

Training and Resources for **Clinical Research Professionals**

COURSE AND PUBLICATIONS CATALOG | JANUARY – JUNE 2012



**Live and Web-Based Training Courses, Customized Training,
and Publications for Clinical Research Professionals including:**

Clinical Research Sites
Project Management
Drug Safety
Statistics
Medical Devices
Investigators

Clinical Research Associates/Coordinators
Sponsors/CROs
Regulatory Affairs
Research and Development
Data Management
Quality Assurance

On-Site Training from Barnett

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

- **Comprehensive Training Programs:**

- Over 50 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 8 or more



- **Annual Training Program Development:**

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



- **Curriculum/Train-the-Trainer:**

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

Accredited Content:

- Professional development and nursing CEUs are available from ACPE and NJSNA

Experienced Instructors:

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

Personalized Service:

- Contact Naila Ganatra at (215) 413-2471 or nganatra@barnettinternational.com for more information about how to leverage Barnett's resources to meet your in-house training goals



BARNETT EDUCATIONAL SERVICES



January 2012

Dear Colleagues,

It is with great pleasure that we present you with our January-June 2012 catalog. Included are complete details about Barnett's public in-person and web-based course offerings, our reference guides and textbooks, as well as details about our training consulting, in-house training, eLearning, and train-the-trainer programs. Some key highlights that we'd like to point out as you review the catalog are:

New In-Person Courses:

- The Clinical Data Management (CDM) Component of Clinical Trials for the Non-CDM Professional
- Developing CRAs as Study Managers

New Web-Based Courses:

- Design Considerations for GCP Training Programs
- Going Independent: Fundamentals for Independent Consultants
- How Sites Can Own the Study Process
- Investigator Selection Criteria and Strategies for Investigator Qualification
- Proposed Changes to DHHS Human Subjects Research Protections: Enhancing Subject Protection and Reducing Ambiguity for Investigators
- Quality Risk Management in Clinical Trials and Pharmacovigilance
- Re-Inventing Investigator Meetings: From "Bore and Snore" to "Engaging and Effective"
- SOP Lunch and Learn Web Seminar Series
- Strategies for Protocol Operationalization and Adherence
- To Rejuvenate the Study or Not: The "Who, What, When, Where, and How" of Study Rejuvenation Meetings
- Tools for Trainers: Clinical Research Job-Aids and Checklists

In addition to these new offerings, you will also find many course updates and content revisions for 2012. We understand that strong training programs and resources begin with clearly identified goals and objectives, strong instructional design practices, high-level trainers, and relevant, interactive exercises and simulations that are geared toward adult learners.

Finally, we are also pleased to announce the launch of our new GCP Training and Assessment Program, an initiative which many of our clients are adopting as a new standard of certification for their teams. The program consists of an interactive, scenario-based GCP self-paced training course, followed by a robust application-based assessment which tests participants' understanding of how GCP is applied in workplaces. More detail about this program can be found on page 136 or by contacting us for more information.

Thank you again for the opportunity to continue to serve you. We look forward to seeing you at an upcoming course!

Kind regards,

A handwritten signature in black ink that reads 'Naila Ganatra'.

Naila Ganatra
General Manager
Barnett International

A handwritten signature in black ink that reads 'Phillips Kuhl'.

Phillips Kuhl
President
Cambridge Healthtech Institute

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Courses Listed by City

Boston, MA Club Quarters Boston

Auditing Techniques for Clinical Research Professionals	February 6-7, 2012
Data Management in the Electronic Data Capture Arena: Regulatory Considerations and Practical Applications for eCDM	February 6-7, 2012
Clinical Project Management: Advanced	February 9-10, 2012
Conducting Clinical Trials in Resource-Limited Settings and Enrolling Vulnerable Subjects: Challenges and Solutions	March 1-2, 2012
Patient Recruitment & Retention: Successful Planning and Management	March 1-2, 2012
Source Documentation Best Practices	March 9, 2012
Study Site Start-Up: Opening and Managing a Successful Clinical Research Site	March 9, 2012
Conducting Clinical Trials in Emerging Regions: Asia Pacific, Eastern Europe, India & Latin America	April 10-11, 2012
Medical Terminology for Clinical Research Professionals	April 10-11, 2012
Facilitation Skills for Clinical Research Team Members	April 13, 2012
Clinical Project Management: Introduction to Practical Clinical Trial Planning for Project Managers	May 2-3, 2012
Conducting Clinical Trials Under ICH GCP	May 3-4, 2012
Fraud in Clinical Research: Detection and Deterrence	May 3-4, 2012
Advanced Good Clinical Practice: Practical Application and Implementation	June 4-5, 2012
Clinical Project Management: Intermediate	June 4-5, 2012
Monitoring Clinical Drug Studies: Advanced	June 6-7, 2012
Adverse Events: Managing and Reporting for Pharmaceuticals	June 7-8, 2012
Effectively Writing Clinical Trial Protocols	June 7-8, 2012
Medical Device Approval Process: Preparation and Processing of 510(k)s, IDEs, and PMAs	June 11-12, 2012
Pharmacovigilance in Europe: Impact of Regulatory Changes on Investigational & Marketed Products	June 11-12, 2012
Comprehensive Monitoring for Medical Devices	June 12-14, 2012
Monitoring Clinical Drug Studies: Beginner	June 13-15, 2012
Global IND Submissions	June 14-15, 2012
Introduction to Clinical Data Management	June 14-15, 2012
CRA & CRC: Beginner Program	June 18-20, 2012
The CRA Manager Course	June 18-19, 2012
Statistical Concepts for Non-Statisticians	June 20-21, 2012
Working with CROs: Building a Partnership for Project Success	June 20-21, 2012
Gap Analysis: How to Bridge the Non-Approvable to the Approved Marketing Application	June 22, 2012
Monitoring Clinical Drug Studies: Intermediate	June 25-26, 2012
Preparing IND Submissions: How to Organize, Write, Submit, and Track Submissions	June 28-29, 2012
Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) in Site Management	June 28-29, 2012

Philadelphia, PA Club Quarters Philadelphia

Comprehensive Monitoring for Medical Devices	February 7-9, 2012
CRA & CRC: Beginner Program	February 7-9, 2012
Clinical Project Management: Introduction to Practical Clinical Trial Planning for Project Managers	February 14-15, 2012
Monitoring Clinical Drug Studies: Intermediate	February 16-17, 2012
Monitoring Clinical Drug Studies: Beginner	February 20-22, 2012
Advanced Good Clinical Practice: Practical Application and Implementation	February 23-24, 2012
Adverse Events: Managing and Reporting for Medical Devices	February 23-24, 2012
Adverse Events: Managing and Reporting for Pharmaceuticals	March 1-2, 2012
Clinical Project Management: Intermediate	March 1-2, 2012
Monitoring Clinical Drug Studies: Advanced	March 6-7, 2012
Effectively Writing Clinical Trial Protocols	March 8-9, 2012
Introduction to the FDA	March 8-9, 2012
Pharmacokinetics: A Comprehensive Overview of Principles and Applications	March 20-21, 2012
Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) in Site Management	March 20-21, 2012
Medical Device GCP Overview	March 20-21, 2012
Working with CROs: Building a Partnership for Project Success	March 29-30, 2012
Advanced Clinical Research Coordinator (CRC) Training	April 13, 2012
Report Writing for CRAs	April 13, 2012
Statistical Concepts for Non-Statisticians	April 16-17, 2012
Combination Products: How to Get a Product Through The FDA Approval Process	April 16-17, 2012
Institutional Review Boards (IRBs): The Changing Landscape and the Effect on the Conduct of Clinical Research	April 19-20, 2012

Courses Listed by City

Philadelphia, PA *Club Quarters Philadelphia*

Regulatory Intelligence 101	April 20, 2012
Signal Detection and Pharmacovigilance	April 20, 2012
Negotiation Skills for Clinical Research Professionals	April 24-25, 2012
Pharmacovigilance in Europe: Impact of Regulatory Changes on Investigational & Marketed Products	April 24-25, 2012
Planning and Conducting Global Clinical Trials	April 26-27, 2012
Comprehensive CRC Training	April 26-27, 2012
Global GCP Monitoring: Domestic and International Compliance	May 3-4, 2012
Patient Registry Programs: Strategy, Design, Operations, and Output	May 3-4, 2012
Drug Development and FDA Regulations: A Regulatory Overview	May 8-9, 2012
The Highly Effective CRA: Soft Skills for Taking Your Work to the Next Level	May 8-9, 2012
Clinical Trials for Pharmaceuticals: Design and Development	May 9-10, 2012
Mastering Cost Management for Global Clinical Trials	May 9-10, 2012
FDA Meetings 101: How to Hold a Successful Meeting with Regulatory Agencies	May 10, 2012
Good Clinical Practice for the Laboratory Scientist	May 10, 2012
Writing for Clinical Research	May 10-11, 2012
Auditing Techniques for Clinical Research Professionals	June 5-6, 2012
Data Management in the Electronic Data Capture Arena: Regulatory Considerations and Practical Applications for eCDM	June 5-6, 2012
Drug Approval Process: Preparation and Processing of INDs and NDAs	June 14-15, 2012
Drug Safety and Pharmacovigilance: Effective Drug Safety Reporting and Surveillance	June 14-15, 2012
How to Prepare and Submit a Bullet Proof 510(k): Addressing the Latest FDA Proposed Changes to the Process	June 20, 2012
The Pharmacovigilance Audit: How to Prepare for an Inspection	June 20, 2012
Query Creation & Processing: Assessing Data Discrepancies and the Communications for Corrections	June 20, 2012
Clinical Project Management: Advanced	June 28-29, 2012

San Diego, CA *Courtyard San Diego Downtown*

Monitoring Clinical Drug Studies: Advanced	January 26-27, 2012
Conducting Clinical Trials Under ICH GCP	February 16-17, 2012
Regulatory Intelligence 101	February 17, 2012
Medical Device Approval Process: Preparation and Processing of 510(k)s, IDEs, and PMAs	February 27-28, 2012
The Highly Effective CRA: Soft Skills for Taking Your Work to the Next Level	February 27-28, 2012
Developing Clinical Study Budgets	March 1, 2012
Good Clinical Practice for the Laboratory Scientist	March 1, 2012
The Pharmacovigilance Audit: How to Prepare for an Inspection	March 1, 2012
Clinical Project Management: Introduction to Practical Clinical Trial Planning for Project Managers	March 12-13, 2012
Medical Device Postmarketing Vigilance Reporting: New Update, Guidance, and Expectations for Manufacturers	April 17, 2012

San Francisco, CA *Hilton San Francisco*

Clinical Drug Development	March 15-16, 2012
Preparing IND Submissions: How to Organize, Write, Submit, and Track Submissions	March 15-16, 2012
The CRA Manager Course	March 15-16, 2012
Effectively Writing the Investigator's Brochure	March 26, 2012
Drug Safety and Pharmacovigilance: Effective Drug Safety Reporting and Surveillance	March 27-28, 2012
Introduction to Clinical Data Management	March 27-28, 2012
Auditing Techniques for Clinical Research Professionals	April 10-11, 2012
Monitoring Clinical Drug Studies: Beginner	April 11-13, 2012
Advanced Good Clinical Practice: Practical Application and Implementation	April 12-13, 2012
Clinical Project Management: Intermediate	April 12-13, 2012
Clinical Trials for Medical Devices: Design and Development	April 12-13, 2012
Global IND Submissions	April 12-13, 2012
Comprehensive Monitoring for Medical Devices	April 17-19, 2012
Clinical Project Management: Advanced	April 19-20, 2012
Monitoring Clinical Drug Studies: Intermediate	April 26-27, 2012
Complying with Quality System (QS) Regulation Requirements and Exceeding Expectations: One-Day Primer for Medical Device Manufacturers	April 30, 2012
Negotiation Skills for Clinical Research Professionals	May 9-10, 2012
CRA & CRC: Beginner Program	May 9-11, 2012
Adverse Events: Managing and Reporting for Medical Devices	June 25-26, 2012
Conducting Clinical Trials in Resource-Limited Settings and Enrolling Vulnerable Subjects: Challenges and Solutions	June 25-26, 2012



Advanced Clinical Research Coordinator (CRC) Training

Course Description

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

Learning Objectives

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

Who Should Attend

- This course has been developed for the individual CRC, nurse coordinator, site manager or investigator who has a solid background in the CFRs, ICH E6 Guidelines, and is involved in or manages the daily operation of clinical research at a trial site. The course can also be beneficial to the CRA and members of the sponsor/CRO industry

Instructors

This course will be taught by one of the following instructors

Nikki Christison, B.S.
Lily Romero, P.A., C.C.R.C.
Karen Gilbert, B.S., C.C.R.A.
Jackie Stader, C.O.T., C.C.R.C.
Kimberly Turner, C.M.A., A.S., B.H.S., C.R.A.

Interactive Activities

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

Course Dates and Locations

April 13, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SAAA0412
\$800 by March 9
\$1,000 after March 9

Academic Discount

A **\$100** academic discount is available to those who qualify.

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include
assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

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

Participants will receive 7 hours (0.7 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will mail ACPE statements within three weeks of program completion. ACPE#: 0778-000-09-047-L01-P. Released: 3/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Recap, including updates, of CFRs, ICH, GCP and relevant guidance documents

Trends and changing landscape in clinical research

Study Management: Prioritizing

Study Management: Financial

Training the Clinical Research Staff

FDA inspections/Preparing for an Inspection

Corrective and Preventive Action Plans/Case Study

Case study

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Advanced Good Clinical Practice: Practical Application and Implementation

Course Description

This course provides an advanced, in-depth review of the structural elements of Good Clinical Practice (GCP). Participants will learn practical application of GCP regulations and guidelines for critical components of the clinical research process. Specific attention will be given to how quality systems, or a lack thereof, impact overall data quality and regulatory risk. This program is designed for professionals with at least two years of experience in the clinical research industry.

Learning Objectives

- Develop and implement site-specific approaches for corrective action of non-compliance
- Describe the elements of a functional Quality System
- Define key GCP terms
- Examine recent trends in non-compliance
- Identify the universal and local components of GCP

- Explain the differences between the legal and procedural elements of GCP
- Recognize key differences in pharmaceutical, device, and biologics GCP
- Describe the overlap between GCP and GMP

Who Should Attend

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

Instructors

This course will be taught by one of the following instructors

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

Interactive Activities

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

Course Dates and Locations

February 23-24, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SADA0212
\$1,595 by January 20
\$1,795 after January 20

April 12-13, 2012
San Francisco, CA 94102
Hilton San Francisco
Course #: SADF0412
\$1,595 by March 9
\$1,795 after March 9

June 4-5, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SADB0612
\$1,595 by May 4
\$1,795 after May 4

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include
assorted breakfast items that
will be available each day ½
hour prior to the start of the
seminar. Also included is a
Networking Lunch that will
be served each training day.

Accreditation

 Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-000-09-017-L01-P. Released: 7/09.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

GCP Terminology: Beyond the ABCs

New Developments and Emerging Trends in GCP

Principles of GCP: Different Perspectives: Examination; application; implementation

The “Forgotten” Elements of GCP: Regulations; laws; guidelines

Day Two: 8:30 a.m. – 5:00 p.m.

Quality Systems: The Roadmap to GCP:

Quality control; quality assurance; quality improvement

The Role of Standard Operating Procedures in GCP: Rationale; development; training; implementation; maintenance

GCP Across Investigational Products: Drugs; devices; biologics

Are We There Yet?: Recent Non-Compliance Issues with Discussion

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



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

Who Should Attend

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

Instructor

Douglas E. Albrecht, B.S.N., C.C.R.A.

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 Dates and Locations

February 23-24, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SDAA0212
\$1,595 by January 20
\$1,795 after January 20

June 25-26, 2012
San Francisco, CA 94102
Hilton San Francisco
Course #: SDAF0612
\$1,595 by May 25
\$1,795 after May 25

Academic Discount

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Registration

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Accreditation

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Overview of Safety: History; need for safety surveillance and what it can accomplish; FDA regulations; Good Clinical Practices; CIOMS recommendations; ICH considerations

Adverse Event Reporting in Clinical Trials: Review of FDA regulations, definitions, and concepts; Good Clinical Practices; IDE safety reporting

Coding: Narrative descriptions; electronic records; coding principles, standardized dictionaries: COSTART, WHO-ART, and MedDRA

Day Two: 8:30 a.m. – 5:00 p.m.

