
- Clinical Trial Site Managers
- Clinical Research Associates
- Clinical Research Coordinators
- Clinical Operations Professionals
- Study/Regulatory Coordinators
- Pharmaceutical Professionals at clinical research sites, pharmaceutical companies, or Contract Research Organizations who are interested in learning more about clinical research project management or who want to pursue project management career opportunities

Instructor

Natalie Currie, B.Sc.

Course Length and Time

1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates

February 19, 2025

May 12, 2025

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-22-019-L04-P. Released: 9/22.

What Participants Say About Barnett Interactive Web Seminars:

"Excellent trainer — very knowledgeable and kept our interest for the length of the session."

GCP Renovation (ICH E8 R1 and ICH E6 R3)

Course Description

In January 2017, the ICH GCP renovation was initiated, ushering in a new era of regulatory guidelines. The finalization of ICH E8 R1 in 2021 has brought forth a clear roadmap for integrating Quality by Design principles into the design and development of clinical trials. Simultaneously, ICH GCP (ICH E6 R3) includes a complete rewrite of existing the guideline, triggering a paradigm shift in how companies approach these changes. While the majority of these changes are anticipated to be embraced by the industry as a means to modernize the regulatory landscape, some formidable challenges will need to be addressed. In this web seminar, we will delve into the subject matter in alignment with the intentions of the International Council for Harmonisation (ICH). We will explore how ICH E6 and E8 complement each other and discuss their implications for the industry's evolving regulatory environment.

Learning Objectives

- Describe the regulatory background that has led to the changes
- Explain the changes within ICH E8 R1
- Explain the changes within ICH E6 R3
- Describe the concept of Quality by Design and its application to clinical development
- Understand the role of risk management and measured quality in Quality by Design

Who Should Attend

- Clinical Research Associates/Monitors
- Clinical Trial Leads
- Data Managers / Data Scientists
- Statisticians
- Regulatory Affairs Professionals
- Pharmacovigilance Professionals
- Executive Management

Instructor

Andy Lawton

Course Length and Time

2.5 hours, 9:00 – 11:30 a.m. and 1:30 – 4:00 p.m. Eastern

Course Dates

February 3, 2025 (1:30-4)

May 28, 2025 (9-11:30)

July 30, 2025 (1:30-4)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-24-032-L99-P. Released: 2/24.

GCP Training for Investigators

Includes R3 Updates

Course Description

This web seminar provides a brief review of new drug development and the clinical trial process as it affects the investigator, and explains where Good Clinical Practice (GCP) fits in. Relevant sections of the Code of Federal Regulations (CFR), International Council for Harmonization (ICH), and Form FDA 1572 are discussed in-depth and in relationship to the investigator's responsibilities for proper conduct of clinical trials. This course will highlight the principles of the ICH GCP E6 Guideline as the foundation for all clinical studies, and demonstrate to the investigator the rationale for sponsor requirements throughout clinical development of an investigational drug.

Learning Objectives

- Identify the key stages of the drug development process
- Describe the elements involved in the clinical trial process
- Apply the principles of ICH GCP to current clinical trials
- Examine the investigator's responsibilities in the conduct of clinical trials as required in the regulations (CFR) and guidelines (ICH)
- Recognize the commitment made in executing the Form FDA 1572

Who Should Attend

- New Principal Investigators
- Seasoned Principal Investigators interested in reviewing responsibilities
- Sub-Investigators
- Physicians interested in participating in clinical research
- Site Research Managers/Directors

Instructor

Jeanne Morris B.S., MT (ASCP)

Course Length

3 hours

Course Dates

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Archived Recording Available in Multiple Formats!

Accreditation

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Blended Curriculum Course

The GCPs of Essential Documents

Includes R3 Updates

Course Description

Understanding the big picture of how essential study documents impact the approval and ethics of a clinical research trial often gets overlooked in the rush of document collection and requests. The foundation of this web seminar is the site study file, what the documents are, and why they are important as related to the ICH GCP E6 Guideline Essential Documents and 21 CFR 50, 54, 56 and 31This 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., T.I.A.C.R.

Course Length and Time

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

Course Dates

February 26, 2025 (1-2:30)

May 21, 2025 (9:30-11)

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-24-019-L99-P. Released: 2/24.

General Data Protection Regulation (GDPR): Developing a Compliant Data Privacy Program

Course Description

In this web seminar, participants will learn how to start-up and launch an effective data compliance and security response program. This course begins with a review of data privacy requirements, including an examination of the challenges posed by the General Data Protection Regulation (GDPR)/Security requirements as well as the benefits of proactively demonstrating that the organization is compliant with the new requirements. This course also focuses on data security, with an emphasis on good security practices, strategies for protecting IT systems, minimizing data hacking, as well as the management of data breaches. Course content will be reinforced through a combination of practical examples and videos, and learners will leave this web seminar with a clear view on how to operationalize the GDPR.

Learning Objectives

- Review data privacy and personal data protection principles
- Understand GDPR security requirements
- Implement good security practices
- Manage data breaches and minimize data hacking

Who Should Attend

- GDPR Preparation Team Members
- Data Managers and Analysts
- Data Scientists
- User Team Supervisors and IT Specialists

Instructor

Barbara Tomasi, Ph.D., CIPPE, CIPM

Course Length

1.5 hours

Course Dates

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

Accreditation

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

What Participants Say About Barnett Interactive Web Seminars:

"Kudos again for a nicely paced, interactive presentation!"

Blended Curriculum Course

Good Clinical Practice: Practical Application and Implementation

Includes R3 Updates

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:

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

Elizabeth Weeks-Rowe, LVN, C.C.R.A.

Course Length and Time

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

Course Dates

March 14, 2025 (9:30-11:30)

May 16, 2025 (12:30-2:30)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-24-020-L99-P. Released: 3/24.

Good Clinical Practice (GCP) for Medical Devices: ICH GCP E6 and ISO 14155

Includes R3 Updates

Course Description

Both the ICH GCP E6 Guideline and ISO 14155 address the elements of Good Clinical Practice in the design, conduct, recording, and reporting of human subject research. Although many sponsors of medical device studies use the ICH GCP E6 Guideline as an ethical and scientific quality standard, ISO is written specifically to protect the rights, safety, and well-being of human subjects, ensure the scientific conduct of the clinical investigation and the credibility of the results, define the responsibilities of the sponsor and Principal Investigator, and assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.

Learning Objectives

- Discuss the purpose and governing bodies of ICH and ISO
- Explore the core principles of each document
- Describe similarities and key differences in content and approach
- Identify additional sources of information relating to the compliant conduct and oversight of medical device studies

Who Should Attend

- Project Managers
- Clinical Research Associate Managers
- Clinical Research Associates
- Clinical Investigators
- Study Coordinators
- Clinical Quality Assurance Professionals
- Institutional Review Board Professionals

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

1.5 hours 9:30 – 11:00 a.m. and 2:00 – 3:30 p.m. Eastern

Course Dates

February 27, 2025 (9:30-11)

May 5, 2025 (2-3:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-23-057-L99-P. Released: 8/23.

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.

Good Laboratory Practice for Non-Clinical Studies

Course Description

This web seminar will provide a general overview of the regulatory requirements for non-clinical studies conducted at both pre-clinical facilities as well as bio-analytical laboratories. The course is divided into two sessions: The first session will focus on general regulatory requirements from the facility and the organization's perspective and the second session will focus on audits conducted per study. This web seminar provides training for the pre-clinical facility and the bio-analytical laboratory personnel as well as quality assurance staff on maintaining compliance to 21 CFR Part 58.

Learning Objectives

- Describe the general regulatory requirements for non-clinical studies
- Describe the pre-clinical facility requirements and the bio-analytical laboratory requirements
- Describe pre-clinical study specific requirements

Who Should Attend

- Pre-Clinical Facility Personnel
- Facility Management
- Study Directors/Research Personnel
- Quality Professionals

Instructor

Shelia Russell McCullers, M.S., D.M.

Course Length

4 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 HHS Common Rule: What You Need to Know

Course Description

In January 2017, the Revised Common Rule (45 Part 46) was published, providing an update to GCP. The Rule is notable as much for what it does not contain as for what it does. This web seminar reviews: Definitions; biospecimens and identifiable information; informed consent; broad consent; IRB continuing review; IRB limited review; exclusions and exemptions, and single IRB requirements for cooperative research. This web seminar will go beyond a simple review of the changes and focus on the immediate implications of the Rule and steps for each party in the clinical research enterprise to achieve compliance.

Learning Objectives

- Appraise the breadth and depth of the HHS Common Rule
- Design a plan for implementation and compliance
- Identify challenges and obstacles to implementation

Who Should Attend

- Clinical Research Managers
- Clinical Research Educators
- Regulatory Specialists
- Clinical Research Associates
- Clinical Research Coordinators
- Project Managers
- Quality Assurance Professionals
- Clinical Investigators
- IRB Members and Managers

Instructor

Robert Romanchuk, B.H.S.H., CIP, C.C.R.C., C.C.R.C.P.

Course Length

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.

Archived Recording Available in Multiple Formats!

Accreditation

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

What Participants Say About Barnett Interactive Web Seminars:

"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."

HIPAA Compliance Monitoring and Auditing

Course Description

In this web seminar, participants will learn strategies for conducting effective HIPAA compliance audits. We will review the compliance process while focusing specifically on the Administrative Simplification Rules of HIPAA, including transactions, code sets, and identifiers (which are all key elements in the HIPAA-mandated electronic health care transmissions). Real-world examples will be provided to discuss HIPAA and the Privacy Rule, which govern patient rights and disclosure of protected health information (PHI). Given that computerized systems currently are an integral part of health care and clinical research, how they fit into the Security Rule will also be discussed. Most importantly, strategies for how to implement effective HIPAA monitoring and auditing programs within your institution will be provided.

Learning Objectives

- Discuss current HIPAA laws and regulations as they pertain to clinical research
- Describe key elements of a strong HIPAA compliance program
- Discuss practical aspects of HIPAA compliance program implementation
- Develop effective HIPAA compliance monitoring and auditing practices

Who Should Attend

- HIPAA Professionals
- Compliance Officers
- Project/Program Managers
- Compliance and QC/QA Directors
- Clinical Trial Office Directors
- Research Nurses
- Clinical Research Coordinators
- Clinical Research Associates

Instructor

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

Course Length

3 hours

Course Dates

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

Accreditation

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

Blended Curriculum Course

HIPAA Team Training: Fundamental Training Specifically for Clinical Research Settings

Course Description

This web seminar presents concepts and terminology of HIPAA specific to conducting clinical trials. The core elements with methodologies for blending the concepts into established clinical trial best practices will be discussed. 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, it's 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

Instructors

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

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

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

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

Course Length and Time

2 hours 9:30 – 11:30 a.m. and 11:30 a.m. – 1:30 p.m. Eastern

Course Dates

February 21, 2025 (9:30-11:30) May 6, 2025 (11:30-1:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-25-004-L99-P. Released: 2/25.

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

How to Complete the Form FDA 1572, Adequately and Accurately

Course Description

Proper completion of the Statement of Investigator has been greatly debated. Many stakeholders differ in opinions on what is accurate and adequate in completing this form. For example, who should be listed as sub-investigators, do we need to complete a 1572 for certain projects, and so forth. This web seminar will review the 2010 FDA information sheet and answer many of the questions about how to properly complete the form. The course will also discuss what is still not clear even after the guidance and how to get the answers.

Learning Objectives

- Review significant final guidance content
- Detail form completion clarifications for key debated sections
- Assess impact on current practices
- Review case studies of documented deficiencies of the form in warning letters and map the guidance to other FDA initiatives

Who Should Attend

- Site Research Managers and Coordinators
- Investigators
- Clinical Research Monitors
- Project Managers
- Clinical Research Associate Managers
- Clinical Research Directors
- Regulatory Affairs Professionals
- Sponsors/CROs
- Clinical Research Associates
- Clinical Research Coordinators

Instructor

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

Course Length

2 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

Blended Curriculum Course

ICH E6 (R3) and ICH E8 (R1) Updates: Impact on Sponsors

Course Description

The principles of GCP are designed to be flexible and applicable to a broad range of clinical trials. The updated E6 guideline, along with ICH E8, encourages thoughtful consideration and planning to address specific and potentially unique aspects of an individual clinical trial. This includes evaluation of trial characteristics, such as the design elements, the investigational product being evaluated, the medical condition being addressed, characteristics of the participants, the setting in which the clinical trial is being conducted, and the type of data being collected. Careful consideration of factors relevant to ensuring trial quality, including critical-to-quality (CTQ) factors, are needed for each clinical trial. This web seminar will provide a high-level overview of the drivers and changes planned for implementation.

Learning Objectives

- Introduce rationale, revisions, and release to ICH E6 (R3)
- Review changes to principles in ICH E6 (R3)
- Introduce rationale, revisions, and release of E8
- Review CTQ factors that should be considered when planning a study
- Demonstrate that ICH E8 provides cross-referencing to other relevant ICH guidelines for planning and executing development program-related studies

Who Should Attend

- Senior Leaders, Directors, and Managers
- Clinical Research Associates
- Clinical Research Coordinators
- Study Managers
- Quality Personnel
- Data Managers
- Business Process Owners

Instructor

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

Course Length and Time

1.5 hours 10:00 – 11:30 a.m. Eastern

Course Dates

February 26, 2025

April 22, 2025

July 16, 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-22-034-L04-P. Released: 8/22.

ICH E8 (R1): Changes Impacting Sponsors/CROs

Includes R3 Updates

Course Description

The ICH E8 (R1) revision is intended to identify and modernize the current conduct of clinical research: Clinical trial design, planning, management, and conduct. The goal of the updated ICH E8 (R1) guidance is to provide flexibility in addressing the increasing diversity of study types and data sources that are being employed to support regulatory and other health policy decisions. This web seminar will describe the ICH E8 (R1) addendum in a step-by-step process and provide a parallel discussion of how the reviewed guideline can improve efficient approaches to trial management. Discussion topics include: A Quality by Design (QbD) approach to the planning, development, and design of a clinical trial; stakeholder engagement during the design and conduct of clinical trials focusing on trial design, recruitment, retention of trial subjects; ethical concerns regarding access to medication post-trial; real-world evidence (RWE) in drug development post-market safety; working with various types of data sources; and the need to leverage more modern technology.

Learning Objectives

- Describe the ICH E8 (R1) guideline changes
- Explain the impact of the ICH E8 (R1) on clinical trial conduct
- Discuss opportunities for implementing the ICH E8 (R1) guideline in your organization

Who Should Attend

- Managers/Directors: Clinical Operations, Clinical Research, Data Management, Quality Management, Compliance, Process Improvement, Risk Management, Quality Risk Management
- Study Managers/Project Managers
- Clinical Research Associates/Monitors
- Regulatory Affairs Professionals
- Biostatisticians, Data Managers
- Clinical Research Nurses, Clinical Research Coordinators, Clinical Investigators

Instructor

Andy Lawton

Course Length and Time

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

Course Dates

February 25, 2025 (1-3)

May 21, 2025 (9-11)

July 10, 2025 (1-3)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **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#: 0778-0000-23-058-L99-P. Released: 7/23.

ICH E8 (R1): Designing Quality into Clinical Studies

Includes R3 Updates

Course Description

ICH E8 (R1) is intended to identify and modernize the present conduct of clinical research, including clinical trial design, planning, management, and conduct. In clinical research, quality assurance activities of retrospective document checking, monitoring, auditing, or inspection are essential, and there has been an overreliance on these tasks versus relying on designing quality into clinical studies during development and throughout clinical research. This web seminar covers the importance of designing quality into clinical trials with a focus on Quality by Design (QbD) of clinical studies, critical factors to quality, essential identification of quality factors, establishing a culture that supports critical thinking and open dialogue regarding proactive quality versus reliance on tools/checklists, and stakeholder engagement.

Learning Objectives

- Describe ICH E8 (R1): Designing quality into clinical studies
- Define critical factors to quality in ensuring human subject protection and generation of reliable and meaningful results
- Identify an appropriate framework for the identification and review of essential elements of quality in clinical studies

Who Should Attend

- Managers/Directors: Clinical Operations, Clinical Research, Data Management, Quality Management, Compliance, Process Improvement, Risk Management, Quality Risk Management
- Study Managers/Project Managers
- Clinical Research Associates/Monitors
- Regulatory Affairs Professionals
- Biostatisticians, Data Managers
- Clinical Research Nurses, Clinical Research Coordinators, Clinical Investigators

Instructor

Andy Lawton

Course Length and Time

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

Course Dates

February 25, 2025 (9-11)

May 21, 2025 (1-3)

July 10, 2025 (9-11)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-059-L99-P. Released: 7/23.

ICH GCP E6 R3 Updates: Impact on Clinical Data Management

Course Description

Clinical Data Management (CDM) plays a pivotal role in the success of clinical trials, ensuring data accuracy, integrity, and compliance with regulatory requirements. The ICH GCP E6 R3 update refines the approach to CDM by incorporating a risk-based framework for managing data and enhancing oversight mechanisms. This web seminar will explore the updated guidelines, focusing on the evolving requirements for electronic systems, data integrity, and the integration of quality management principles throughout the trial lifecycle. Participants will gain insights into the role of risk management in clinical data collection and analysis, now positioned as a standard practice rather than an optional strategy. The session will also cover best practices, industry standards, and practical approaches to achieving compliance with the revised guidelines. Additionally, the seminar will highlight the implications of the R3 updates and how they reshape CDM processes, ensuring data quality and regulatory adherence.

Learning Objectives

- Define the recommended SOPs for electronic systems used to collect and manage clinical trial data under ICH GCP E6 R3
- Discuss data integrity considerations and their critical role in clinical trials, as outlined in the revised guidelines
- Identify risk management principles in clinical trial conduct and their direct connection to Clinical Data Management practices
- Review quality management principles and tools to implement a risk-based quality approach in clinical trials

Who Should Attend

- Clinical Data Managers
- Clinical Data Scientists
- Clinical Quality Assurance Professionals
- Clinical Compliance Personnel

Instructor

Denise G. Redkar-Brown, MT

Course Length and Time

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

Course Dates

January 7, 2025 (9:30-11)

April 22, 2025 (1-2:30)

July 29, 2025 (9:30-11)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-25-032-L99. Released: 4/25.

Blended Curriculum Course

ICH GCP E6 R3 Updates: Implementing Risk Management Approaches for Compliance

Course Description

The ICH GCP E6 R3 updates introduce a refined, standardized approach to risk management that builds on previous revisions. A key shift in the updated guidelines is the emphasis on a comprehensive, risk-based approach to quality management, with a clear focus on critical process and data identification, risk evaluation, and mitigation strategies. While Risk-Based Quality Management (RBQM) is now standard practice, the R3 revision also ensures that risk assessment and mitigation plans are required across all clinical trials, regardless of RBQM adoption. This web seminar will explore these updated requirements, focusing on risk management principles, including risk identification, evaluation, control, and reporting. Practical strategies for implementing the updated guidelines, along with step-by-step methodologies for risk management, will be provided.

Learning Objectives

- Define the three-way risk evaluation methodology introduced in the ICH GCP E6 R3 update
- Distinguish between risk mitigation and risk acceptance, and understand their application in clinical trials
- Describe the concept of "predefined tolerance limits" as part of risk-based management
- Explain the role of centralized monitoring in risk management and quality assurance
- Develop a best practice implementation process for risk management based on practical experience

Who Should Attend

- Managers/Directors in Clinical Operations, Clinical Research, Data Management, Quality Management, Compliance, Process Improvement, Risk Management, and Quality Risk Management
- Study Managers/Project Managers, Clinical Research Associates/ Monitors (Centralized, On-site)
- Business Process Owners

Instructor

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

Course Length and Time

2.5 hours 9:00 – 11:30 a.m. and 1:00 – 3:30 p.m. Eastern

Course Dates

January 29, 2025 (9-11:30) April 9, 2025 (1-3:30) July 30, 2025 (9-11:30)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-25-033-L99. Released: 4/25.

ICH GCP E6 R3 Updates: Key Changes Impacting Clinical Investigators, Sites, and IND Holders (Sponsor-Investigators and Institutions)

Course Description

The ICH GCP E6 R3 update introduces significant advancements to clinical trial management, emphasizing flexibility, efficiency, and risk-based approaches. This revision refines key areas such as investigator responsibilities, quality management, and trial oversight to better align with the complexities of modern clinical research. This web seminar will provide an in-depth look at the changes brought about by the R3 update, focusing on their impact on clinical investigators, trial sites, and Sponsors-Investigators. Topics will include the expanded responsibilities of investigators, sponsors, and institutions regarding oversight, monitoring plans, risk assessments, and data integrity. Learners will also explore practical strategies for updating organizational SOPs, processes, and staff training to ensure compliance with the new guidelines.

Learning Objectives

- Identify key changes affecting investigator responsibilities and roles under the ICH GCP E6 R3 guidelines
- Explain how the revisions impact clinical trial sites and Sponsors-Investigators
- Evaluate potential solutions for adapting organizational SOPs, processes, procedures, and staff training to the updated guidelines
- Apply best practices for effective implementation of the ICH GCP E6 R3 guidelines in clinical trials

Who Should Attend

- Quality Assurance/Compliance Personnel
- Principal Investigators/Sub-Investigators
- Research Site Staff (Managers, CRCs, Data Managers/Data Entry)
- Managers/Directors: Clinical Operations, Clinical Research, Data Management, Quality Management, Compliance, Process Improvement, Risk Management, Quality Risk Management
- Study Managers/Project Managers, CRAs/Monitors (Centralized, On-site)

Instructor

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

Course Length and Time

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

Course Dates

January 8, 2025 (9-11) April 7, 2025 (1-3) July 15, 2025 (9-11)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-25-030-L99. Released: 4/25.

ICH GCP E6 R3 Updates: Key Changes Impacting Sponsors and CROs

Course Description

The release of ICH GCP E6 R3 represents a significant evolution in clinical trial management, building on the changes introduced in the R2 revision. With a focus on improving efficiency and adaptability in the face of growing trial complexity, the R3 updates bring more flexible and risk-based approaches to trial design, conduct, and oversight. This web seminar will guide participants through the essential updates in the ICH E6 guidelines, highlighting the direct impact on sponsors, CROs, and clinical trial teams. Practical strategies for incorporating these revisions into trial management processes will be explored, along with insights into how the R3 updates can streamline operational workflows while maintaining high standards of quality and compliance. Specific topics include the evolving roles of sponsors and CROs in this updated framework.

Learning Objectives

- Identify three key changes in the ICH GCP E6 R3 updates that affect sponsors and CROs, along with their impact on individual roles
- Explain how the revisions influence clinical trial conduct and organizational practices
- Discuss practical opportunities for implementing the revised guideline to improve trial management efficiency and compliance

Who Should Attend

- Managers/Directors: Clinical Operations, Clinical Research, Data Management, Quality Management, Compliance, Process Improvement, Risk Management, Quality Risk Management
- Study Managers/Project Managers, Clinical Research Associates/ Monitors (Centralized, On-site)

Instructor

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

Course Length and Time

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

Course Dates

January 13, 2025 (1-3)

April 8, 2025 (9-11)

July 17, 2025 (1-3)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-25-031-L99. Released: 4/25.

ICH GCP E6 R3 Updates: Overview of Changes Impacting Sponsors, CROs, and Clinical Investigators/ Sites

Course Description

The release of ICH GCP E6 R3 marks a significant update to the previous versions of the guidelines, reflecting a more flexible, risk-based approach to clinical trial management. This revision enhances the framework for clinical trial design, conduct, oversight, and reporting, with an emphasis on improving trial efficiency, data integrity, and the protection of human subjects. The R3 update also refines roles and responsibilities for sponsors, CROs, and clinical investigators/sites, aligning them with current best practices and regulatory expectations. This web seminar will provide an overview of the key updates in ICH GCP E6 R3, including new definitions, sponsor/CRO and investigator responsibilities, and essential documents. We will also explore how these updates influence clinical trial processes and provide practical guidance on how to implement these changes within your organization.

Learning Objectives

- Explain the rationale behind the ICH GCP E6 R2 and R3 updates, and their intended impact on clinical trial management
- Describe the key terms and definitions that were introduced or updated in the ICH GCP E6 R3
- Identify the specific changes in the ICH GCP E6 R3 update and proposed updates impacting sponsors, CROs, and clinical investigators/sites
- Recognize the significance of these changes for sponsor/CRO and investigator/site responsibilities, and their potential impact on clinical trial conduct

Who Should Attend

- Managers/Directors in Clinical Operations, Clinical Research, Quality Management, and Compliance
- Study Managers, Project Managers
- Clinical Research Associates/Monitors
- Quality Assurance Personnel

Instructor

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

Course Length and Time

2.5 hours 9:00– 11:30 a.m. and 12:00 – 2:30 p.m. Eastern

Course Dates

January 14, 2025 (9-11:30)

April 21, 2025 (12-2:30)

July 10, 2025 (9-11:30)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-25-034-L99. Released: 4/25.

ICH GCP E6 R3 Updates: Sponsor Quality Management – Risk-Based/Risk Management Requirements and Approaches for Compliance

Course Description

The ICH GCP E6 R3 update refines the focus on quality management in clinical trials, shifting towards a more structured and risk-based approach to trial oversight. Building on the previous guidance from E6 R2, the R3 revision emphasizes the importance of a Clinical Quality Management System (cQMS) to ensure quality throughout the entire clinical trial lifecycle—from design through to archiving. This web seminar will explore the sponsor's responsibilities in implementing and maintaining a risk-based quality management system, highlighting new requirements introduced in E6 R3. Industry benchmarks, standards, and best practices for establishing cQMS, as well as practical approaches to achieve compliance will also be covered. Additionally, the web seminar will address the implications of the R3 updates, including how these changes influence risk management and trial quality oversight.

Learning Objectives

- Describe two new requirements for sponsor quality management (QM) in clinical trials as outlined in ICH GCP E6 R3
- Identify two risk-based approaches to achieving compliance with QM throughout the clinical trial lifecycle
- Determine next steps for evaluating and implementing the new quality management requirements in clinical trials

Who Should Attend

- Trial Managers
- Project Managers/Directors
- Clinical Quality Assurance/Compliance Personnel

Instructor

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

Course Length and Time

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

Course Dates

January 29, 2025 (1-3)

April 24, 2025 (8:30-10:30)

July 31, 2025 (1-3)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-25-035-L99. Released: 2/25.

NEW! Identifying Safety Signals in Clinical Trial Data

Course Description

Safety signals are defined as "reported information on a possible causal relationship between an adverse event and a drug, the relationship being previously unknown or incompletely documented," and it is of considerable importance to identify safety issues during the conduct of clinical trials. This web seminar will present the concept of identifying safety signals in clinical trials based on systematic and analytical approaches. A case study will be reviewed to present the approach to the identification of signals and the rationale behind the importance of recognizing safety issues.

Learning Objectives

- Describe the rationale behind the identification of a safety signal
- Recognize the process involved in defining safety signals by reviewing a case study

Who Should Attend

- Clinical Operations Personnel
- Clinical Data Managers

Instructor

Denise G. Redkar-Brown, MT

Course Length and Time

1.5 hours 1:00 - 2:30 p.m. Eastern

Course Dates

March 18, 2025

June 4, 2025

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-24-060-L99-P. Released: 9/24.

Implementing Quality Agreements

Course Description

Quality Agreements are a mainstay of the Good Manufacturing Practice (GMP) sphere as defined in ICH Q7 Section 16.12, and in Good Laboratory Practice (GLP) as inferred in 21 CFR Part 58.1 and 58.35. They have become more common in the Good Clinical Practice (GCP) arena of clinical trial operations as risk-based study management becomes firmly established. Quality Agreements delineate the quality expectations of both the sponsor and outsourced provider and are structured in a shared agreement. Web seminar participants will learn the purpose of, factors that are considered in, and explore possible content of Quality Agreements.

Learning Objectives

- Define the purpose of a Quality Agreement
- Examine the differences between a Quality Agreement and a Contract for Services
- Identify the critical factors that should be addressed in order to have an effective Quality Agreement
- Evaluate and determine who is responsible for developing Quality Agreements
- Determine who is responsible for enforcing Quality Agreements
- Strategies for managing reticence from vendors about Quality Agreements
- Determine when Quality Agreements should be developed and agreed upon
- Explore possible content of Quality Agreements

Who Should Attend

- Managers/Directors: Clinical Operations, Quality Management, Compliance
- Clinical Quality Assurance Professionals

Instructor

Shana Zink, B.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

Course Dates

March 19, 2025 (9:30-11)

June 3, 2025 (1-2:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-24-052-L99-P. Released: 9/24.

Blended Curriculum Course

Incorporating Denials Management into Clinical Research Billing

Course Description

Clinical Research Billing (CRB) is a very complex process that depends on a multitude of factors to align in order to be compliant. Organizations with clinical research activity face the challenge of maintaining a compliant CRB program without adversely impacting patients. This web seminar will explain the process of analyzing patient denials for trends related to participation in a clinical research study and leveraging this information to influence the coverage determination during the Medicare Coverage Analysis (MCA) process. Participants will learn a 360 approach to increasing CRB compliance and reducing the burden to the patients participating in clinical research studies.

Learning Objectives

- Describe the dynamics of the MCA process
- Explain the impact of MCA on patient billing and the revenue cycle
- Understand denials management and identify trends
- Apply denials management into the MCA process

Who Should Attend

- Analysts involved in the Medicare Coverage Analysis process
- Study Coordinators
- Managers of Clinical Research Billing

Instructor

Mary L. Veazie, M.B.A., CPA, CHC, CHRC

Course Length and Time

2 hours 1:00 – 3:00 p.m. Eastern

Course Dates

June 5, 2025

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-24-021-L99-P. Released: 6/24.

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 CRF 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

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

Course Length and Time

1.5 hours 9:30 – 11:00 a.m. and 2:30 – 4:00 p.m. Eastern

Course Dates

February 3, 2025 (9:30-11)

May 5, 2025 (2:30-4)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-23-060-L99-P. Released: 8/23.

Blended Curriculum Course

Informed Consent Procedure: Lessons Learned from Inspection Findings

Course Description

Informed consent irregularities remain one of the leading findings in U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) inspections. In this web seminar, we will examine real-world examples of FDA Warning Letters addressing informed consent inspection findings, and discuss appropriate corrective and preventive actions (CAPA). Learners will come away with solutions to avoid common informed consent pitfalls, and ultimately, avoid inspection findings. Participants are encouraged to share their experiences as we discuss methods to aid in compliance through appropriate techniques for the informed consent process. 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., T.I.A.C.R., F.A.C.R.P.

Course Length and Time

1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates

March 20**,** 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-24-022-L99-P. Released: 3/24.

Blended Curriculum Course

Inspection Readiness: Understanding BIMO Inspection Requirements for Sponsors, CROs, Monitors and Investigators

Course Description

The primary reason the FDA performs inspections is to support its mission to protect the public by ensuring the safety and efficacy of drugs, biologics, and medical devices. In 2006, the FDA announced an initiative to modernize the regulation of clinical trials, including the Compliance Program Guidance Manual (CPGM) Bioresearch Monitoring Program (BIMO). The purpose of the FDA compliance program is to provide instructions to the FDA field investigator and the FDA center personnel in the conduct of FDA inspections. This web seminar will review both the FDA CPGM BIMO for sponsors, CROs, and monitors and the FDA CPGM BIMO for Clinical Investigators and Sponsor-Investigators.

Learning Objectives

- Describe how the FDA CPGM BIMO is used in FDA inspections
- Define the types of FDA inspections
- Identify the most common type of Inspection findings for sponsors, CROs, and Investigators
- Examine how the FDA CPGM BIMO can aid in preparation for an inspection prior, during, and at the completion of a clinical trial

Who Should Attend

- Clinical Investigators
- Clinical Research Coordinators
- Clinical Quality Assurance and Compliance Auditors
- Clinical Research Associates
- Medical Monitors
- Project Managers
- Regulatory Affairs Professionals

Instructor

Shana Zink, 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

January 23, 2025 (1-3)

April 17, 2025 (9-11)

July 24, 2025 (1-3)

Archived Recording Available in Multiple Formats!

FEE: $735*

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ACPE#: 0778-0000-23-016-L99-P. Released: 1/23.

Blended Curriculum Course

Introduction to Clinical Research

Includes R3 Updates

Course Description

Have you ever wondered what clinical trials are and how they are conducted? This web seminar is designed to answer those basic questions. We will look at how drugs progress from discovery to testing in humans, and learn what it takes to obtain approval to treat a disease or condition. We will discuss the similarities and differences between drug and medical device development. Finally, we will review how Good Clinical Practice (GCP) is applied to clinical trials around the world and how it is designed to protect clinical trial participants and ensure that the information obtained during a clinical trial is accurate and reliable.

Learning Objectives

- Describe the different phases of drug development
- Differentiate between drug development and medical device development
- Discuss the historical events and importance of GCP throughout the world in clinical research

Who Should Attend

- Aspiring Clinical Research Associates and Clinical Research Coordinators
- Clinical Research Associates and Clinical Research Coordinators with less than six months of experience
- College Students and New Graduates in a Scientific Field
- Nurses
- Individuals considering participating in a clinical trial or know of someone who is considering participating in a clinical trial

Instructors

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

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

Elizabeth Weeks-Rowe, LVN, 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 20, 2025 (9:30-11)

May 20, 2025 (1-2:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-061-L99-P. Released: 8/23.

Blended Curriculum Course

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 27, 2025 (9:30-11:30)

April 15, 2025 (12:30-2:30)

July 23, 2025 (9:30-11:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-014-L99-P. Released: 1/23.

Introduction to Medicare Coverage Analysis: Impact on Site Revenue Cycles

Course Description

This web seminar will describe the Medicare Coverage Analysis (MCA) process, the creation of the MCA, the multiple uses for this document, and its impact on site revenue cycles. Participants will learn how to utilize the MCA in the financial consultation process when a patient is considering participating in a clinical research study. This web seminar will help revenue cycle personnel enhance the pre-authorization process and ensure an understanding of the appropriate coverage for tests/procedures included in the clinical research study.

Learning Objectives

- Learn how to create a Medicare Coverage Analysis (MCA) and the importance of ensuring its accuracy
- Understand multiple uses for the MCA
- Learn how to incorporate the MCA into the revenue cycle

Who Should Attend

- Personnel responsible for the financial aspects of a clinical research study
- Research Nurses
- Clinical Research Coordinators
- Patient Business Service Personnel

Instructor

Mary L. Veazie, M.B.A., CPA, CHC, CHRC

Course Length and Time

2 hours 9:30 – 11:30 a.m. Eastern

Course Dates

May 29, 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-24-053-L99-P. Released: 8/24.

Introduction to Statistics for Non-Statisticians

Course Description

This web seminar is intended for clinical research professionals who have little or no background in statistics. In it, we will cover the basic statistical concepts needed to understand the roles statistics play in health research. The topics addressed include types of variables, levels of measurement, descriptive statistics, precision, confidence intervals, and an introduction to hypothesis testing. This web seminar is beneficial to all clinical research professionals involved in the design, monitoring, interpretation, and reporting of clinical trials. Emphasis will be placed on understanding statistical information and not on calculations or statistical formulae.

Learning Objectives

- Recognize and interpret descriptive statistics
- Summarize continuous data with appropriate descriptive statistics
- Interpret confidence intervals, and explain how they are calculated
- Interpret P-values, and explain the concepts behind hypothesis testing (using Student's t-test as an example)
- Employ statistical terms used in clinical research
- Identify approaches to be comfortable communicating with statisticians

Who Should Attend

- Monitors who assist in designing and evaluating studies
- Clinical Research Associates who communicate with statisticians
- Clinical Project Leaders who design and evaluate studies
- Regulatory Professionals who utilize statistical concepts in their reports
- Medical Writers who must interpret statistical reports

Instructor

Misha Eliasziw, Ph.D.

Course Length and Time

3 hours 12:00 – 3:00 p.m. Eastern

Course Dates

March 4, 2025

June 10, 2025

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 3 hours (0.3 CEUs)** of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-23-015-L99-P. Released: 3/23.

What Participants Say About Barnett Interactive Web Seminars:

"I will apply tips from the lesson when on-site. The instructor was great and I look forward to participating in future trainings."

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Hold this Course at Your Company: In-person or On the Web! Call +1 215.413.2471 for more information.

Blended Curriculum Course

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

Instructors

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

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Elizabeth Weeks-Rowe, LVN, C.C.R.A.

Course Length and Time

1.5 hours 9:00 – 10:30 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates

February 20, 2025 (1-2:30)

May 8, 2025 (9-10:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-22-026-L04-P. Released: 8/22.

Blended Curriculum Course

Investigator Initiated Trials: Roles and Responsibilities

Course Description

Investigator Initiated Trials (IITs), also referred to as Sponsor-Investigator (SI) Trials are increasing in popularity. A Sponsor-Investigator is anyone who functions as the Clinical Investigator (CI) of a given study and who also holds the investigational marketing application, i.e., the IND or IDE. How does the CI ensure compliance to both the investigator and sponsor responsibilities? This web seminar will present the responsibilities, discuss risk, and provide suggestions for compliance.

Learning Objectives

- Define an Investigator Initiated Trial (IIT)
- Review the applicable federal regulations for IITs, including sponsor and investigator responsibilities
- Review the steps involved in initiating an IIT with a sponsor and review regulatory reporting requirements
- Identify essential documentation (Trial Master File) for the Sponsor-Investigator using the DIA TMF Reference Model to remain audit ready
- Identify approaches to minimize risks associated with IITs by avoiding common pitfalls – learn from existing FDA Warning Letters of deficiencies

Who Should Attend

- Investigators/Site Study Team Members
- Sponsor Study Team Members
- Ethics Committee Members

Instructors

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

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

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

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

Course Length and Time

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

Course Dates

January 9, 2025 (12-2)

April 17, 2025 (9:30-11:30)

July 22, 2025 (12-2)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-25-010-L99-P. Released: 1/25.

Key Considerations in Medical Writing: The Clinical Study Protocol, Investigator's Brochure, Informed Consent Form, and Adverse Events Narratives

Course Description

This web seminar includes a high-level review of the key considerations and the current trends for the clinical study protocol, the Investigator's Brochure (IB), the informed consent form, and adverse event narratives. While these documents form the basis and often predict the success of any drug or device development program, there is much variation between companies and individuals on how to approach writing these critical documents. In this web seminar, key considerations that should be taken into account in the development and maintenance of these documents will be discussed.

Learning Objectives

- Describe current trends and key considerations for clinical study protocol writing
- Review required and optional elements of informed consent, criteria for language and comprehension by research subjects
- Review serious adverse event reporting requirements and narrative writing
- Discuss how to translate safety updates into informed consent and Investigator's Brochure amendments

Who Should Attend

- Medical Directors and Physician Investigators
- Medical Writers/Regulatory Affairs Professionals
- Clinical Research Associates and Project Team Leaders
- Research and Development Personnel/Grant Administrators

Instructor

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

Course Length and Time

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

Course Dates

March 13, 2025 (9-11)

June 5, 2025 (1-3)

Archived Recording Available in Multiple Formats!

Fee: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 2.0 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#: 0778-0000-24-023-L99-P. Released: 3/24.

Blended Curriculum Course

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

Instructor

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

Course Length and Time

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

Course Dates

February 21, 2025 (9-11)

May 27, 2025 (1-3)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-22-028-L04-P. Released: 8/22.

Blended Curriculum Course

Managing CRAs to Improve Performance and Study Outcomes

Course Description

Monitoring a clinical trial is a required activity completed by sponsors of FDA regulated research that significantly affects the outcomes of product development and approval. Effectively managing the performance of Clinical Research Associates (CRAs) by sponsors is essential. Performance Management and Improvement is a science involving logical processes and applications. This web seminar will present the concepts of the Human Performance Improvement (HPI) Model and apply it directly to the management of the CRA to promote improvements. The HPI CRA Management Model will be presented and applied via case scenarios for better understanding.

Learning Objectives

- Define the Human Performance Improvement Model
- Recognize an HPI CRA Management Model
- Apply the model into current practice: Proactive CRA management
- Apply the model into current practice: Managing CRA performance issues
- Analyze case scenarios

Who Should Attend

- Project Managers
- Lead Clinical Research Associates
- Clinical Research Associate Managers

Instructor

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Course Length and Time

2.5 hours 9:00 – 11:30 a.m. and 2:00 – 4:30 p.m. Eastern

Course Dates

January 9, 2025 (2-4:30)

April 2, 2025 (9-11:30)

July 16, 2025 (2-4:30)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-23-062-L99-P. Released: 7/23.

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

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 in Multiple Formats!

Accreditation

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

What Participants Say About Barnett Interactive Web Seminars:

"The information presented was very thorough and I will reference the knowledge when writing my reports and preparing for my next monitoring visits."

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

Managing Phase I Clinical Trials

Course Description

Phase I clinical trials aim to determine the safety, tolerability and pharmacokinetics (PK) of a compound. This web seminar will explore the challenges of developing Phase 1 clinical study protocols to ensure that the right patients are enrolled and that the right data are collected to demonstrate a drug is safe and efficacious, while at the same time managing study costs and complexity, especially in trials that involve early-phase drug metabolism, imaging and interventional procedures. Key factors to consider when developing protocols and techniques to minimize complexity while ensuring trial success will also be discussed.

Learning Objectives

- Understand the FDA requirements for Phase I clinical trials and review the different Phase I trial designs
- Discuss challenges with early phase studies for Sponsors, Contract Research Organizations (CROs), third-party vendors and sites
- Discuss how to optimize protocol design for a special population
- Identify risks in early phase clinical trials and mitigation strategies
- Address strategic planning and budgetary considerations for Phase I designs

Who Should Attend

- Clinical Operations and Clinical Research Associates
- Medical Affairs Specialists and Leaders
- Project Managers/Team Leaders
- New Clinical or other Project Team Leaders who will be managing projects
- Physician Investigators and Coordinators
- Regulatory Affairs Professionals
- Quality Assurance/Control (QA/QC) Professionals

Instructor

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

Course Length and Time

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

Course Dates

January 16, 2025 (1-2:30)

April 10, 2025 (9:30-11)

July 15, 2025 (1-2:30)

Archived Recording Available in Multiple Formats!

Fee: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-25-011-L99-P. Released: 1/25.

Blended Curriculum Course

Managing Risks in Outsourced Clinical Trials: Practical Approaches and Tools

Course Description

Partnerships with clinical service providers are critical to the success of a trial. Sponsors, as well as service providers who hire third parties, require both performance and quality oversight. Whether your organization hires different service providers 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 based on the revisions in ICH GCP E6 R3. We will discuss the internal and external factors for the organization to identify, assess, manage, and continuously monitor throughout the life cycle of a project and/or partnership.

Learning Objectives

- Identify sponsor's oversight requirements included in ICH GCP E6 R3 updates
- Describe the attributes of a risk management framework for use in outsourced clinical trials
- 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

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

Course Length and Time

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

Course Dates

February 5, 2025 (9:30-11:30)

May 6, 2025 (12-2)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-24-054-L99-P. Released: 8/24.

NEW! Mastering Clinical Research Audits: Effective Responses and CAPAcDevelopment

Course Description

This two-part, comprehensive 4-hour web seminar equips clinical research professionals with essential skills for responding to audits and developing effective Corrective and Preventive Action (CAPA) plans. Participants will learn how to critically assess audit observations and craft robust responses. Best practices for root cause analysis, CAPA development, and implementation to address audit observations will be discussed. Through case studies and practical exercises, learners will also gain confidence in navigating the audit response process and enhancing their organization's quality management systems.

Learning Objectives

- Assess audit observations and discern the true focus of observations
- Utilize root cause analysis techniques to identify underlying issues in audits
- Develop strategies for effective preparation, assessment, and implementation of CAPA plans and ensure efficacy
- Enhance CAPA systems to ensure compliance and improve quality management practices

Who Should Attend

- Quality Assurance Professionals
- Principal Investigators
- IRB Chairs and Administrators
- Clinical Operations Professionals

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

4 hours, two days 9:30 – 11:30 a.m. Eastern each day and 1:00 – 3:00 p.m. Eastern each day

Course Dates

Offering #1:

January 23 & January 30, 2025 (9:30-11:30)

Offering #2:

March 11 & March 18, 2025 (1-3)

Offering #3:

June 13 & June 20, 2025 (9:30-11:30)

FEE: $1,195*

**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#: 0778-0000-25-022-L99-P. Released 1/25.

Medical Writing Fundamentals: How to Write Regulatory Documents

Course Description

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

Learning Objectives

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

Who Should Attend

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

Instructor

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

Course Length and Time

1.5 hours 9:30 – 11:00 a.m. and 12:00 – 1:30 p.m. Eastern

Course Dates

February 18, 2025 (9:30-11)

May 30, 2025 (12-1:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

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ACPE#: 0778-0000-23-071-L99-P. Released: 8/23.

Blended Curriculum Course

Minimizing Risk in Negotiating Clinical Trial Contracts and Budgets

Course Description

Most of the attention in negotiating clinical trial budgets and contracts is focused on fair compensation for the conduct of clinical research. Experience has shown however, that the greatest risk in such negotiations arise from rules and regulations outside Good Clinical Practice (GCP) that can result in heavy fines and penalties to the unwary. This web seminar will clarify these regulations and rules and provide practical direction on how to navigate these waters safely.

Learning Objectives

- Discuss the implications of Stark Law, Anti-Kickback Statute, False Claims Act and Medicare Secondary Payer Rule in clinical trial contracts and budgets negotiation
- Identify contract and budget risks and how to negotiate them safely
- Discuss creative processes to maximize revenue while minimizing risk
- Demonstrate skills with live exercises

Who Should Attend

- Research Managers
- Research Compliance Professionals
- Business Managers

Instructor

Robert Romanchuk, B.S.H.S., CIP

Course Length and Time

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

Course Dates

March 6, 2025 (9:30-11)

June 23, 2025 (1-2:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-23-063-L99-P. Released: 9/23.

Blended Curriculum Course

Monitoring Medical Device Trials: An Introduction

Course Description

This web seminar will provide the core concepts involved in monitoring medical device studies, including activities conducted at the investigator site, communication between monitor visits, and monitoring with centralized systems. We will explore the monitoring concepts as provided by the FDA in the Risk-Based Monitoring Guidance, as well as the ICH as interpreted for medical device trials. The basics of clinical monitoring and appropriate documentation to support adequate oversight of the study will be covered. Sponsor responsibilities and the role of the Clinical Research Associate/Monitor will be explored.

Learning Objectives

- Describe the regulatory purpose of monitoring device studies
- Define the basic types of monitoring visits and documentation requirements
- Explore the roles and responsibilities of the Clinical Research Associate (Monitor) for the various types of visits
- Discuss the meaning of protocol and regulatory (GCP) compliance
- Recognize the rationale behind adequate documentation of monitoring including identification of issues, corrective and preventive action and evaluation of effectiveness for issues (both site and sponsor)

Who Should Attend

- Clinical Research Associates
- Project Managers
- Personnel responsible for monitoring or managing medical device trials

Instructors

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

Heather Marshall, M.S.N., B.S.N., R.N.

Shana Zink, B.S., C.C.R.A.

Course Length and Time

2 hours 9:00 – 11:00 a.m. Eastern

Course Dates

January 14, 2025

May 22**,** 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-017-L99-P. Released: 1/23.

Monitoring Oncology Clinical Trials

Course Description

This web seminar will provide attendees with a general overview of oncology clinical trials and their distinct characteristics. We will review how oncology clinical trials differ from those in other therapeutic areas, with a special emphasis on the unique challenges of monitoring oncology clinical trials. Distinctions will be drawn between early and later phase trials. Attention will be paid to Adverse Event (AE) and Serious Adverse Event (SAE) reporting. All aspects of oncology clinical trials and how to successfully monitor them will also be discussed.

Learning Objectives

- Identify the differences between monitoring oncology early phase clinical trials vs. later phase clinical trials
- Identify ways in which oncology clinical trials differ from those in other therapeutic areas
- Describe the complexities of AE and SAE monitoring in oncology clinical trials
- Utilize Common Terminology Criteria for Adverse Events (CTCAE) grading and apply CTCAE to AE source data
- Describe the common challenges in monitoring and apply tools and techniques to overcome them

Who Should Attend

- Monitors who are new to or are interested in learning more about oncology clinical trials

Instructor

Vanessa Laroche, M.S. (Biotech), C.Q.A., C.I.P.

Course Length and Time

2 hours 12:30 – 2:30 p.m. Eastern

Course Dates

January 14, 2025

April 10, 2025

July 8, 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

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ACPE#: 0778-0000-23-018-L99-P. Released: 1/23.

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

Course Length

2 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

Blended Curriculum Course

Monitoring Plan Development

Course Description

Although monitoring plans are not defined or specifically required by FDA regulations, the FDA endorses the use of this tool in a Quality Systems management approach to clinical research. The traditional approach to monitoring plan development has relied upon reinforcing SOP-mandated monitoring activities with little focus on project and/or protocol-specific monitoring needs. This web seminar provides participants with concepts and templates to establish a monitoring plan that supports unique project risks and links to valuable data regarding investigative site and Clinical Research Associate (CRA) performance.

Learning Objectives

- Identify the contents of a monitoring plan including affiliated monitoring procedural documents, tools
- Develop a monitoring plan to meet the unique needs of a project and protocol
- Determine the triggers for revisions to monitoring plans and the importance of version control
- Explain FDA recommendations for risk-based monitoring plans
- Describe the relationship of the monitoring plan to the CRA for monitoring and managing site performance, meeting project goals and promoting continuous improvement

Who Should Attend

- Clinical Research Associates
- Project Managers
- Clinical Research Associate Managers

Instructor

Instructors

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

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

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Course Length and Time

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

Course Dates

February 6, 2025 (9:30-11:30)

May 20, 2025 (1-3)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **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#: 0778-0000-23-019-L99-P. Released: 2/23.

Monitoring Reports: 10 Rules of Effective Report Writing

Course Description

The Clinical Research Associate (CRA) creates reports that have many audiences, one being regulatory authorities reviewing essential documentation of clinical trials linked to marketing application approvals. This web seminar presents 10 categories of scientific report writing in the context of the role of the CRA and the reports that they write. The applicable reports are monitoring visit reports, e-mails, telephone reports, Memos to File, and more. The concepts of writing in a scientific voice versus first person, objective versus subjective, and many more are presented. This course is invaluable for the CRA, as well as the individual who critiques the various reports.

Learning Objectives

- Examine the impact of poor report writing
- Apply the definitions and concepts of scientific report writing
- Implement the 10 rules of quality report writing for CRAs
- Apply the 10 rules to CRA activities
- Write action items, deviations, queries
- Integrate essential document mapping within a monitoring report
- Describe the challenges of CRA report writing and report review

Who Should Attend

- Clinical Research Associates
- Contract Clinical Research Associates
- Clinical Research Associate Managers
- Project Managers

Instructors

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

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Elizabeth Weeks-Rowe, LVN, 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 10, 2025 (8:30-11:30)

June 2, 2025 (12-3)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 3 hours (0.3 CEUs)** of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-25-012-L99-P. Released: 2/25.

What Participants Say About Barnett Interactive Web Seminars:

"The best web seminar I have attended in my 10 years! A lot to take away."

Blended Curriculum Course

Monitoring Visit Reports for Medical Device Studies

Course Description

In this web seminar, we will discuss how to write effective monitoring visit reports for medical device studies. Participants will learn the purpose for monitoring investigational sites and the importance of documenting the visit. We will examine the requirements for the documentation in the Code of Federal Regulations and ICH, and discuss how the report is used by various stakeholders. Tools will be provided to enable learners to scrutinize various sections of the report to better document what was accomplished on the visit. This documentation supports the adequate monitoring obligation expected by regulatory authorities.