Adverse Event Reporting for Marketed Products:

Managing domestic spontaneous reports: maximizing information, minimum requirements for a valid report; managing events from other sources: foreign, literature, and FDA; reporting requirements to the FDA and other authorities

Considerations When a Device Delivers a Drug/Biologic: Overview of drug/biologic adverse event definitions and concepts; overview of reporting requirements in clinical trials and post-marketing

FDA's Role in Device Safety: FDA audit procedures; post-inspection reports and findings

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Adverse Events: Managing and Reporting for Pharmaceuticals

Course Description

This course provides an excellent introduction for newcomers to the field of drug and biologic product AE reporting, a comprehensive overview of current approaches and regulations for professionals in the field, and challenging questions and ideas for the experienced safety information scientist.

Learning Objectives

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

Who Should Attend

- Clinical Trial Personnel responsible for collecting, reviewing, and reporting investigational adverse events
- Safety Surveillance Personnel responsible for the acquisition, classification, entry, analysis, and reporting of adverse events in marketed products

- Regulatory Affairs Personnel responsible for submitting safety reports to FDA and international regulatory authorities
- Quality Control Personnel involved in the investigation of adverse event reports
- This course contains medical device content related only to use in combination products

Instructors

Jackie Stader, C.O.T., C.C.R.C.

Interactive Activities

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

Course Dates and Locations

March 1-2, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SAEA0312
\$1,595 by January 27
\$1,795 after January 27

June 7-8, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SAEB0612
\$1,595 by May 4
\$1,795 after May 4

Academic Discount

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

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: 8:30 a.m. – 5:00 p.m.

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

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Auditing Techniques for Clinical Research Professionals

Course Description

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

Learning Objectives

- Apply auditing standards based in current law, regulations, and guidelines
- Utilize special, not often taught, auditing techniques as part of your daily monitoring or auditing activities
- Develop Simple, Efficient, and Effective Quality Systems (SEEQS – pronounced See Q's)
- Utilize SEEQS for detecting root causes of performance deficiencies and developing and implementing effective Corrective and Preventative Action (CAPA)
- Employ techniques for auditing and monitoring electronic medical records
- Identify the differences between monitoring and auditing and how to integrate auditing techniques into monitoring procedures

- Select investigators and records for auditing or special monitoring emphasis
- Conduct clinical investigator and Sponsor-Monitor-CRO audits
- Detect, prove, and prevent scientific fraud and misconduct
- Write audit plans and reports

Who Should Attend

- Clinical Quality Assurance Professionals who audit the quality of clinical trials
- Clinical Research Associates (CRAs) 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

Instructor

Jeanne Morris, B.S., MT (ASCP)

Interactive Activities

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

Course Dates and Locations

February 6-7, 2012

Boston, MA 02110

Club Quarters Boston

Course #: SFCB0212

\$1,595 by January 6

\$1,795 after January 6

April 10-11, 2012

San Francisco, CA 94102

Hilton San Francisco

Course #: SFCF0412

\$1,595 by March 9

\$1,795 after March 9

June 5-6, 2012

Philadelphia, PA 19103

Club Quarters Philadelphia

Course #: SFCA0612

\$1,595 by May 4

\$1,795 after May 4

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0778-0000-10-004-L01-P.
Released: 8/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

The Standards: Important aspects of GCP-related law and regulations: Food, Drug, and Cosmetic Act, Title 18 Criminal Statutes, HIPAA, 21CFR 11, 50, 54, 56, 312, and 812; Corporate standards

Trial Center Auditing Methods: Selecting centers to audit, auditing and inspection procedures and methodology, including special procedures for "e-trials"; differences between auditing and monitoring; Defining and determining the adequacy of source documentation; developing and implementing Simple, Effective, and Efficient Quality Systems to improve clinical site performance

Fraud and Misconduct: Motives; discovering, reporting, and preventing fraud and misconduct, including special techniques for e-trials

Day Two: 8:00 a.m. – 4:30 p.m.

Data Trend Analysis: Definition and description of this special auditing technique; multiple examples; how to practically use this technique; Special subsection on detecting the signs and symptoms of impeding failure at a trial center

Auditing Techniques Exercise: Perform data trend analysis; audit to determine document validity and data accuracy; perform root cause analysis; build a CAPA; work individually and within a group of your peers

Essential Documents: Define and prioritize; auditing the essential document binder or files; the legal and regulatory basis behind the EDs

Enforcers & 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

Hold this Course at Your Company: In-person or On the Web!

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NEW! The Clinical Data Management (CDM) Component of Clinical Trials for the Non-CDM Professional

Course Description

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

Learning Objectives

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

Who Should Attend

- Clinical Trial Managers
- Project Managers
- Clinical Operations personnel
- Clinical Research Professionals associated with the conduct of clinical trials who want to have a better understanding of what is actually involved in the Clinical Data Management portion of a clinical trial

Instructor

Denise G. Redkar-Brown

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 Locations

February 27-28, 2012

Boston, MA 02110

Club Quarters Boston

Course #: SMBO0212

\$1,595 by January 27

\$1,795 after January 27

May 9-10, 2012

San Francisco, CA 94102

Hilton San Francisco

Course #: SMSF0512

\$1,595 by April 6

\$1,795 after April 6

Academic Discount

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

Registration

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

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: 8:30 a.m. – 5:00 p.m.

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

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Clinical Drug Development

Course Description

Drug development is the process of incorporating data from multiple disciplines into a logical and coherent argument for the efficacy and safety of a drug product resulting in regulatory approval. This course will describe the whole process, focusing on the clinical aspects of drug development. Multiple exercises will allow participants to gain an appreciation for team responsibilities and how people with different priorities work together for the common good. Following preparation of a development strategy, participants will prepare individual study designs that implement the strategy. The logistics of the process will be examined to optimize time and cost. The dynamic tension between a pharmaceutical company and regulatory agency will be examined in the context of optimizing development.

Learning Objectives

- Summarize the process of transforming a drug candidate into a drug product
- Discern the decision-making process that efficiently moves a drug through development
- Describe how individual departments work together to reduce the project timeline and cost

- Prepare a clinical development plan and resulting clinical study designs
- Describe the strategy and logistics of a meeting between the company project team and regulatory agency

Who Should Attend

- Clinical investigators and clinical research organization (CRO) personnel
- Sponsor personnel (e.g., scientists, CRAs, project managers, statisticians) who are new to clinical drug development

Instructor

Robert L. Kunka, Ph.D.

Interactive Activities

- Craft a clinical development plan and transform the plan into specific clinical studies
- Role-play individuals on a clinical development team as they respond to a regulatory question
- Work towards consensus on a team
- Respond to a medical need
- Present a development plan to the FDA and defend it

Course Dates and Locations

March 15-16, 2012
San Francisco, CA 94102
Hilton San Francisco
Course #: SCDF0312
\$1,595 by February 17
\$1,795 after February 17

Academic Discount

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

Registration

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Accreditation

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778-000-09-048-L01-P.
Released: 3/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Pharmaceutical Company Structure and Function: Key groups within R&D; understanding the structure and dynamics of teams; stages of drug development

FDA Structure and Function: Overall FDA organization with focus on CDER; dynamics of interactions with regulatory agencies; stages of clinical development: Phases 0-4; key regulatory documents: IND, NDA, sNDA, and aNDA; milestone meetings with the agency; role of advisory committees

Stages of Clinical Development: Phase 0 – first time in man; Phase I – pharmacokinetic, pharmacodynamic, safety; Phase IIa and IIb – efficacy and safety; Phase III – pivotal efficacy and safety; Phase IV – post-approval; design questions: healthy subjects vs. patients, objective vs. subjective endpoints, single dose vs. multiple dose, blinded vs. unblinded; regulated product submission (RPS)

Day Two: 8:30 a.m. – 5:00 p.m.

Developing a Clinical Plan: Review relevant package inserts to identify key questions; develop study designs to address questions; strengths and weaknesses of using a clinical research organization; role of pharmacokinetics in drug development

Pediatric Drug Development: Key FDA and EMEA initiatives; utilization of adult data; bridging studies; utilization of pharmacokinetic and pharmacodynamic data; strategies for overcoming inherent limitations of working in children

Applications for Drug Delivery Systems: Generic; immediate and modified-release oral products; inhalation; product extensions

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Clinical Project Management: Introduction to Practical Clinical Trial Planning for Project Managers

Course Description

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

Learning Objectives

- Develop a project plan
- Manage project timelines
- Use project management tools effectively
- Build high performance project teams
- Gather performance metrics and use them to improve project success
- Identify reasons to outsource and choose a contractor
- Write optimal policies and procedures for clinical trial management
- Describe, in detail, all aspects of clinical trial operation

Who Should Attend

- New Project Managers
- Project Managers with little or no drug development or clinical trial experience
- Staff from Pharmaceutical Companies or Contract Research
- Organizations (CROs) involved with the management of clinical trials
- New Clinical or other Project Team Leaders who will be managing projects
- Managers unfamiliar with clinical project management
- 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

Instructors

This course will be taught by one of the following instructors

Tim Krupa, M.S., M.B.A.
Eric Morfin, M.B.A., P.M.P.

Interactive Activities

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

Course Dates and Locations

February 14-15, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SPMA0212
\$1,595 by January 13
\$1,795 after January 13

March 12-13, 2012
San Diego, CA 92101
Courtyard San Diego
Downtown
Course #: SPMD0312
\$1,595 by February 10
\$1,795 after February 10

May 2-3, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SPMB0512
\$1,595 by March 30
\$1,795 after March 30

Academic Discount

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Introduction to Project Management:

Overview of project management; roles and responsibilities of a project manager; establishing project teams

Project Planning: Developing a project plan; project projections; analyzing risks and challenges; templating study activities

Process Mapping as a Planning and Management Tool:

Why map a process; types of mapping; dissection of the clinical trial process; creation of process maps from trial planning through final clinical study report

Timeline Management: Understanding project scope; creating realistic timelines; monitoring the timeline

Day Two: 8:00 a.m. – 4:30 p.m.

Management of Project Budgets: Creation of project budgets; ongoing financial monitoring

Project Tracking: Tracking requirements; identifying and establishing project metrics; project meetings

Ongoing Project Management

Communication and Team Building: Team building; motivating and mentoring team members; conflict solution; communication strategies; effective communication skills

Contractors – Managing Outsourcing:

Factors influencing outsourcing; choosing a contractor; determining out of scopes

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Clinical Project Management: Intermediate

Course Description

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

Learning Objectives

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

Who Should Attend

- Clinical Project Managers who have mastered project management basics

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

Instructors

This course will be taught by one of the following instructors

Tim Krupa, M.S., M.B.A.
Eric Morfin, M.B.A., P.M.P.

Interactive Activities

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

Course Dates and Locations

March 1-2, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SMIA0312
\$1,595 by January 27
\$1,795 after January 27

April 12-13, 2012
San Francisco, CA 94102
Hilton San Francisco
Course #: SMIF0412
\$1,595 by March 9
\$1,795 after March 9

June 4-5, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SMIB0612
\$1,595 by May 4
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778-000-09-018-L01-P.
Released: 8/09.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Strategic Planning and Development: Goals; design; strategy; anticipating

Trial Design: Study objectives; endpoints; data collection; quality; study populations; protocol

Resourcing: Sponsors; CROs; forecasting needs; planning

Risk Management: Process planning; identification; analysis; response; monitoring and control; tools

Best Practices and Project Management

Tools: Standardizing data collection; benchmarking; tools

Day Two: 8:30 a.m. – 5:00 p.m.

Managing Performance and Improving Outcomes: Metrics; issues; analysis; reporting; standardization

Investigator Performance: Identifying; performance

Patient Recruitment and Retention: Identifying; techniques; minority enrollment; retention

Conduct of International Trials: Culture; diversity; logistics; financial issues; recruitment; international guidelines

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Clinical Project Management: Advanced

Course Description

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

Learning Objectives

- Master quality and timeline tracking and monitoring, and track and prevent delays
- Navigate ever-changing international regulations
- Strategically approach negotiations in light of global cultural, language, and healthcare differences
- Ensure high quality data results from your global clinical trial
- Employ best practices for managing global outsourced providers
- Identify and prioritize potential problems, and implement root cause analysis and corrective and preventive action plans

- Design a GCP and SOP compliant Project Operating Guideline (POG) for high performance clinical trials
- Employ effective communication within project teams
- Design a performance environment that motivates all through clear expectations and consequences
- Manage operational challenges in patient recruitment and retention

Who Should Attend

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

Instructors

This course will be taught by one of the following instructors

Tim Krupa, M.S., M.B.A.
Eric Morfin, M.B.A., P.M.P.

Interactive Activities

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

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Introduction: Pressures from a changing environment; fundamental components for success; key decision points; trends

Performance Management and Site Management: Quality and timeline tracking and monitoring; team and sub-team roles and responsibilities; stakeholder communication plan

Advanced Time Management: Delay tracking and prevention; timeline management core concepts; tracking progress against objectives and the use of milestones; strategies for accelerating clinical trial timelines

Global Clinical Regulations: International regulatory bodies and changing regulations; HIPAA and international informed consent and privacy regulations; the European Clinical Trial Directive

Global Clinical Trials: Cultural, language, and ethical issues; variations in practice conventions and health care services; logistics

Global Investigator and Patient Recruitment Strategy: Country specific regulations; locating and retaining qualified investigators; ensuring adequate regional patient supply and enrollment interest before beginning trial; enrollment targets and timelines; advertising campaigns and dollars; centralized recruiting services; newsletters;

tracking enrollment; strategies when enrollment is not progressing

Ensuring High Quality Data Results from Clinical Trials: Data management logistics; methods of getting paper to and from the sites; Electronic Data Capture (EDC); adverse event reporting on a global scale

Day Two: 8:30 a.m. – 5:00 p.m.

Misconceptions About Managing Trials in Asia: Each country was not created equally; how to select the right international collaboration

Best Practices for Managing Outsourced Service Providers: Key concepts for implementing and managing outsourcing projects; implementing controls; risk management; transition; close-out

Preventing Potential Problems: Identifying, prioritizing, and preventing potential problems; developing preventive and contingent actions

Decision-Making and Troubleshooting: Specifying the decision framework; agreeing and negotiating objectives; selecting and evaluating alternatives; root cause analysis (RCA); corrective and preventive action (CAPA)

Designing a GCP and SOP Compliant Project Operating Guideline (POG) for High Performance Clinical Trials

Negotiation Skills Across Cultural Barriers

Course Dates and Locations

February 9-10, 2012

Boston, MA 02110

Club Quarters Boston

Course #: SMYB0212

\$1,595 by January 6

\$1,795 after January 6

April 19-20, 2012

San Francisco, CA 94102

Hilton San Francisco

Course #: SMYF0412

\$1,595 by March 16

\$1,795 after March 16

June 28-29, 2012

Philadelphia, PA 19103

Club Quarters Philadelphia

Course #: SMYA0612

\$1,595 by May 25

\$1,795 after May 25

Academic Discount

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

Registration

ON-LINE:

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Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,

CALL: (800) 856-2556

Registration fees include assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-005-L01-P. Released: 2/12.

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Clinical Trials for Medical Devices: Design and Development

Course Description

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

Learning Objectives

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

Who Should Attend

- Staff from medical device manufacturers or Contract Research Organizations (CROs) who will be involved in the design of clinical trials and have responsibility for protocol development

- Project Managers who have little or no clinical trial experience
- Project Team Leaders who will be designing clinical trials
- Clinical, Regulatory, and Development Staff who would like to learn how to design a clinical trial program
- Investigators who would like to learn how to design a clinical trial and about protocol development

Instructor

Douglas E. Albrecht, B.S.N., C.C.R.A.

Course Dates and Locations

April 12-13, 2012
San Francisco, CA 94102
Hilton San Francisco
Course #: SMMF0412
\$1,595 by March 9
\$1,795 after March 9

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

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assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Historical Overview: Overview of the regulatory process and general ethical considerations

Device Regulations Pertaining to Device

Trial Design and Development: “Least Burdensome” approach in the USA; Europe; Japan; “Rest of World”

Impact of ICH on Device Trials and Development:

Investigational Plan: Strategic planning; risk analysis; clinical operations; regulatory planning; marketing considerations

Trial Design Considerations: Definitions; types; randomizing; blinding or masking; outcomes

Day Two: 8:30 a.m. – 5:00 p.m.

Trial Design Considerations, continued:

Investigator selection

Protocol Structure and Format: Sections and sub-divisions

Populations: Inclusion/exclusion criteria; cultural considerations

Determining Sample Size; Statistical Power: Qualitative and quantitative endpoints, equivalence, rare events; single group

Objectives and Hypothesis Testing: Null vs. alternative hypothesis; Type I and Type II errors; single vs. multiple objectives; statistical concepts for non-diagnostic devices and diagnostic tests (IVD)

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Clinical Trials for Pharmaceuticals: Design and Development

Course Description

This course addresses the practical issues in the design of pharmaceutical trials and protocol development, as well as broader issues relating to the interface of clinical trial design with overall drug development.