Learning Objectives

- Describe the requirements of documenting monitoring activities for a device study
- Recognize the importance of a well written monitoring visit report, auditable by the regulatory authorities
- 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

Instructors

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

Heather Marshall, M.S.N., B.S.N., R.N.

Shana Zink, 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

January 30, 2025 (1-3)

April 24, 2025 (9-11)

July 29, 2025 (1-3)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-064-L99-P. Released: 7/23.

Blended Curriculum Course

NEW! Navigating FDA's June 2024 BIMO Inspection Guidance: A Practical Approach

Course Description

This web seminar provides a comprehensive overview of the FDA's June 2024 draft guidance on Processes and Practices Applicable to Bioresearch Monitoring (BIMO) Inspections. Participants will gain insights into the key elements of BIMO inspections, including types of inspections, communication best practices, and post-inspection procedures. The course will equip attendees with strategies for preparing for and managing FDA inspections effectively.

Learning Objectives

- Identify types of BIMO inspections and their purposes in FDA-regulated research
- Explain the role of Remote Regulatory Assessments in BIMO oversight
- Discuss expectations for communication before, during, and after an inspection
- Examine BIMO processes and practices and publicly available resources
- Review relevant sections of the FDA's Investigations Operations Manual (2024)

Who Should Attend

- Clinical Trial Managers
- Regulatory Affairs Specialists
- Quality Assurance Managers
- Clinical Research Coordinators
- Principal Investigators
- Compliance Officers
- Clinical Operations Directors
- CRO Project Managers
- Institutional Review Board (IRB) Administrators

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

1.5 hours 9:00 – 10:30 a.m. and 1:30 – 3:00 p.m. Eastern

Course Dates

February 3, 2025 (9-10:30)

April 15, 2025 (1:30-3:00)

June 6, 2025 (9-10:30)

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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 mid-term, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-25-023-L99-P. Released 2/25.

Blended Curriculum Course

Negotiation Skills for Clinical Research Professionals

Course Description

The ability to negotiate effectively is a core competency for all clinical research professionals. Yet many people find negotiating to be an intimidating experience. Take this interactive web seminar and dramatically improve your ability to negotiate in any situation. With specific examples and real world case studies drawn from clinical research, you will be able to immediately implement the skills you learn with ease. This web seminar will provide a rich learning experience in implementing negotiation best practices.

Learning Objectives

- Formulate and approach to confidently influence without authority
- Explain how to persuasively communicate and negotiate in face-to-face and virtual settings
- Analyze a negotiation matrix
- Perform effective negotiations
- Employ approaches to transform conflict and negotiating tactics into constructive collaboration

Who Should Attend

- Clinical Research Assistants
- Clinical Research Associates
- Clinical Research Managers
- Clinical Research Directors
- Project Managers
- Contract Associates and Managers
- Team Leaders
- Regulatory Associates and Managers

Instructor

Natalie Currie, B.Sc.

Course Length and Time

1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates

May 21**,** 2025

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 1.5 hours (0.15 CEUs)** of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-24-024-L99-P. Released: 5/24.

Blended Curriculum Course

Overcoming Site Challenges: Managing Sponsor Payment Delays

Course Description

From financial feasibility to study close outs, many sites struggle with the financial aspects of clinical trials. This is largely due to sponsor delays and overlooked costs associated with the clinical trial. This web seminar will focus on mitigating sponsor delays with remitting payments to study sites. Attendees of this course will be provided with best practice approaches for overcoming these important challenges.

Learning Objectives

- Understand the financial aspects of a clinical trial
- Review overlooked costs and strategies for accounting for these costs
- Understand the reasons for the sponsor delays
- Implement approaches for reducing and eliminating these delays

Who Should Attend

- Financial Analysts
- Financial Managers
- Clinical Research Coordinators
- Research Nurses

Instructor

Mary Veazie, MBA, CPA, CHC, CHRC

Course Length and Time

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

Course Dates

March 6, 2025 (9:30-11)

June 10, 2025 (1- 2:30)

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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#: 0778-0000-23-034-L99-P. Released: 3/23.

Blended Curriculum Course

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
- Describe 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

Instructors

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

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

Nazma M. Rosado, MAOL, P.M.P., CPLP, 6σ, CMQ/OE

Course Length and Time

2.5 hours 9:00 -11:30 a.m. and 1:00 – 3:30 p.m. Eastern

Course Dates

February 24, 2025 (9-11:30)

May 13, 2025 (1-3:30)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 2.5 hours (0.25 CEUs)** of continuing education credit for full participation, including the completion of a mid-term, final exam, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-24-070-L99-P. Released: 8/24.

Phase I Study Management

Course Description

Because the early life of a compound is dependent on the data and analysis derived from Phase I Studies, it is imperative that these trials are managed and conducted with the highest quality and care. Therefore, well-honed project management skills that can address the unique issues associated with Phase I Studies are needed. This web seminar will examine the importance of Phase I Studies in drug development, the issues commonly associated with conducting a Phase I Study from a sponsor perspective and provide project management best practices specific to overseeing a Phase I Study.

Learning Objectives

- Define Phase I Studies
- Examine the importance of Phase I data in clinical development
- Review general considerations for planning and conducting a Phase I Study
- List project management best practices specific for Phase I clinical trials

Who Should Attend

- Project Managers
- Study Directors
- Site Monitors

Instructor

Daniel J. Filoramo, R.N., B.S.

Course Length

1.5 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

What Participants Say About Barnett Interactive Web Seminars:

"The trainer was very well-spoken and very knowledgeable. Used great examples and kept the class engaged and involved!"

Preparation, Management, and Response to Inspections and Audits

Course Description

Faced with an impending audit or inspection, how do you prepare? If inspection results in findings, do you have the skills and tools to best respond to these issues to avoid further actions? This web seminar will provide an overview of what to expect and how to prepare for an audit or inspection. Real case scenarios in a workshop format will be used to help solve the dilemmas faced by both sites and industry when faced with discoveries from regulatory authorities or auditors. Steps for preparation, on-site auditing and follow-up actions will be explained. Interactive exercises will be incorporated utilizing FDA Warning Letters. Participants will learn how to perform root cause analysis (RCA) and prepare corrective and preventive actions (CAPAs).

Learning Objectives

- Describe the anatomy of a regulatory inspection
- Recognize how to best prepare and manage expectations
- Discuss appropriate strategies for responding to inspection findings and implementing realistic and appropriate corrective and preventive actions (CAPA)
- Employ the right corrective actions to resolve the major and critical inspection findings

Interactive Activities

- Root Cause Analysis exercise
- Forensic examination of FDA Warning Letters

Who Should Attend

- Investigators
- Clinical Research Coordinators
- Clinical Research Associates
- Compliance Professionals
- Project Managers and Site Managers
- Quality Assurance Personnel

Instructor

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Course Length and Time

4 hours 10:00 a.m. – 2:00 p.m. Eastern

Course Dates

March 25**,** 2025

May 27**,** 2025

Archived Recording Available in Multiple Formats!

FEE: $1,045*

**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#: 0778-0000-25-013-L99-P. Released: 3/25.

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

Instructor

Shana Zink, B.S., C.C.R.A.

Course Length and Time

2.5 hours 9:00 – 11:30 a.m. and 12:00 – 2:30 p.m. Eastern

Course Dates

January 28, 2025 (12-2:30)

April 30, 2025 (9-11:30)

July 10, 2025 (12-2:30)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-23-020-L99-P. Released: 1/23.

Blended Curriculum Course

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:

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Elizabeth Weeks-Rowe, LVN, 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

March 11, 2025 (9:30-11)

May 29, 2025 (3-4:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-065-L99-P. Released: 9/23.

Blended Curriculum Course

Protocol Deviations: Documenting, Managing, and Reporting

Course Description

According to both U.S. regulations and the ICH GCP E6 Guideline, Clinical Investigators are required to conduct a clinical trial in compliance with the investigational plan/protocol. Protocol deviations should not be implemented without sponsor agreement and the prior approval/favorable opinion from the IRB/IEC, except when necessary to eliminate an immediate safety issue for research subjects. However, unapproved protocol deviations occur in every study and at every site. There is a growing recognition within the industry as to the importance of appropriately managing protocol deviations. This web seminar provides tips and strategies to help participants anticipate, manage, and minimize the impact of protocol deviations. Investigators and Clinical Research Associates (CRAs) will learn how to appropriately document and report protocol deviations, with a focus on preventing recurrence. Internal study team members will learn how to implement a structured approach to managing significant deviations that impact subject safety and/or data integrity.

Learning Objectives

- Describe the components of protocol deviation documentation and reporting
- Identify stakeholder roles in the management of protocol deviations
- Describe a process to proactively identify, track, and evaluate deviations for greater effectiveness in study management

Who Should Attend

- Sponsor/CRO Project Managers
- Sponsor/CRO Study Managers
- Sponsor/CRO Clinical Research Associates
- Sponsor/CRO Clinical Research Associate Managers
- Clinical Investigators
- Clinical Research Coordinators
- Quality Assurance Professionals

Instructor

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

Course Length and Time

2 hours 1:00 – 3:00 p.m. Eastern

Course Dates

January 21, 2025

May 28**,** 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-24-025-L99-P. Released: 1/24.

Quality by Design in Clinical Research: Is This Only for the Protocol?

Course Description

Over the past few years, Quality by Design (QbD) for clinical trials has been a focus for protocol development and execution. However, even though it is increasingly expected of the industry by regulatory agencies, translating this QbD approach into "building in quality for the business" is rarely shared for the "how do I do this?" This web seminar will de-code and translate QbD and quality for the research enterprise with examples that will solidify the concepts and framework presented for use within any organization. We will discuss the critical first step of defining quality; how to simplify QbD; how QbD and Quality Management Systems (QMS) relate to each other; determining whether your organization has these in place; what the best QbD principles and methods are; how to go beyond plans and create checklists for quality; and, finally, strategies for effective implementation.

Case Study: QbD for a CRA Study Management Plan

Job Aid: QbD Worksheet

Learning Objectives

- Differentiate QbD and QMS in clinical research
- Determine if your organization's practices reflect elements of a QMS and QbD principles and methods
- Identify QbD practices to utilize in the functional area and/or business enterprise

Who Should Attend

- Clinical Operations Professionals
- Project Managers
- Quality Assurance and Compliance Personnel
- Business Process Owners
- Risk Management Specialists

Instructor

Debbie Harper, B.Sc., P.M.P.

Course Length

1.5 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

NEW! The Quality Mindset and Risk-Based Thinking Connection

Course Description

As clinical professionals, we all perform activities that create an environment for Patient Safety and Data Integrity. However, many of us are so caught up in our day-to-day activities and focused on pressing timelines, that we can lose our ability to or deprioritize the need to make space for quality and focus on what matters most. Quality Mindset thinking helps keep quality front of mind. That same thinking also helps us take a risk-based approach. But what does that mean? In this practical, interactive web seminar, you will be introduced to Quality Mindset thinking and provided with tools that can help keep quality front of mind. You will make the connection between Quality Mindset and risk-based thinking, and learn how to apply these abstract concepts to your day-to-day activities and decision making.

Learning Objectives

- Define Quality Mindset
- Define risk-based approach
- Identify the six key behaviors of Quality Mindset thinking
- Describe how to utilize Quality Mindset tools in day-to-day activities and decision making
- Explain how these six key behaviors support taking a risk-based approach
- Connect how to use Quality Mindset tools for risk-based approach thinking and scenarios

Who Should Attend

- Clinical Operations Personnel
- Data Management Professionals
- Quality and Regulatory Affairs Professionals

Instructors

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

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

Kirsten Morasco, B.S.

Course Length and Time

3 hours 8:30-11:30 a.m. Eastern

Course Dates

March 20**,** 2025

May 14**,** 2025

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 3 hours (0.3 CEUs)** of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-24-062-L99-P. Released: 9/24.

Quality Systems: A Controlled Approach to GCP Compliance

Includes R3 Updates

Course Description

A Quality Systems approach to establishing and maintaining regulatory compliance allows sponsors to better leverage their resources and Clinical Investigators to meet their obligations for clinical research oversight. This web seminar will review the elements of a Quality System at the Clinical Investigator site and how it functions to proactively control site-level noncompliance.

Learning Objectives

- Discuss an overview of sponsor and Clinical Investigator responsibilities
- Explain how to identify the active elements of a functional Quality System at the clinical research site
- Discuss how implementation of a Quality System can assist in the requirements for meeting obligations of sponsors and Clinical Investigators
- Determine how Quality System overlaps with FDA and ICH Guidance
- Examine recent compliance concerns and how applying the Quality System framework at the site level can address them

Who Should Attend

- Directors of Clinical Operations at clinical research sites
- Clinical Principal Investigators
- Clinical Research Coordinators
- Clinical Research Associates
- Project Managers
- All Clinical Research Personnel involved in selecting and/or overseeing clinical research sites

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

2 hours 9:30 – 11:30 a.m. and 2:30 – 4:30 p.m. Eastern

Course Dates

January 16, 2025 (2:30-4:30)

April 14, 2025 (9:30-11:30)

July 16, 2025 (2:30-4:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 2 hours (0.2 CEUs)** of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-24-026-L99-P. Released: 1/24.

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

Instructor

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

Course Length

2 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

Blended Curriculum Course

Recent Trends in Noncompliance: Critical Review and Analysis of Recent Regulatory Letters and Communications from the FDA, EMA, and Health Canada

Course Description

As the clinical research environment evolves in response to both internal and external changes, regulatory agency communication appears to be focused on particular areas of GCP compliance. Regulatory agencies' recent findings for Clinical Investigators, sponsors, and Institutional Review Boards (IRBs) tend to reflect historic areas of noncompliance; however, more attention is being placed on ensuring that corrective and preventive action plans are developed to secure compliance. This web seminar will examine the trends in recent regulatory communication and open discussion for review of acceptable versus unacceptable responses.

Learning Objectives

- Review recent FDA, European Medicines Agency (EMA), and Health Canada findings for Clinical Investigators (sites), sponsors, and IRBs
- Determine areas of compliance concentration for regulatory agencies
- Discuss what factors may be helping drive the present approach and what it may mean for future compliance considerations
- Examine best practices for responding to a regulatory communication

Who Should Attend

- Clinical Research Associates
- Project Managers
- Principal Investigators
- Clinical Research Coordinators
- IRB Administrators and Members
- Clinical Quality Assurance Auditors
- All other personnel responsible for ensuring compliance with GCP regulations

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

2 hours 11:30 a.m. – 1:30 p.m. Eastern

Course Dates

March 7, 2025

June 6, 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 2 hours (0.2 CEUs)** of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-24-027-L99-P. Released: 3/24.

RECIST 1.0 and 1.1: Overview and Data Challenges in Oncology Clinical Trials

Course Description

RECIST stands for Response Evaluation Criteria in Solid Tumors. The National Cancer Institute is the best resource for information, and defines RECIST criteria as "a voluntary, international standard, and not an NCI standard. They are based on a simplification of former methods (WHO, ECOG) and based on measurable disease, i.e., the presence of at least one measurable lesion." RECIST criteria provide a way to standardize measurement of solid tumors worldwide for any clinical trials that include this data to define study endpoints.

RECIST 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 RECIST 1.0 and 1.1
- Describe the components of RECIST/tumor data
- Apply how to correctly calculate disease response
- Identify and predict common trends with tumor data
- Use working knowledge of common trends to help develop Case Report Forms for oncology trials

Who Should Attend

- Clinical Research Coordinators
- Clinical Research Associates
- Clinical Team Managers
- Primary Investigators who are interested in participating in oncology clinical trials, but who do not specialize in oncology or radiology

Instructor

Vanessa Laroche, M.S. (Biotech), C.Q.A., C.I.P.

Course Length and Time

2 hours 12:30 – 2:30 p.m. Eastern

Course Dates

March 19, 2025

June 2, 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-021-L99-P. Released: 3/23.

Regulatory Intelligence

Course Description

The constantly changing regulatory environment necessitates keeping abreast of current information from a variety of sources. Regulatory Intelligence (RI) is the act of gathering and analyzing regulatory information for impact or changes in laws, regulations, directives, guidance documents, etc. There is more to RI than keeping up with the latest regulations and guidelines. Regulatory precedence, industry practices, regulatory agency opinions, and competitor information are just a few of the valuable sources of information that can help regulatory affairs professionals to develop successful regulatory strategies.

This web seminar examines the scope of RI which encompasses: Information sources, monitoring the regulatory landscape (periodic vs. ongoing), using an RI database and other sources to research the regulatory question, and how to summarize, analyze, integrate, and present RI.

Learning Objectives

- Define Regulatory Intelligence and its importance to companies
- Identify multiple sources of Regulatory Intelligence
- Evaluate the constantly changing regulatory landscape
- Evaluate a regulatory research question into researchable units, and conduct the research using a Regulatory Intelligence database
- Summarize and present Regulatory Intelligence findings back to a team

Who Should Attend

- Seasoned Regulatory Affairs Professionals looking to develop their skill set
- Research and Development Professionals who are interested in learning a new skill

Instructor

Treena Jackson, M.S., M.A., C.Q.A., R.A.C., C.S.S.G.B.

Course Length and Time

1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates

March 18, 2025

June 24, 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-072-L99-P. Released: 8/23.

Research Billing Processing: Leveraging Technology to Maintain Compliance and Mitigate Risk

Course Description

This web seminar will describe how to leverage technology such as an electronic health record to maintain compliance and mitigate risk. We will review the three categories of charges, including how to leverage the charge routers in electronic health records to appropriately segregate charges and the appropriate medical documentation that enables charges associated with a clinical research study to move through the insurance claims process with ease. Participants will leave this web seminar equipped with pertinent information to enhance their research billing programs.

Learning Objectives

- Understand how to leverage an electronic health record to route charges associated with a clinical research study
- Learn to collaborate with personnel from the patient business services office to mitigate risk
- Learn how to maximize clinical workflows in an electronic health record to enable novel compounds like CAR-T cell trials to be implemented in a timely manner

Who Should Attend

- Personnel responsible for the financial aspects of a clinical research study
- Research Nurses
- Clinical Research Coordinators
- Patient Business Service Personnel

Instructor

Mary L. Veazie, M.B.A., CPA, CHC, CHRC

Course Length and Time

2 hours 1:00 – 3:00 p.m. Eastern

Course Dates

January 23, 2025

July 28, 2025

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-23-001-L99-P. Released: 1/23.

Blended Curriculum Course

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 9:00 – 11:00 a.m. Eastern

Course Dates

March 24**,** 2025

June 17**,** 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-23-066-L99-P. Released: 9/23.

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

May 6**,** 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-22-009-L04-P. Released: 5/22.

Blended Curriculum Course

Risk-Based Monitoring and Quality Management of Clinical Trials: Recent Guidance Updates from the FDA and EMA

Course Description

The FDA and EMA describe their expectations for risk-based approaches to quality management and monitoring in the 'FDA Guidance Oversight of Clinical Investigations: A Risk- Based Approach to Monitoring' and the 'EMA Reflection Paper on risk-based quality management in clinical trials,' both of which are reviewed in this web seminar, which also includes industry think tank contributions.

Learning Objectives

- Discuss the FDA Guidance and EMA Reflection Paper for clinical trial risk management and monitoring
- Evaluate industry think tank trends (TransCelerate, CTTI)
- Review best practices for risk management for trial oversight and monitoring

Who Should Attend

- Clinical Investigators and Staff
- Clinical Research Associates
- Study and Clinical Research Associate Managers
- Sponsors/CROs Clinical Operations
- Clinical Quality Compliance and Quality Assurance Professionals

Instructor

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

Course Length and Time

1.5 hours 9:00 – 10:30 a.m. and 1:00 – 2:30 p.m. Eastern

Course Dates

February 19, 2025 (1-2:30)

May 5, 2025 (9-10:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-23-076-L99-P. Released: 8/23.

Risk-Based Monitoring for Sites: Prepare Your Site for Success

Course Description

Over the past few years, a new term has emerged in the clinical research industry: Risk-Based Monitoring (RBM). What is it? Why is it becoming more widely used? How does it impact Investigators and sites? This web seminar will provide an overview of the principles of RBM and describe how this new approach to monitoring differs from "traditional" monitoring. Learners will gain an understanding of both regulatory and industry factors influencing the adoption of Risk-Based Monitoring. This web seminar will help participants anticipate the possible changes brought on by RBM, and provide strategies to prepare their sites for success.

Learning Objectives

- Describe the concepts and activities of a Risk-Based Monitoring approach
- Investigate the regulatory and industry rationales for Risk-Based Monitoring
- Identify expected changes for sites as a result of Risk-Based Monitoring adoption
- Formulate a transition plan to prepare your site for success in a Risk-Based Monitoring world

Who Should Attend

- Site Research Managers
- Investigators
- Clinical Research Coordinators

Instructor

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

Course Length

1.5 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

What Participants Say About Barnett Interactive Web Seminars:

"I will apply tips from the lesson when on-site. The instructor was great and I look forward to participating in future trainings."

Risk-Based Quality and Compliance Management in Combination Product Trials

Course Description

A risk-based approach to clinical trials requires not only a strategy, but tools to define key indicators to measure specific risks. As referenced in the most recent U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) guidance documents, Key Risk Indicators (KRIs) and Critical to Quality (CTQ) metrics should focus on "what really matters," and safety of research subjects and data integrity should be emphasized. Combination products can increase risks while being tested in clinical trials, therefore, these metrics should be linked to particular processes within a development program for combination products.

Learning Objectives

- Review the different types of combination products
- Review current regulatory updates and guidelines for combination products
- Discuss streamlined approach for combination products
- Describe principles of Quality by Design (QbD) and new regulatory requirements for risk-based monitoring and how it applies to trials with combination products
- Develop relevant metrics as quality and performance indicators for
- Risk-Based Quality Management (RBQM) systems for combination products
- Perform a cause-effect analysis for identified risks and develop mitigation strategies

Who Should Attend

- Clinical Quality Assurance Auditors
- Clinical Quality and Compliance Professionals
- Clinical Research Associates
- Project Managers
- Medical Monitors
- Regulatory Affairs Professionals
- Clinical Research Investigators and Coordinators

Instructor

Marina Malikova, Ph.D., MSci, MA, C.C.R.A., RAC

Course Length and Time

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

Course Dates

February 21, 2025 (1-2:30)

May 8, 2025 (9:30-11)

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-22-031-L04-P. Released: 8/22.

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

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Course Length and Time

1.5 hours 9:00 - 10:30 a.m., 12:00 – 1:30 p.m. and 1:00 – 2:30 p.m. Eastern

Course Dates

January 16, 2025 (1-2:30)

April 16, 2025 (12-1:30)

July 31, 2025 (9-10:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-022-L99-P. Released: 1/23.

Blended Curriculum Course

"Risk-Based Thinking": How Monitors Can Develop an Auditor's Perspective

Course Description

The regulations require that sponsors ensure the selection of qualified monitors and the proper monitoring of clinical investigations. However, sponsors are frequently cited by the FDA for failure to meet those requirements. These regulatory communications note that although monitors might have identified issues, they did not appreciate the significance of those findings. As a result, opportunities to promptly secure compliance might be missed.

Clinical research is structured to incorporate monitoring processes more frequently than auditing. Yet as monitoring integrates a risk-based approach, monitors can utilize many auditing techniques to assist them in more effectively performing their tasks and meeting their obligations. This web seminar will explore the processes for critically reviewing findings to discern the implications and impact on subject safety and data integrity.

Learning Objectives

- Utilize auditing techniques when performing monitoring tasks
- Define "proper monitoring" and who is responsible for its conduct
- Discuss monitoring findings within the context of regulatory risk
- Review standard monitoring report templates and discuss ways to adapt them to develop a compliance assessment
- Describe processes for discerning patterns in information reviewed
- Explore methods for developing monitoring tools that facilitate a systems review and communication

Who Should Attend

- Clinical Research Associates
- Clinical Research Associate Managers
- Project Managers

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

1.5 hours 9:30 – 11:00 a.m.

Course Dates

July 31, 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-067-L99-P. Released: 7/23.

Risk-Proof Your Sites: Monitoring Strategies for Managing Risks

Course Description

The concepts and processes of risk management are well known and often used in clinical research project management. Yet, few clinical research monitors realize the value of applying these activities to site management. This web seminar starts with an overview of risk assessment and management. The learner is then guided through the application of these techniques through all phases of study conduct: Site selection and initiation, routine monitoring, and site close-out. The course focuses on identification of site strengths and weaknesses and implementing strategies to address weaknesses before they lead to deviations or noncompliance.

Learning Objectives

- Perform a risk assessment for investigational sites focusing on the issues that matter most
- Identify key questions to evaluate potential risks during the site selection and initiation phase
- Recognize areas of greatest risk at investigative sites during study conduct
- Discuss techniques to monitor potential risks and take action if/when they become problematic
- Identify strategies to conduct site close-out visits so sites remain "audit-ready"

Who Should Attend

- Clinical Research Associates
- Clinical Research Associate Managers
- Clinical Research Professionals with responsibility for site selection and management
- Quality Assurance Professionals

Instructor

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

Course Length

2 hours

Course Dates

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

Accreditation

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

Blended Curriculum Course

Root Cause Analysis: Applying the Concept for Better Study Compliance Management

Course Description

Managing compliance in the research industry is vital to successful clinical trials. Regulatory authorities expect that all stakeholders identify non-compliance, intervene, and then evaluate the effectiveness of the intervention. Without root cause analysis, interventions cannot be effectively identified and designed. This web seminar will present the scientific concepts of root cause analysis and apply them specifically in the clinical trial setting. Root cause analysis is invaluable for all stakeholders in clinical research, the sponsor, CRO, site, and Institutional Review Board (IRB).