Learning Objectives

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

Who Should Attend

- Staff from Pharmaceutical Companies or Contract Research Organizations (CROs) who will be involved in the design of clinical trials and have responsibility for protocol development
- Project Managers who have little or no clinical trial experience
- Project Team Leaders who will be designing clinical trials

- Clinical, Regulatory, and Development Staff who would like to learn how to design a clinical trial program
- Investigators who would like to learn how to design a clinical trial and about protocol development

Instructor

Edith A. Zang, Ph.D.

Interactive Activities

- Ethical Issues
- Case Studies: Improving Clinical Trials
- Control Groups
- Group Assignments
- Rationale Evaluation
- Protocol Modifications
- Sample Size
- Study Objectives

Course Dates and Locations

May 9-10, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SCTA0512
\$1,595 by April 6
\$1,795 after April 6

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include
assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

 Barnett International is accredited by the ACPE 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-10-005-L01-P. Released: 10/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Historical Overview: Overview of the regulatory process; general ethical considerations

Clinical Investigational Plan: Strategic planning; special clinical trial opportunities; clinical trial simulation

Phases of Drug Development: Phase I and II; Phase IIIa and IIIb; Phase IV

Regulations and Guidelines Pertaining to Clinical Trial Design: USA; Europe; Japan; "Rest of the World"

Impact of the ICH on Clinical Trials: Principles of ICH GCP; clinical trial protocol and protocol amendments; statistical principles; clinical trial reports; structure and content

Day Two: 8:30 a.m. – 5:00 p.m.

Clinical Trial Design: Definitions; types (controlled and uncontrolled); relative and absolute efficacy; placebo controversy (ethical considerations)

Protocol Structure and Format: Subdivisions of individual sections

Patient Populations: Inclusion and exclusion criteria; sub-population choices

Sample Size: Qualitative endpoint; quantitative endpoint; establishing equivalence; rare events; single group

Trial Objectives and Hypothesis Testing: Single versus multiple objectives; a priori and posteriori hypothesis testing; assessment instruments (number and sensitivity; variations for centers in multicenter studies; pharmacoeconomic and quality of life considerations)

Hold this Course at Your Company: In-person or On the Web!
Call (215) 413-2471 for more information



Combination Products: How to Get a Product Through The FDA Approval Process

Course Description

This course provides a comprehensive approach to the preparation and submission of FDA documents for approval of combination products. Participants receive a foundation of knowledge about the combination product process, submission preparation, and the underlying scientific and regulatory principles involved.

Participants will gain knowledge about the FDA Office of Combination Products, the combination product process, request for designation submission, primary mode of action determination, and the entire combination product system.

Learning Objectives

- Describe what combination products are
- Navigate the Office of Combination Products
- Describe primary mode of action determination
- Understand the combination products process
- Understand Request for Designation submissions

Who Should Attend

This course is intended for Regulatory, Clinical, Research, Quality, Manufacturing, and other personnel who require an in-depth knowledge of the FDA combination product process.

Instructor

Albert A. Ghignone, M.S., R.A.C.

Interactive Activities

- Review scenarios and identify solutions

Course Dates and Locations

April 16-17, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SPOA0412
\$1,595 by March 16
\$1,795 after March 16

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include
assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

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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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-046-L01-P. Released: 3/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

FDA History, Laws, regulations, policies and Guidelines

FDA Definitions

What are Combination Products

- Drug/Biologic
- Drug Device
- Biologic Device
- Other

FDA Office of Combination Products

- History
- Organization
- Responsibilities

Combination Product Acts, Rules and regulations

- Food and Drug Act
- 21 CFR

Day Two: 8:30 a.m. – 5:00 p.m.

Primary Mode of Action

- Definition
- Examples

Request for Designation Submission

- Information in a RFD
- Comprehensive review of all RFD sections

Primary Jurisdiction

- CDER
- CBER
- CDRH

General Questions About Combination Products

- Questions

Guidance Documents for Combination Products

- Guidance Documents

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Complying with Quality System (QS) Regulation Requirements and Exceeding Expectations:

One-Day Primer for Medical Device Manufacturers

Course Description

The process of assuring FDA compliance to quality system requirements is different for every company, depending on company size, operations, and priorities. Current good manufacturing practice (cGMP) requirements are set forth in FDA's Quality System (QS) regulation. The requirements in the QS regulation and in 21 CFR 820 govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. In the QS regulation, FDA has identified the essential elements that a quality system shall embody, without prescribing specific ways to establish these elements. Manufacturers must choose, develop, and implement specific procedures tailored to their particular processes and devices. This interactive course will provide guidance and direction that will allow you to develop strategies, add business value, and minimize delays by providing strategic/tactical solutions that facilitate the achievement of regulatory and quality milestones.

Learning Objectives

- Describe the importance of written, executable, and enforceable policies and procedures
- Determine and relate to the benefits of compliance vs. risk of noncompliance

- Implement FDA's QSIT and strategy for inspecting device manufacturers and latest trends
- Describe the importance of good housekeeping for both the facility and documentation management system
- Describe the importance of change control
- Implement strategies for proper auditing and other surveillance tools and techniques
- Establish and maintain a quality system that is appropriate for your device
- Review recent and various enforcement actions taken

Who Should Attend

This course is both a primer for personnel new to the FDA regulated industry or an excellent refresher course for those who need to revisit the basics and fundamentals for a defendable, justifiable, and sustainable compliance program.

Instructor

David R. Dills

Course Dates and Locations

April 30, 2012
San Francisco, CA 94102
 Hilton San Francisco
 Course #: SQSF0412
 \$800 by March 23
 \$1,000 after March 23

Academic Discount

A **\$100** academic discount is available to those who qualify.

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
 Submit Registration Form (page 152) with Payment to Barnett Customer Service.

**For assistance,
 CALL: (800) 856-2556**

Registration fees include assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Regulatory Background and Snapshot

- History
- Definitions and terminology
- Guidelines and other informational sources
- 21 CFR 820 (Quality System Regulation)

Critical and Key Sections

- Quality System Requirements
- Management, design, production, process, and document controls
- Validation, maintenance, and calibration
- Corrective and Preventive Action (CAPA)
- Acceptance activities
- Purchasing and supplier management and controls
- Product identification and traceability
- Purpose and role of written procedures/SOPs and other quality procedures
- Handling deviations and nonconforming product
- Handling, storage, distribution, and installation of your devices
- Complaints and failure investigations
- Records: device master records, DMR, and other quality records
- Servicing and statistical techniques
- Training and surveillance
- Change control and Good Documentation Practices (GDP)

Execution

- Who is involved and what "pay now or pay later" implies with FDA Inspections
- FDA trigger points and red-flags
- The cost of non-compliance and how much is enough in terms of risk mitigation
- Techniques and strategies on how to survive the inspection – do's and don'ts
- Recent enforcement actions taken against device firms and common issues
- Why QSIT (Quality System Inspection Technique) is a critical inspectional strategy, but preparation is the key to success
- RBPs (Recommended Best Practices)

Interactive Q&A, Wrap-Up and Adjourn

- Q&A, including their real-world challenges.
- Group discussion with emphasis on using good judgment when developing quality systems, and applying those sections of the QS regulation that are applicable to specific products and operations.

Accreditation

 Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 7 hours (0.7 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-006-L01-P. Released: 3/11.

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Comprehensive CRC Training

Course Description

This course provides an in-depth survey of the roles and responsibilities of the investigator site Clinical Research Coordinator (CRC). The course begins with an overview of the drug development process and regulatory environment in which the CRC operates. From there, critical CRC responsibilities will be discussed, including patient recruitment and retention, informed consent adverse event reporting, and investigational product accountability. The CRC's role at the site will be explored, from study start-up through site close-out, and all of the activities, site visits, and documentation that occur along the way. Finally, site audits and inspections will be reviewed, with an emphasis on the CRC's role in that process.

Learning Objectives

- Discuss the CRC role in the development of new drugs
- Describe "letter" and the "spirit" of FDA regulations, ICH Guidelines, and ethical considerations pertinent to conducting clinical trials
- Prepare for all sponsor contacts and/or site visits
- Develop strategies for recruiting and retaining subjects
- Review the reporting requirements of adverse events
- Employ study documentation requirements and standards for collecting and reporting clinical trials data
- Develop strategies for preparing, implementing, and managing clinical studies

- Identify strategies for issues management include root cause analysis and corrective and preventive action plans
- Prepare your site for an FDA inspection

Who Should Attend

- CRCs with limited experience in managing industry-sponsored investigational drug studies
- Experienced Coordinators seeking to enhance their skills to more efficiently and effectively manage their studies
- CRAs who are interested in gaining a better understanding of the CRC and investigator roles

Instructors

This course will be taught by one of the following instructors

Nikki Christison, B.S.
Erica Elefant, R.N., B.S.N., M.S.W.
Gary B. Freeman, M.S., C.C.R.A.
Karen Gilbert, B.S., C.C.R.A.
Beth D. Harper, B.S., M.B.A
Hillary Kimes, R.N., M.S.N., C.C.R.A., C.C.R.C.
Marcellina N. Oparaoji, Ed.D., B.S.N., N.R., C.C.R.P.
Elizabeth Ronk Nelson, M.P.H
Lily Romero, P.A., C.C.R.C.
Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.
Jackie Stader, C.O.T., C.C.R.C.
Jennifer Stanford, R.N., M.S.N.

Interactive Activities

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

Course Dates and Locations

April 26-27, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SCRA0412
\$1,595 by March 23
\$1,795 after March 23

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include
assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

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 mail ACPE statements within three weeks of program completion. ACPE#:
0778-0000-10-006-L01-P.
Released: 9/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Overview of Drug Development and Good Clinical Practice: Terminology; phases of drug development and introduction to GCP

The Clinical Research Team: Roles and responsibilities; appropriate delegation of investigator responsibilities

The Site Selection Process: Criteria for site selection; planning and preparing for the site qualification visit

IRBs and the Protocol Approval Process: IRB membership and operational requirements; sponsor-site-IRB relationships

Study Start-up and Study Initiation Visits: Preparations and activities

Subject Recruitment and Retention: Advertising and payment guidelines; strategies for successful recruitment

The Informed Consent Process: Documentation requirements; execution considerations

Day Two: 8:30 a.m. – 5:00 p.m.

Study Implementation and Study Documents: Regulatory files, source documents and case report forms; records retention

Monitoring Visits: Preparation and activities; simulation exercise

Managing and Reporting Adverse Events: Definitions and reporting requirements; differences in various sponsor policies

Drug Accountability and Close-Out Visits: Preparation and activities

Budgets: Development of study budgets; coordinator's role in negotiation

FDA Audits: Mechanics of an FDA inspection; common audit findings

Time Management and Prioritization: Simulation exercise

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Comprehensive Monitoring for Medical Devices

Course Description

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

Learning Objectives

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

Who Should Attend

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

Instructors

This course will be taught by one of the following instructors
Douglas E. Albrecht, B.S.N., C.C.R.A.
Gary B. Freeman, M.S., C.C.R.A.
Hillary Kimes, R.N., M.S.N., C.C.R.A., C.C.R.C.

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
- Selecting Study Sites
- Coaching Tips for an FDA Inspection

Course Dates and Locations

February 7-9, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SDOA0212
\$1,695 by January 6
\$1,895 after January 6

April 17-19, 2012
San Francisco, CA 94102
Hilton San Francisco
Course #: SDOF0412
\$1,695 by March 16
\$1,895 after March 16

June 12-14, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SDOB0612
\$1,695 by May 11
\$1,895 after May 11

Academic Discount

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Registration

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For assistance,
CALL: (800) 856-2556

Registration fees include
assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-10-007-L01-P. Released: 6/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Introduction to the FDA and the Medical Device Approval Process: Introduction to the FDA; ICH overview; definitions; medical device regulatory processes

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: 8:30 a.m. – 5:00 p.m.

Study Documentation: Sponsor files; investigator files; source documentation; case report forms; communication

Monitoring: Roles and responsibilities of the monitor during periodic visits; source document verification; case report form review and correction onsite; data retrieval and correction; document retrieval; protocol, investigational plan and GCP deviations; monitoring documentation

Day Three: 8:30 a.m. – 5:00 p.m.

Device Accountability: Sponsor responsibilities as they relate to device accountability; investigator responsibilities as they relate to device accountability

Close-out Visits: Reasons for a closeout visit; roles and responsibilities of the monitor during a closeout visit; investigator responsibilities after closeout

Managing and Reporting Adverse Events: Adverse event terminology; variations in adverse event reporting and documentation; sponsor obligations relating to adverse event reporting; investigator obligations relating to adverse event reporting

FDA Audits: Purpose, types and mechanics of FDA audits; common audit findings; FDA actions following an audit; the "do's and don'ts" in the event of an FDA audit

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Conducting Clinical Trials in Emerging Regions: Asia Pacific, Eastern Europe, India & Latin America

Course Description

In order to speed up the clinical research and product registration process, it is critical to carry out clinical studies outside what is considered traditional countries/regions (United States and Western Europe). However, conducting studies in developing countries requires very careful planning to succeed. Being ready to take full advantage of a global patient population can provide very positive patient access results, and today, emerging regions like Asia Pacific, Eastern Europe, and Latin America play a very important role in global clinical trials. Accessing these populations requires an understanding of how to approach cultural differences, language barriers, and their unique regulatory environments.

Learning Objectives

- Overcome the challenges of conducting international clinical trials in emerging regions
- Consider cultural and regulatory differences and approaches when conducting clinical trials in emerging regions
- Assess the critical issues to be considered at the time of planning a clinical trial in emerging regions
- Identify the key differences in conducting clinical trials in emerged regions versus emerging ones

Who Should Attend

This program has been designed for those clinical research professionals who are involved in the planning and execution of global clinical trials

Instructors

This course will be taught by one of the following instructors

Anna Filimonova, M.D., Ph.D.

Karen Chu, Pharm.D.

Leylén Colmegna, M.D., Ph.D.

Interactive Activities

- The workshop is based on a real case study. Attendees will be provided with sample clinical trial protocols

Course Dates and Locations

April 10-11, 2012

Boston, MA 02110

Club Quarters Boston

Course #: SDRB0412

\$1,595 by March 9

\$1,795 after March 9

Academic Discount

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

Registration

ON-LINE:

barnettinternational.com

FAX or MAIL:

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For assistance,

CALL: (800) 856-2556

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Accreditation

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Understanding the Central Eastern Europe and Latin American Environments

Clinical Trial Environment and Recommended Countries

Understanding the Overall Health Care Environment

Cultural Considerations and Approaches

Regulatory Environment

Start-Up Strategy

Day Two: 8:30 a.m. – 5:00 p.m.

India and Asia Pacific

Project Plan Development: Study start-up and regulatory plan; risk management plan (including scientific, regulatory, quality and logistic considerations); perform a study feasibility assessment; develop a patient recruitment plan

Workshop: study cases based on sample clinical protocols will be provided by the instructors and considered for different regions/countries to achieve the most efficient patient recruitment timelines and the best data quality.

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Conducting Clinical Trials in Resource-Limited Settings and Enrolling Vulnerable Subjects: Challenges and Solutions

Course Description

Globalization is a core component of the business models of pharmaceutical companies, and includes the conduct of clinical trials. Major drivers are the anticipated lower costs of research, the large pool of (treatment naive) patients, expected lower regulatory investments, and access to emerging economies. This makes the conduct of clinical trials also in resource-limited settings attractive. However, the complexity of social and ethical issues of clinical research must not be underestimated and neglected. Predictable risks and burdens must be compared to foreseeable benefits for the participants or communities under investigation. This mandates any sponsor conducting trials in resource limited settings to come up with fair and practicable solutions. Sensitivity for cultural differences is key when interacting with local investigators, authorities, monitors, and study participants. Good local knowledge is needed to navigate the challenges of the regulatory landscape. Particularly in Africa, capacities and infrastructure must often be strengthened, and many achievements taken for granted in the Western research world may pose barriers in resource-limited settings.

This course will provide practical insights into the particular challenges and caveats of the conduct of clinical trials in resource-limited settings and involving vulnerable populations, and will provide hands-on solutions and approaches.

Learning Objectives

- Identify the ethical particularities and caveats of the enrollment of vulnerable subjects from resource-limited settings into clinical trials
- Identify the consequences and implications of the conduct of clinical trials in resource-limited countries or settings
- Address the basic issues when dealing with competent authorities in resource-limited countries
- Build a basis in understanding the potential operational and logistical challenges
- Recognize the limitations of GCP and its translation into clinical research under challenging circumstances
- Recognize the impact of cultural and religious factors on the conduct of clinical research
- Build knowledge on the informed consent procedures in trials involving subjects of various cultural backgrounds
- Meet the challenges of monitoring in resource-limited settings

Who Should Attend

Clinical Research Professionals who are new to running clinical trials in resource-limited settings

Instructor

Gabriele Pohlig, Ph.D.

Interactive Activities

- Group work; case studies; role plays; discussions

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Introduction into Clinical Research in Resource-Limited Settings: Background; misconceptions; challenges

Site Selection & Capacity Building: Strategies; means; solutions

Working with Resource-Limited Competent Authorities: IECs; IRBs; regulatory authorities

The Many Ethical Caveats of Resource-Limited Settings: Overview; guidelines; respectful approaches

Informed Consent: Different cultural contexts; vulnerable populations; local languages

Day Two: 8:30 a.m. – 5:00 p.m.

The Challenge of Safety Reporting: Creating awareness and understanding; dealing with different concepts

Quality Management: No Compromises? GCP Implementation; monitoring; audits

Monitoring in Difficult Settings: Special challenges; approaches and communication; the ideal monitor

Data Capture & Management and Study Documentation & Archiving: Optimization for sites with poor infrastructure

Course Dates and Locations

March 1-2, 2012

Boston, MA 02110

Club Quarters Boston

Course #: SCCB0312

\$1,595 by January 27

\$1,795 after January 27

June 25-26, 2012

San Francisco, CA 94102

Hilton San Francisco

Course #: SCCF0612

\$1,595 by May 25

\$1,795 after May 25

Academic Discount

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

Registration

ON-LINE:

barnettinternational.com

FAX or MAIL:

Submit Registration Form (page 152) with Payment to Barnett Customer Service.

**For assistance,
CALL: (800) 856-2556**

Registration fees include assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-084-L01-P. Released: 8/11.

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Conducting Clinical Trials Under ICH GCP

Course Description

This course provides a comprehensive review of Good Clinical Practice (GCP) and FDA regulations and requirements. Participants receive a foundation of knowledge about GCP, practical examples, and the underlying scientific and regulatory principles involved. Guidelines for each aspect of research are provided, as well as information on the structuring and preparation of protocols, consent forms, and investigator 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.

Learning Objectives

- Summarize FDA GCP regulations
- Recognize how GCP impacts the clinical research process
- Prepare concise documents and provide necessary information for the clinical studies
- Maintain an ongoing relationship with the FDA

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

Instructor

Albert A. Ghignone, M.S., R.A.C.

Course Dates and Locations

February 16-17, 2012
San Diego, CA 92101
Courtyard San Diego
Downtown
Course #: SGCD0212
\$1,595 by January 13
\$1,795 after January 13

May 3-4, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SGCB0512
\$1,595 by March 30
\$1,795 after March 30

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

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Accreditation



Barnett International is accredited by the **ACPE**® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-10-008-L01-P. Released: 10/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Introduction to ICH and FDA GCPs:
History; law; regulations; definitions; FDA organization; bioresearch monitoring group; evolution of GCP; ICH process
Clinical Research Process – A Discussion and Overview of the Whole Process and Where GCP Interact: IND process; clinical research process; clinical studies

Day Two: 8:30 a.m. – 5:00 p.m.

USA Good Clinical Practice: Sponsor responsibility; investigator responsibility; IRB responsibility
ICH: Sponsor responsibility; investigator responsibility; ethics committee responsibility

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



CRA & CRC: Beginner Program

Course Description

This beginner course provides an excellent introduction to clinical research and the job responsibilities of Clinical Research Associates and Clinical Research Coordinators. It explores topics relevant to those considering a career as an entry-level monitor or site coordinator. Specifically, this course is appropriate for individuals seeking a new career or career change, but don't know which job track within clinical research to pursue.

Learning Objectives

- Describe the drug development process
- Review FDA regulations and guidelines for Good Clinical Practices
- Define the roles and responsibilities of the Clinical Research Associate and the Clinical Research Coordinator
- Describe the role of the Investigator in 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 required elements for the informed consent document, exceptions for obtaining consent, and the role of the CRA and the CRC in the process
- Describe an overview of Monitoring Visit, the responsibilities of the CRA and CRC including pre- and post-Monitoring Visit activities
- Define source documents and Case Report Forms (CRFs) in relation to the source document verification

- Identify strategies to manage clinical research site activities
- Review the identification and management of issues during a clinical trial

Who Should Attend

- Aspiring Clinical Research Coordinators
- Aspiring Clinical Research Associates – In-house or Field-based
- College Students
- Nurses
- New College Graduates – Any Discipline
- NOTE: This course is also appropriate for CRAs or CRCs with less than 6 months experience.

Instructors

This course will be taught by one of the following instructors

Nikki Christison, B.S.
 Erica Elefant, R.N., B.S.N., M.S.W.
 Karen Gilbert, B.S., C.C.R.A.
 Beth D. Harper, B.S., M.B.A.
 Hillary Kimes, R.N., M.S.N., C.C.R.A., C.C.R.C
 Elizabeth Ronk Nelson, M.P.H
 Marcellina N. Oparaoji, Ed.D., B.S.N., R.N.,
 C.C.R.P.
 Lily Romero, P.A., C.C.R.C.
 Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A.,
 C.C.R.C.
 Jackie Stader, C.O.T., C.C.R.C.
 Jennifer Stanford, R.N., M.S.N.
 Kimberly Turner, C.M.A., A.S., B.H.S., C.R.A.

Interactive Activities

- Situational Reviews
- Study Protocol Review Simulation
- Informed Consent Review Simulation
- CRC Simulation
- CRA Simulation

Course Dates and Locations

February 7-9, 2012
Philadelphia, PA 19103
 Club Quarters Philadelphia
 Course #: SCOA0212
 \$1,695 by January 6
 \$1,895 after January 6

May 9-11, 2012
San Francisco, CA 94102
 Hilton San Francisco
 Course #: SCOF0512
 \$1,695 by April 6
 \$1,895 after April 6

June 18-20, 2012
Boston, MA 02110
 Club Quarters Boston
 Course #: SCOB0612
 \$1,695 by May 18
 \$1,895 after May 18

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
 Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-10-016-L01-P. Released: 6/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Acronyms & Terminology

FDA Regulations and Guidelines for Good Clinical Practice

Clinical Research Team: Roles & Responsibilities

Day Two: 8:30 a.m. – 5:00 p.m.

The Clinical Investigator and Site Selection

Clinical Study Protocol Elements & Statistical Considerations

Institutional Review Board, the Consent of Human Volunteers

Interactive Exercise I

Study Monitoring, Data Management and the Study Initiation Visit

Day Three: 8:30 a.m. – 5:00 p.m.

Safety Reporting: Definitions & Reporting Requirements

Accountability for the Test Article & the Termination Visit

Regulatory Compliance & Quality Assurance: Audits & Inspections

Managing Your Time & the Interview

Interactive Exercise II

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



The CRA Manager Course

Course Description

The focus of this workshop is to strengthen the skills required of the CRA Manager to effectively manage, motivate, and optimize the performance of CRA teams. In this course, you will sharpen your people skills and develop an understanding of the key components of successful project and performance management. This course is a must for new and aspiring managers.

Learning Objectives

- Practice the basics of writing clear, fair objectives
- Identify competency models, including metrics, to establish performance expectations
- Define motivational methods for employees
- Practice strategies for "Win-Win" conflict resolution
- Discuss the goals and limitations of performance reviews
- Examine how to remove barriers to effective delegation
- Identify the elements of a high performing team
- Review the development of contingency plans for projects

Who Should Attend

- Managers, Clinical Project Coordinators, or newly promoted Project Team Leaders who are responsible for managing clinical personnel

- Experienced CRAs who are becoming involved, or hope to become involved, in managing projects and/or people
- Technically-Trained Staff with little or no management experience

Instructors

This course will be taught by one of the following instructors

Gary B. Freeman, M.S., C.C.R.A.
 Karen Gilbert, B.S., C.C.R.A.
 Beth D. Harper, B.S., M.B.A.
 Marcellina N. Oparaoji, Ed.D., B.S.N., R.N., C.C.R.P.
 Elizabeth Ronk Nelson, M.P.H.
 Lily Romero, P.A., C.C.R.C.
 Sandra "SAM" Sather, R.N., C.C.R.A., C.C.R.C.

Interactive Exercises

- Developing a Performance Model Based on Performance Competencies
- Active Listening
- Effective Feedback
- Analyzing Motivation
- Identifying Conflict
- Conflict Management Style Survey
- Problem Solving
- Delegation: A Self-test
- Several document templates will be provided for you to customize and use during your daily activities as a Manager
- Examples and interactive exercises will pertain specifically to managing Clinical Research Associates (CRAs)

Course Dates and Locations

March 15-16, 2012
San Francisco, CA 94102
 Hilton San Francisco
 Course #: SCMF0312
 \$1,595 by February 17
 \$1,795 after February 17

June 18-19, 2012
Boston, MA 02110
 Club Quarters Boston
 Course #: SCMB0612
 \$1,595 by May 18
 \$1,795 after May 18

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
 Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-10-009-L01-P. Released: 10/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Introduction: Defining the role of the CRA manager

Establishing Competencies, Setting Objectives, and Metrics: Establishing a model for performance expectations; the process of establishing competencies; writing a "good" performance objective

Interviewing CRA Candidates: Candidate selection: the process; developing a "blueprint" for each job description

Listening Skills: Behaviors leading to effective communication; verbal/nonverbal communication

Effective Feedback: Criteria for useful feedback; "I" messages; providing praise; constructive criticism

Motivation: Motivational theory; how power factors into motivation; rewards, discipline/punishment; motivational techniques

Day Two: 8:30 a.m. – 5:00 p.m.

Coaching and Counseling: When you should coach versus counsel; coaching/counseling methods; unfreezing a difficult situation

Conflict Resolution: Characteristics of conflict; conditions for constructive resolutions of conflict; initiating a "Win-Win" confrontation

Analyzing Performance Problems: Steps for analysis; cause factors; managing difficult employees; progressive discipline

Performance Appraisals: Steps for performance appraisal delivery; performance appraisal tips

Delegation: Benefits to delegation; effective delegation steps

Project Management Overview and Team Building: Rationale for planning project; the project plan; contingency planning; project/

team communication skills; elements of teamwork

Management Tips

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



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

Course Description

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

Learning Objectives

- Assess the impact of the regulations on Data Management
- Discuss the rationale and enhancements regarding the utilization of EDC

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

Who Should Attend

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

Instructor

Denise G. Redkar-Brown

Interactive Activities

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

Course Dates and Locations

February 6-7, 2012

Boston, MA 02110

Club Quarters Boston

Course #: SELB0212

\$1,595 by January 6

\$1,795 after January 6

June 5-6, 2012

Philadelphia, PA 19103

Club Quarters Philadelphia

Course #: SELA0612

\$1,595 by May 4

\$1,795 after May 4

Academic Discount

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

Registration

ON-LINE:

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For assistance,
CALL: (800) 856-2556

Registration fees include assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-039-L01-P. Released: 10/09.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

The Regulatory Environment for the Utilization/Consideration of EDC: Overall review of the 21 CFR Part 11 regulations; e-signature requirements for FDA, EU, and Japan

Transitioning from Paper CRF to EDC: Examine the considerations surrounding the adoption of EDC while still working in a paper environment

The Changing Role of the CDM: The CDM was process driven, whereas the EDC environment has moved the focus from process to Project Management

Study Start-up, Protocol Synopsis Review, eCRF Development: Examine the activities associated with the study start-up in an EDC environment; discuss eCRF development and also the impact that CDISC/CDASH may have on future CDM endeavors

Best Practices in eCRF Development: Review the best practices as they relate to EDC activities and the issues surrounding eCRF creation/testing

Day Two: 8:30 a.m. – 5:00 p.m.

User Acceptance Testing (UAT): How does the application work? How do we test it or try to “break” it?

Creating the Data Management Plan: The documentation required for a robust DMP when utilizing an EDC application; reviewing the components of the DMP as described by the Society of Clinical Data Management Good Clinical Data Management Practices (SCDM GCDMP)

Ancillary Documentation for EDC: What do we need for training the users in the application? Navigation documentation, query resolution hints, report generation

External Electronic Data: Lab data, ECG data – can the application accept data uploads?

Outsourcing EDC DM Issues: Vendor outsourcing, discussion surrounding evaluation of vendors for total CDM projects or vendor development of eCRFs

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Developing Clinical Study Budgets

Course Description

This course provides the practical skills needed to construct and negotiate study budgets that appropriately compensate investigative sites for resource needs required as a result of clinical research protocols.

Learning Objectives

- Analyze protocols to assess resource needs
- Develop study budgets that adequately reimburse sites for their time and effort
- Use various approaches for structuring study budgets
- Utilize software to develop budgets and track study costs
- Identify important aspects of negotiating study budgets

Who Should Attend

- Clinical Trial Personnel (Clinical Research Coordinators, Investigators) responsible for preparing and implementing study budgets

- Sponsor Representatives in the pharmaceutical industry
- Contract Research Organization and Consultant Representatives whose function is to design and/or apply study budgets for sites

Instructors

This course will be taught by one of the following instructors

Karen Gilbert, B.S., C.C.R.A.
Marcellina N. Oparaoji, Ed.D., B.S.N., R.N.,
C.C.R.P.
Lily Romero, P.A., C.C.R.C.
Jackie Stader, C.O.T., C.C.R.C.

Interactive Activities

- Core Concepts
- Case Study

Course Dates and Locations

March 1, 2012
San Diego, CA 92101
Courtyard San Diego
Downtown
Course #: SDBD0312
\$800 by January 27
\$1,000 after January 27

Academic Discount

A \$100 academic discount is available to those who qualify.

Registration

ON-LINE:
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Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

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

Participants will receive 7 hours (0.7 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-002-L01-P. Released: 3/11.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Protocol Dissection Techniques: Assessing protocol feasibility; determining resource needs

Negotiation Considerations: Identifying negotiable items; performance-based contracts; payment schedules

Developing the Study Budget: Identifying line items; accounting for the site's time; fee for service, fixed and fixed-unit pricing structures; case study

Technology to Enhance the Budget Development Process

Protocol Dissection Techniques: Using spreadsheets; clinical study software programs

Tracking Payments and Financial Reports: Accounting systems; tracking and managing payments; financial reports



NEW! Developing CRAs as Study Managers

Course Description

The person that has the most contact with the site is the 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. 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 study managers in their skills.

Learning Objectives

- Evaluate the role of the CRA as the first point of contact and expert on a study
- Explain the importance of live conversations with the site
- Demonstrate advanced monitoring and communication techniques for the challenging site

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

Who Should Attend

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

Instructors

This course will be taught by one of the following instructors

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

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 Locations

March 15-16, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SPXF0312
\$1,595 by February 17
\$1,795 after February 17
June 7-8, 2012
San Francisco, CA 94102
Hilton San Francisco
Course #: SPBO0612
\$1,595 by May 4
\$1,795 after May 4

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-027-L01-P. Released: 3/12.

COURSE OUTLINE

- Day One: 8:30 a.m. – 5:00 p.m.**
- Introduction: The CRA as a Study Manager
 - Adult Learning Techniques
 - Techniques for Managing Challenging Situations
 - Developing Conversation Techniques: Hands-On Activity
 - Addressing Difficult Topics during a Monitoring Visit
 - Recruitment and Retention Tools
 - Introduction of a Recruitment Plan

- Day Two: 8:30 a.m. – 5:00 p.m.**
- Review of Building Blocks from Day One
 - What a CRA Needs to Successfully Manage a Site
 - Prioritizing Workload and Challenges: Hands-On Activity
 - Developing a Recruitment Action Plan: Hands-On Activity
 - Action Plan Overview and Debrief
 - Monitoring Plan Development: Must-Haves to Support CRAs
 - Project Management Tools and Techniques
 - Putting Project Management into Practice for Site Management

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Drug Approval Process: Preparation and Processing of INDs and NDAs

Course Description

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

Learning Objectives

- Navigate the FDA drug approval system
- Prepare an IND
- Prepare an NDA
- Navigate the FDA review process

Who Should Attend

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

Instructor

Albert A. Ghignone, M.S., R.A.C.

Course Dates and Locations

June 14-15, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SDPA0612
\$1,595 by May 11
\$1,795 after May 11

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include
assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

 Barnett International is accredited by the ACPE 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-10-003-L01-P. Released: 10/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

General Perspective: History; law; definitions; overview of FDA; establishment registration; product listing; regulatory strategy

IND Process: FDA IND Form 1571; cover letter; table of contents; introduction; investigational plan; chemistry, manufacturing, and control; nonclinical studies (pharmacology and toxicology); clinical studies; investigator brochure; labeling; USAN procedures; compiling IND; IND filing; IND review process; amendments to IND; safety reports; annual reports; IND withdrawal; IND termination

Day Two: 8:30 a.m. – 5:00 p.m.