Learning Objectives

- Define root cause analysis concepts
- Implement Gilbert's Root Cause Analysis Diagnostic Process
- Apply root cause analysis in clinical trial study site management
- Assign the right intervention for successful solutions
- Integrate proactive root cause analysis to manage stakeholder compliance: Research site management, Clinical Research Associate (CRA) management, and more

Who Should Attend

- Clinical Research Coordinators
- Clinical Research Associates
- Site Managers
- Clinical Research Associate Managers
- Project Managers

Instructor

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

Course Length and Time

2.5 hours 11:00 a.m. – 1:30 p.m. and 3:00 – 5:30 p.m. Eastern

Course Dates

February 3, 2025 (3-5:30)

May 13, 2025 (11-1:30)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-068-L99-P. Released: 8/23.

Software as a Medical Device: Clinical Considerations

Course Description

In the EU, software has been considered a medical device since 2007. With the proliferation of software technology, this thinking is infiltrating the U.S. FDA regulatory policies as well. In this web seminar, we will discuss the clinical considerations for software as a medical device, including the importance of human factor studies, adverse event monitoring, linking clinical outcomes to software, and identifying and managing the risks unique to software as a medical device.

Learning Objectives

- Examine the clinical impact of human factors and the software interface
- Discuss how to connect clinical effects to software
- Describe risks attributable to software versus physical device

Who Should Attend

- Medical Device Professionals
- Project Managers
- Clinical Data Specialists/Analysts
- Clinical Data Managers
- Clinical Operations Professionals

Instructor

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

Course Length

1.5 hours

Course Dates

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

Accreditation

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

What Participants Say About Barnett Interactive Web Seminars:

"The seminar content fully addressed each course objective. It included an impressive amount of detail for a 3-hour course."

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

Blended Curriculum Course

Source Documentation: What is Adequate and Accurate?

Course Description

Lack of adequate and/or accurate source documentation has been noted as a common deficiency in inspection findings of Clinical Investigators, and regulators report that quality source documents reinforce quality site data. Regulatory requirements (FDA, ICH) will be reviewed in this web seminar. Further, the following topics will be covered: Variability of stakeholder requirements (sponsor-to-sponsor, per study, sponsor to site), case report forms (CRFs) as source data, electronic medical records, shadow charts, source document worksheets, protocol deviations, telephone and email contacts, good documentation practices, making corrections to source documents, late entries, back-dating (oh no!), and details of FDA inspection methods and findings regarding source documents. Leading practices will be discussed to assist sites with implementing the regulatory requirements for source documents.

Learning Objectives

- Define source data and source documents
- Identify regulatory required characteristics of source data and source documents
- Identify three attributes of source document worksheets
- Describe three attributes of ALCOAC (attributable, legible, contemporaneous, original, accurate, complete) for source documents
- Discuss CRFs as source data

Who Should Attend

- Site Research Directors/Managers
- Clinical Research Coordinators
- Principal Investigators
- Clinical Research Associates
- Project Managers
- Clinical Research Associate Managers
- Quality Assurance Personnel

Instructors

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

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

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Course Length and Time

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

Course Dates

January 28, 2025 (1-3) July 8, 2025 (1-3)

April 16, 2025 (9:30-11:30)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-23-023-L99-P. Released: 1/23.

Blended Curriculum Course

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

Instructor

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Course Length and Time

2 hours 9:00 - 11:00 a.m. and 10:00 a.m. – 12:00 p.m. Eastern

Course Dates

February 24, 2025 (9-11)

May 28, 2025 (10-12)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-25-014-L99-P. Released: 2/25.

Sponsor Responsibilities for Global Drug Studies

Includes R3 Updates

Course Description

This web seminar covers the sponsor's responsibilities for the conduct of a global drug study. Participants will learn the responsibilities assigned to a sponsor for a global clinical study based on the International Council for Harmonization (ICH) requirements. These essential requirements for compliance to regulations are useful when dealing with the FDA, Medicines and Healthcare Products Regulatory Agency (MHRA), European Medicines Agency (EMA), and Health Canada (HC), among other global regulatory authorities. Focusing on the importance of documentation, participants will learn how to put these concepts into practice.

Learning Objectives

- Discuss the sponsor responsibilities assigned in ICH GCP E6 Guideline and expected by the regulatory authorities across the globe
- Describe how these concepts are put into practice, with special focus on documentation to support sponsor oversight of these responsibilities

Who Should Attend

- Clinical Operations Staff
- Project Managers
- Regulatory Affairs Professionals
- Quality Assurance Personnel
- All other personnel responsible for ensuring compliance with sponsor responsibilities in the conduct of a clinical trial (especially for start-up and smaller biotech companies)

Instructor

Treena Jackson, M.S., M.A., C.Q.A., R.A.C., C.S.S.G.B.

Course Length and Time

1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates

February 4**,** 2025

May 22**,** 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-24-028-L99-P. Released: 2/24.

State Laws Governing Clinical Trial Regulatory Compliance

Course Description

Although many clinical trial sponsors and investigators focus primarily on FDA regulations related to the conduct and design of clinical trials, their failure to comply with state laws and regulations may expose sponsors, investigators, IRBs, institutions, or individuals may call into question the potential integrity of clinical data. Today's U.S.-based clinical trials must meet not just federal requirements, but an increasingly complex array of state-specific requirements, many of which are critical and foundational to clinical studies. The capacity to consent to experimental therapy has its foundational basis and is governed by state law. In this web seminar, we will review many of these key areas, and discuss specific differences. Learners will be provided with examples from more than a dozen practical areas, including age of consent, capacity to consent, IRB and clinical protocol requirements, notification of state agencies, experimental drug dispensing requirements, HIV testing rules, genetic testing, and legal representatives. Also, we will explore strategic considerations that certain states afford specific therapeutic classes. Learners will have the opportunity to ask direct questions regarding clinical trial requirements in their research state.

Learning Objectives

- Recognize areas in which state-specific regulations may affect clinical trial research
- Reduce risk and liability by applying state-specific knowledge to clinical trials
- Utilize state licensing authorities and agencies to address state-specific concerns
- Describe the strategic aspects of clinical trial site selection

Who Should Attend

- Site Research Managers
- Clinical Research Associates
- Clinical Project Managers
- Principal Investigators
- Site Research Managers
- Clinical Research Coordinators

Instructor

John Serio, J.D.

Course Length and Time

1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates

February 18, 2025

May 28, 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or tollfree 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 of continuing education credit for full participation, including the completion of a pretest, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-22-032-L04-P. Released: 7/22.

NEW! "Statistical Intuition" for Clinical Research Data Managers

Course Description

This web seminar is designed to familiarize the Clinical Data Manager (CDM) with the practical and applicable concepts behind the statistical analyses being performed on clinical trial data. Basic statistical concepts, such as descriptive statistics and inferential statistics examining confidence intervals will be discussed as well as the different data types and measurement scales that relate to clinical data. By the end of the seminar, learners can expect to have gained a newfound confidence in understanding and interpreting the statistical results of clinical trial data.

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

Who Should Attend

- Clinical Data Managers
- Clinical Data Assistants

Instructor

Denise G. Redkar-Brown, MT

Course Length and Time

3 hours, two days 9:30-11:00 am Eastern each day

Course Dates

Offering #1:

January 9 & January 16**,** 2025

Offering #2:

May 20 & May 27**,** 2025

FEE: $1,195*

**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#: 0778-0000-24-061-L99-P. Released: 10/24.

Blended Curriculum Course

Strategies for Active Listening

Course Description

Active listening is an essential skill for the development of our relationships, collaboration, and efficiency in our work. However, active listening is so rarely valued in this fast-paced, increasingly volatile landscape. With each new emerging technology, our skills are not only practiced less, we are losing our ability to listen more rapidly than expected. Active listening is not simply about understanding and storing the content of what another person is saying. It includes being able to hold a focus, attention, and communicate in an authentic and non-verbal manner to another that they have been heard. This web seminar will help learners develop deeper listening skills through a mix of behavioral science techniques, real-life scenarios, and hands-on practice.

Learning Objectives

- Define the multiple layers of active listening and why we need it
- Distinguish between listening for content and active listening
- Describe and practice listening skills for management and conflict resolution
- Develop an understanding of general personality characteristics to best adjust listening and communication skills
- Apply best practices to real-life scenarios

Who Should Attend

- Site Managers
- Sponsor Managers
- Project Managers
- Project Leads
- Principal Investigators
- Clinical Research Associates

Instructors

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

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

Nazma M. Rosado, MAOL, P.M.P., CPLP, 6σ, CMQ/OE

Course Length and Time

1.5 hours 11:00 a.m. – 12:30 p.m. and 1:30 - 3:00 p.m. Eastern

Course Dates

February 4, 2025 (11-12:30)

May 7, 2025 (1:30-3)

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 1.5 hours (0.15 CEUs)** of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-24-029-L99-P. Released: 2/24.

NEW! Strategies for Assessing Risk Tolerance

Course Description

There are big expectations when it comes to risk in clinical trials. ICH E6 (R2) and the draft of ICH E6 (R3) underscores the importance of adopting a risk-based approach and is a tool health authorities expect clinical research professionals to utilize. But are all risks the same? How do you know what risks can be tolerated vs. those requiring significant time and resources? This web seminar will help learners gain a better understanding of risk and how to determine risk tolerance levels.

Learning Objectives

- Define risk
- State a commonly held myth about risk and explain why it is a myth
- Describe risk tolerance
- Describe the methodology for determining risk tolerance

Who Should Attend

- Clinical Operations Personnel
- Data Management Professionals
- Quality and Regulatory Affairs Professionals

Instructors

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

Holly Deiaco-Smith, M.S. Ed.

Kirsten Morasco, B.S.

Course Length and Time

2.5 hours 8:30 – 11:00 a.m. and 1:00 – 3:30 p.m. Eastern

Course Dates

March 12, 2025 (1-3:30)

May 8, 2025 (8:30-11)

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 2.5 hours (2.5 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#: 0778-0000-24-063-L99-P. Released: 9/24.

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., M.A., C.Q.A., R.A.C., C.S.S.G.B.

Course Length

1.5 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

Strategies for Developing Effective Training and Facilitation Skills in Clinical Research

Course Description

In clinical research, there is an on-going need to conduct training whether it is at the onset of a study, due to a change in staff or new staff, as a result of an amendment, or because of an identified noncompliance issue during a study. If our goal in training is to pass on knowledge and to ask learners to apply that information, we need to consider our approach in how to make this happen.

It is important to consider how essential every communication is within research; the information shared can have a huge impact on study timelines, data integrity, and compliance. If information is not internalized by the learner, then the time spent discussing it is a waste and the consequences may be significant. In this web seminar, training and facilitation methodology, skills, and fundamentals will be discussed. We will focus on the practical application and tools needed to ensure that an audience is able to remember and apply the information shared.

Learning Objectives

- Review the application of training and good facilitation skills in clinical research
- Discuss adult learning principles and styles
- Identify successful training techniques applied to a clinical research setting

Who Should Attend

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

Instructor

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

Course Length

1.5 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

Strategies for Effective Remote Monitoring

Course Description

With sponsors/CROs continuing to focus on expanding approaches to monitoring clinical trials remotely, this web seminar will evaluate process and documentation, explore techniques for identifying issues at sites remotely, and examine the regulatory expectations for managing compliance. Better utilization of remote monitoring is critical to ensure sites are compliant and the data is accurate and consistent. Strategies for remote monitoring will be addressed, including the review of data trends, remote study management and communication, and "red flags" that may indicate issues on site.

Learning Objectives

- Evaluate development of monitoring plans through protocol analysis for remote risk management
- Discuss tools and risk evaluation approaches for remote monitoring
- Explain techniques for practical corrective and preventive actions to ensure clear communication and resolution and documentation of issues

Who Should Attend

- Clinical Research Associate Managers
- Clinical Research Associates
- Project Managers
- Clinical Trial Managers
- Study Coordinators

Instructor

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

Course Length and Time

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

Course Dates

April 29, 2025 (9:30-11)

June 18, 2025 (1-2:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-23-024-L99-P. Released: 4/23.

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."

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 in Multiple Formats!

Accreditation

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

Blended Curriculum Course

Strategies for Having Difficult Conversations

Course Description

Conflict is an essential part of working with others. When done well, it helps to move an agenda forward in a creative and inspired way. When done poorly, it can end in toxicity and the dismantling of strategy and culture. Conflict is necessary for any organization that wants to succeed, it is therefore important to learn to do it well by being courageous and having difficult conversations. These conversations require a certain finesse and awareness to conduct them in a professional and generative manner, and not succumb to anxiety and reactivity. This web seminar will focus on what gets in the way of our ability to have difficult conversations, provide learners with a tool that will help to navigate these dialogues, plus will help to grow confidence and awareness to address conflict from a place of courage.

Learning Objectives

- Identify personal roadblocks and blind spots
- Translate latest behavioral research into real-world scenarios
- Utilize a tool to help navigate difficult conversations
- Compare various communication styles of conflict
- Develop a feedback strategy

Who Should Attend

- Site Managers
- Sponsor Managers
- Project Managers
- Project Leads
- Principal Investigators
- Clinical Research Associates

Instructors

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

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

Nazma M. Rosado, MAOL, P.M.P., CPLP, 6σ, CMQ/OE

Course Length and Time

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

Course Dates

February 10, 2025 (9:30-11)

June 10, 2025 (1-2:30)

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-24-030-L99-P. Released: 2/24.

Blended Curriculum Course

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 web seminar the question is addressed through real life case scenarios that deal with the different kinds of "difficult" sites, for example: The overwhelmed site, the unmotivated site, the passive aggressive site, the research naïve site. All of these types of behaviors at sites can lead to poor performance that does not respond to typical CRA action item management. Hear ideas on how to successfully work with the difficult site to promote efficiency and positive study outcomes that include helpful job aids, soft skill coaching, and diagnostic techniques to help improve approaches to interventions and management of the "difficult" site.

Learning Objectives

- Define the causes of why sites can be "difficult"
- Discuss approaches for dealing with the different types of "difficult" sites
- Develop trending techniques to anticipate site issues
- Implement proactive diagnosis techniques to develop a CRA communication plan
- Describe techniques for resolving conflict and promoting successful outcomes

Who Should Attend

- Clinical Research Associate Managers
- Clinical Research Associates
- Project Managers

Instructors

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

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

Nazma M. Rosado, MAOL, P.M.P., CPLP, 6σ, CMQ/OE

Course Length and Time

2 hours 9:00 – 11:00 a.m. and 12:00 – 2:00 p.m. Eastern

Course Dates

January 27, 2025 (12-2)

April 25, 2025 (9-11)

July 30, 2025 (12-2)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-24-055-L99-P. Released 7/24.

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 web seminar 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., T.I.A.C.R.

Course Length

1.5 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

Blended Curriculum Course

Strategies for Remote Auditing of Investigative Sites

Course Description

Under federal regulation, sponsors are responsible for ensuring the integrity of safety and efficacy data submitted to the FDA to support their application; they are also responsible for ensuring clinical studies are conducted in accordance with the approved protocol. Audits are an opportunity to assess compliance and not just the quality of data, but the systems that generate that data. This web seminar will highlight the collaborative requirements for facilitating remote auditing and identify key considerations for future studies.

Learning Objectives

- Review the purpose and process of audits
- Examine critical Clinical Investigator quality systems, subsystems, processes
- Explore study risk assessments to inform the remote auditing plan
- Discuss the use of technology to verify objective evidence
- Address challenges and potential solutions of virtual audits
- Incorporate new FDA guidance and ISO standards to develop a remote audit process

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

6 hours, two days 8:30 - 11:30 a.m. Eastern each day

Course Dates

Offering #1:

March 11 & March 18**,** 2025

Offering #2:

June 2 & June 9**,** 2025

Archived Recording Available in Multiple Formats!

FEE: $1,195*

**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 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#: 0778-0000-23-025-L99-P. Released: 3/23.

Study Feasibility: Eliminating Low and Late Enrollment

Course Description

This web seminar is designed for sponsor/CRO personnel responsible for protocol design and development, country allocation, site selection, and study feasibility assessments. The current study feasibility assessment process is inefficient and is incapable of identifying the best investigative sites to conduct a clinical trial. Feasibility questionnaires and the current process are often not effective in predicting site success in implementing a given clinical trial. This session will explore novel approaches and technologies that can be used to significantly improve the feasibility assessment process at the protocol, country, and site level.

Learning Objectives

- Evaluate the traditional approach to study feasibility assessment
- Examine what's working, what's not, and why not
- Define the concepts of study feasibility at the protocol, country, site level
- Discuss the purpose and objectives for conducting feasibility assessments
- Explore paradigm shifts in the methods for evaluating study feasibility
- Examine a live demonstration of several new methods, technologies, and approaches
- Identify the characteristics of a high-enrolling site for a given study
- Identify how a protocol can be optimized for enrollment and how the sponsor can maximize enrollment at each site
- Employ practical, statistical, and simulation based methods for country allocation and site selection practices

Who Should Attend

- Directors of Clinical Operations
- Regional Medical Directors
- Clinical Project Managers
- Site Selection Specialists
- Clinical Research Associates
- Clinical Research Associate Managers

Instructor

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

Course Length

2 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

Study Site Start-Up: Organization and Management Tips for the Novice Clinical Research Site

Course Description

The role of the research site is vital in the success of a clinical trial. Quality research sites are in great demand in the current research environment. This web seminar presents an overview of the core components for a successful research site. Examples of successful sites for benchmarking will be included as well as resources for more information.

Learning Objectives

- Identify components of a successful research site through benchmarking elite performers
- Identify the primary elements of business and marketing planning for a research site
- Discuss the importance of site GCPs and components of SOPs
- Discuss marketing, staffing, recruitment, contracting, and budgeting concepts key to research sites

Who Should Attend

- Clinical Research Site Managers/Directors
- Clinical Research Coordinators
- Industry Consultants
- Principal Investigators or Potential Principal Investigators
- Entrepreneurs

Instructor

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

Course Length

2.5 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

Blended Curriculum Course

Subject Recruitment: Proactive Project Plans and Issues Management

Course Description

This web seminar presents an overview of the patient recruitment arena, and focuses on strategies for successful clinical trials including: Systematic protocol feasibility, pre-screening approaches, insourcing and outsourcing options, and social media considerations. Included in the program are discussions for handling tough populations and the ethics of participant recruitment in clinical trials.

Learning Objectives

- Explore updates on clinical trial participant recruitment worldwide
- Discuss an overview of participant recruitment practices including the use of social media
- Examine keys to success: Systematic practice approaches to recruitment in clinical trials
- Employ pre-screen practices to improve screening successes
- Examine the consenting process in regard to subject recruitment and retention
- Determine approaches to retain quality subjects to support data integrity
- Evaluate efforts: The recruitment report card

Who Should Attend

- Clinical Research Coordinators
- Site Research Managers
- Clinical Research Monitors
- Sponsor Project Managers

Instructor

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Course Length and Time

2.5 hours 1:00 – 3:30 p.m. Eastern

Course Dates

February 19**,** 2025

May 22**,** 2025

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-25-015-L99-P. Released: 2/25.

What Participants Say About Barnett Interactive Web Seminars:

"Very helpful tools and suggestions that can be applied to a couple of very high visibility projects that we are just beginning."

Blended Curriculum Course

A Systematic Approach to

Study Start-Up: Improving Site Activation

Course Description

The success of a trial relies on the strong bond between trial operations and project management throughout the trial life cycle. It is important to develop a specific knowledge of the strengths, weaknesses, and pitfalls of assumed risks at inception in order to devise mitigation strategies throughout the implementation phase. Systematic assessment of risk factors and key performance indicators at the start-up phase can allow for more efficient execution of a clinical trial and ensure better accrual rates. Best practices to expedite the start-up phase will also be discussed.

Learning Objectives

- Develop a sound business strategy for a more efficient study start-up
- Identify key performance indicators and risk factors contributing to start-up delays
- Perform cause-effect analysis of factors attributing to delays of start-up phase
- Implement mitigation strategies to avoid delays and allow for a successful trial launch

Who Should Attend

- Directors of Clinical Operations
- New Clinical or other Project Team Leaders who will be managing projects
- Clinical, Regulatory, Research and Development (R&D) Staff
- Physician Investigators
- Clinical Research Coordinators and Clinical Research Associates, Data Managers or others working in biomedical product development
- Regulatory Affairs
- Quality Control Professionals, Quality Assurance Specialists

Instructor

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

Course Length and Time

1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates

June 26**,** 2025

Archived Recording Available in Multiple Formats!

Fee: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-24-039-L99-P. Released: 11/24.

Technology Innovation and Intellectual Property (IP) in the Biomedical Industry

Course Description

This web seminar covers how companies use intellectual property (IP) to protect their investments in knowledge assets, including the healthcare sector and biotech industry. Participants will develop a basic understanding of economic and legal aspects of intellectual property systems such as patents, copyrights, trademarks, and trade secrets and their applications, as they have become important business tools throughout the knowledge-based economy. Participants will also gain insights into the effective use of IP in licensing and partnership strategies.

Learning Objectives

- Develop a basic understanding of economic and legal aspects of intellectual property systems
- Gain insights into the fundamentals of patents, copyrights, trademarks, and trade secrets
- Understand how IP systems drive competition and strategy in technology-intense fields
- Develop an understanding of what IP assets are and how they work
- Examine the use of IP in licensing and partnership strategies

Who Should Attend

- Life Sciences Professionals
- Research and Development Specialists
- Director of Business Strategy
- Project Managers
- Pre-Clinical and Clinical Researchers
- Biotechnology Professionals
- Business Analysts

Instructor

Marina Malikova, Ph.D., MSci, MA, C.C.R.A., RAC

Course Length and Time

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

Course Dates

February 5, 2025 (9:30-11)

May 15, 2025 (1-2:30)

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-031-L99-P. Released: 2/23.

TMF/eTMF Audit Strategies

Course Description

The process for managing the Trial Master File (TMF) has changed drastically in the last 10 years. Many organizations have moved to an electronic TMF (eTMF), yet some organizations still operate with a paper TMF or a hybrid of the two. A successful audit evaluates the processes that were used to manage the TMF to ensure that they are consistent with procedural documents and study plans. We will explore strategies for using the power of an eTMF to identify gaps that could result in inspection findings. The power of the TMF Reference Model in organizing the audit and identifying key artifacts that potentially impact Good Clinical Practice (GCP) compliance will also be discussed. Finally, we will examine strategies for the audit of a paper TMF as well as an eTMF, including critical files to review and how to spot trends in non-compliance.

Learning Objectives

- Explain the value of the TMF Reference Model in organizing an audit to ensure efficient identification of GCP non-compliance
- Identify strategies for conducting an audit of an eTMF that employ the enhanced capabilities of an eTMF
- Identify strategies for auditing a TMF that focuses on artifacts impacting the quality and GCP compliance of the TMF/eTMF

Who Should Attend

- Good Clinical Practice Auditors
- Trial Master File Directors
- Trial Master File Managers
- Trial Master File Coordinators
- Clinical Operations Directors
- Trial Managers
- Records Management Team Members

Instructor

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

Course Length

1.5 hours

Course Dates

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

Archived Recording Available in Multiple Formats!

Accreditation

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

TMF/eTMF Regulatory Agency Expectations, Inspections, and Findings

Course Description

Recently the EMA has published guidance in managing the TMF. FDA's regulations are general and require that sponsors and investigators maintain adequate and accurate records of any clinical investigations that are carried out. This web seminar will examine these expectations and discuss recent regulatory findings. We will also discuss strategies for implementing corrective and preventive actions (CAPAs) that result in successful outcomes to regulatory findings associated with TMF inspections.

Learning Objectives

- Explain regulatory expectations regarding TMF/eTMF management
- Identify two recent regulatory findings directed at TMF/eTMF management
- Describe strategies for preparing effective CAPAs that address regulatory findings
- Discuss plan for preparing for a regulatory inspection

Who Should Attend

- Good Clinical Practice Auditors and Quality Assurance Directors
- Trial Master File Directors, Managers, and Coordinators
- Clinical Operations Directors and Trial Managers
- Records Management Team Members

Instructor

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

Course 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.

Archived Recording Available in Multiple Formats!

Accreditation

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

Blended Curriculum Course

Trial Master File (TMF) for Sponsors: Set-Up and Maintenance

Course Description

The Trial Master File (TMF) is a collection of the essential documents for a sponsor to demonstrate that they have fulfilled their obligations as sponsor for a clinical trial project as defined by the health authorities. This web seminar reviews the activities that a sponsor uses to set-up, maintain, and perform oversight of the TMF. It examines the changing regulatory landscape that defines sponsors responsibility in managing the TMF. This web seminar will also include handouts and discussion of the TMF Reference Model.

Learning Objectives

- Discuss the changing regulatory climate and apply this to the TMF management practices of a sponsor of clinical trials
- Examine the required components of a TMF
- Recommend policy for managing and providing oversight to the TMF
- Discuss maintenance and quality control of the TMF

Who Should Attend

- Project Managers
- Quality Assurance Personnel
- Policy Development and Maintenance Personnel
- Sponsor/CRO Personnel involved in the policy, set-up, maintenance, auditing of the TMF

Instructors

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

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

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Course Length and Time

2 hours 12:00 – 2:00 p.m. Eastern

Course Dates

April 15**,** 2025

Archived Recording Available in Multiple Formats!

Fee: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-23-073-L99-P. Released: 10/23.

Understanding Clinical Laboratory Regulatory Requirements

Course Description

This web seminar will provide a general overview of the regulatory requirements for clinical laboratories that perform routine safety testing of clinical samples for clinical trials. Routine safety testing generally includes hematology, chemistry, urine analysis, and coagulation. Most of the clinical safety testing laboratories in the U.S. are accredited by CAP/CLIA and/or JCAHO. This testing can be used for patient care as well as for collecting data for submission to the regulatory bodies in support of a clinical study. This web seminar provides training for clinical laboratory technicians/ quality assurance staff on maintaining compliance.

Learning Objectives

- Describe the general regulatory requirements for a routine safety testing laboratory
- Identify why some laboratories follow CAP/CLIA and some follow JCAHO as well
- Define regulatory requirements specific to safety testing

Who Should Attend

- Laboratory Technicians/Technologists
- Laboratory Managers/Directors
- Laboratory Quality Professionals

Instructor

Shelia Russell McCullers, M.S., D.M.