NDA Process: FDA NDA Form 356(h); cover letter; index; labeling; summary; chemistry section (chemistry, manufacturing, and controls information; samples; methods validation package); nonclinical pharmacology and toxicology section; human pharmacokinetics and bioavailability section; clinical data section; safety update report; statistical section; case report tabulations; case report forms; patent information on any patent which claims the drug; patent certification; establishment description; debarment certification; field copy certification; user fee cover sheet; compiling NDA; NDA amendments; NDA review process; post-approval requirements

Exploratory IND: Clinical information; CMC information; safety program designs; GLP compliance

Clinical Trials: Phase 0 studies; Phase 1 studies; Phase 2 studies; Phase 3 studies; Phase 4 studies

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Drug Development and FDA Regulations: A Regulatory Overview

Course Description

This course provides a comprehensive overview of the drug development process, including GLP, GCP, and GMP processes. It is specially geared toward new industry professionals who need to develop an understanding of the drug development process.

Learning Objectives

- Discuss the FDA's role in drug development
- Explain the logic of the drug development process
- List content requirements of IND/NDA
- Cite the basics of clinical trial structure and design
- Explain the post-approval responsibilities of sponsors
- Describe the fundamentals of Good Laboratory Practice (GLP), Good Clinical Practice (GCP), and Good Manufacturing Practice (GMP)
- Examine the structure and process of the FDA review of an IND/NDA

Who Should Attend

- Clinical Research Associates and Auditors who want a greater understanding of the drug development process and their role in it

- Regulatory Affairs Professionals who may be new to their positions or want a more complete understanding of how the FDA regulates new drug development
- Clinical Research Coordinators who want to learn about the drug development process
- GMP Specialists and those involved in device development that find themselves moving into the drug development area
- Project Managers who need an overview of all areas of drug development and the interrelationship and interdependence of other departments

Instructors

This course will be taught by one of the following instructors

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

Interactive Activities

- What is a New Drug? Group Activity
- Patient Enrollment through Various Phases of Development

Course Dates and Locations

May 8-9, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SDDA0512
\$1,595 by April 6
\$1,795 after April 6

Academic Discount

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

Registration

ON-LINE:
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For assistance,
CALL: (800) 856-2556

Registration fees include
assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

 Barnett International is accredited by the ACPE 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-019-L01-P. Released: 10/09.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

- Introduction
- History
- Law
- Logic of Drug Development
- The FDA's Role in Drug Development
- Non-Clinical Drug Testing – Good Laboratory Practices
- The Gateway to Clinical Testing: FDA advisory committees
- The IND: General content of the IND; commercial INDs; investigator INDs; treatment INDs; emergency-use INDs
- The FDA's IND Review: The structure of FDA review; the 30-day review process

Day Two: 8:30 a.m. – 5:00 p.m.

- The Clinical Testing of New Drugs:** The structure of clinical trials (Phase I, II, and III); clinical trial design – five types of controls
- Good Clinical Practices:** The three elements of GCP (sponsor responsibility, investigator responsibility, IRB responsibility)
- The NDA and the NDA Review:** NDA content; sponsor responsibility during NDA review; the FDA and its review; FDA advisory committees
- Post-Approval Sponsor Responsibilities:** NDA field alert; annual reports; adverse drug reports; advertising/promotional labeling; GMP review process

Hold this Course at Your Company: In-person or On the Web!
Call (215) 413-2471 for more information



Drug Safety and Pharmacovigilance: Effective Drug Safety Reporting and Surveillance

Course Description

This course will deliver an introduction to the basics of drug safety and pharmacovigilance, including regulatory requirements, adverse event reporting, signaling and risk management. This course addresses the regulatory issues across global government 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 the regulatory references, processes, best practices, and analysis and investigation techniques to minimize risk, avoid product recall, and meet international safety and reporting standards.

Learning Objectives

- Work to international standards by meeting regulatory requirements for product safety
- Perform signaling and risk management functions

- Collect, assess, report, and analyze adverse events
- Create signaling analyses based on FDA Good Pharmacovigilance Practices
- Identify differences between US and European legal requirements

Who Should Attend

- Drug Safety Professionals
- Pharmacovigilance Staff
- Regulatory Affairs Professionals
- Clinical Development Staff

Instructor

Steve Jolley

Interactive Activities

- Signaling Exercises: Analysis of PSUR data by MedDRA System Organ Class, Preferred Term, Age Range, Sex, Country, Time to Onset, and Concomitant Medications
- Quiz on "The Pharmacovigilance Audit"

Course Dates and Locations

March 27-28, 2012
San Francisco, CA 94102
Hilton San Francisco
Course #: SSVF0312
\$1,595 by February 24
\$1,795 after February 24

June 14-15, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SSSVA0612
\$1,595 by May 11
\$1,795 after May 11

Academic Discount

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

Registration

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Overview of Pharmacovigilance: Thalidomide and History of Pharmacovigilance; Limitations of Pre-approval Clinical Trials; Post-Marketed AEs; Pharmacovigilance Definitions; Assessing Adverse Events; Serious vs. Severe; Causality; Expectedness; SUSAR; Minimum Criteria for Reporting; Reporting Format; Managing Blinded Therapy Cases; Sponsor Responsibilities; Monitor Responsibilities; Principal Investigator Responsibilities; Adverse Reaction Types; Safety Signal Generation

Day Two: 8:30 a.m. – 5:00 p.m.

Pharmacovigilance Compliance: Matrix of Safety Regulations; International Conference on Harmonisation (ICH); CIOMS; Key EU Components; EU Member States; Eudravigilance; EU Clinical Trial Directive; Volume 10; Volume 9A; European Signaling Regulations; ASR, IND, DSUR reports

PV Audits - Preparing for a Pharmacovigilance Audit; Achieving Best Practices; Scope; PV Checklist; Case Studies; Eight Domains of PhV; Key Findings by MHRA; Quiz on Regulations & Compliance

Signaling & Risk Assessment: Need for Signal Detection; the Cost of Failure; Regulatory Requirements for Signaling; EMEA Signaling Legislation; MHRA & Signal Detection; Approach to Signal Detection; Sample Signaling Analyses; Methodologies: MGPS, BCPNN, PRR; Signaling Process; Product Safety Profile; Risk Management Planning; Quick Quiz for Signaling

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Effectively Writing Clinical Trial 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 ultimately market approval.

Over the course of any development plan, new protocols, protocol amendments, and protocol concept sheets will be needed on an ongoing basis. Though they require similar information, protocols for Phases 1, 2, 3 and 4 require different writing approaches. As a writer of a protocol, you need to know what the agency expects to see 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. Amendments need to be managed efficiently to avoid costly implementation or delays to the ongoing trial.

Learning Objectives

- Improve basic writing skills
- Implement a style guide
- Describe the overall structure of a protocol and regulatory requirements
- Differentiate between the phases of investigation and how Phase 1-4 protocols differ in their content
- Identify who contributes to the protocol development and amendments
- Manage the timeline for protocols and their amendments
- Manage the review and commenting process
- Hold protocol review meetings
- Describe the requirements for a protocol, including:
 - Establishing the indication(s)
 - Writing the Concept Sheet to guide research
 - Types of studies (prospective, observational, retrospective)
 - Design (single blind, double blind, randomized, etc.)
 - How to conduct literature searches, organize the articles, and develop a background for the disease

including the current standard of care (SOC)

- Using regulatory precedence and literature to establish metrics, and primary and secondary endpoints
- What to do when there are no established metrics for a particular indication
- Establishing the hypothesis
- What is safety and efficacy and how do you establish either or both
- Using the Synopsis as an outline for the protocol
- Determining inclusion/exclusion criteria
- Determining the Schedule of Events
- Determining the initial expected adverse events and serious adverse events and rate of occurrence (based on background disease and related compounds)
- Adverse and serious adverse event reporting
- Statistics (sample size, etc.)
- External Key Opinion Leader review
- How to manage the references
- QA and final sign off of protocol
- Informed consent development based on final protocol
- Case report form development based on the final protocol

- Determine what happens next: distribution to regulatory agencies, sites, and IRB review
- Develop protocol amendments: how and when to do it and documentation needed

Who Should Attend

Drug or device professionals looking to explore the mechanics of putting together a clinical protocol including: medical writers, clinical research associates, study coordinators, regulatory affairs personnel, engineers, pre-clinical personnel, or physicians.

Instructor

Meredith Brown-Tuttle, R.A.C.

Interactive Activities

- Mock drug will be researched
- Protocol for a Phase 1, 2, or 3 drug will be constructed in a group activity

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

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

Day Two: 8:30 a.m. – 5:00 p.m.

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

Course Size will be limited to 16.

Course Dates and Locations

March 8-9, 2012
Philadelphia, PA 19103
 Club Quarters Philadelphia
 Course #: STPA0312
\$1,595 by February 10
\$1,795 after February 10

June 7-8, 2012
Boston, MA 02110
 Club Quarters Boston
 Course #: STPB0612
\$1,595 by May 4
\$1,795 after May 4

Academic Discount

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Registration

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Effectively Writing 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 about the compound changes, and is critical in clinical research as physicians and IRBs refer to the IB on an ongoing basis to answer questions about Serious Adverse Events, Adverse Events, dosing information, manufacturing information, clinical and nonclinical study results. The IB needs to be updated during the course of the clinical investigation; update frequency is dictated by the product and the company.

To facilitate the transfer of information, the IB must be concise, well written and provide a summary for a physician to quickly reference. While ICH E6 and 21 CFR 312.23 provide an outline of the requirements, how companies address these requirements and the degree of information provided differs. We will review the IB's required contents, tips and techniques

for creating a "highlights" synopsis, strategies for gathering the required data, effective writing techniques with teams, and strategies for the editing, review, and frequency of content updates.

Learning Objectives

- Describe the IB, section by section
- Discuss regulatory requirements and definitions of an IB per ICH E6 and 21 CFR 312.23
- Identify who contributes to the IB
- Provide timing of construction of the IB
- Identify the IB audience (s)

Who Should Attend

- Regulatory Affairs
- Medical Writers
- Clinical Research
- Research and Development

Instructor

Meredith Brown-Tuttle, R.A.C.

Interactive Activities

Review of effective and not so effective Investigator's Brochures.

Course Dates and Locations

March 26, 2012
San Francisco, CA 94102
Hilton San Francisco
Course #: SEWF0312
\$800 by February 24
\$1,000 after February 24

Academic Discount

A **\$100** academic discount is available to those who qualify.

Registration

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Accreditation

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Participants will receive 7 hours (0.7 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test and program evaluation. Barnett International will mail ACPE statements within three weeks of program completion. ACPE# 0778-0000-11-083-L01-P. Released: 9/11.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

- Review the need and regulatory requirements for an IB
- Review of the IB, Section by Section
- Managing the review team and timeline for first drafts and updates
- Length of IB
- How a Target Product Profile or Draft Package Insert can be drafted based on IB
- When should the IB be updated, by who and what documents the update effects
- Audience for the IB (including their needs and perspective)
- How to write the various sections of the IB
- How best to conduct the IB team review and edit the IB (initial and update)
- How to write the Draft Package Insert based on the IB
- When to update the IB and what to include



Facilitation Skills for Clinical Research Team Members

Course Description

A facilitator can be defined as an individual whose job is to help manage a process of information exchange. Clinical research team members' roles include facilitation, but many are not trained in this skill set, even though it is one that is considered not inherent. Facilitation has systemic impacts on the success of projects that depend on efficient information exchange. A Sponsor/CRO and/or Research Site team member's success as a facilitator can greatly impact the success of a clinical trial, from patient recruitment to final report submission processes. This course defines facilitation specifically within a clinical research setting with a focus on successful clinical trials, including compliance performance improvement. The presentation is in a workshop format, providing application of facilitation tools presented.

Learning Objectives

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

Who Should Attend

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

Instructors

This course will be taught by one of the following instructors

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

Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Jackie Stader, C.O.T., C.C.R.C.

Elizabeth Weeks-Rowe, L.V.N., C.C.R.A.

Interactive Activities

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

Course Dates and Locations

April 13, 2012

Boston, MA 02110

Club Quarters Boston

Course #: SFSB0412

\$800 by March 9

\$1,000 after March 9

Academic Discount

A \$100 academic discount is available to those who qualify.

Registration

ON-LINE:

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Accreditation

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Current State of Affairs Between Clinical Research Stakeholders:

Key problem issues in the industry will be discussed relating to the current approach's successes and failures; a collection of success factors will be assessed for common themes; effective facilitation will be noted as one of the key leadership qualities of those successes and missing in many of the failures

Facilitation: Definition of core terms and concepts; applying definitions to industry positive and negative examples

Developing Research Team Members' Skills for Facilitation

Facilitation Core Practices: Each core practice will be presented and practiced with the attendees; combinations of practices will also be presented; industry case scenarios will be presented to emphasize the impact of strong and weak facilitation practices on projects

Core Practice Application: In Facilitation core practices applied to specific issues in clinical trials for different stakeholder; recruitment, compliance, and more. Interactive exercises applied so that the participants work to identify effective and ineffective practices in facilitation

Facilitation Practice Tools: Many of the dozens of tools to support effective facilitation will be presented and applied in break-out sessions; ranking the value of the tools in certain settings will be accomplished

Designing Project Communication to

Support Effective Facilitation: Cross stakeholder application of core practices and tools within current best practices, including pre-study to termination activities

Developing Research Team Members' Skills for Facilitation:

The multiple tools supplied in the course will be applied throughout for different roles in the teams, sponsors, and sites

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



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

Course Description

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

Learning Objectives

- Discuss types of FDA meetings
- Apply the regulations and guidance for meeting with the Agency
- Develop questions and issues for the meeting request and package
- Time the meeting request
- Time the meeting package

- Organize the meeting package (using the traditional or Target Product Profile format)
- Manage meeting logistics (including who should attend)
- Manage meeting decorum
- Conduct meeting rehearsals
- Take meeting minutes and submit them to the Agency
- Confirm Agency meeting minute receipt
- Ask for clarification if the agency's meeting minutes do not reflect important discussion points
- Examples of mock meeting packages will be provided for discussion and to illustrate how the types of meetings differ at each stage of development

Who Should Attend

Any part of the device or drug development team who wishes to know more about FDA meeting logistics such as regulatory, quality assurance, manufacturing, clinical, project management, and pre-clinical personnel will all benefit from this course.

Instructor

Meredith Brown-Tuttle, R.A.C.

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 Dates and Locations

May 10, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SF1A0512
\$800 by April 6
\$1,000 after April 6

Academic Discount

A **\$100** academic discount is available to those who qualify.

Registration

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

- Introduction to the ABCs and 123s of FDA meetings
- How to develop and track questions and issues for a meeting request and package
- The basic components of a meeting request and timing for submission (this will be a class activity for a mock product or real one if provided by participant)
- Timing of the meeting request and coordination of the team's schedule
- Scheduling the meeting with the FDA
- Meeting package contents and/organization
- Managing the timeline
- Drafting, reviewing, and finalizing the meeting package
- Meeting package submission logistics

- Meeting logistics (where to stay, travel schedule arrangement)
- Meeting decorum
- Meeting rehearsals
- How to take meeting minutes and when to submit them to the Agency
- How to ask for clarification if the Agency's meeting minutes do not reflect all important discussion points
- Mock Meeting - A mock meeting package will be provided to the participants for reading ahead of the course along with "Rules of Engagement" for the mock meeting. One half of the class will represent a specific discipline from the Sponsor and defend the package while the other half of the participants will represent a specific discipline from the FDA

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Fraud in Clinical Research: Detection and Deterrence

Course Description

The issue of fraud has once again become a focus within the clinical research industry. Although high-profile cases tend to periodically pique our interest, ensuring the integrity of data and the protection of participants during the conduct of clinical research is an ongoing process. Developing and incorporating systems for detecting and preventing fraud should be a standard part of any compliance plan.

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

Learning Objectives

- Define, and differentiate between, fraud and misconduct/noncompliance
- Develop an understanding of why and how fraud occurs
- Describe the current focus of regulatory and Congressional bodies
- Examine methods for detecting and preventing fraud and misconduct
- Explain the Sponsor/CRO, IRB, Clinical Investigator, and Study Staff role in detection and prevention

- Assess the impact and consequences of fraud in clinical research
- Review regulatory and industry documents from recent fraud cases
- Implement proactive risk analysis and internal controls for investigating and containing suspect clinical data

Who Should Attend

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

Instructor

Elizabeth Ronk Nelson, M.P.H.

Interactive Activities

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

Course Dates and Locations

May 3-4, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SFUB0512
\$1,595 by March 30
\$1,795 after March 30

Academic Discount

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

Registration

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Fraud versus Noncompliance: Review and Identification

Elements of Fraud

Everyone is Suspect: Key Players in Perpetration and Prosecution

Landmark and Recent Cases of Fraud in Clinical Research

Day Two: 8:30 a.m. – 5:00 p.m.