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.

NEW! Understanding ICH E6 R3 (GCP) Updates: Key Changes from R2

Course Description

The ICH announced an update to GCP guidelines following the release of ICH E6 R2. After eight years, ICH E6 R3 has now been launched, reflecting the modernization needed to align with the evolving clinical development landscape. Along with ICH E8 R1, this update sets the stage for addressing future challenges. The revised guidelines bring both significant conceptual shifts and smaller updates aimed at streamlining the clinical trial process. Many of these updates will be well received across the industry, though some new challenges will need to be navigated. The changes in ICH E8(R1) and their direct impact on ICH E6(R3) will also be examined.

Learning Objectives

- Learn about the regulatory context behind the changes
- Understand the key goals of ICH E6 R3
- Compare ICH E6 R3 with ICH E6 R2 and identify the major differences
- Gain an introduction to Quality by Design and its role in clinical development
- Understand the impact of risk management and quality measures in Quality by Design

Who Should Attend

- Clinical Operations, Onsite Operations, Data Management, and Statistics Managers
- Regulatory Professionals
- Pharmacovigilance Teams

Instructor

Andy Lawton

Course Length and Time

2 hours 9:00 - 11:00 a.m. and 1:30 - 3:30 p.m. Eastern

Course Dates

March 6, 2025 (1:30-3:30)

April 10, 2025 (9-11)

May 6, 2025 (1:30-3:30)

June 11, 2025 (9-11)

FEE: $835*

**Includes up to 20 participants per login at a single 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 logins for other locations please 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#: 0778-0000-25-037-L99-P. Released: 3/25.

Blended Curriculum Course

Use of Notes to File in Clinical Trial Essential Documentation

Course Description

Notes to File (NTF), also known as Memo to File, are commonly used as essential documentation in sponsor and site files. Many times the content of the NTF does not serve the purpose for use or serves no purpose at all. This web seminar will discuss the appropriate and inappropriate uses of NTF, the questions to ask to determine if NTF would be beneficial, and the components of a quality NTF, if being used.

Learning Objectives

- Discuss the current overuse and misuse of NTF, including FDA Warning Letters noting deficiencies in interventions that include NTF
- Identify what is an appropriate NTF, patient and non-patient specific
- Compose an effective NTF, when applicable
- Describe reference industry tools relating to NTF

Who Should Attend

- Quality Assurance Personnel
- Clinical Research Associates
- Clinical Research Coordinators
- Investigators
- Clinical Research Associate Managers
- Project Managers

Instructor

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

Course Length and Time

1.5 hours 9:00 – 10:30 a.m. and 3:30 – 5:00 p.m. Eastern

Course Dates

January 23, 2025 (9-10:30)

April 3, 2025 (3:30-5)

July 29, 2025 (9-10:30)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-070-L99-P. Released: 7/23.

Utilization of Real-World Evidence (RWE) and Real-World Data (RWD) and Regulations

Course Description

The use of computers, mobile devices, wearables and biosensors to gather and store large amounts of health-related data has been rapidly accelerating. Real-world data (RWD) and real-world evidence (RWE) are playing an increasing role in healthcare decisions. In this web seminar, participants will gain insights into how this data holds potential to allow us to better design and conduct clinical trials and studies in the healthcare setting to answer questions previously considered infeasible. We will also examine FDA's current practices for RWD and RWE to monitor postmarket safety and adverse events and to make regulatory decisions.

Learning Objectives

- Develop a basic understanding of RWD and RWE
- Provide an overview of FDA regulations for RWD and RWE
- Become familiar with the framework for FDA's Real-World Evidence Program
- Examine current FDA practices for RWD/RWE
- Gain insights into RWD/RWE utilization by healthcare professionals, medical product developers, clinical investigators, and regulators

Who Should Attend

- Healthcare Professionals
- Research and Development Specialists
- Directors of Business Strategy
- Project Managers
- Regulatory Professionals
- Clinical Investigators
- Data Managers
- Clinical Operations Specialists

Instructor

Marina Malikova, PhD, MSci, MACI, RAC, CCRA

Course Length and Time

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

Course Dates

March 28, 2025 (9:30-11)

June 12, 2025 (1-2:30)

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-23-032-L99-P. Released: 3/23.

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

Course Length

1.5 hours

Course Dates

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

Accreditation

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

Blended Curriculum Course

Working with Clinical Research Sites: Strategic Planning and Operations for Sponsors and CROs

Course Description

This web seminar will examine the concepts and applied techniques for cost estimation, budget development, risk management, quality assurance, strategic planning, and operations for clinical research conducted at academic centers vs. private clinics. Project management principles and methodology will be reviewed with a special focus on planning, controlling, and coordinating individual and group efforts in managing the life cycle of the clinical research project in different settings.

Learning Objectives

- Apply an in-depth understanding of infrastructure in clinical research and clinical operations in biopharmaceutical companies and clinical sites
- Develop skills for strategic planning of clinical trials
- Perform cost estimation for a project in different settings (private clinics vs. academic centers) and develop a schedule for completion of milestones
- Establish systems for quality control, risk management, and monitoring of clinical trials
- Identify resources needed to complete projects and reasons to outsource
- Utilize performance metrics to improve project success

Who Should Attend

- Clinical Operations Professionals involved in project planning and execution throughout life cycle of the clinical research project
- Medical Affairs Professionals
- Project Managers
- Clinical Research Associates, Clinical Research Coordinators involved in the planning, monitoring, and execution of clinical trials
- Grant Managers
- Principal Investigators
- Financial Planning and Billing Compliance Specialists
- Legal Professionals involved in contract negotiations with clinical sites

Instructor

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

Course Length and Time

1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates

May 27**,** 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

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ACPE#: 0778-0000-22-033-L04-P. Released: 11/22.

Writing and Updating the Investigator's Brochure

Course Description

During the course of clinical research, the Investigator's Brochure (IB) is the data repository for an investigational product; effectively this is the product's "label" during the investigational stage. The IB is a dynamic document which changes as the information changes. It is critical in clinical research as physicians and Institutional Review Boards (IRBs) refer to the IB on an ongoing basis to answer questions about Serious Adverse Events, Adverse Events, dosing, manufacturing, and clinical and nonclinical study results. To facilitate the transfer of information, the IB must be concise, well-written, and provide a summary for a physician to quickly reference. ICH GCP E6 Guideline provides an outline of the requirements, how companies address these requirements and the degree of information provided differs. The required contents will be reviewed in this web seminar. Tips and techniques for effective writing, including pulling together the needed information, working with a team, and writing a summary will also be discussed.

Learning Objectives

- Identify who contributes to the IB
- Determine the timing of construction of the IB
- List IB requirements per the ICH GCP E6 Guideline and effectively implement these requirements
- Perform a research literature review for the background section, and re-use it in other documents
- Examine how a Target Product Profile or Draft Package Insert can be drafted based on the IB
- Examine approaches that support physician's reading of the IB: The IB Summary
- Determine when the IB should be updated, by whom, and what documents the update effects

Who Should Attend

- Regulatory Affairs Professionals
- Medical Writers
- Clinical Research Professionals
- Research and Development Personnel

Instructor

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

Course Length and Time

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

Course Dates

March 6, 2025 (1-3)

June 26, 2025 (9-11)

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 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#: 0778-0000-24-031-L99-P. Released: 3/24.

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
  - Understand how study type varies during the different stages of drug/device development
  - Design a scientifically rigorous study to meet regulatory needs
  - Explain what safety and efficacy is and how you establish either or both
  - Identify the hypothesis and develop endpoints to test the hypothesis
  - Determine inclusion/exclusion criteria
  - Determine the Schedule of Events
  - Determine adverse and serious adverse event reporting
  - Work with cross-functional teams and use tools to assist in protocol development
  - Understand when to amend a protocol

Who Should Attend

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

Instructor

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

Course Length and Time

3 hours 12:00 – 3:00 p.m. Eastern

Course Dates

March 13, 2025 June 12, 2025

Archived Recording Available in Multiple Formats!

FEE: $835*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

Accreditation

Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. **Participants will receive 3 hours (0.3 CEUs)** of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will issue a receipt of completion for earned CEUs within three weeks of program completion.

ACPE#: 0778-0000-23-026-L99-P. Released: 3/23.

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

- Translate protocol and data into clear concise submission documents
- Describe the elements required for the CSR and how this differs from standard pharma CSRs
- Differentiate between the types of data and their interpretation
- Describe where the CSR fits into a 510(k) submission and some interdependencies

Who Should Attend

- Medical Directors
- Medical Writers
- Clinical Research Associates
- Clinical Scientists
- Research and Development Personnel
- Regulatory Affairs Professionals
- CRO Personnel
- Personnel planning a change from the pharma sector to the diagnostic sector

Instructor

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

Course Length

1.5 hours

Course Dates

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

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Accreditation

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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

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

Course Length

1.5 hours

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Writing Quality SOPs: Guidelines, Tools, and Templates for Easy SOP Creation

Course Description

Standard Operating Procedures (SOPs) are detailed written instructions that allow one to execute a process uniformly. Many SOPs are not well defined or well written, and actually fall short of providing the details needed for one to complete the process. In fact, many who are assigned the task of creating SOPs lack the basic understanding of what constitutes a well written SOP. Often SOPs appear to be no more than a brief Note to File, leaving gaps in the proper execution of the task delegated. Poorly written SOPs also leave organizations vulnerable in the event of an audit. In this web seminar, FDA Warning Letters will be reviewed to demonstrate the consequences of poorly written SOPs. This course offers guidance to those who recognize they need SOPs, or more detailed SOPs, but do not know how or where to start. Participants will be provided with guidelines and templates that ensure that new and updated SOPs are uniform and user-friendly.

Learning Objectives

- Describe the purpose of SOPs
- Identify the basic elements of well written SOPs
- Design an SOP from the templates provided
- Relate the SOP to other activities such as performance evaluations

Who Should Attend

- SOP Authors/Reviewers
- Research Site Administrators
- Clinical Monitors
- Study Coordinators
- Quality Assurance Auditors
- Project Mangers

Instructor

Janet Ellen Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P.

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.

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Accreditation

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What Participants Say About Barnett Interactive Web Seminars:

"The information I learned in today's webinar will give me and my company an advantage with our client against other competing CROs."

Writing the Clinical Study Report

Course Description

The Clinical Study Report (CSR) is a critical document in the drug development and regulatory submission process. This web seminar presents the basic tools required to generate CSRs for the pharmaceutical industry. Participants will learn the elements of the CSR and the appendices, methods for turning the protocol and statistical outputs into one cohesive document, the basics of writing and preparing a document for submission, and the guidances to follow for reference.

Learning Objectives

- Translate protocol and data into clear concise submission documents
- Describe the elements required for the CSR and the appendices
- Differentiate the various types of statistical outputs and handling of the results
- Identify the phase of drug development differences and similarities
- Utilize style guides and templates
- Understand how new regulations in transparency impact CSR development

Who Should Attend

- Medical Directors
- Medical Writers
- Clinical Research Associates
- Clinical Scientists
- Research and Development Personnel
- Regulatory Affairs Professionals
- CRO Personnel

Instructor

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

Course Length and Time

3 hours 12:00 – 3:00 p.m. Eastern

Course Dates

January 14**,** 2025

April 18**,** 2025

July 17**,** 2025

Archived Recording Available in Multiple Formats!

FEE: $735*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for pricing.*

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ACPE#: 0778-0000-23-027-L99-P. Released: 1/23.

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Barnett reserves the right to change the instructors and timing of our courses. Efforts will be made to notify participants in either event. Barnett will not be responsible for any costs incurred as a result of a cancellation, instructor, or date and time change of any course.

Course Policies

Course Cancellation Policy

Your notice of cancellation must be received in writing by email to Barnett's Customer Service Department at customer.service@barnettinternational.com prior to the start of the course. Note that Barnett does not refund your registration fee.

- Prior to 10 business days before the course: You will receive an Event Pass. This Event Pass may be applied toward a future Barnett course 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 course. (This can be done by email only.) Event Passes are not transferable to any other type of program, such as conferences or product orders.
- Within 10 business days before course: No Event Pass will be issued.

Course 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 email to Barnett's Customer Service Department at customer.service@barnettinternational.com prior to the start of the course.

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 services for your course. 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 (Core Curriculum Courses Only)

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 course description page for full participation (full attendance and completion of the pre- and post-test or the mid-term and/or final exam, 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

Course registration is usually limited to 30 people due to the interactive nature of our programs. Please submit your registration well in advance to secure a seat. Full payment must accompany registration.

Special Requirements

If you have any special requirements, please contact Barnett International at +1 781.972.5400 or toll-free in the U.S. at 800.856.2556.

Instructor Biographies

Nikki Christison, B.S., C.C.R.A., T.I.A.C.R., has worked extensively with both sponsors and CROs as a Study Coordinator, CRA, Project Manager, Auditor, and Director of Clinical Operations over the past 20 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).

Sonja Cooper, Ph.D., M.B.A., has 20+ years of experience in clinical research and the pharmaceutical industry. She has extensive working knowledge of clinical research trials inclusive of procurement, program management, study start-up, recruitment tactics and challenges, clinical trial management, employee retention strategies, and audit processes. Dr. Cooper is well versed in building and fostering key relationships that lead to performance improvements, DEI initiatives, and constructing strategic alliances. She has held roles as Sr. Clinical Operations Manager, Project Manager, Trial Manager, Lead CRA, and CRA. Dr. Cooper serves as an expert in creating clinical monitoring processes such as monitoring evaluation programs, CRA oversight programs, central monitoring (risk-based) departments, role specific competencies learning sessions, and CPA-CRA-CTM step ladder promotion programs. Additionally, she serves as a mentor for Morehouse School of Medicine - Clinical Trials Office and has worked in higher education as an administrator and professor for 8 years.

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 25 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 IIIb-IV studies. Natalie holds an honors life science degree from the University of 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.

Holly J. Deiaco-Smith, M.S.Ed., brings over seventeen years of management consulting experience to her clients, helping them change to be more successful. Holly's tenure in Big 4 consulting, including Accenture and IBM Global Services, grounded her with a foundation of best methodologies, leading practices, and outstanding client experience. It was these experiences that inspired and compelled her to found a management consulting organization serving the agriculture, education, financial services, pharmaceutical, and retail industries. Holly's experience includes strategic planning, process improvement, benchmarking for leading practices, organizational improvement, learning design and development, and change management. Given the critical need today for organizations to develop a talented workforce, Holly has helped her clients define and improve their learning strategies. Holly's unique collaborative approach of truly partnering with her clients and her strong focus on change management enable her to provide excellent service and results.

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.

Misha Eliasziw, Ph.D., is a biostatistician and has over 30 years of experience in the design, management, and analysis of clinical trials and longitudinal cohort studies. Dr. Eliasziw has applied her skills to a wide spectrum of research areas, including acute and secondary prevention of stroke, multiple sclerosis, advanced brain imaging, cancer biomarkers, prevention of substance use among adolescents, reduction of traffic-related air pollution through filtration, prenatal nutrition, and prevention of obesity among children with autism spectrum disorder and intellectual disabilities. She has published over 250 peer-reviewed articles, and paralleling her research efforts, Dr. Eliasziw has taught biostatistics to graduate students, postgraduate medical education trainees, healthcare professionals, and clinical faculty. In recognition of her exemplary teaching abilities, she has received several teaching awards. Currently, she is an Associate Professor in the Department of Public Health and Community Medicine at Tufts University in Boston, Massachusetts. Dr. Eliasziw graduated from the University of Western Ontario with a doctorate in Epidemiology and Biostatistics and completed her post-doctoral training in biostatistics at Harvard University.

Daniel J. Filoramo, R.N., B.S., is a successful pharmaceutical professional with over 18 years of diversified clinical research experience. Daniel's experience encompasses multiple roles in all phases of drug development and marketing. He has been employed with a large pharmaceutical company for the past 10 years as a Sr. Clinical Scientist in the department of Early Clinical Translational Research. In this capacity, he has had the opportunity to author protocols and clinical study reports, and monitor and manage operations for Phase I and Pharmacology studies. Daniel is also responsible for the overall operational management of early assets. With his strong clinical research background, he is instrumental with process improvement activities, authoring of Standard Operating Procedures, and providing training on various clinical research topics. In addition, Daniel's experience spans across multiple therapeutic areas such as Anti-Infectives, Cardiovascular, Immunology, Metabolic, and the Neurosciences.

Joy Frestedt, Ph.D., C.P.I., R.A.C., F.R.A.P.S., F.A.C.R.P., has over 40 years of experience in clinical research, regulatory negotiation, quality system development and business leadership in the pharmaceutical, medical device, and food industries. She has experience running clinical trials, conducting laboratory analyses and assisting firms with strategic decisions involving clinical research programs, regulatory strategies and quality system management to compete globally. Dr. Frestedt has served as Regulatory Director at the University of Minnesota Academic Health Center, as a member of the Allina IRB and she previously held key positions at Ortho Biotech, Medtronic, Mayo Clinical Trial Services, AstraZeneca, and Orphan Medical. She holds a B.A. from Knox College and a Ph.D. in pathobiology from the University of Minnesota Medical School. Dr. Frestedt is a member of American Society of Clinical Oncology (ASCO), Society of Clinical Research Associates (SoCRA), and is a Fellow of Regulatory Affairs Professionals Society (RAPS) and Association of Clinical Research Professionals (ACRP). Author of FDA Warning Letters about Food Products: How to Avoid or Respond to Citations (Elsevier, 2017) and Warning Letters: 2016 Reference Guide (Barnett International, 2016), Dr. Frestedt was honored in 2011 as one of the "100 Most Inspiring People in the Life Sciences Industry" by PharmaVOICE and one of the top 25 "Industry Leaders," a "Women in Business Award" by the Minneapolis/St. Paul Business Journal.

Karen L. Gilbert, B.S., C.C.R.A., has worked in the clinical research industry since 1994 monitoring pharmaceutical and medical device trials, managing an investigational site, and serving as a global study manager. Her experience also includes two years serving as Clinical Trainer & Curriculum Manager with Barnett Educational Services. Karen's training courses and presentations have been delivered internationally to industry clients and at global professional conferences. She has co-authored two articles published in the clinical research industry journal, Clinical Researcher (formerly The Monitor). Ms. Gilbert received her certification as a Certified Clinical Research Associate (CCRA) through the Association of Clinical Research Professionals (ACRP) in 2005 and remains active in this organization.

Glenda Guest, RQAP-GCP, C.C.R.A., specializes in medical device monitoring and project management, auditing and training on U.S.-regulated research, Quality Systems and Good Clinical Practices in clinical research settings. With her extensive background in a clinical CRO environment, she has developed a unique perspective, not only of the regulatory requirements for product development and market approval, but also the insights from collaboration with multiple sponsor companies' varying approaches in meeting those requirements. Ms. Guest has had the opportunity to work with large and small manufacturers in both the premarket approval and 510(k) realms. She is an active member of the MedTech Association, as well as the Association of Clinical Research Professionals (ACRP), Model Agreements & Guidelines International (MAGI), and the Society of Quality Assurance (SQA). She has been an ACRP Certified Clinical Research Associate status since April of 2002 and an SQA Registered Quality Assurance Professional – Good Clinical Practices since April 2007.

Beth D. Harper, B.S., M.B.A., has extensive clinical research consulting experience, focused on the delivery of timely and predictable clinical trials, and enrollment and site performance management. Previously, Beth was President of Clinical Performance Partners, Inc., a clinical research consulting firm specializing in enrollment and site performance management. In addition to her 25+ years of clinical research experience, she is an Adjunct Assistant Professor at the George Washington University, and has published and presented extensively in the areas of study feasibility, site selection, patient recruitment, and protocol optimization. Beth received her B.S. in Occupational Therapy from the University of Wisconsin, and an M.B.A. from the University of Texas.

Debbie Harper, B.Sc., P.M.P., is a highly skilled Consultant and Trainer with broad and extensive knowledge (>20 years) of the global clinical research industry, covering all phases of drug development, in multiple therapeutic areas. She has a wealth of expertise in the development and execution of operational strategy, including serving as a VP of Operations for a large CRO. Ms. Harper has demonstrated abilities in leadership excellence, training design and delivery, early clinical development, process improvement and strategic initiatives. She is Project Management certified through PMI and possesses significant experience developing and delivering gold standard customized project management and clinical research related training courses for project leads and clinical operations.

Janet E. Holwell, C.C.R.C., C.C.R.A., T.I.A.C.R., F.A.C.R.P., specializes in maximizing excellence in GCP quality, compliance and training for both sites and industry. She works with domestic and international clients to provide training and mentoring in the clinical research process, specializing in ICH-GCP compliance and quality oversight. She prepares clients for inspections/ audits as well as helps them write effective CAPAs and SOPs, develop quality plans and create internal QA processes. She began her career as a clinical research coordinator in academia over 35 years ago. She has held positions as a clinical research associate, site selection specialist, study manager with oversight of vendor CRAs, clinical operations quality management and trainer for several pharmaceutical companies. She is a fellow and dual-certified by the ACRP. Ms. Holwell has been an active member of the Association of Clinical Research Professionals (ACRP) since 1992, having served on the board of trustees, North American Council and various forums.

Treena Jackson, M.S., M.A., C.Q.A., R.A.C., C.S.S.G.B., provides global quality auditing, regulatory, process improvement, and training services with a focus on GCP and GLP. She has taught as an adjunct professor at both Campbell University and Durham Technical College in the Clinical Research Programs. At Campbell University, Treena taught in the undergraduate and graduate degree programs for Clinical Research and developed an online class on Pharmaceutical Compliance and QA. She has worked in the pharmaceutical industry for over 20 years working for a major pharmaceutical company, a small biotech, and CROs 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, a MA degree in Christian Education and a BS degree in Laboratory Animal Science. She is currently working on her PhD in Organizational Leadership. Treena 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), Regulatory Affairs Professional Society (RAPS), Society of Quality Assurance (SQA) as well as other organizations. Treena is also an author who has contributed to several regulatory affairs textbooks.

Indu Kayarat is an experienced drug safety professional with over 12 years of pharmacovigilance, project management, business development and people management. Indu currently is employed as Associate Director with a leading global provider of clinical research services in their Aggregate Report Department. Her primary responsibilities involve project management, client interface, quality review of periodic reports, mentoring, training and contributing to leadership initiatives and innovations. She has also been involved in automation, preparing SOPs/guidance documents and process updates within her domain. She is also involved in people management and mainly responsible for performance of direct reports (quality, compliance, productivity, profitability, and utilization to name few). Indu has an undergraduate degree in Biotechnology and a postgraduate degree in Pharmaceutical Management.

Vanessa Laroche, M.S. (Biotech), C.Q.A., C.I.P., is a clinical research professional with over 20 years of experience specializing in the management and regulatory oversight of domestic and international clinical trials in multiple therapeutic areas. She has advanced knowledge of federal regulations, ICH GxP guidelines and ethical codes governing the protection of human subjects. Ms. Laroche has many years of hands-on experience with conducting internal and external audits of suppliers/vendors and Investigator site visits, as well as evaluating Quality Management Systems and leading process improvement initiatives. She has served in many roles, including: Clinical Research Coordinator; CRA; Clinical Program & Operations Manager managing over 70 Phase II-IV investigational drug and medical device trials; Compliance Officer for the IRB oncology board at a prestigious academic medical center; and Clinical QA Manager at a large CRO and mid-size biotech company.

Andy Lawton has extensive experience in computing, statistics, data management, RDE/RDC, system design, Risk Based Approach in both CSV and clinical trials. He currently works with a variety of companies and institutions on the implementation of ICH E6 R2, ICH E8, QMS/QbD and Risk Based Monitoring. Previously, Andy held the position of Global Head of Clinical Data Management at Boehringer Ingelheim were he also held positions of increasing responsibility during his 32 years with BI. Andy was a Founding Committee Member of ACDM, Member of TransCelerate RBM work stream and a Member of EFPIA WG on Data Transparency. His most notable publications is the paper with Dr. Alistair Ross on GP Audit — throughout 80's and 90's this was the most quoted paper in the BMJ, and he won "best author of the year 2015 and 2016" from the DIA, for the TransCelerate papers on SDV and Central Monitoring in the TIRS Journal.

Susan M. Leister, M.B.A., Ph.D., CQA, CSSBB, has over 20 years of experience covering the pharmaceutical, medical device, and clinical arena, including extensive working knowledge of GCP, cGMP, GLP, ICH E6 GCP, and HSP. She has managed various inspections including ISO, CE Mark, Health Canada, MHRA, EMA, DEA, Maryland Board of Pharmacy, and FDA. Dr. Leister provides QM oversight to multiple government and commercial clients from large pharma to the small biotech startup. She currently oversees a QA auditing team comprised of ~ 20 FTEs who verify monitoring performance and internal audits with a global reach, conduct quality trend analysis including analysis of reports and associated data, and provides recommendations and quality consultative services. She is experienced in managing NIH drug repository and stability lab for domestic and international clinical trials and is skilled in developing plans for resolutions to deviations and CAPAs, analyzing QA/QC results, and recommending process improvements with 6Σ. Dr. Leister is seasoned in mock inspections and overall inspection readiness.

Marina Malikova, Ph.D., MSci, M.A., C.C.R.A., RAC, has over 17 years of experience in the clinical research field, with 8 years' experience on executive level. She has managed Phase I – IV studies involving investigational drugs, devices, biologics and combination products. She has worked on Industry-sponsored and Investigator-initiated trials in the fields of Surgery, Cancer Diagnostics and Interventional Radiology. Dr. Malikova graduated from the Institute of Biochemistry, Russian Academy of Science, in Moscow, Russia with a PhD in Biochemistry. She has a strong background in biomedical sciences and has completed her postdoctoral fellowship in the field of cell signaling and cell migration. She also holds a Master's Degree in Clinical Investigation, Certification in Project Management from Boston University and dual board certified in Regulatory Affairs (RAC) for pharmaceutical products and medical devices by Regulatory Affairs Professionals Society (RAPS). She also holds professional certification in Clinical Safety and Pharmacovigilance by Drug Information Association (DIA).