Developing the Case: Detection, Documentation, and Dissemination

Regulatory Authorities: Current Focus and Findings

Novel Approaches: Elements for Prevention of Fraud in Clinical Research

Interactive Case Studies

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Gap Analysis: How to Bridge the Non-Approvable to the Approved Marketing Application

Course Description

A gap analysis is an assessment tool to help identify differences between "the space where we are and where we want to be." A gap analysis helps bridge that space by highlighting which requirements are being met and which are not. The tool provides a foundation for measuring the investment of time, money, and human resources that's required to achieve a particular outcome, such as an approved marketing application.

It is with much anticipation and effort that an NDA/BLA is planned and published, as the goal of your company is to get an approved NDA and a marketed product. You implement this goal by creating a regulatory strategy to ensure (with all the factors that are in your control) that the NDA gets approved the first time it is submitted. How do you do this? By performing a gap analysis. In drug development, a gap analysis is the review of each component of a drug development plan, by non-stakeholders or internal stakeholders, at a certain point in time to identify "gaps" in the filing. This gap analysis will ultimately lead to creating a strategy to deal with the "gaps" and reduce the chance of another review cycle.

Learning Objectives

- Determine what a Target Product Profile and Regulatory strategy documents can look like
- Identify the "tools" needed to conduct a gap analysis from the perspective of:
 - Clinical
 - Nonclinical-CMC
 - Publishing
- Discuss gap analysis fundamentals
 - Why conduct a gap analysis
 - How to organize a gap analysis
 - Choose external experts and consultants to help conduct or review the gap analysis

- Budget and prepare a timeline for the gap analysis (for both large and small companies)
- Bring together all consultant feedback and present finding to the team in an organized and concise manner for risk determination and mitigation planning
- Get the needed information to put together the review package
- Determine what will the final product look like
- Determine who will put the package together and review the final output
- Integrate the findings in the drug development process/regulatory strategy
- Improve your marketing application's chance of getting approved during its first cycle review

Who Should Attend

Any part of the drug development team who wishes to know more about gap analysis and first cycle approval. Regulatory quality assurance, manufacturing, clinical, project management, and pre-clinical personnel will all benefit from this course.

Instructor

Meredith Brown-Tuttle, R.A.C.

Interactive Activities

A mock drug development program will be reviewed, and participation from the attendees will be used to help locate "gaps" to approval. Templates will be provided to the attendees to help produce a gap analysis.

Course Dates and Locations

June 22, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SGYB0612
\$800 by May 18
\$1,000 after May 18

Academic Discount

A **\$100** academic discount is available to those who qualify.

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include
assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

 Barnett International is accredited by the ACPE Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 7 hours (0.7 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test and program evaluation. Barnett International will mail ACPE statements within three weeks of program completion. ACPE#: 0778-000-10-019-L01-P. Released: 9/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

- Target Product Profile
 - Regulatory Strategy
 - Gap Analysis Fundamentals: How, Who, Where, When, and Why
 - Internal reviews
 - External reviews
 - Budget
 - First cycle approval rates
- How to apply the findings to the current drug development program
 - How to maintain the gap analysis
 - Hands on exercise: conducting a mock gap analysis

Hold this Course at Your Company: In-person or On the Web!
Call (215) 413-2471 for more information



Global GCP Monitoring: Domestic and International Compliance

Course Description

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

Learning Objectives

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

Who Should Attend

- Clinical Research Coordinators
- Clinical Research Associates
- Principal and Sub-Investigators
- Clinical Research Assistants
- Quality Assurance and Other Regulatory Professionals

Instructors

This course will be taught by one of the following instructors

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

Interactive Exercises

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

Course Dates and Locations

May 3-4, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SGMA0512
\$1,595 by March 30
\$1,795 after March 30

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include assorted breakfast items that will be available each day $\frac{1}{2}$ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

 Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-10-011-L01-P. Released: 10/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

- Introduction and Welcome
- Ethics in Clinical Research – An Overview
- FDA GCP
- ICH GCP
- European Union Directive and GCP
- Summary and Q&A

Day Two: 8:30 a.m. – 5:00 p.m.

- Specific Country Regulatory Bodies
- Culture Impacts on GCP
- GCP Exercises
- Wrap-up and Course Evaluation

Hold this Course at Your Company: In-person or On the Web!
Call (215) 413-2471 for more information



Global IND Submissions

Course Description

As drug companies seek to penetrate global markets and get new drugs to markets more quickly, they are increasingly conducting drug and biologic clinical studies outside the United States. The regulatory affairs professional must keep abreast of the ever-changing regulatory climate, and be able to complete IND-like submissions in a variety of formats, and with country/regulatory agency-specific requirements in mind.

This course will walk the participants through the country requirements, IND submission requirements, and timelines for approval in Canada, the EU, South Africa, Australia, Asia, and South America using the U.S. IND as the basis for comparison. After the initial IND filings are reviewed, what work will be needed for maintaining the submission and closing the trial will be examined.

Learning Objectives

At the end of this course, the participant will be familiar with how to:

- Find information about country specific regulations
 - Navigate regional regulatory requirements for IND-like submissions
 - File an IND-like submission
 - Identify translations needed
 - Establish timelines for approval of submissions
 - Maintain an IND-like submission
 - Anticipate what is needed when the trial ends
- The focus of the course will be on in-depth coverage of the Canadian and EU Clinical Trial Application (CTA), going over the forms, required contents, re-use of information, and country specific requirements information. In addition, for Canada, the EU, and the other countries, the following information will be covered:
- Overview of the country
 - Pertinent laws and regulations
 - MOH address and contact

- Clinical trial documents needed
- Clinical Trial Applications
- Responding to agency questions
- Regulatory approval, process, and timelines
- Submission logistics
- GCP and GMP requirements
- Ethics committee requirements
- Informed consent
- Insurance requirements
- Labeling of clinical supply
- Importing requirements
- Fees
- Serious adverse event reporting
- Annual reporting
- Amendments
- Inspections

Mock EU and Canadian CTAs will be provided as a reference.

Who Should Attend

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

Instructor

Meredith Brown-Tuttle, R.A.C.

Interactive Activities

- As a team, preparing a list all the documents needed to start a trial and compare them across different countries
- Understanding the requirements for Canadian and EU forms and applications

Course Dates and Locations

April 12-13, 2012
San Francisco, CA 94102
Hilton San Francisco
Course #: SRGF0412
\$1,595 by March 9
\$1,795 after March 9

June 14-15, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SRGB0612
\$1,595 by May 11
\$1,795 after May 11

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

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Accreditation

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

The following countries will be reviewed, in detail, for their IND-like submissions and maintenance:

- Canada
- EU (all EU countries, including Iceland, Switzerland, and Norway but not Liechtenstein, Luxemburg, Monaco, or San Marino)
- Eastern EU (Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Russia, Slovak Republic, Slovenia, Turkey, and Ukraine; but not Belarus, Moldova, or Yugoslavia)
- EU Accession Countries (Albania, Bosnia-Herzegovina, Croatia, Kosovo, Macedonia, Montenegro, and Serbia)

Day Two: 8:30 a.m. – 5:00 p.m.

Review the IND-like contents, submissions requirements, maintenance, and end-of-trial documents for:

- West and South Africa
- India
- China
- Japan
- Australia
- Middle East (Egypt, Israel, Saudi Arabia, United Arab Emirates)
- Asian countries overview of clinical trial documentation requirements
- Latin South American countries overview of clinical trial documentation requirements

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Good Clinical Practice for the Laboratory Scientist

Course Description

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

Learning Objectives

- Review the drug development process from discovery through post-market
- Describe the regulated environment in which clinical studies are conducted, including the handling/analyzing of biological specimens
- Discuss the fundamentals of GLP, GCP and GMP and where/how they apply
- Provide examples and impact of non-compliance with GLP/GCP

- Describe the role of quality management in GCP laboratories and the standards to have in place that will ensure compliance
- Discuss outsourcing clinical laboratory activities to minimize compliance risks
- Identify the role of laboratory accreditation in clinical studies
- Discuss the additional challenges related to specimen collection when conducting global studies

Who Should Attend

- Laboratory scientists
- Research assistants
- Laboratory supervisors
- Principal scientists
- Research personnel that write protocols and/or handle/analyze biological specimens collected during a clinical study (analysis for drug metabolites, biomarkers, investigational products)

Instructor

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

Interactive Activities

Group activities:

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

Course Dates and Locations

March 1, 2012
San Diego, CA 92101
Courtyard San Diego
Downtown
Course #: SGLD0312
\$800 by January 27
\$1,000 after January 27

May 10, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SGLA0512
\$800 by April 6
\$1,000 after April 6

Academic Discount

A **\$100** academic discount is available to those who qualify.

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

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Accreditation

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Overview of the drug development process

- Discovery through post-market

Working in a regulated environment

- Definitions of GLP, GCP, and GMP
- Global regulatory authorities – mission and responsibilities
- Regulations – US (Code of Federal Regulation); ex-US (International Conference on Harmonization – ICH; 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

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



The Highly Effective CRA: Soft Skills for Taking Your Work to the Next Level

Course Description

Good monitoring skills are not the only critical skills a CRA needs to be effective in their role. A highly effective CRA is a great communicator; focuses on building relationships and partnership with their key stakeholders to position their projects/studies for success; resolves conflict with confidence, bravery, and laser-sharp solution focus; is able to anticipate potential challenges and barriers to success and takes the steps to remove and/or mitigate them; and identifies and solves problems.

This course is for the CRA who wants to build upon their existing communication, problem solving, and conflict resolution skills, and ultimately increase their effectiveness at the study site. Through highly interactive role-play and real-world case study activities, we will address:

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

Learning Objectives

- Identify the key components and behaviors of a strong, professional relationship
- State how a CRA can build relationships and ultimately partnership

- Describe the CRA/Investigative Team relationship lifecycle during a study
- Identify common pain points in this relationship, their root cause, prevention, and solutions
- Identify five motivators and points of leverage in the investigator-CRA relationship
- Model active listening behaviors
- Identify conversational clues to compliance issues, and individual motivations during a simulated investigative team discussion
- Discuss how emotional intelligence is related to a CRA's effectiveness
- Describe key elements of negotiations
- Define partnership

Who Should Attend

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

Instructor

Holly J. DeIaco-Smith, M.S.

Interactive Activities

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

Course Dates and Locations

February 27-28, 2012

San Diego, CA 92101

Courtyard San Diego
Downtown

Course #: SHED0212

\$1,595 by January 27

\$1,795 after January 27

May 8-9, 2012

Philadelphia, PA 19103

Club Quarters Philadelphia

Course #: SHEA0512

\$1,595 by April 6

\$1,795 after April 6

Academic Discount

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

Registration

ON-LINE:

barnettinternational.com

FAX or MAIL:

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For assistance,

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Accreditation

ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-085-L01-P. Released: 10/11.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

- The Highly Effective CRA Defined
- Mapping the CRA: Investigative team relationship lifecycle during a study
- Common Pain Points
- Root Cause Analysis
- Problem Solving Relay
- Case Study Review

Day Two: 8:30 a.m. – 5:00 p.m.

- Effective Communication
- Active Listening
- Key Components of Conflict
- Conflict Resolution Framework
- Being Brave: Tips for having the difficult discussions
- Conflict Resolution Simulation
- Moving to Partnership
- Case Study Review

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



How to Prepare and Submit a Bullet Proof 510(k): Addressing the Latest FDA Proposed Changes to the Process

Course Description

This course is a primer and overview to the 510(k) premarket notification process, including Traditional, Special, and Abbreviated. The Special and Abbreviated 510(k) methods were developed under the "New 510(k) Paradigm" to help streamline the 510(k) review process. Product modifications that could significantly affect safety and effectiveness are subject to 510(k) submission requirements under 21 CFR 807, as well as design control requirements under the Quality System (QS) regulation. Under the QS regulation, all Class II and III devices and certain Class I devices are required to be designed in conformance to 21 CFR 820.30 Design Controls. This course will address key resources when making critical decisions in this process.

In comments submitted to FDA in response to the agency's August 2010 release of more than 60 proposals to change the 510(k) process, industry has advocated that instead of implementing an extensive list of potentially disruptive proposals, FDA should focus on the proposals the agency has advanced that enjoy broad agreement and consensus. Examples include increased reviewer training, development of specific and relevant guidance documents, and enhancements or improvements to the *de novo* review pathway, among other suggestions. This course will provide a status update to these proposals, but more importantly, provide direction, guidance, and clarity on preparing for, executing, and submitting your 510(k) application.

Learning Objectives

- Differentiate between the Traditional, Special, and Abbreviated submissions
- Determine and apply Substantial Equivalence criteria
- Determine who is required to submit the application to FDA
- Determine where to submit the 510(k) and what to expect with the review and approval process
- Determine when it is and when it is not required if you are a device company
- List the exemptions to the submission process and special considerations
- Locate a "predicate" device and go through the content and format of the 510(k)
- Describe the De Novo process and the expectations for possibly marketing a low risk device
- Describe the potential impact of FDA's proposed changes to the 510(k) process and why manufacturers need to pay attention

Who Should Attend

This course is both a primer for personnel new to the FDA 510(k) process, or an excellent refresher course for those who need to revisit the basics and fundamentals for a better understanding on how to prepare and submit your application to ensure regulatory and compliance success.

Instructor

David R. Dills

Course Dates and Locations

June 20, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: S51A0612
\$800 by May 18
\$1,000 after May 18

Academic Discount

A **\$100** academic discount is available to those who qualify.

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

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0778-0000-11-005-L01-P.
Released: 4/11.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Introduction and Regulatory Background

- Review 21 CFR 807 Subpart E, which describes requirements for a 510(k) submission
- Current trends with the 510(k) process

The Process

- When a 510(k) is required, when it is not, and who is required to submit one
- Locating and justifying the predicate
- Substantial Equivalence (SE) and demonstration of SE to another legally U.S. marketed device
- Prepare and submit a 510(k)

- List of forms associated with Premarket Notification 510(k) submissions

- Decide when to submit a 510(k) for a change to an existing device
- Determine what happens and your responsibilities if FDA requires additional information and data

Interactive Q&A, Wrap-Up, and Adjourn

- Q&A with all participants and attendees, including their real-world challenges
- Group discussion and review of recent 510(k) clearances and proposals, as well as recommendations between FDA and industry

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Institutional Review Boards (IRBs): The Changing Landscape and the Effect on the Conduct of Clinical Research

Course Description

This course examines the evolution of the Institutional Review Board and how current events are shaping its future and that of the conduct of clinical research. Special attention is given to how IRBs can develop internal systems that assist in meeting their regulatory obligations of protecting human research participants in response to new requirements.

Attendees will learn how the role of the IRB has changed since the regulations that govern them were codified and how clinical research professionals, institutions, and regulatory agencies have adapted to secure compliance while keeping pace with the changes in the clinical research industry. Primary attention will be given to examination and development of Quality Systems within the Institutional Review Board and their positive impact on meeting the demands for regulatory compliance and the protection of human research subjects. The content is appropriate for any professional working with IRBs that review, approve, and oversee clinical investigations regulated by the FDA.

Learning Objectives

- Explain the regulations, agencies, and guidance that govern IRB composition and function
- Compare and contrast the IRB model of past and present and how IRBs have adapted to meet their objectives
- Identify the new and proposed regulations, guidance, and legislation and the impact on IRB function and operation
- Discuss current IRB-specific compliance concerns and how they impact on Good Clinical Practice standards for Principal Investigators, Sponsors, and Contract Research Organizations (CROs)
- Implement methods for developing and/or assessing a proactive, risk-based human research protection program

- Utilize corrective and preventative action plans and other tools to detect and deter noncompliance
- Describe how regulatory authorities inspect and assess IRBs, their current findings, and proper responses
- Define Quality Improvement (QI) and explore how to leverage it to help fulfill IRB responsibilities
- Examine how the IRB's approach to the protection of human research participants intersects and differs from those of other key clinical research team members

Who Should Attend

- This course is recommended for experienced Clinical Quality Assurance Professionals
- Clinical Research Associates
- Project Managers, or others involved in site and IRB assessment and/or selection
- Clinical Investigators
- Study Coordinators
- IRB Members
- IRB Professionals
- Institutional Officials involved in oversight of clinical research
- GCP-Focused Regulatory Affairs Professionals working with IRBs that review, approve, and oversee clinical investigations regulated by the FDA.

Instructor

Elizabeth Ronk Nelson, M.P.H.

Interactive Activities

- Critical Review of Regulatory and Industry Documents
- Assessment of Corrective and Preventative Action Plans and Responses
- FDA Mock Audit/Inspection Exercise
- Case Studies
- Problem Solving Scenarios
- Group Discussions of Best Practices

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

The Role of IRBs in Clinical Research:
Established and Evolving

New Developments and Emerging Trends in IRB Oversight and Function

Scandal and Scrutiny: Current Compliance Concerns and the "Ripple Effect"

Day Two: 8:30 a.m. – 5:00 p.m.

Operational Quality Systems for the IRB:
Format for Compliance

Regulatory Authority Inspections and Assessments: Current Focus and Processes

Using Risk Management Assessments and Quality Improvement as Tools for Securing Compliance

Course Dates and Locations

April 19-20, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SOCA0412
\$1,595 by March 16
\$1,795 after March 16

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

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Accreditation

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778-000-09-032-L04-P.
Released: 8/09.



Introduction to Clinical Data Management

Course Description

This course provides an excellent introduction to clinical data management (CDM) in the pharmaceutical industry. 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 drug development process.

Learning Objectives

- Navigate the drug 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
- Explain the rationale of the MedDRA dictionary
- Identify the role that CDISC and CDASH play in the standardization of data collection and reporting

- Ensure quality control and quality assurance
- Discuss database lock and release
- Conduct adverse event reporting and reconciliation
- Identify the changing CDM role towards project management and the issues associated with managing mega-trials and CROs

Who Should Attend

- 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 drug development process

Instructor

Denise G. Redkar-Brown

Interactive Exercises

- Core Definitions and Concepts
- To "Split" or Not to Split
- Identifying Data Checks

Course Dates and Locations

March 27-28, 2012
San Francisco, CA 94102
 Hilton San Francisco
 Course #: SIMF0312
 \$1,595 by February 24
 \$1,795 after February 24

June 14-15, 2012
Boston, MA 02110
 Club Quarters Boston
 Course #: SIMB0612
 \$1,595 by May 11
 \$1,795 after May 11

Academic Discount

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 0778-0000-10-012-L01-P.
 Released: 10/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Introduction to Drug Development: Good clinical practice – purpose and history; roles and responsibilities of the FDA/ICH; phases of drug research and development

The Clinical Research Team and Overview of Clinical Data Management: Personnel involved in the conduct of clinical trials - their roles and responsibilities; 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 attributes; 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.

Case Report Form Design and Development: Standard and study specific case report form modules; organization of a case report form; CRF design guidelines; data collection methods; CRF tracking; data capture, flow and entry; remote data capture

Day Two: 8:30 a.m. – 5:00 p.m.

Data Review and Validation: Data errors; frequently encountered problems; identifying and developing data checks; data queries

Coding: Purpose of coding; MedDRA dictionary development, structure, rationale of single medical concept, common coding dictionaries; computerized coding (autoencoding); coding philosophies

CDISC: The history and development of CDISC initiative and its impact on regulatory submissions

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; SAE reconciliation

Project Management and Other CDM Issues: Managing mega-trials; CROs; the changing role of data management personnel.

Hold this Course at Your Company: In-person or On the Web!
 Call (215) 413-2471 for more information



Introduction to the FDA

Course Description

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

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

Learning Objectives

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

Who Should Attend

Those who need to have an understanding of FDA in research, clinical, regulatory affairs, quality, and administrative positions.

Instructor

Albert A. Ghignone, M.S., R.A.C.

Interactive Activities

- Scenario reviews
- Discussion

Course Dates and Locations

March 8-9, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SFDA0312
\$1,595 by February 10
\$1,795 after February 10

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include
assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

 Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-045-L01-P. Released: 2/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

- **Introduction To FDA**
- **FDA History/Background**
- **FDA Laws/Regulations/Policies/Guidances**
- **FDA Definitions**
- **FDA Centers**
 - CDER
 - CBER
 - CDRH
- **FDA Combination Products**
 - FDA Office of Combination Products

Day Two: 8:30 a.m. – 5:00 p.m.

- **FDA Activities**
 - FDA Relationships
 - FDA Meetings
 - FDA Meeting Preparation
 - FDA Review Process
- **FDA Submissions**
 - CDER (IND, NDA)
 - CBER (IND, BLA)
 - CDRH (510(k), IDE, PMA)
- **FDA Clinical Trials**
 - Phase 0
 - Phase 1
 - Phase 2
 - Phase 3
 - Phase 4
- **FDA Advisory Committees**
 - CDER
 - CBER
 - CDRH
- **FDA Inspections**
 - GMP
 - GCP
 - GLP

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Mastering Cost Management for Global Clinical Trials

Course Description

This course builds on basic, intermediate, and advanced project management concepts to examine some of the most difficult issues encountered in domestic and global clinical trials. This workshop focuses on cost management, the most challenging factor of any drug development project as per the theory of triple constraints. Trials conducted outside the United States present additional challenges such as language, cultural differences, variations in medical practices, and much more. They can, however, significantly contribute to keeping the cost/budget estimates in line with the desired target. This course is presented in a dynamic, interactive manner to facilitate learning and retention.

Learning Objectives

- Master cost, time, and people issues through advanced project management tools
- Ensure the success of your teams by developing effective communication skills and mastering relationships within project teams
- Master the financial concepts and tools required for high performance trials
- Communicate with financial staff and get what you need
- Design a performance environment that motivates all through clear expectations and consequences
- Manage operational challenges in patient recruitment and retention
- Strategically manage CROs and other partner projects to achieve substantial cost performance

- Lead a cross-cultural team by positive influence
- Plan for contingency, but more importantly, take preventive actions on potential risks to avoid common cost and financial pitfalls
- Take advantage of emerging countries and Asia for maximum cost effectiveness, and get up-to-date cost data for these regions

Who Should Attend

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

Instructor

Eric Morfin, M.B.A., P.M.P.

Interactive Activities

- Identify the potential financial risks related to a global trial and select the best set of preventive and contingent actions
- Select the best package for the international launch of a once daily pill
- Assess the impact of cultural biases on the financial assessment and performance of the clinical trials you manage

Course Dates and Locations

May 9-10, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SCSA0512
\$1,595 by April 6
\$1,795 after April 6

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include
assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

 Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-007-L01-P. Released: 5/12.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

"Stage Gates," Product Profiles, and Budget Management: "Stage Gate" process for optimal portfolio and budget management; relationship between the minimum Target Product Profile (TPP) and the overall project cost

Developing a Budget for Meeting Project Objectives: Frequently overlooked costs; timelines; critical path; Gantt chart; external and outsourcing costs; impact of FDA review process on the budget

Projects and Project Management within a Financial Context: Financial and business drivers behind projects; financial quantification of project benefits and payback

Working with Finance Staff to Assess and Plan Project Funding Options

Financial Planning for Projects and Outsourcing Budget Versus Cost Management

Potential Problem Analysis for More Accurate Financial Planning: Identifying and prioritizing risks and their causes; developing preventive and contingent actions

Day Two: 8:30 a.m. – 5:00 p.m.

The Need for Financial Planning and Management: Accounting and financial concepts and terminology; an executive summary of project financial critical factors

Define Outsourcing Strategies: Transactional through alliance approaches; functional versus full service sourcing; cost and contract management; managing costs with overseas trials; leveraging emerging markets for cost performance

Clinical Operations Performance Review: Impact of investigators, sites, and other parameters on your cost estimate

Portfolio Management

Managing Change and Mastering Change Management

Project Implementation, Monitoring, and Control

Making Rationale Budget Decisions to Avoid Costly Mistakes

Best Practices for Budget Negotiation: Adapting to cultural differences; top down versus bottom up; frequently overlooked costs

Improving R&D Productivity by Capitalizing on Characteristics Unique to Asia: Most recent costs data on clinical trials in Asia; managing outsourced service providers in Asia

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Medical Device Approval Process: Preparation and Processing of 510(k)s, IDEs, and PMAs

Course Description

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

Learning Objectives

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

Who Should Attend

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

Instructor

Albert A. Ghignone, M.S., R.A.C.

Course Dates and Locations

February 27-28, 2012
San Diego, CA 92101
Courtyard San Diego
Downtown
Course #: SD9D0212
\$1,595 by January 27
\$1,795 after January 27

June 11-12, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SD9B0612
\$1,595 by May 11
\$1,795 after May 11

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation



Barnett International is accredited by the **ACPE**® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-10-013-L01-P. Released: 9/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Introduction to the FDA: History; law; definitions; overview of FDA; establishment registration; product listing

510(k) Process: Substantial equivalence; letter of notification; truthful and accurate statements; cover page; table of contents; checklist for filing; executive summary; intended use; device description; table of comparison; similarities and differences; environmental testing; comparative performance; clinical performance; software; biocompatibility; voluntary standards; sterility; reusable or single use device control; labeling; kit information; 510(k) summary; FDA 510(k) review

Day Two: 8:30 a.m. – 5:00 p.m.

Investigational Device Exemption (IDE):

Significant risk versus nonsignificant risk; prior investigations; investigational plan; methods, facilities, and controls; investigator agreement; IRB; institutions; sale of device; environmental assessment; labeling; informed consent; others; GCP; FDA actions on applications

Premarket Approval (PMA): Applicant; table of contents; summary; device description; standards; non-clinical studies; clinical studies; one investigator; bibliography; samples; labeling; environmental assessment; other; PMA amendments; PMA supplements; FDA action on PMA; post-approval requirements

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Medical Device GCP Overview

Course Description

This course provides information across the full range of medical device clinical trial activities. It is an ideal source of information for those new to clinical research and those requiring information specifically relating to regulatory and practical aspects of medical device clinical research.

Learning Objectives

- Navigate the regulatory pathways for medical devices in the U.S.
- Explore practical aspects of investigator and monitor selection
- Comply with the fundamentals of Good Clinical Practice (GCP)
- Explore practical aspects of conducting international clinical trials

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

Instructor

Albert A. Ghignone, M.S., R.A.C.

Interactive Exercises

- Clinical and Data Management Discussions
- Review of Regulatory Documents

Course Dates and Locations

March 20-21, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SD8A0312
\$1,595 by February 17
\$1,795 after February 17

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
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For assistance,
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assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Introduction to the FDA: History; law; definitions

Medical Device Process: Three classes of device; 510(K); IDE; PMA

Clinical Research Process: Types of clinical studies; clinical study controls; international studies; ICH process; guideline process

Day Two: 8:30 a.m. – 5:00 p.m.

ICH GCP: Sponsor obligations; investigator obligations; IRB/IEC obligations

Monitoring: Five basic monitoring visits

Adverse Device Experience: Expected; unexpected

Data Management: Data entry; data query; validation

FDA Bioresearch Monitoring Program: Site audits

Hold this Course at Your Company: In-person or On the Web!
Call (215) 413-2471 for more information



Medical Device Postmarketing Vigilance Reporting: New Update, Guidance, and Expectations for Manufacturers

Course Description

Major postmarketing vigilance revisions are now in force. A revised medical device guidance document on postmarketing vigilance (MEDDEV 2.12-1 rev 5) came into force on January 1, 2008. Providing more guidance than the previous version, the new document includes new reporting terminology and concepts such as "periodic summary reporting" and "trend reporting." In addition, the terms "advisory notice," "near incident," and "recall" have been eliminated or replaced. Although MEDDEVs are not legally binding, it is likely that all European Competent Authorities will follow the new guidelines and will expect organizations involved in the management and reporting of adverse incidents to follow them as well. Seminar topics include new terms and definitions, the guideline's extended scope, reporting criteria and timelines, filing safety notices and field safety corrective actions, the vigilance aspects of revising Directive 2007/47/EC, and more.

As an added bonus, for those device manufacturers seeking the CE Mark, you will learn the expectations and requirements and understand the "road" to CE Marking of your devices. For most products sold in the EU, the use of CE Marking and a Declaration of Conformity are mandatory.

Learning Objectives

- Examine the latest changes, new terminology, and new concepts to MEDDEV and Medical Device Vigilance and impact on medical device manufacturers
- Consider how to implement the suggested or recommended changes for postmarket vigilance guidelines as of January 1, 2008
- Report incidents as recommended by the guidance
- Examine why Global Harmonization Task Force (GHTF) is an integral component of the new postmarketing vigilance guidelines
- Manage expectations for reporting and timelines
- Recognize which amendments impact the European vigilance system
- Interpret the new guidelines that cover incidents involving devices that carry the CE mark and devices that do not carry the CE mark
- Submit periodic summary reports of incidents to Competent Authorities
- Examine controversial aspects of the guidelines
- Identify the conditions under which reporting is not required
- Identify the CE Marking directive(s) and conformity assessment procedures that are applicable to your product
- Ensure that your device fulfills the essential CE Marking requirements and prepare technical documentation

- Prepare the Declaration of Conformity and make documentation available to Competent Authorities (EU Members)
- Affix CE marking on your product and/or its packaging and accompanying literature as stated in the directive... and now sell your device in the EU

Who Should Attend

- Regulatory Affairs
- Compliance
- QA
- Management Representatives
- Marketing & Sales
- Consultants
- Distributors and Representatives
- Operations

Instructor

David R. Dills

Interactive Activities

- Group Discussions and Substantive Review of the Guidance and Manufacturers' Next Step for Deploying and/or Revising Policies and Procedures
- Review and discussion of sample reports impacted by the MEDDEVs

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Introduction to the New Guidance:

Directive 2007/47/EC; MEDDEV documents; harmonization initiatives of the Global Harmonization Task Force (GHTF)

New Terminology, Replaced Terminology, New Concepts: Periodic summary reporting; trend reporting; advisory notice; near incident; recall

Impact of Guidance on Medical Device

Manufacturers: timeline of incorporation of new changes; complying with amended requirements; expectations of Competent Authorities

Materials Requiring Revision: quality manual, SOPs for complaint handling; incident reporting; recall; field corrective action; advisory notices; clinical investigation; authorized representative and distributor agreements.

Reports Impacted by the MEDDEVs: Periodic trend reporting; summary reporting; adverse event reporting; other reports; new reporting timelines

The Road to CE Marking: Relevant directives; conformity assessment procedure; meeting essential requirements; maintaining technical documentation; Declaration of Conformity

Course Dates and Locations

April 17, 2012
San Diego, CA 92101
Courtyard San Diego
Downtown
Course #: SDVD0412
\$800 by March 16
\$1,000 after March 16

Academic Discount

A \$100 academic discount is available to those who qualify.

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

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

Participants will receive 7 hours (0.7 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test, and program evaluation. Barnett International will mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-002-L01-P. Released: 4/12.

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



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 and disease states. Students will investigate the structure of medical terms, and analyze spoken and 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
- Identify and define normal body system functions
- Identify and define medical terms for body systems and disease conditions
- Interpret the meanings of spoken and written communication
- Identify medical conditions and terms

Who Should Attend

Clinical Trial Personnel: Monitors, Managers, Support Staff, Data Entry, and Study Coordinators responsible for: 1) documenting, collecting, and reviewing medical history and adverse events occurring in clinical trials of new and marketed products.

Instructor

Felicia Glover, M.P.A., B.S., R.N.

Interactive Activities

- Flash cards
- Patient History
- Patient Assessments
- Puzzles
- Interactive CD

Course Dates and Locations

April 10-11, 2012
Boston, MA 02110
Club Quarters Boston
Course #: STRB0412
\$1,595 by March 9
\$1,795 after March 9

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include assorted breakfast items that will be available each day $\frac{1}{2}$ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-045-L01-P. Released: 3/11.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Overview of medical terminology from a body system approach

Identify the medical terms and body systems you know

Break down medical terms into the elements: prefix, suffix, and root words

Identify and define basic prefixes and suffixes to define the medical term

Day Two: 8:30 a.m. – 5:00 p.m.

Continue the discussion of body systems

Combining forms: Learn to take a root word and a prefix or suffix with a combining vowel to form a medical term

Review of patient assessments to identify any adverse events and serious adverse events

Hold this Course at Your Company: In-person or On the Web!
Call (215) 413-2471 for more information



Monitoring Clinical Drug Studies: Beginner

Course Description

This fundamental "how to" and "why" workshop focuses on current regulatory requirements to promote successful monitoring of studies. Participants will learn about the role and responsibilities of the monitor, the investigator, and the IRB from pre-study through post study. References and resources (including those available online) will be provided. Best practice techniques for site management will be provided. 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.

Learning Objectives

- Describe the role of the FDA in the drug development process
- Define GCP
- Identify qualified investigators and the investigative site
- Describe the informed consent process
- Prepare for pre-study visits
- Conduct study initiation visits
- Prepare for monitoring visits
- Describe adverse events/serious adverse events and reporting requirements
- Discuss investigational product accountability
- Describe essential document management
- Complete study close-out visits
- Identify, report, and manage site performance and study related issues
- Describe the inspection/audit purpose and process

Who Should Attend

Entry level Clinical Research Associates, Medical Research Associates and Clinical Scientists: This is a practical, hands-on introduction to the job and how clinical tasks are performed. This course would be beneficial if you have been monitoring for less than one year, manage team members in this role, or are in-house CRA or project assistant who supports CRA monitoring activities.