Jim Markley assists clients in the management of TMFs and maintaining oversight throughout the life of their studies. He has worked in the clinical research industry for the past eight years and has applied his ICH-GCP knowledge at a clinical site, a large CRO, and in support of several sponsors. He has experience helping clients prepare for and manage FDA, EMA, MHRA and PMDA inspections.

Heather Marshall, M.S.N., B.S.N., R.N., has over 20 years of research experience in the pharmaceutical and medical device arena focused on global Clinical Research in various roles and therapeutic areas including cardiovascular, CT surgery, neurology, and orthopedic surgery. As the Director of Clinical Affairs for a leading medical device company, Heather is leading numerous clinical studies, ensuring compliance with regulatory standards and advancing innovations in orthopedics. Prior to this role Mrs. Marshall led a safety team for a medical device CRO working with Medical Monitors, Data Safety Monitoring Boards, and Clinical Events Committees. In addition to her professional accomplishments, she is an experienced educator, having taught continuing education courses for cardiac nurses. Her commitment to education and her ability to convey complex concepts in an accessible manner make her an exceptional instructor for our research training programs. Participants can look forward to gaining insights from her vast experience and leadership in clinical research and medical device development. Mrs. Marshall holds an M.S.N in Nursing Leadership and Administration from the University of Phoenix.

Shelley Marti, M.S.N., P.M.P., has extensive background in global pharmaceutical corporations with proven expertise in GCP and GCLP standards, worldwide health authority regulations, and quality assurance/compliance systems. Shelley has leveraged deep operational knowledge of drug development to empower and drive performance with cross-functional teams, ensuring companies achieve strategic goals while maintaining high-level quality/efficiency through strategic target setting, focus on execution and creating strong collaborations with stakeholders at all levels. Shelley is inclusive, practical, organized and a solution-oriented contributor known for leading by example with a positive 'can-do' attitude. Areas of expertise include: Quality, Audit Plan Strategies (Risk Based), Quality Agreements / Oversight Plans, Global Quality Project Leadership, Lead & Manage Quality Governance Frameworks, Quality Dashboard Development & Execution, Inspection Readiness Efforts, Investigation & Management of Quality Events, Onboarding & Training Strategies (Internal / External) and Quality Insight Analysis.

Shelia Russell McCullers, M.S., D.M., is a Quality Assurance Manager with 30 years of scientific experience including quality assurance, regulatory compliance, clinical research, auditing, biotechnology quality control, safety monitoring, biomedical diagnostic testing and training. Dr. McCullers has conducted audits and hosted several successful inspections including internal inspections, EMA, CLIA and FDA. While serving in the military, she researched toxins that were potential biological weapons, and she was a member of the Human Use Committee in support of clinical trials at the United States Army Medical Research Institute of Infectious Diseases (USAMRIID). She has conducted research on the health effects and trends of tobacco use for NCI. As a Clinical Research Information Specialist, she prepared IND Annual Reports for submission to the FDA on behalf of the NCI. While researching sepsis, Dr. McCullers discovered a novel antibody to an adhesion molecule. She has completed training in Quality Assurance, GMP, GLP, GDP and GCP including the Protection of Human Research Subjects courses. While working as a Quality Manager, Dr. McCullers maintained a Key Performance Indicator score of greater than 90% for each quarter, and she submitted Medical Incident Reports, health department notifications, deviations and CAPAs with 100% on-time delivery.

Anne McDonough, M.P.H., C.C.R.A., M.I.C.R., C.Sci., has over 16 years of experience in a variety of roles in clinical research. Ms. McDonough started her career working in investigational sites for HIV trials, spent over 10 years working in the American and European divisions of an international CRO, and is currently a freelance clinical research consultant based in London providing monitoring, project management, clinical science, medical writing, and training services. She has broad international experience in a full range of clinical trials (Phases I to IV, pharmaceuticals, biotechnology products, diagnostics, devices, and vaccines) and in a variety of therapeutic areas. She also currently serves on the exam committee for the CCRA exam (Association of Clinical Research Professionals) and is past chair of the European exam committee.

Denis R. Miller, M.D., earned his AB and MD degrees at Cornell University and completed his post-doctoral training at Children's Hospital, Boston and Harvard Medical School. He has over 25 years of experience in academic medicine in pediatric hematology/oncology at Cornell, Memorial Sloan Kettering Cancer Center, and Northwestern University. Most of his clinical and laboratory research focused on hematologic malignances. He was a long-standing member and Vice Chairman of Children's Cancer Group, a past president of the American Society of Pediatric Hematology/Oncology, and the Scientific Director of the Cancer Treatment Research Foundation. He has published over 300 peer-reviewed articles, chapters, books, and abstracts and was on the editorial boards of the British Journal of Hematology and American Journal of Clinical Oncology. Deny has 17 years of experience in industry and has worked for Roche, Aventis, and J&J PRD as well as at multiple CROs.

Linda Patricia Miller, M.D., has more than 20 years of experience in industry where she worked with Organon and Eisai as Director of Clinical Development, with Clinsys as VP of Clinical Development and Chief Scientific Officer, and PPD as Executive Director for Global Product Development. She served as Editorial Coordinator for the classic textbook, Blood Disease in Infants and Children. Dr. Miller received her MS and MD degrees from Rutgers University and completed her residency in pediatrics at New York Hospital-Cornell Medical Center. Her primary area of research and many of her publications are the design and conduct of new agent studies and early phase drug development.

Kirsten Morasco, B.S., 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.

Danny Nasmyth-Miller, B.A. (Hons), M.B.A., began his career in clinical research in 1996, as a Clinical Research Associate (CRA). From CRA, he moved into project management (PM), leading global projects (phases I, II, III) and a 416-person Project Planning and Support department at a global CRO. In his roles, he oversaw the management of projects around the globe as a Vice President and Executive President. He continues to lead global projects for clients across pharma, biotech and device companies. Danny holds a degree in business studies and a Master in Business Administration (MBA), and passed his PMP certification from the Project Management

Institute (PMI) in 2005. In 2023 he was awarded City & Guilds level 3 teacher and training certificate. Danny is passionate about sharing his project management experience and in helping the next generation of PMs to deliver successful clinical research project management.

Elizabeth Ronk Nelson, M.P.H., has over 20 years of experience in medical and clinical research. During her career, she has managed clinical trial site operations as a clinical research program coordinator and researcher, and has served as an IRB Quality Assurance Specialist and a Senior (GCP) Auditor, Trainer, and Compliance Director. Her professional areas of specialization include fraud detection and prevention; mock FDA audits; customized, audit finding-specific, risk-based training; independent GCP quality systems and compliance audits; SOP and training program development and gap analysis; corrective and preventive action (CAPA) and quality systems improvement plans for GCP; customized skill-based training for clinical research professionals; clinical investigator site and IRB development and quality improvement (QI) plans; vendor audits assessments; and site selection qualification assessments. Ms. Nelson has extensive experience in investigating and pursuing suspect clinical data cases and has worked professionally with industry and government representatives to pursue legal actions for severe noncompliance cases.

Denise G. Redkar-Brown, MT, leads Barnett's Data Management training initiatives. She also consults and conducts audits for the Data Management, Biostatistics and Medical Writing disciplines. In addition to consulting on projects using real world data (RWD), she has also established a successful Clinical Data Management department at a CRO. Ms. Redkar-Brown is past chair of the Educational Committee and past Board member for the Society of Clinical Data Management (SCDM). She is published in the European Journal of Pharmacology for her work in pharmacology while at AstraZeneca and was also published in the Good Clinical Practices Journal. She is a contributing author of the Good Clinical Practice Question and Answer Guide, (Barnett International, 2017, 2018, 2020, 2022, 2024) and is co-author of the chapter on Selecting an EDC Application in the Good Clinical Data Management Practices (GCDMP) published by the Society of Clinical Data Management.

Robert Romanchuk, B.S.H.S., CIP, is a seasoned clinical research professional with experience in both research operations and human subjects protections. Currently serving as a vice-chair for a prominent independent IRB, his IRB experience includes management of a local IRB in a community hospital, site visits for independent IRBs, and membership on three local IRBs at different periods during his career. He is familiar with the conduct of research due to a 15-year tenure at a large community hospital system with 13 hospitals and 450 physician practices in a multistate footprint. During that time he oversaw and led the growth of research from a single site within this organization to a fully functional, centralized research operation serving the entire system with central contract negotiation, uniform clinical trial billing practices, CTMS and EMR. He is a frequent speaker at national and international venues and is passionate about human subjects protections.

Lily Romero, P.A., C.C.R.C., has over 30 years of experience in clinical research. Her experience includes positions as Director of Global Development Training at Elan Pharmaceuticals, an Associate Director of Clinical Operations at Quintiles, Inc., a Clinical Research Coordinator and Research Administrator at the Allergy & Asthma Medical Group and Research Center, and a P.C. in San Diego, CA. She has worked on Phase I-IV clinical trials including pediatric studies. She was an instructor for and assisted in the development of an investigator GCP training workshop for the American Academy of Pharmaceutical Physicians. She is on the Advisory Board and an instructor for the Clinical Trials Design and Management certificate program at the University of California at San Diego (UCSD) Extension. Currently, she is a member of the Academy Board for the Associates of Clinical Research Professionals (ACRP).

Nazma M. Rosado, MAOL, P.M.P., CPLP, 6σ, CMQ/OE has over 27 years of experience in the Biopharma industry having worked with companies such as Pfizer, Medimmune, Genentech, Astellas, EMD Serono/Merck KGaA, Janssen, Alexion, CuraGen, and various consulting companies. Ms. Rosado was involved with TransCelerate Biopharma, Inc. for 2 years and served as a Co-Lead for the Change Management Council and as the Change Champion for Astellas Pharma. She has been a Program Manager, Project Manager, Study Manager, and CRA before her move to leadership positions. She is an Adjunct Professor at Suffolk University Law School where she teaches a course on Pharmaceutical Development. She also teaches at MassBioEd's Apprenticeship program. Ms. Rosado has a B.A. in Neuroscience and a B.A. in Psychology from Colgate University and an M.A. in Organizational Leadership from Gonzaga University.

John Serio, J.D., represents pharmaceutical, biotechnology, nutraceutical, and medical device companies, particularly as to patent prosecution, licensing, and litigation matters. Mr. Serio also has extensive expertise in food and drug law involving pharmaceuticals and medical devices. He advises companies on a wide variety of regulatory issues, including the national and international conduct of clinical studies, manufacturing, the preparation and filing of regulatory documents, compliance with FDA regulations, and FDA enforcement matters. Mr. Serio is a recognized expert on direct to consumer advertising of pharmaceuticals. As a licensed pharmacist and a registered patent attorney, Mr. Serio has a multilateral understanding of complex scientific principles and drug development within the pharmaceutical industry. He is an accredited speaker with the American College of Pharmaceutical Education and regularly speaks and writes on pharmaceutical issues. Mr. Serio received his undergraduate degree at the University of Rhode Island College of Pharmacy, and his law degree from Western New England School of Law. His recent publications include State-by-State Clinical Trial Requirements Reference Guide, Barnett International, 2019; "Pharma and Social Media: The Leaders and Followers," A FirstWord Market Intelligence Report (August 2009); and "Connecting with Patients, Overcoming Uncertainty," Regulatory Issues in Social Media for Pharmaceutical Marketers (2008).

Barbara Tomasi, Ph.D., CIPPE, CIPM, is an experienced privacy professional with a demonstrated history of working in the pharmaceuticals industry. Skilled in Data Privacy, Personal Data Protection, Intercultural Relations, Privacy Law, Clinical Research, and Clinical Trials, her credo is that Data Privacy compliance is an enhancing and quality factor if taken deeply into account at the early stage of projects.

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 RQAP-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 Truax-Bellows, M.S., FNP, C.C.R.A., RQAP-GCP, has an extensive background in the pharmaceutical and medical device industries, having worked for both industry and a CRO as a Monitor, Medical Communications Associate, Project Manager, Senior Quality Auditor, Senior Trainer, and Regulatory and SOP Consultant. Lee has been involved in regulated research the past 25 years and currently specializes in product development, GCP auditing and SOP development and training on regulated research and Good Clinical Practice. She is an active member of the Association of Clinical Research Professionals (ACRP), New York State MedTech Association and Society of Quality Assurance (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 (RQAP-GCP).

Mary L. Veazie, M.B.A., CPA, CHC, CHRC, is a Certified Public Accountant with over 16 years of experience in clinical research finance. Collectively, she has over 30 years of financial and auditing experience. She established and directed a clinical research finance office for a large academic medical center. She is certified in Healthcare Research Compliance and Healthcare Compliance. Ms. Veazie's skill set includes full comprehension of the clinical research billing process, auditing of health system's clinical research billing program, and its impact on an organization's clinic operations and revenue cycle. She is a professional coach, an author and serves on the board of directs of several non-profit organizations.

Elizabeth Weeks-Rowe, LVN, C.C.R.A., has 23 years of diverse clinical research experience, having worked as a study coordinator, CRA, CRA Trainer and CRA Manager. Her experience as a CRA includes phase 1-4 studies, and studies in the areas of oncology, neurology, vaccines, endocrinology, critical care, women's health, dermatology and some ophthalmology. She gained specific expertise in site evaluation and investigational models by spending 11 years on a dedicated pre study evaluation visit team for a large CRO. She has a passion for coaching/development and has worked as a dedicated CRA evaluator, conducting monitoring sign off visits on new CRAs and performance monitoring assessment visits on experienced CRAs to ensure quality in monitoring. She has developed CRA training content and delivered classroom and field training to new and experienced CRAs and has a passion for coaching and development. Ms. Weeks-Rowe has also authored several publications on the CRA role and has written >50 articles/ blogs for various clinical research publications, such as ACRP, CenterWatch, PharmaTimes, Clinical Leader and the Journal of Best Research Practices, and authored a monthly clinical research column entitled "Pulse on Study Conduct" about life as a traveling CRA.

Laura Wiggins, M.B.A., has over 20 years of experience in the clinical research and marketing industries. Her earlier work included patient recruitment, media planning and buying, participant outreach, business development and medical writing within the Phase 1 and multi-site CRO space. Laura currently coordinates TMF management activities and works with clients to analyze, develop and implement processes that support business use of electronic clinical systems to ensure TMF quality and completeness. Laura has a passion for organization and collaboration with her colleagues and clients to achieve results.

Shana Zink, B.S., C.C.R.A., has more than 25 years of research experience in the pharmaceutical and medical device arena with the past 15 years focused on global clinical research in various therapeutic areas including cardiovascular, orthopedic surgery, bariatric, oncology and plastic surgery. From 2013 - 2018, Shana served as Vice President of Clinical Affairs at AtriCure, Inc., an innovative leader in the treatment of atrial fibrillation. Prior to AtriCure, she held positions with a variety of responsibilities including quality assurance and clinical affairs at J&J, Proctor & Gamble, and Searle Pharmaceuticals (a Monsanto Company). She holds a B.S. in Biological Sciences from Northern Illinois University and obtained a certificate in Project Management from Boston University Corporate Education Center.

Courses Listed by Month

January

ICH GCP E6 R3 Updates: Impact on Clinical Data Management	*Virtual Web Seminar*	**January 7, 2025**
Essential Documentation in Clinical Trials at Research Sites	*Virtual Web Seminar*	**January 7, 2025**
20-Hour Fundamentals of Clinical Research Series: Getting Started in Clinical Research	*Virtual Web Seminar*	**January 7, 2025 - February 11, 2025**
ICH GCP E6 R3 Updates: Key Changes Impacting Clinical Investigators, Sites, and IND Holders (Sponsor-Investigators and Institutions)	*Virtual Web Seminar*	**January 8, 2025**
Auditing Techniques: A Problem-Solving Practicum	*Virtual Web Seminar*	**January 8, 2025**
Investigator Initiated Trials: Roles and Responsibilities	*Virtual Web Seminar*	**January 9, 2025**
FDA Drug Approval Process	*Virtual Web Seminar*	**January 9, 2025**
Managing CRAs to Improve Performance and Study Outcomes	*Virtual Web Seminar*	**January 9, 2025**
"Statistical Intuition" for Clinical Research Data Managers	*Virtual Web Seminar*	**January 9, 2025 & January 16, 2025**
Adverse Events: Best Practices for Reporting and Communicating Safety Information to IRBs	*Virtual Web Seminar*	**January 13, 2025**
Clinical Trial Start-Up: Using a Work Breakdown Structure (WBS) for Effective Planning	*Virtual Web Seminar*	**January 13, 2025**
ICH GCP E6 R3 Updates: Key Changes Impacting Sponsors and CROs	*Virtual Web Seminar*	**January 13, 2025**
Monitoring Medical Device Trials: An Introduction	*Virtual Web Seminar*	**January 14, 2025**
ICH GCP E6 R3 Updates: Overview of Changes Impacting Sponsors, CROs, and Clinical Investigators/Sites	*Virtual Web Seminar*	**January 14, 2025**
Writing the Clinical Study Report	*Virtual Web Seminar*	**January 14, 2025**
Monitoring Oncology Clinical Trials	*Virtual Web Seminar*	**January 14, 2025**
10-Hour Advanced Clinical Project Management Skills Development	*Virtual Web Seminar*	**January 15, 2025 - February 12, 2025**
Decoding FDA's Draft Guidance on Remote Regulatory Assessments: A Practical Guide	*Virtual Web Seminar*	**January 16, 2025**
Adverse Event Monitoring for CRAs	*Virtual Web Seminar*	**January 16, 2025**
Managing Phase I Clinical Trials	*Virtual Web Seminar*	**January 16, 2025**
Risk-Based Site Monitoring	*Virtual Web Seminar*	**January 16, 2025**
Quality Systems: A Controlled Approach to GCP Compliance	*Virtual Web Seminar*	**January 16, 2025**
9-Hour Preparing IND Submissions: How to Organize, Write, Submit, and Track Submissions	*Virtual Web Seminar*	**January 16, 2025 – February 20, 2025**
Electronic Medical Records: Approaches for Ensuring Source Document and 21 CFR Part 11 Required Components	*Virtual Web Seminar*	**January 21, 2025**
Protocol Deviations: Documenting, Managing, and Reporting	*Virtual Web Seminar*	**January 21, 2025**
10-Hour Clinical Trial Start-Up Series	*Virtual Web Seminar*	**January 21, 2025 - February 18, 2025**
Use of Notes to File in Clinical Trial Essential Documentation	*Virtual Web Seminar*	**January 23, 2025**
Inspection Readiness: Understanding BIMO Inspection Requirements for Sponsors, CROs, Monitors and Investigators	*Virtual Web Seminar*	**January 23, 2025**
Research Billing Processing: Leveraging Technology to Maintain Compliance and Mitigate Risk	*Virtual Web Seminar*	**January 23, 2025**
Mastering Clinical Research Audits: Effective Responses and CAPA Development	*Virtual Web Seminar*	**January 23 & January 30, 2025**
30-Hour Clinical Project Management Fundamentals Certification Program	*Virtual Web Seminar*	**January 23, 2025 - March 27, 2025**
10-Week CRA & CRC Beginner Program	*Virtual Web Seminar*	**January 23, 2025 - March 27, 2025**
30-Hour Clinical Research Auditing Certification Program	*Virtual Web Seminar*	**January 23, 2025 - April 10, 2025**
Introduction to Data Management	*Virtual Web Seminar*	**January 27, 2025**
Strategies for Managing Difficult Clinical Research Sites	*Virtual Web Seminar*	**January 27, 2025**
Preparing Clinical Research Sites for FDA Inspections	*Virtual Web Seminar*	**January 28, 2025**
Source Documentation: What is Adequate and Accurate?	*Virtual Web Seminar*	**January 28, 2025**
ICH GCP E6 R3 Updates: Implementing Risk Management Approaches for Compliance	*Virtual Web Seminar*	**January 29, 2025**
ICH GCP E6 R3 Updates: Sponsor Quality Management – Risk-Based/Risk Management Requirements and Approaches for Compliance	*Virtual Web Seminar*	**January 29, 2025**
Monitoring Visit Reports for Medical Device Studies	*Virtual Web Seminar*	**January 30, 2025**

February

Navigating FDA's June 2024 BIMO Inspection Guidance: A Practical Approach	*Virtual Web Seminar*	**February 3, 2025**
The IND in a CTD/eCTD Format	*Virtual Web Seminar*	**February 3, 2025**
GCP Renovation (ICH E8 R1 and ICH E6 R3)	*Virtual Web Seminar*	**February 3, 2025**
Root Cause Analysis: Applying the Concept for Better Study Compliance Management	*Virtual Web Seminar*	**February 3, 2025**
12-Hour Clinical Trial Management Series	*Virtual Web Seminar*	**February 3, 2025 - March 17, 2025**
10-Week Fundamentals of Drug Development Series	*Virtual Web Seminar*	**February 3, 2025 - April 14, 2025**
Strategies for Active Listening	*Virtual Web Seminar*	**February 4, 2025**
Sponsor Responsibilities for Global Drug Studies	*Virtual Web Seminar*	**February 4, 2025**
Establishing Quality Tolerance Limits (E6 R2 and E6 R3)	*Virtual Web Seminar*	**February 5, 2025**
Technology Innovation and Intellectual Property (IP) in the Biomedical Industry	*Virtual Web Seminar*	**February 5, 2025**
Managing Risks in Outsourced Clinical Trials: Practical Approaches and Tools	*Virtual Web Seminar*	**February 5, 2025**
Monitoring Plan Development	*Virtual Web Seminar*	**February 6, 2025**
Case Report Form Design, Strategy, and Standards	*Virtual Web Seminar*	**February 7, 2025**
Monitoring Reports: 10 Rules of Effective Report Writing	*Virtual Web Seminar*	**February 10, 2025**
Strategies for Having Difficult Conversations	*Virtual Web Seminar*	**February 10, 2025**
CAP and CLIA Requirements for Clinical Research Laboratories	*Virtual Web Seminar*	**February 11, 2025**
Developing and Negotiating Research Site Clinical Study Budgets and Contracts	*Virtual Web Seminar*	**February 11, 2025**
Developing Clinical Study Budgets for Sponsors	*Virtual Web Seminar*	**February 11, 2025**

March

18-Hour Writing Clinical/Performance Evaluation Reports ... *Virtual Web Seminar* ... **March 12, 2025 - May 28, 2025**
Key Considerations in Medical Writing: The Clinical Study Protocol, Investigator's Brochure, Informed Consent Form, and Adverse Events Narratives ... *Virtual Web Seminar* ... **March 13, 2025**
Writing Clinical Study Protocols ... *Virtual Web Seminar* ... **March 13, 2025**
Good Clinical Practice: Practical Application and Implementation ... *Virtual Web Seminar* ... **March 14, 2025**
Drug Safety and Pharmacovigilance: Effective Drug Safety Reporting and Surveillance ... *Virtual Core Curriculum Course* ... **March 17-18, 2025**
Monitoring Clinical Drug Studies: Beginner ... *Virtual Core Curriculum Course* ... **March 17-19, 2025**
Data Quality in Clinical Trials: Rationale and Impact ... *Virtual Web Seminar* ... **March 18, 2025**
Regulatory Intelligence ... *Virtual Web Seminar* ... **March 18, 2025**
Identifying Safety Signals in Clinical Trial Data ... *Virtual Web Seminar* ... **March 18, 2025**
Clinical Project Management: Fundamentals of Project Management ... *Virtual Core Curriculum Course* ... **March 18-19, 2025**
Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) in Site Management ... *Virtual Core Curriculum Course* ... **March 18-19, 2025**
Implementing Quality Agreements ... *Virtual Web Seminar* ... **March 19, 2025**
Building Quality by Design (QbD) and Risk-Based Quality Management (RBQM) Systems into Clinical Operations ... *Virtual Web Seminar* ... **March 19, 2025**
RECIST 1.0 and 1.1: Overview and Data Challenges in Oncology Clinical Trials ... *Virtual Web Seminar* ... **March 19, 2025**
WORKSHOP: Case Report Form Design, Strategy, and Standards ... *Virtual Web Seminar* ... **March 20, 2025**
Informed Consent Procedure: Lessons Learned from Inspection Findings ... *Virtual Web Seminar* ... **March 20, 2025**
Clinical Research Financial Management for Investigative Sites ... *Virtual Web Seminar* ... **March 20, 2025**
The Quality Mindset and Risk-Based Thinking Connection ... *Virtual Web Seminar* ... **March 20, 2025**
Auditing Techniques for Clinical Research Professionals ... *Virtual Core Curriculum Course* ... **March 20-21, 2025**
Statistical Concepts for Non-Statisticians ... *Virtual Core Curriculum Course* ... **March 20-21, 2025**
Monitoring Clinical Drug Studies: Intermediate ... *Virtual Core Curriculum Course* ... **March 20-21, 2025**
Conducting Clinical Trials Under ICH GCP E6 ... *Virtual Core Curriculum Course* ... **March 24-25, 2025**
CRA & CRC: Beginner Program ... *Virtual Core Curriculum Course* ... **March 24-26, 2025**
Risk-Based Auditing: Effective Compliance Strategies ... *Virtual Web Seminar* ... **March 24, 2025**
Preparation, Management, and Response to Inspections and Audits ... *Virtual Web Seminar* ... **March 25, 2025**
Clinical Project Management: Advanced Concepts in Project Management ... *Virtual Core Curriculum Course* ... **March 25-26, 2025**
Comprehensive Monitoring for Medical Devices ... *Virtual Core Curriculum Course* ... **March 25-27, 2025**
Introduction to Clinical Research ... *Virtual Core Curriculum Course* ... **March 27-28, 2025**
Utilization of Real World Evidence (RWE) and Real Word Data (RWD) and Regulations ... *Virtual Web Seminar* ... **March 28, 2025**
Monitoring Clinical Drug Studies: Advanced ... *Virtual Core Curriculum Course* ... **March 31 - April 1, 2025**
Clinical Trial Assistant Fundamentals ... *Virtual Core Curriculum Course* ... **March 31 - April 1, 2025**
Clinical Trial Start-Up: Effective Planning for Sponsors, CROs, and Sponsor-Investigators ... *Virtual Core Curriculum Course* ... **March 31 - April 1, 2025**

April

10-Week Establishing a Vendor Qualification and Management Program ... *Virtual Web Seminar* ... **April 1, 2025 - June 10, 2025**
Managing CRAs to Improve Performance and Study Outcomes ... *Virtual Web Seminar* ... **April 2, 2025**
Essential Documentation in Clinical Trials at Research Sites ... *Virtual Web Seminar* ... **April 3, 2025**
Use of Notes to File in Clinical Trial Essential Documentation ... *Virtual Web Seminar* ... **April 3, 2025**
Electronic Medical Records: Approaches for Ensuring Source Document and 21 CFR Part 11 Required Components ... *Virtual Web Seminar* ... **April 4, 2025**
10-Week Risk Management/Risk-Based Quality Management for Clinical Trials Certification Program ... *Virtual Web Seminar* ... **April 4, 2025 - June 6, 2025**
ICH GCP E6 R3 Updates: Key Changes Impacting Clinical Investigators, Sites, and IND Holders (Sponsor-Investigators and Institutions) ... *Virtual Web Seminar* ... **April 7, 2025**
20-Hour Fundamentals of Clinical Research Series: Getting Started in Clinical Research ... *Virtual Web Seminar* ... **April 7, 2025 - May 7, 2025**
12-Hour Clinical Trial Management Series ... *Virtual Web Seminar* ... **April 7, 2025 - May 12, 2025**
eTMF Quality Oversight: A Risk-Based Approach ... *Virtual Web Seminar* ... **April 8, 2025**
ICH GCP E6 R3 Updates: Key Changes Impacting Sponsors and CROs ... *Virtual Web Seminar* ... **April 8, 2025**
15-Hour Clinical Trial Assistant Fundamentals Training Program ... *Virtual Web Seminar* ... **April 8, 2025 - April 29, 2025**
Adverse Event Monitoring for CRAs ... *Virtual Web Seminar* ... **April 9, 2025**
ICH GCP E6 R3 Updates: Implementing Risk Management Approaches for Compliance ... *Virtual Web Seminar* ... **April 9, 2025**
30-Hour Clinical Research Auditing Certification Program ... *Virtual Web Seminar* ... **April 9, 2025 - July 16, 2025**
Managing Phase I Clinical Trials ... *Virtual Web Seminar* ... **April 10, 2025**
Understanding ICH E6 R3 (GCP) Updates: Key Changes from R2 ... *Virtual Web Seminar* ... **April 10, 2025**
9-Hour Preparing IND Submissions: How to Organize, Write, Submit, and Track Submissions ... *Virtual Web Seminar* ... **April 10, 2025 - May 15, 2025**
Monitoring Oncology Clinical Trials ... *Virtual Web Seminar* ... **April 10, 2025**
Quality Systems: A Controlled Approach to GCP Compliance ... *Virtual Web Seminar* ... **April 14, 2025**
FDA's Draft Guidance on Integrating Randomized Controlled Trials for Drug and Biological Products into Routine Clinical Practice ... *Virtual Web Seminar* ... **April 14, 2025**
eTMF Implementation Strategies ... *Virtual Web Seminar* ... **April 15, 2025**
Trial Master File (TMF) for Sponsors: Set-Up and Maintenance ... *Virtual Web Seminar* ... **April 15, 2025**
Introduction to Data Management ... *Virtual Web Seminar* ... **April 15, 2025**
Navigating FDA's June 2024 BIMO Inspection Guidance: A Practical Approach ... *Virtual Web Seminar* ... **April 15, 2025**
Source Documentation: What is Adequate and Accurate? ... *Virtual Web Seminar* ... **April 16, 2025**
Risk-Based Site Monitoring ... *Virtual Web Seminar* ... **April 16, 2025**
30-Hour Clinical Project Management Fundamentals Certification Program ... *Virtual Web Seminar* ... **April 16, 2025 - June 18, 2025**
Inspection Readiness: Understanding BIMO Inspection Requirements for Sponsors, CROs, Monitors and Investigators ... *Virtual Web Seminar* ... **April 17, 2025**

May

ICH E8 (R1): Designing Quality into Clinical Studies ... *Virtual Web Seminar* ... **May 21, 2025**
Monitoring Medical Device Trials: An Introduction ... *Virtual Web Seminar* ... **May 22, 2025**
EU Guideline on Computerised Systems and Electronic Data in Clinical Trials ... *Virtual Web Seminar* ... **May 22, 2025**
Sponsor Responsibilities for Global Drug Studies ... *Virtual Web Seminar* ... **May 22, 2025**
Subject Recruitment: Proactive Project Plans and Issues Management ... *Virtual Web Seminar* ... **May 22, 2025**
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June

Monitoring Reports: 10 Rules of Effective Report Writing ... *Virtual Web Seminar* ... **June 2, 2025**
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Statistical Concepts for Non-Statisticians ... *Virtual Core Curriculum Course* ... **June 2-3, 2025**
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Introduction to Clinical Research ... *Virtual Core Curriculum Course* ... **June 4-5, 2025**
Monitoring Clinical Drug Studies: Beginner ... *Virtual Core Curriculum Course* ... **June 4-6, 2025**
Incorporating Denials Management into Clinical Research Billing ... *Virtual Web Seminar* ... **June 5, 2025**
Key Considerations in Medical Writing: The Clinical Study Protocol, Investigator's Brochure, Informed Consent Form, and Adverse Events Narratives ... *Virtual Web Seminar* ... **June 5, 2025**
Auditing Techniques for Clinical Research Professionals ... *Virtual Core Curriculum Course* ... **June 5-6, 2025**
Navigating FDA's June 2024 BIMO Inspection Guidance: A Practical Approach ... *Virtual Web Seminar* ... **June 6, 2025**
Recent Trends in Noncompliance: Critical Review and Analysis of Recent Regulatory Letters and Communications from the FDA, EMA, and Health Canada ... *Virtual Web Seminar* ... **June 6, 2025**
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FDA's Draft Guidance on Ethical Considerations for Clinical Investigations of Medical Products Involving Children ... *Virtual Web Seminar* ... **June 10, 2025**
FDA's Draft Guidance on Integrating Randomized Controlled Trials for Drug and Biological Products into Routine Clinical Practice ... *Virtual Web Seminar* ... **June 10, 2025**
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Strategies for Having Difficult Conversations ... *Virtual Web Seminar* ... **June 10, 2025**
Understanding ICH E6 R3 (GCP) Updates: Key Changes from R2 ... *Virtual Web Seminar* ... **June 11, 2025**
Monitoring Clinical Drug Studies: Intermediate ... *Virtual Core Curriculum Course* ... **June 11-12, 2025**
Comprehensive Monitoring for Medical Devices ... *Virtual Core Curriculum Course* ... **June 11-13, 2025**
Utilization of Real World Evidence (RWE) and Real Word Data (RWD) and Regulations ... *Virtual Web Seminar* ... **June 12, 2025**
Writing Clinical Study Protocols ... *Virtual Web Seminar* ... **June 12, 2025**
ABCs of Clinical Research for Clinical Administrative Support Staff ... *Virtual Web Seminar* ... **June 12, 2025**
ABCs of GCP and the Principles of ICH GCP E6 ... *Virtual Web Seminar* ... **June 12, 2025**
Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) in Site Management ... *Virtual Core Curriculum Course* ... **June 12-13, 2025**
Mastering Clinical Research Audits: Effective Responses and CAPA Development ... *Virtual Web Seminar* ... **June 13 & June 20, 2025**

July

BARNETT INTERNATIONAL Publications

What Makes Barnett's Publications Unique?

Unparalleled in industry, Barnett's comprehensive reference guides, publications, self-study tools, and job aids are one-of-a-kind resources for the pharmaceutical and medical device professional. Barnett is the source for must-have publications for clinical research, regulatory affairs, and research and development professionals with sponsor companies, CROs, and clinical research sites.

What Type of Information is Included?

Barnett publications cover the basics, address emerging issues, and answer your toughest questions:

- Barnett's annually updated publications provide up-to-the-minute data and regulations, best practices, and compliance insights that affect every clinical research professional.
- Our reference manuals contain valuable analysis, case studies, and insights garnered from thought leaders on the most important new developments in the industry.
- Barnett's unique question and answer format to reference guides brings readers' questions to life, responded to by sought after subject matter experts.
- Self-study materials provide learners with self-paced training with comprehensive content and exercises that test their knowledge.
- Unique textbooks provide both novice and experienced regulatory professionals the direction and detail they need to meet regulatory challenges.
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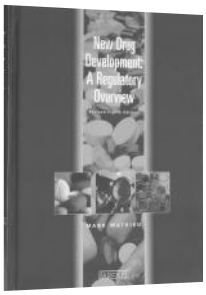
New Drug Development: A Regulatory Overview



*"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."*

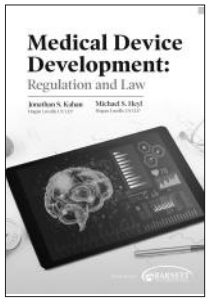
- Peter Barton Hutt, Covington & Burling

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: NDD8 ..... **Price: $145.00**

Medical Device Development: Regulation and Law



*"I can safely say this is **the most practical and comprehensive book** on the subject of FDA regulation of medical devices. This edition includes a detailed but understandable review of all the key device regulatory issues faced by the device industry as well as an up-to-date review of the most salient developments in device regulation such as the new Cures Act provisions relating to medical device software and the most recent developments in the regulation of combination products."*

- Mary Monovoukas, VP, Chief Global Regulatory and Privacy Counsel, Boston Scientific Corporation

The all-new **Medical Device Development: Regulation and Law 2020 Edition,** is the must-have practical reference for regulatory affairs professionals. This authoritative text provides the most comprehensive and updated analysis of U.S. medical device and diagnostics development and approval requirements anywhere. The new edition offers analysis of new FDA device regulations, including all new significant guidance documents, and addresses how emerging developments and trends are reshaping medical device and combination product regulations in the United States.

- Update on the new medical device provisions of the 21st Century Cures Act and the Food and Drug Administration Reauthorization Act of 2017.
- New statutory provisions and guidance documents related to regulation of software as a medical device, digital health/machine learning, cybersecurity, general wellness products, real-world evidence, use of benefit risk information for both premarket and post-market processes, and when post-clearance changes require submission of a new 510(k) notice.
- New guidance documents, statutory changes, and cases relating to combination products incorporating medical devices.
- Updates to the pre-submission process, including new MDUFA IV goals for meetings and feedback.
- Updates to FDA's "refusal to accept" and review policies relating to 510(k)s, PMAs, and pre-submissions.
- Update on the investigational device exemption process including new guidance documents and policies related to clinical trials, including IDE benefit-risk considerations, new Good Clinical Practices (GCPs) guidance and policy for use of foreign data, policies regarding ClinicalTrials.gov registration, as well as guidance documents on adaptive design, leveraging data for pediatric use, and demographic factors in clinical studies.
- Changes to the premarket approval application process including FDA guidance on distinguishing between 30-Day Notice PMA Supplements and Site Change PMA Supplements.
- New policies and guidance documents concerning in vitro diagnostic products, including updates on research and investigational use and laboratory developed tests.
- Update on device compliance issues, including the 2016 medical device reporting guidance.
- New guidance documents, statutory changes, and cases relating to combination products incorporating medical devices.
- New changes to FDA's review of requests for issuance of certificates to foreign governments.
- FDA policy regarding the regulation of third party reprocessors.

Publication Code: MEDDEV20..... **Price: $195.00**

Recently Updated to Include ICH GCP E6 R2

Barnett's Clinical Research Associate (CRA) Training Series: A 7-Volume CRA Self-Study Curriculum

This unique self-study curriculum is designed to provide a hands-on perspective surrounding the day-to-day work of the clinical research monitor. Newly updated to include requirements of ICH GCP E6 R2, this 7-volume set provides the fundamentals of being a Clinical Research Associate (CRA) in today's environment. Each volume can be used as a stand-alone reference or as a complete self-study training series. The following content is included (by volume):

Volume 1: An Overview of Drug Development is written to introduce new CRAs to the drug development process, while contextualizing it to the role of the CRA. Included are important terms and acronyms encountered by CRAs, as well as what happens before and after a clinical study.

Volume 2: Identifying and Screening Investigators focuses on the characteristics of good clinical investigators and the process of finding investigators who meet the needs of the protocol, the formal plan for the study. Included are procedures for investigator identification and screening, first contact and investigator selection.

Volume 3: Conducting Prestudy Visits describes the process of preparing for the site visit, conducting the visit, and assessing the site. Included are details regarding meeting agendas and scheduling, budget negotiation techniques, site assessment criteria and necessary discussion points, and recommended procedures and documentation.

Volume 4: Conducting Study Initiation Visits covers the training of site staff to conduct the study. Included are guidelines for planning, conducting and documenting a study initiation visit, including the objectives, preparation, task analysis and documentation and follow-up.

Volume 5: Conducting Routine Monitoring Visits describes how to prepare for, conduct, and follow up monitoring visits from the time that the first subject is enrolled to the final site visit. Included are strategies for ensuring that the study is being conducted according to the protocol and good clinical practice (GCP).

Volume 6: The CRA's Reference for Adverse Events serves as a reference for the AE-reporting process and provides procedures for the monitor to follow.

Volume 7: Test Your CRA Knowledge is filled with exercises which test your knowledge and understanding of the material presented in the previous volumes. Answers for each of the questions are included in the second section of the manual, making immediate feedback available.

Purchase individually or as a complete 7-volume set!

Publication Code: CRAS18..... Price: $599.00

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Recently Updated to Include ICH GCP E6 R2

Barnett's Study Site Training Series: A 6-Volume Self-Instructional Training Series for Investigative Teams

"A common sense, practical introduction to the roles of the study coordinator and investigator. It is excellent preparation for anyone at a research site — or at a study sponsor or CRO — who wants to understand how studies are conducted at sites."

- Norman M. Goldfarb, Managing Director, First Clinical Research LLC

Designed to provide the essentials of roles and responsibilities of the clinical study team as well as the tasks involved, this 6-volume set provides the basics of conducting clinical research in today's environment. Equipped with exercises and learning activities, each manual can be used as a stand-alone reference or as a complete self-instructional training series. The following content is included (by volume):

Volume 1: The Clinical Study Site Team: Roles and Responsibilities
Volume 1 is designed to provide readers with an understanding of the roles, responsibilities, and associated tasks of clinical research team members at investigative sites.

Volume 2: FDA Clinical Research Regulations and GCPs: The Essentials
This volume describes the "rules" and "guidelines" developed by regulatory agencies designed to regulate the conduct of clinical research, emphasizing those requirements that most directly impact investigative site teams.

Volume 3: IRBs/IECs and Informed Consent: Protecting the Rights of Human Subjects
This volume includes what investigative site team members need to know regarding protection of the rights and safety of human subjects. In addition to presenting applicable regulations and practical implications, the roles of the IRB/IEC and the study sponsor are also discussed.

Volume 4: Sponsor Visits and Regulatory Audits: What You Need to Know
Here, the several types of visits to study sites and when they each occur is described. Included are examples and learning exercises designed to prepare study site teams for sponsor visits, study closeout, audits and regulatory inspections.

Volume 5: Your Role in Reporting Adverse Experiences
Volume 5 covers how to observe, manage, classify, record and report AEs during clinical studies. It is also intended to familiarize study team members with the many specific procedures required by regulatory agencies to ensure patient safety.

Volume 6: Understanding, Evaluating, and Implementing Clinical Protocols
This volume is designed to assist teams in protocol implementation. Included are the features of protocols, evaluation strategies, implementation assessment, as well as basic protocol design and writing.

Purchase individually or as a complete 6-volume set!

Publication Code: SSSV181-6 ..... Price: $499.00

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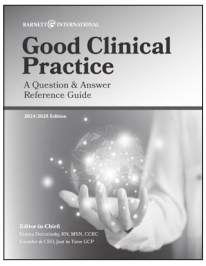
Recently Updated!

Good Clinical Practice: A Question & Answer Reference Guide



In the past several years we have seen the release of many new regulations and guidances throughout the world. We are coming out of a pandemic which has changed how we conduct and manage clinical trials, and we are dealing with an unstable world where research subjects are living in war torn regions. The 2024/2025 edition of Barnett's **Good Clinical Practice: A Question & Answer Reference Guide** has been reorganized with added topics to address this new era of clinical research.

This industry-leading GCP reference guide answers over 1,500 of the most common and difficult questions regarding the interpretation and implementation of U.S. and international GCP standards for drugs, biologics, and medical device clinical trials.

Some highlights of the completely updated and expanded guide include:

- An all-new section on risk-based quality management (RBQM) and Quality by Design, which are receiving ever more emphasis from global regulators
- Emphasis on Quality Tolerance Limits (QTLs), Key Risk Indicators (KRIs) and approaches to outsourcing RBQM
- Updates specific to ICH E6 and E8 including the ICH E6 (R3) Draft
- Public comments from regulators and references to other industry guidance/sources
- Impact of the new Clinical Trial Regulations in the EU and how Clinical Trial Information System (CTIS) are used for SUSAR reporting in Europe
- Content covering Decentralized Clinical Trials (DCTs) and what evidence regulators require for data quality
- Questions and answers regarding the balancing of equity and equality in trials (including study design, patient recruitment, compensation structures)
- Details around the use of real-time data monitoring and participant engagement technologies and their ethical implications
- A new section on conducting a clinical trial during a pandemic and/or war including trial management, risk assessments, monitoring activities, investigational product management, informed consent, and site change considerations
- And much more…!

Designed for the clinical researcher, it covers commonly asked questions and answers regarding Good Clinical Practice standards categorized into 21 different areas, including:

- Clinical monitoring
- Investigators/site compliance
- Source data and documentation
- Quality assurance activities
- Study auditing
- Inspections
- Decentralized trial management
- Diversity
- Equity and inclusion
- Informed consent
- Managing the trial master file
- And many other important areas

Available in Electronic Format!

- Fully searchable by keyword
- Active links internally and externally
- Bulk pricing and custom covers available

Written by more than 20 expert authors specializing in QA, monitoring, compliance, site management, the trial master file, data management, privacy, safety, and many other core clinical research areas, this must-have guide focuses on practical implementation challenges faced by organizations and the most common emerging best practices in the industry.

Publication Code: GCP24 ..... Price: $139.00
Electronic Version: GCP24E ..... Price: $129.00

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The Clinical Research Finance Roadmap: A Comprehensive Guide to the Financial Aspects of Clinical Research

In the age of technology, many organizations struggle with incorporating federal and billing regulations with electronic systems. This comprehensive guide takes the reader through the clinical research financial road map in a step-by-step fashion. It focuses on the financial feasibility of considering a clinical research study, incorporating the study into integrated systems, and managing patient and sponsor billing. **The Clinical Research Finance Roadmap: A Comprehensive Guide to the Financial Aspects of Clinical Research** provides an in-depth look at the applicable regulations, operational efficiencies and risk mitigation strategies through the implementation of a compliant Clinical Research Billing (CRB) program. Readers will learn how to leverage study and patient data to maintain and enhance a comprehensive and compliant CRB program.

- Chapter 1: History of Clinical Research and Protecting Human Subjects
- Chapter 2: The Feasibility Assessment Phase: Deciding to Participate in Clinical Research Study With a Focus on Financial Feasibility
- Chapter 3: Creating a Medicare Coverage Analysis (MCA): A Step-By-Step Approach; Billing Regulation Review
- Chapter 4: Clinical Trial Budgets and the Hidden Costs
- Chapter 5: Negotiating a Clinical Trial Budget
- Chapter 6: Integrating with the Electronic Health Record – Creating a Billing Grid
- Chapter 7: Investigator and Study Team Preparedness – Training and Study Initiation
- Chapter 8: Patient Billing: Charge Review Process and Medical Documentation
- Chapter 9: Participant Remuneration
- Chapter 10: Study Revisions/Contract and Budget Amendments
- Chapter 11: Sponsor Billing: Payment Milestones
- Chapter 12: Study Close-Out: Reconciliation Processes and Ensuring All Payments Received
- Chapter 13: Leverage Data: Using Patient and Study Data to Manage Current and Future Studies

Publication Code: FIN19 ..... **$169.95**

The Clinical Research Finance Roadmap Companion Reference Guide: Tools, Templates and Resources

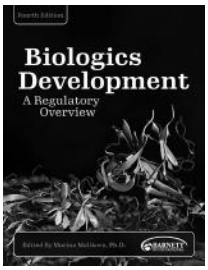
This companion reference guide to The Clinical Research Finance Roadmap: A Step-by-Step Guide to Putting Regulations into Operation provides tools, templates and resources to assist the Principal Investigator and others with navigating through the clinical research finance processes. **The Clinical Research Finance Roadmap Companion Reference Guide: Tools, Templates and Resources** provides helpful forms, templates, standard operating procedure and policy outlines. The tools and resources aid with developing a risk-based approach to managing the clinical research portfolio, navigating decision trees for determining financial feasibility, development of Medicare Coverage Analysis (MCA), developing budgets, tracking milestones, managing sponsor payments, and patient remuneration. The guide is provided in electronic format.

Specific Tools, Templates and Resources Include:

- Calendar for the Identification of Procedures and Timepoints
- Charge Review Tracking Tool
- Clinical Research Decision-making Go/No-Go Decision Making Tool
- Clinical Research Patient Revenue Tracking Tool (ROI for Your Organization)
- Creating a Clinical Trial Budget Template
- Decision Tree for Reviewing NCD/LCD for Coverage
- Fee Justification Documents and Associated SOPs
- Financial Clearance for Subjects Forms: Insurance Pre-authorizations and Denials
- Monitor Visits Tracking Tool for Reconciliation with Contract Terms for Payments
- Participant Remuneration Worksheet
- Productivity Models
- Qualifying Clinical Trial Objectives Tool
- Risk-based Approach to Charges Review Tool
- Staffing Model Development Tool
- Study Close Out – Reconciliation Process Tool for Ensuring All Payments Received
- Study Metrics Tracking Tool
- Templates for Standardizing Study Notes
- Timeline Tool for Missed Patient Appointments and Schedule Adjustments

Electronic Edition: FINCOM19E **$119.95**

Biologics Development: A Regulatory Overview



Originally written by CDER and CBER officials and industry experts, the newly-updated **Biologics Development: A Regulatory Overview** offers an extensive examination of the FDA's regulations and guidelines for biologic products, from preclinical testing to post-marketing regulatory requirements, and from user fees to electronic submissions. The book also provides a detailed look inside the approval pathway for today's biological products along with an analysis of each stage of the biological product development process, including:

- CDER organization and processes for regulating and reviewing therapeutic biological products.
- CDER's processes for regulating and reviewing cellular/tissue-based products and gene therapies, vaccines, and blood products.
- How CDER and CBER have evolved their procedures and requirements to address new challenges including risk management priorities and internal agency initiatives.
- Applications of updated ICH GCP E6 and E8 guidelines to biological products development.
- Emerging standards for the clinical and nonclinical testing of biological products, including combination products and biosimilars.

About previous editions

*"Authored by FDA and industry officials, **Biologics Development: A Regulatory Overview** is the first text to provide a detailed analysis of the FDA's regulation of the development process for… biological products. [It] gives special emphasis to the recent wave of organizational, management, and operating initiatives within… CBER… including lot release, user fees, and promotional labeling policies."*

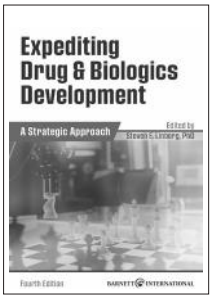
- RAPS News

"A first-rate information source on the biologics approval process! This text provides an up-to-date reference for the expert, and an excellent overview for the novice. More important, it is one of the precious few sources for obtaining the detailed thoughts of current CBER officials."

- Gary E. Gamerman, M.S., J.D., Fenwick & West

Publication Code: BIODEV4..... **Price: $195.00**

Expediting Drug and Biologics Development: A Strategic Approach



From the initial planning to the NDA/BLA review process, **Expediting Drug and Biologics Development** shows you how to use reverse-engineering techniques to drive and improve each aspect of a drug and biologic product development program's design and implementation. Written by dozens of leading experts, this book is a real-world "doer's" guide. It provides templates, forms, and tools to assist those "in the trenches" of new drug and biologic development today.

With this book, you will learn how to:

- Make planning the central part of all aspects of drug and biologics development.
- Establish a Target Product Profile (TPP) to critically evaluate the needs of the evolving package insert and eventual marketing application before getting deeply into clinical trials.
- Understand that the clinical development program dictates much of the nonclinical development program, and that both dictate the chemistry, manufacturing and controls development program.
- Involve thoughtful ethics in the planning and execution of clinical research.
- Leverage standardization to drive and expedite the entire development process, from the development of clinical trial protocols to the development of clinical data presentations.
- Critically assess the needs of a final study report before developing the clinical protocol.
- Use the data identified in the analysis plan and gathered by various data collection tools to dictate the content of the procedures section of the clinical protocol.
- The role of monitoring as one part of a multi-faceted approach to evaluating safety in a clinical trial.
- Anticipate the demands of the regulatory authority review process, the audits that will support data integrity, and the mechanics of Advisory Committee reviews.

Publication Code: EXP21 ..... **Price: $195.00**

BARNETT INTERNATIONAL

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.

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- Customized content development
- Role-based assessments
- Competency map development
- Curriculum gap analysis and training curriculum plan development
- Employee satisfaction surveys
- Employee communications and logistics services
- Good Clinical Practice (GCP) training and assessment programs
- Licensing of Barnett's Content
- Mock audits and findings-based training
- Virtual meetings support services
- eLearning module development
- Acquisition Integration: Strategy and Implementation Services
- SOP Development and Training

Who are Barnett's Consultants?

Barnett's consultants have deep experience in training and development programming, including training needs assessment, curriculum development, competency mapping and program development. In addition, by utilizing their hands-on experience in the roles in which they consult, Barnett consultants bring a unique approach to your organization.

How Do I Get Started?

To receive a quote for your project, contact Barnett today at +1 215.413.2471.

Good Clinical Practice (GCP) Training and Assessment Program

How do you ensure that your teams are following the same GCP processes and standards set forth by your organization? Barnett International is pleased to offer formal Good Clinical Practice (GCP) training and assessment for global clinical research professionals. Barnett's training and assessment processes were created in response to an increase in requests for a third-party industry standard for GCP training, as well as recognition from the industry of Barnett's years of experience and expertise in GCP education and training initiatives.

Using a rigorous test question development and validation process, Barnett assesses employees in the area of GCP compliance. Barnett's approach includes a multi-tiered approach that ensures the exam is fully vetted by industry subject matter experts, and that test questions go beyond the simple recall of facts and require practical knowledge demonstration and application.

By passing Barnett's GCP training and assessment, you can be certain:

- Participants are fully aware of the regulations and their implications for practice
- Participants have demonstrated proficiency in the practical application of GCPs
- Participants have been tested by a credible third-party administrator
- Participants' core GCP competency has been assessed

Deliverables include:

- Comprehensive role-based GCP exams which can be tailored to your organization's SOPs
- Core GCP training in the training platform of your choice: in-person, live or recorded web-based training or self-paced online training modules
- Certification and accreditation for GCP training and assessment activities
- Tracking and record keeping of completion status by teams, studies, and across global organizations

For more information about Barnett's GCP Certification, contact Barnett International at +1 215.413.2471 or nganatra@barnettinternational.com.

Curriculum Compliance Assessment and Development (C-CAD) Programs

Building on our deep expertise as a training organization, Barnett's training consultants and subject matter experts work with your training departments or functional areas to develop exciting and interactive curriculum plans for your employees that combine technical, regulatory, and leadership development training. Through our curriculum compliance assessment and development services, your organization can leverage Barnett's 30+ years of experience in clinical research training program planning, design and implementation. Focused on the adult learner, Barnett's expertise includes working with your training leads to optimize performance of clinical research professionals worldwide, through the design of engaging and outcomes-oriented training program development.

Deliverables include:

- Competency map development for clinical research functional areas and specific roles
- Curriculum gap analysis
- Training curriculum plan development
- Employee satisfaction surveys
- Employee communications and logistics services
- Customized content development
- Role-based assessments

Let Barnett leverage our training experience and resources for your employees. To learn more and to receive a sample curriculum, contact Barnett International at +1 215.413.2471 or nganatra@barnettinternational.com.

Mock Audits and Findings-Based Training

Recent FDA 483s, warning letters, and other regulatory documents issued to Sponsors, CROs, IRBs, and Clinical Investigators indicate that the most frequently cited areas for noncompliance are also those that are most easily addressed with focused training programs. However, perhaps the most overlooked purpose of an audit is to provide an opportunity for education and training. Barnett Educational Services is pleased to provide your organization with Mock Audit and Findings-Based Training services, customized to address audit findings. Post-audit training allows you to disseminate information in real-time and therefore effect the timely development of corrective action plans.

An audit is defined as a systematic and independent examination of trial-related activities and documents to determine whether all elements of the clinical research infrastructure are functioning in accordance with the tenants of good clinical practice (GCP) and applicable regulatory requirement(s). Audits allow an opportunity to capitalize on identified strengths and develop process improvement plans for areas of potential weakness in a highly focused manner.

Deliverables include:

- Detailed audit agendas
- Detailed audit reports incorporating findings, global and regulatory risk assessment, and corrective and preventive action plan recommendations
- Audit certificates
- Tailored finding-specific training delivered at your facility or choice of venue, designed to incorporate the most current information available on the regulations, agencies, and guidance that govern the conduct of clinical research
- Current information on new developments and emerging trends within the clinical research industry for consideration

Move away from costly, reactive high-level quality control activities and further maximize resources by placing your training focus on areas that are of greatest regulatory risk.

For more information, contact Barnett International at +1 215.413.2471 or nganatra@barnettinternational.com.

Licensing of Barnett's Content

Why start from scratch when you can access Barnett's library of courses for your organization? With over 30 years of experience, Barnett's expertise can be leveraged for your organization through the in-licensing of our core course content. From single courses to usage of Barnett's comprehensive curriculum, your organization can access Barnett's resources for your internal usage. The development of effective training content is time consuming and costly, and Barnett's licensing services can help you to significantly reduce these costs for your organization. Developed by subject matter experts who are chosen not only for their experience working in the industry but also for their experience with learning engagement, Barnett's content is unmatched in the industry.

Deliverables include:

- Licensing of Barnett's content for usage within your organization
- Train-the-trainer programs and trainer certification
- Customization of modules to incorporate your organization's SOPs, processes and culture
- Accreditation and certification
- Delivery of course modules by Barnett trainers as needed

Why reinvent the wheel when Barnett is already developing training content that includes industry proven approaches and up-to-date regulatory compliance details? Leverage our training library for your organization today.

For more details, contact Barnett International at +1 215.413.2471 or nganatra@barnettinternational.com.

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.

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eLearning Courses

What is a Barnett eLearning Course?

Barnett's eLearning courses offer a highly interactive experience, and require the user to engage with the content through consideration of core content, scenarios and situations experienced on the job, knowledge checks and assessments. The courses are self-paced modules designed to accommodate the busy schedules of clinical research professionals. Courses can be accessed at any time of day or night – whatever is convenient for each user. As participants move through the course, their learning is "bookmarked," in case it is necessary to leave the course and return at another time. Access is completed when the final course assessment is passed and a score of 80% or higher is achieved.

What are the Benefits?

Barnett's courses are unique in the following ways:

- Highly-relevant, scenario-based training modules that can be accessed anytime, anywhere
- Designed to engage learners with adult learning principles in mind
- Convenient, customizable and focused on application
- Include emphasis on most frequent audit and inspection findings globally

How Do I Pass the Course and Receive My Certificate?

Once the course is completed and the post-test is passed (80% or higher), participants are taken to a certificate screen and can print a completion certificate.

Registration:

Registration for Barnett's eLearning courses is available online at: barnettinternational.com

Once you select your course and register, you will receive your login details to access the course within a 24-hour period.

Customized Courses Available:

All of Barnett's "off-the-shelf" eLearning courses are available for customization and integration into your organization's Learning Management System. For details about this option, contact Naila Ganatra at +1 215.413.2471.

Barnett's On-Demand Good Clinical Practice for Sponsors and CROs

Includes ICH GCP E6 R2 Coverage

Too Busy To Attend A Course?

While covering the core concepts of Good Clinical Practice (GCP), this sponsor and CRO-focused course is based on a series of "challenge" scenarios, including real-life situations that are encountered at clinical research sites. The course also includes an application-based post exam and once successfully completed, a certificate is provided.

Course Learning Objectives

- Learn and practice the application of GCP principles to real-world clinical research situations through the use of warning letters, scenarios, and simulations
- Ensure participants are consistently trained on International Council for Harmonization Good Clinical Practice (ICH GCP) to achieve:
  - » Consistent global interpretation of GCP
  - » Increased focus on patient safety
  - » Consistent delivery of quality data

Key Features Include:

- Comprehensive ICH GCP E6 R2 coverage as well as top findings from FDA and EMA
- Focus on practical application of GCP principles and application-based activities
- Glossary of terms, bookmarking tool, ongoing scenario-based "knowledge checks" and post-course exam
- Includes a Barnett certificate of training
- Applicable for global clinical research professionals

Customized versions available for company-specific teams, including regional adaptation and SOP inclusion.
Contact Barnett today at +1 215.413.2471 to learn more!

For more details, visit:
https://www.barnettinternational.com/on-demand-elearning/good-clinical-practice-for-sponsors-cros

Barnett's On-Demand Good Clinical Practice for Investigators

Includes ICH GCP E6 R2 Coverage

Too Busy To Attend A Course?

This scenario-based eLearning course is designed with the busy Principal Investigator in mind. Based on real-life issues encountered by investigative site teams, this highly focused 7-module training is designed to ensure comprehensive understanding of the key components of ICH GCP (including E6 R2). The structure includes two assessment and completion options, depending on experience level. Upon successful completion, a certificate is provided.

Course Learning Objectives

Upon completion of this scenario-based course, participants will be able to:

- Describe Investigator responsibilities in the context of study protocol oversight and GCP compliance
- Recognize critical elements of human subject protection
- Discuss the requirements for investigational product management and maintenance of adequate and accurate records for research trials
- Recognize key requirements for patient safety management and regulatory reporting
- Discuss mandatory critical interactions with Institutional Review Boards (IRBs) or Ethics Committees (ECs)

Key Features Include:

- Comprehensive ICH GCP E6 coverage as well as top findings from FDA and EMA
- Focus on practical application of GCP principles and application-based activities
- Glossary of terms, bookmarking tool, ongoing scenario-based "knowledge checks" and post-course exam
- Includes a Barnett certificate of training
- Applicable for global clinical research professionals

Customized versions available for company-specific teams, including regional adaptation and SOP inclusion.
Contact Barnett today at +1 215.413.2471 to learn more!

For more details, visit:
https://www.barnettinternational.com/on-demand-elearning/good-clinical-practice-for-investigators

Barnett's On-Demand Good Clinical Practice for Study Coordinators

Includes ICH GCP E6 R2 Coverage

Too Busy To Attend A Course?

This scenario-based eLearning course is designed specifically for Clinical Research Study Coordinators. Based on real-life issues encountered by investigative site teams, this highly focused 7-module training is designed to ensure comprehensive understanding of the key components of ICH GCP (including E6 R2). The structure includes two assessment and completion options, depending on experience level. Upon successful completion, a certificate is provided.

Course Learning Objectives

Upon completion of this scenario-based course, participants will be able to:

- Describe Investigative Team responsibilities in the context of study protocol oversight and GCP compliance
- Recognize critical elements of human subject protection
- Discuss the requirements for investigational product management and maintenance of adequate and accurate records for research trials
- Recognize key requirements for patient safety management and regulatory reporting
- Discuss mandatory critical interactions with Institutional Review Boards (IRBs) or Ethics Committees (ECs)

Key Features Include:

- Comprehensive ICH GCP E6 R2 coverage as well as top findings from FDA and EMA
- Focus on practical application of GCP principles and application-based activities
- Glossary of terms, bookmarking tool, ongoing scenario-based "knowledge checks" and post-course exam
- Includes a Barnett certificate of training
- Applicable for global clinical research professionals

Customized versions available for company-specific teams, including regional adaptation and SOP inclusion.
Contact Barnett today at +1 215.413.2471 to learn more!

For more details, visit:
https://www.barnettinternational.com/on-demand-elearning/good-clinical-practice-for-study-coordinators

Barnett's On-Demand Fundamentals of Good Clinical Practice

Includes ICH GCP E6 R2 Coverage

Too Busy To Attend A Course?

This introductory course provides learners with the necessary background required when working in a Good Clinical Practice (GCP) environment. Designed for those not directly interfacing with clinical research sites, the course includes application-based examples and the rationale behind GCP principles. Upon successful completion, a certificate is provided.

Course Learning Objectives

- Describe the foundations, background, principles and application of ICH GCP
- Identify key regional regulations that impact the conduct of clinical trials
- Recognize the importance of complying with ICH GCP, as well as the impact of noncompliance
- Describe ICH GCP key roles and responsibilities in the conduct of clinical trials

Key Features Include:

- High-level ICH GCP E6 R2 coverage
- Focus on practical application of GCP principles and application-based activities
- Glossary of terms, bookmarking tool, ongoing "knowledge checks" and post-course exam
- Includes a Barnett certificate of training
- Applicable for global clinical research professionals

Customized versions available for company-specific teams, including regional adaptation and SOP inclusion.
Contact Barnett today at +1 215.413.2471 to learn more!

For more details, visit:
https://www.barnettinternational.com/on-demand-elearning/fundamentals-of-good-clinical-practice

Barnett's On-Demand 30-Hour Clinical Research Coordinator On-Boarding Program

Includes ICH GCP E6 R2 Coverage

Too Busy to Attend a Course?

This recorded, self-paced course provides 24/7 access to a comprehensive introduction to clinical research and the job functions of the Clinical Research Coordinator (CRC). Focused on the core skills required of the CRC job role, the learning approach in this course encourages critical thinking for those looking to support, facilitate and coordinate the daily activities of clinical trials at research sites.

Course Learning Objectives

- Describe the roles and responsibilities of the CRC
- Prepare for what a sponsor is looking for in a research site during a pre-study evaluation or site selection visit
- Understand the requirements for source documentation, case report forms, study tool development, and standard operating procedures (SOPs)
- Define informed consent requirements and learn the process of conducting informed consent
- Define safety reporting including definitions and safety reporting requirements
- Discuss regulatory compliance and quality assurance as it relates to audits and inspections

Key Features Include:

- Practical application of Good Clinical Practice principles as they apply to the role of the CRC
- Glossary of terms, quizzes, practice exercises and a mid-term and final exam
- CEU certificate upon successful completion of the mid-term and final exam
- Applicable for global clinical research professionals

Customized versions available for company-specific teams, including regional adaptation and SOP integration. Contact Barnett today at +1 215.413.2471 to learn more!

For more details, visit:
https://www.barnettinternational.com/on-demand-elearning/30-hour-clinical-research-coordinator-on-boarding-program

Barnett's On-Demand 30-Hour Monitoring Oncology Clinical Trials Program

Too Busy to Attend a Course?

This recorded, self-paced course provides 24/7 access to practical, hands-on training for those interested in gaining knowledge about monitoring in the oncology therapeutic area. As demand for CRAs in the oncology arena continues to grow, this course offers practical, hands-on training covering oncology-specific logistical, clinical and ethical considerations. The application of clinical monitoring skills is reinforced through core content, exercises, case studies, and practice-based activities. The course also includes an application-based post-course exam, and once successfully completed, a certificate is provided.

Course Learning Objectives

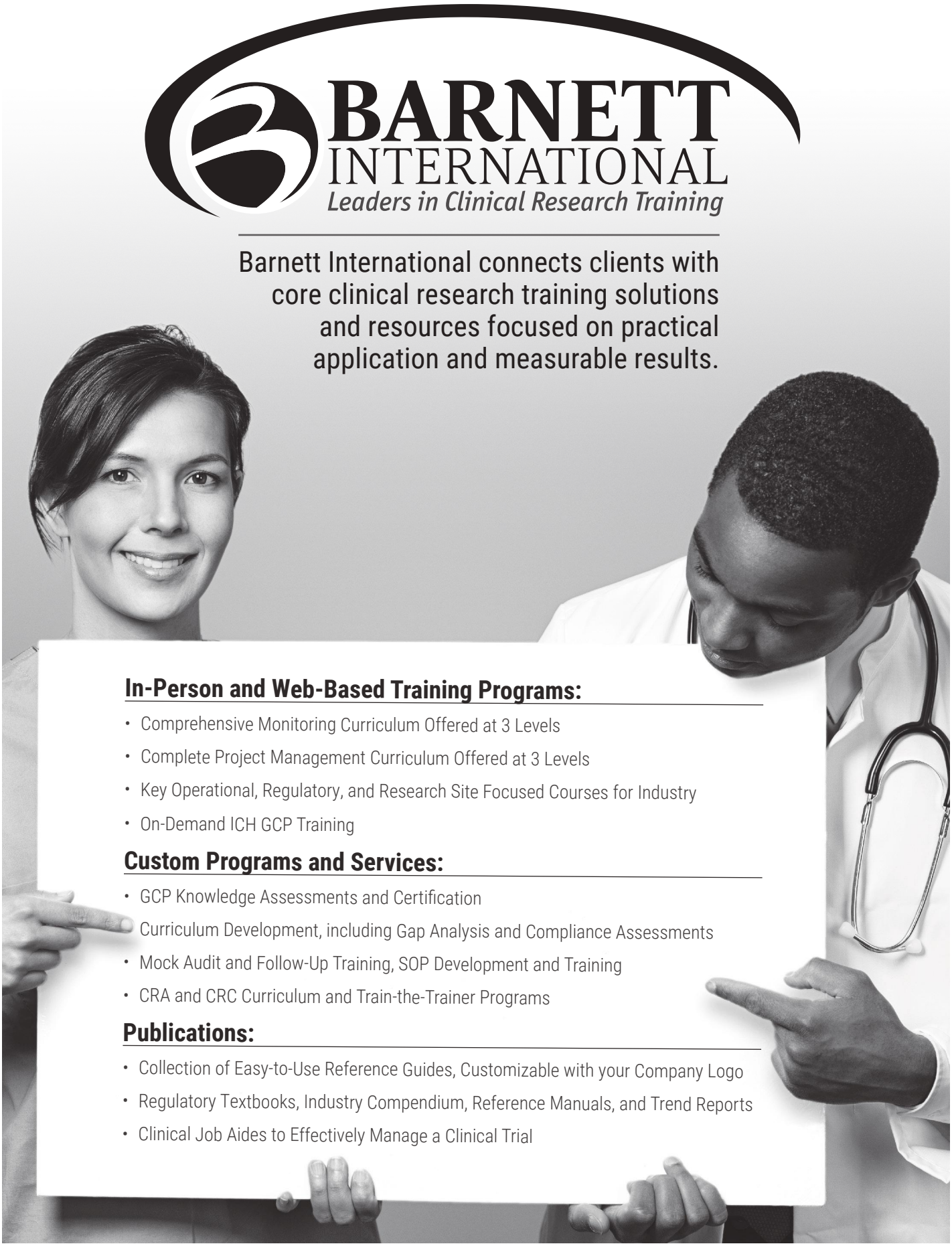
- Manage challenges associated with oncology trials
- Describe common characteristics of the Institutional Review Board (IRB) review and communications in oncology trials
- Examine approaches for decision-making at sites for dosing toxicities and dose modifications
- Apply standardized grading criteria to adverse events in oncology studies
- Establish strategies for source documentation and monitoring visits

Key Features Include:

- Application-based exercises and examples
- Focus on practical application of principles and job functions
- Knowledge checks, assessments 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 integration. Contact Barnett today at +1 215.413.2471 to learn more!

For more details, visit:
https://www.barnettinternational.com/on-demand-elearning/on-demand-30-hour-monitoring-oncology-clinical-trials-program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Leaders in Clinical Research Training
Barnett International connects clients with core clinical research training solutions and resources focused on practical application and measurable results.
In-Person and Web-Based Training Programs:
• Comprehensive Monitoring Curriculum Offered at 3 Levels
• Complete Project Management Curriculum Offered at 3 Levels
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Publications:
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• Regulatory Textbooks, Industry Compendium, Reference Manuals, and Trend Reports
• Clinical Job Aides to Effectively Manage a Clinical Trial

Training Portal Subscription

Clinical Research Training & Development for Individuals & Teams

BARNETT INTERNATIONAL

Barnett is pleased to now offer subscription-based access to our numerous on-demand training courses. By subscribing, you will have access to up-to-date training courses covering the key functional areas of clinical research. Subscribe as an individual or a team!

Subscription Includes:

- Choice of up to 35 courses annually from Barnett's extensive (150+ courses) on-demand library
- GCP certification/annual refresher training
- Access to Barnett's most popular eBooks, including our ICH GCP Q&A Guide
- Discounts on Barnett's live training courses

Barnett's Solution Includes:

- Individual and organizational-level reporting on your team's training records
- Completion status tracking and ongoing reporting
- Ability to complete training whenever convenient
- Cost-effective access to comprehensive and timely training content

Over 150 Course Options Are Available To Subscribers!

Price includes access to up to 35 on-demand courses, eBooks and more! Purchase by individual user. Team discounts available for even more value – the more users you register, the more you save. Discounts on additional Barnett products also included!

To Get Started, Contact Barnett Today for Details and Pricing:

For Individuals, Contact Customer Service:

customer.service@barnettinternational.com
+ 1 781 972 5402

For Teams, Contact Naila Ganatra:

nganatra@barnettinternational.com
+ 1 215 413 2471

BarnettInternational.com

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Course Registration Form

A) Complete and return this entire form by fax or mail. (Please photocopy form for additional attendees)

Course Number _____

Course Name _____

Course Date(s) _____

Dr. Mr. Ms. (First) _____(Last)_____

Job Title _____ Department_____

Company _____

Mailing Address_____

_____

Phone (required) (Area Code)_____

Cell Phone (Area Code)_____

Fax (Area Code) _____

E-Mail (required for course confirmation) _____

❍ YES! Add me to your mailing list. ❍ YES! Add me to your e-mail list.

B) Method of Payment: Full payment must accompany registration form. Registrations received without payment will not be processed.

❍ *CHECK enclosed

Amount: $ _____

(Make checks payable to Barnett International, in U.S. funds drawn on a U.S. bank)

*Signature: _____

*CREDIT CARD (Please provide the information below)
❍ VISA ❍ MC ❍ AMEX

Name of Cardholder:

Card # _____

Exp. Date: _____

Amount: $ _____

*Signature: _____

By signing, I agree that I have read and understand Barnett's cancellation and substitution policies.

Three Fast and Easy Ways to Register:

INTERNET: barnettinternational.com

FAX: +1 781.972.5425

MAIL: Registration Form with payment to:

Barnett International
250 First Avenue, Suite 300
Needham, MA 02494

REGISTER EARLY:

Courses are limited to 30 participants! Team Discounts Available!

Course Cancellation Policy

Your notice of cancellation must be received in writing by email to Barnett's Customer Service Department at customer.service@barnettinternational.com prior to the start of the course. Note that Barnett does not refund your registration fee.

- Prior to 10 business days before the course: You will receive an Event Pass. This Event Pass may be applied toward a future Barnett course 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 course. (This can be done by email only.) Event Passes are not transferable to any other type of program, such as conferences or product orders.
- Within 10 business days before course. No Event Pass will be issued.

Course Substitution

If you are unable to attend a course, you may provide a substitute person (for the same course 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 course.

E-MAIL: customer.service@barnettinternational.com

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

Force Majeure

The performance of this Agreement by either party is subject to Force Majeure, government authority, severe weather, disaster, strikes, civil disorders, or other emergencies, or causes beyond reasonable control of the parties hereto, any of which make it illegal or impossible to provide the services for your course. 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.

BARNETT INTERNATIONAL

Clinical Guides, Resources, and Reference Manuals Published by Barnett

Publication Order Form

Three Easy Ways to Order:

Online: www.barnettinternational.com
Telephone/Fax: +1 781.972.5400 or toll-free in the U.S. 800.856.2556. Or Fax Order Form to: +1 781.972.5425
Mail Check to: Barnett International, 250 First Avenue, Suite 300, Needham, MA 02494

Publications	Code	Price	Qty	Subtotal
Reference Guides and Job Aids				
The Clinical Research Finance Roadmap: A Comprehensive Guide to the Financial Aspects of Clinical Research (2019)	FIN19	$169.95		
The Clinical Research Finance Roadmap Companion Reference Guide: Tools, Templates and Resources (2019) Electronic Edition	FINCOM19E	$119.95		
NEW EDITION! Good Clinical Practice: A Q&A Reference Guide (2024/2025)	GCP24	$139.00		
NEW EDITION! Good Clinical Practice: A Q&A Reference Guide Electronic Edition (2024/2025)	GCP24E	$129.00		
The Self-Study CRA Training Series (7 volume set)* (2018)	CRAS18	$599.00		
The Self-Instructional Study Site Training Series (6 volume set)* (2018)	SSSV181-6	$499.00		
Compendia, Textbooks, and Trend Reports				
New Drug Development: A Regulatory Overview 8th Edition (2008)	NDD8	$145.00		
Medical Device Development: Regulation and Law (2020)	MEDDEV20	$195.00		
Expediting Drug & Biologics Development: A Strategic Approach (2021)	EXP21	$195.00		
Biologics Development: A Regulatory Overview 4th Edition (2021)	BIODEV4	$195.00		
			Subtotal	
			Standard Domestic Shipping (7-10 business days) (Barnett uses the FedEx rate calculator for all shipments. Contact Barnett for specific rates/shipping options.)	
			TOTAL	

** Volume sets can also be purchased by individual volumes. Call +1 781.972.5400 or toll-free in the U.S. 800.856.2556 for details.*

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PAYMENT INFORMATION: ❒ Credit Card (MC, Visa, AmEx) ❒ Check (Order will NOT be processed until check is received)

❒ Visa ❒ MC ❒ AmEx Card # _____ Expiration _____ /_____

Check Number (Order will NOT be processed until check is received) _____

Signature (REQUIRED FOR CREDIT CARD ORDERS): _____

SHIPPING INFORMATION: (Please Print)

Name: _____

Title: _____

Organization: _____

Address: _____

City/State/Zip: _____

Phone: _____

Fax: _____

Email _____

(REQUIRED TO SEND CONFIRMATION AND TRACKING INFORMATION)

BILLING/INVOICING INFORMATION: (THIS IS THE PERSON WHO WILL RECEIVE AN INVOICE VIA EMAIL – an invoice will NOT be sent via regular mail)

Billing/Accounts Payable Contact: _____

Title: _____

Organization: _____

Address: _____

City/State/Zip: _____

Phone: _____

Fax: _____

Accounts Payable/Billing Email (REQUIRED TO SEND INVOICE – Your order will NOT be processed without this information): _____

How Are You Developing Your Clinical Research Workforce?

Barnett offers a number of solutions for ensuring that the training and development needs of your teams are met. Contact Barnett today for a customized training approach for your clinical research initiatives.

- On-Demand GCP Training for all levels of learners
- Membership-based access to Barnett's numerous courses and training resources
- Comprehensive role-based training for key clinical research roles
- Licensing of Barnett's content and train-the-trainer programs
- Training curriculum development
- Virtual training delivery and support

Let Barnett help you to

Maximize Your Training & Development Initiatives

while leveraging our resources for your teams.

BARNETT INTERNATIONAL
Leaders in Clinical Research Training

BarnettInternational.com

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+1 215 413 2471 for Customized Programs

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Your Life Science Network

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