Instructors

This course will be taught by one of the following instructors

Nikki Christison, B.S.
Erica Elefant, R.N., B.S.N., M.S.W.
Gary B. Freeman, M.S., C.C.R.A.
Karen Gilbert, B.S., C.C.R.A.
Hillary Kimes, R.N., M.S.N., C.C.R.A., C.C.R.C.
Elizabeth Ronk Nelson, M.P.H.
Marcellina N. Oparaoji, Ed.D., B.S.N., R.N., C.C.R.P.
Lily Romero, P.A., C.C.R.C.
Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.
Jackie Stader, C.O.T., C.C.R.C.
Kimberly Turner, C.M.A., A.S., B.H.S., C.R.A.
Elizabeth Weeks-Rowe, L.V.N., C.C.R.A.

Interactive Activities

- Basic Monitoring Skills – Hands-on Simulation Exercise
- Informed Consent Critique
- Selecting Clinical Sites
- Adverse Event Scenarios
- Case Scenarios: Study Initiation Visits, Study Close-Out Visits
- Role Playing
- Prioritizing Exercises (Preparing, During, and Post Monitoring Visits)

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Overview of Drug Development and GCP:
Terminology; the drug approval process

The Clinical Research Team: Roles and responsibilities

The Site Selection Process: Locating, screening, and evaluating prospective investigators; selection criteria

Site Qualification Visits: Preparation and activities

IRBs/IECs and the Protocol Approval Process:
Membership requirements; documents and activities

Day Two: 8:30 a.m. – 5:00 p.m.

Informed Consent Documents and Process: FDA and ICH requirements; the role of the monitor in assuring appropriate consent

Study Initiation Visit: Preparation and activities

Essential Documents: Regulatory and subject documents; FDA and ICH requirements

Monitoring Visits: Preparing for, during the visit, and post visit activities

Data Management: Paper-based and electronic case report forms, queries

Day Three: 8:30 a.m. – 5:00 p.m.

Managing and Reporting Adverse Events:
Terminology and examples; investigator and sponsor reporting requirements

Study Termination Visits and Drug Accountability: Preparation and activities; drug storage, documentation, and accountability requirements

Regulatory Authority/FDA Inspections and Sponsor Audits

Monitoring Simulation Exercise: Case study; identifying and resolving discrepancies

Course Dates and Locations

February 20-22, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SSBA0212
\$1,695 by January 20
\$1,895 after January 20

April 11-13, 2012
San Francisco, CA 94102
Hilton San Francisco
Course #: SSBF0412
\$1,695 by March 9
\$1,895 after March 9

June 13-15, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SSBB0612
\$1,695 by May 11
\$1,895 after May 11

Academic Discount

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Registration

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For assistance,
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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 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-013-L01-P. Released: 8/09.

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Monitoring Clinical Drug Studies: Intermediate

Course Description

This course reflects current industry trends and challenges for the more experienced monitor/clinical research associate – with a focus on developing tools and identifying current industry trends and challenges for effective monitoring. FDA/Regulatory Authority inspection findings will be used throughout the seminar to emphasize critical areas in monitoring and managing site compliance. Industry standards/best practices will be discussed with an emphasis on the Sponsor/CRO-Site/Subject relationship. References and resources (including those available online) will be provided. Topics include site management, developing or identifying and modifying tools for effective monitoring and co-monitoring assessments, challenges in our global environment, and successful time management. Discussion will include how sponsors/CROs interpret and implement various aspects of clinical trials such as adverse event reporting and managing non-compliant or underperforming sites.

Who Should Attend

- Experienced Clinical Research Associates and Medical Research Associates seeking to update their knowledge of the GCP regulations and guidelines and fine tune their site management and monitoring skills.
- Clinical research professionals involved in the management of CRAs, and/or study/project management.

Learning Objectives

- Describe various sponsor interpretations of FDA regulations and practical application of ICH guidelines
- Discuss current trends in clinical research

- Evaluate and develop more efficient study tracking and management tools
- Participate in monitoring/co-monitoring assessments
- Prepare for monitoring challenges in a global clinical trial
- Effectively manage sites, and ensure their optimum performance
- Identify strategies for managing issues including root cause analysis and corrective action and preventive action plans
- Implement techniques for training and mentoring the research team
- Prepare sites for an FDA/Regulatory Authority inspection

Instructors

This course will be taught by one of the following instructors

Nikki Christison, B.S.
Erica Elefant, R.N., B.S.N., M.S.W.
Gary B. Freeman, M.S., C.C.R.A.
Karen Gilbert, B.S., C.C.R.A.
Hillary Kimes, R.N., M.S.N., C.C.R.A., C.C.R.C.
Elizabeth Ronk Nelson, M.P.H.
Marcellina N. Oparaoji, Ed.D., B.S.N., R.N., C.C.R.P.
Lily Romero, P.A., C.C.R.C.
Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.
Kimberly Turner, C.M.A., A.S., B.H.S., C.R.A.
Elizabeth Weeks-Rowe, L.V.N., C.C.R.A.

Interactive Activities

- Group Discussion on the Different Interpretations of FDA Regulations and ICH Guidelines for GCP
- The Experienced Monitor's Simulation Exercise
- Sponsor/CRO-Site Interactions (Problem Solving)
- Site Performance

Course Dates and Locations

February 16-17, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SSIA0212
\$1,595 by January 13
\$1,795 after January 13

April 26-27, 2012
San Francisco, CA 94102
Hilton San Francisco
Course #: SSIF0412
\$1,595 by March 23
\$1,795 after March 23

June 25-26, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SSIB0612
\$1,595 by May 25
\$1,795 after May 25

Academic Discount

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Registration

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Regulatory Recap – Practical Applications of GCP: FDA regulations and ICH guidelines; informed consent; IRBs/IECs; compensation to subjects and investigator; source documentation and CRFs, paper based and electronic; recordkeeping; adverse events; investigational product accountability

Monitoring and Co-monitoring, Monitoring Tools and Tracking Systems: Best Practices

Monitoring Challenges in Global Studies:

Identify issues that may develop in studies that are conducted globally

Successful Site Management: Analyzing site performance problems; exploring cause factors; identifying solutions; site performance incentives

Day Two: 8:30 a.m. – 5:00 p.m.

Problem Solving and Prioritizing Monitoring Challenges: Monitoring simulation

FDA/Regulatory Authority Inspections – A Comprehensive Discussion: Mechanics of an FDA inspection; FDA classifications; common deficiencies; possible restrictions

Preparing Sites for a Sponsor Audit or FDA Inspection: Tips for helping sites prepare for an sponsor audit or regulatory inspection

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Monitoring Clinical Drug Studies: Advanced

Course Description

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

Learning Objectives

- Explain the most recent regulations and guidance documents that govern clinical research
- Discuss current issues that affect clinical monitoring
- Describe the 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

- Discuss ways to manage situations involving fraudulent data
- Discuss FDA's BIMO program for sponsor and investigator inspections

Who Should Attend

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

Instructors

This course will be taught by one of the following instructors

Gary B. Freeman, M.S., C.C.R.A.
Karen Gilbert, B.S., C.C.R.A.
Marcellina N. Oparaoji, Ed.D., B.S.N., R.N., C.C.R.P.
Lily Romero, P.A., C.C.R.C.
Kimberly Turner, C.M.A., A.S., B.H.S., C.R.A.

Interactive Exercises

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

Course Dates and Locations

January 26-27, 2012

San Diego, CA 92101

Courtyard San Diego
Downtown

Course #: SSAD0112

\$1,595 by December 16

\$1,795 after December 16

March 6-7, 2012

Philadelphia, PA 19103

Club Quarters Philadelphia

Course #: SSAA0312

\$1,595 by February 3

\$1,795 after February 3

June 6-7, 2012

Boston, MA 02110

Club Quarters Boston

Course #: SSAB0612

\$1,595 by May 4

\$1,795 after May 4

Academic Discount

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

Registration

ON-LINE:

barnettinternational.com

FAX or MAIL:

Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-003-L01-P. Released: 1/12.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Regulatory Update: The latest FDA regulations will be reviewed

Monitoring Visits Update: Risk-Based Monitoring Approach

Monitoring Plans: Writing, evaluating, implementing, and assessing effectiveness

Mentoring, Communication, and Negotiating Skills: Tips for making the most of "mentoring" opportunities

Co-Monitoring/Assessing Monitoring Skills: Techniques for assessing monitors in the Sponsor/CRO environment

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

Day Two: 8:30 a.m. – 5:00 p.m.

Site Management (Performance)

Identifying, Reporting and Managing Study-Specific Issues/Corrective and Preventive Action Plans

Managing Situations Involving Fraudulent Data

Regulatory Compliance: Discussion of sponsor and investigational site inspections by FDA; current information regarding FDA and regulatory authority inspections/audits; practical tips for preparing your site for an audit

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Negotiation Skills for Clinical Research Professionals

Course Description

This interactive workshop is tailored to the key negotiation skills required for clinical research professionals. During this two-day workshop you will discover and put into practice the fundamentals of negotiation. Topics will include: communication mastery, preparing for a negotiation, persuading and influencing without authority, how to identify your negotiating parties needs, how to build rapport to create mutually beneficial negotiating outcomes, addressing difficult behavior and negotiating tactics, and transform conflict into collaboration.

Case studies, scenarios, group discussion, negotiating planning and practice and review of best practices in negotiation will be used throughout the workshop to enhance your learning experience.

Learning Objectives

- Develop key communication (verbal and non-verbal) strategies
- Describe and apply the critical steps for a successful negotiation
- How to influence without authority
- Create and analyze a negotiating matrix (template)
- Design and conduct a successful negotiation (face-to-face or virtually)
- Confidently negotiate in difficult situations
- Develop strategies so that all parties benefit from the negotiation process and outcome

- Respond with ease to an impasses in negotiation
- Develop strategies so that all parties benefit from the negotiation process

Who Should Attend

- Site Managers
- Clinical Research Associates
- Clinical Research, Managers
- Project Managers
- Team Leaders
- Clinical Research Professionals involved in procurement, resource management and negotiations

Instructor

Natalie Currie, B.Sc.

Interactive Activities

- Interactive verbal and non-verbal communication exercises
- Clinical research learning scenarios
- Video clip case study analysis
- Small group negotiation strategy planning
- Team brain-storming exercise
- Strategies for proactively addressing negotiating tactics and conflict
- A multi-party negotiation simulation
- Coaching feedback
- Customizable negotiation strategy planning and personal action planning templates

Course Dates and Locations

April 24-25, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SNCA0412
\$1,595 by March 23
\$1,795 after March 23

May 9-10, 2012
San Francisco, CA 94102
Hilton San Francisco
Course #: SNCF0512
\$1,595 by April 6
\$1,795 after April 6

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

**For assistance,
CALL: (800) 856-2556**

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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 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-036-L04-P. Released: 11/09.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Core Communication Skills

- Develop effective, verbal communication skills
- Discover the role that non-verbal communication plays in negotiating
- Apply simple strategies to enhance cross-cultural negotiation
- Match your communication medium to your objective

- Conduct effective virtual negotiation sessions
- Discover how the environment contributes to the negotiating outcomes

Teams develop their negotiation plan and enhance their negotiating strategy through coaching and group discussion

Day Two: 8:30 a.m. – 5:00 p.m.

Negotiate in Challenging Situations

- Identify difficult behavior and tactics used in negotiation
- Transform tactics and conflict into highly cooperative collaboration
- Proactively address impasses that may occur in negotiations
- Project confidence and communicate persuasively under pressure

Multi-party Negotiation Simulation

- Obtain coaching feedback based on your participation in the negotiation simulation
- Create a 30, 60 and 90 day personal action negotiation plan so that you can immediately apply the concepts and skills learned

Team Dynamics

- Recognize the role that team dynamics play in all negotiations
- Cultivate high performance team behavior
- Apply techniques to foster credibility and trust
- Enhance your emotional intelligence
- Develop skills to become more persuasive and influence without authority

Negotiation Preparation

- Determine your negotiation goals
- Develop an effective negotiation strategy
- Create and analyze a negotiating party map
- Create options for mutual gain through brainstorming
- Determine mutually agreeable negotiating standards to create successful commitments

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Patient Recruitment & Retention: Successful Planning and Management

Course Description

What does it take to successfully plan and implement a successful patient recruitment and retention program be it at the local site level or study-wide level? What's the difference between recruitment sources, strategies and tactics? What are the elements that fundamentally influence or determine a patient's participation in the trial? When and how should recruitment planning discussions take place vis-à-vis the study feasibility assessment process? What's the link between site engagement and successful patient recruitment and retention? If you are interested in exploring the answers to these and other questions, then this seminar is for you. Going beyond a discussion of advertising and outreach tactics, this course will systematically evaluate both theoretical as well as practical aspects of all of the factors necessary for an effective patient recruitment and retention program.

Learning Objectives

- Identify common challenges associated with the use of feasibility questionnaires as a means for validating successful site and enrollment performance in clinical trials
- Review the elements of the "clinical trials participation equation" and the factors that should be addressed during the study feasibility assessment and recruitment planning processes
- Examine the key elements that influence successful clinical trials participation from the patient and site perspectives
- Identify the components of a patient recruitment plan

- Discuss traditional and non-traditional approaches to enhancing patient recruitment and retention
- Employ techniques for overcoming common barriers to study participation
- Discuss practical and ethical considerations associated with enrollment acceleration strategies
- Diagnose and troubleshoot common enrollment problems

Who Should Attend

- Clinical Operations Specialists, Directors, and Project Managers
- Patient Recruitment Specialists (Sponsor, CRO, Site, or Service Providers)
- Site Directors, Research Coordinators, and Site Recruitment Specialists
- CRAs

Instructors

This course will be taught by one of the following instructors

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

Interactive Activities

- Mapping Common Study Challenges to Factors Influencing Successful Site and Patient Participation
- Dissecting a Study Feasibility Questionnaire
- Conducting a Recruitment Funnel Analysis
- Analyzing and Developing an Effective Recruitment Plan
- Troubleshooting Common Enrollment Issues

Course Dates and Locations

March 1-2, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SPTB0312
\$1,595 by January 27
\$1,795 after January 27

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

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assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

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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 mail ACPE statements within three weeks of program completion. ACPE#:
0778-0000-11-056-L01-P.
Released: 9/11.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

The Clinical Trials Participation Framework

Study Feasibility Assessments: Common practices, pitfalls, and new approaches

Validating Enrollment Potential – The Recruitment Funnel Analysis

Fine-tuning the Feasibility Process: Theory and practice

Recruitment Planning – The Basics: Study level and site level planning

Components of a Recruitment Plan

Strategic Site and Patient Communications

Recruitment Plan Templates

Day Two: 8:30 a.m. – 5:00 p.m.

Regulatory and Ethical Considerations

Traditional vs. Novel Approaches

Patient Sources, Strategies, and Tactics – Case Study

Troubleshooting Enrollment Challenges

Global Considerations

Hold this Course at Your Company: In-person or On the Web!

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Patient Registry Programs: Strategy, Design, Operations, and Output

Course Description

This course is designed to serve biopharmaceutical industry participants who wish to gain a comprehensive understanding of patient registry programs. Topics are introduced at the basic level but rapidly progress to cover more advanced, in-depth, and complex issues in program development and implementation. The seminar provides tools for participants involved in registry planning and design as well as for participants involved in registry project management and operations.

Learning Objectives

- Determine whether a registry is the right type of study, given your product profile, timeline, budget, and other study options
- Design a registry to meet both your research and your commercial objectives
- Implement a registry study, and how registry study conduct must differ from phase IIIB-IV clinical programs in order to succeed
- Solve problems that arise during the course of a registry program, and how to make mid-stream corrections and improvements without derailing the project
- Drive enthusiasm for your program and your product, while maintaining high ethical and research standards

Who Should Attend

- Clinical, Marketing, and Medical Affairs personnel
- Staff from pharmaceutical, biotechnology, medical device, or contract research companies involved with the development or implementation of registries
- Research leaders seeking to learn how a well-designed registry study can serve their research agenda
- Product teams considering a registry alongside or in lieu of a phase IIIB or phase IV clinical trial
- Clinical trial personnel desiring greater familiarity and comfort with observational designs
- Project team leaders who are or will be managing a registry program
- CRO personnel wishing to initiate or improve their delivery of registry program services

Instructor

David Stier, M.D.

Interactive Exercises

- Registry development simulation based on mock case-study scenarios
- Seminar participants are encouraged to bring their current program challenges for discussion and problem-solving

Course Dates and Locations

May 3-4, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SPAA0512
\$1,595 by March 30
\$1,795 after March 30

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include
assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-003-L01-P. Released: 6/11.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Introduction to Registries: What differentiates registries from other clinical programs; evolution of registries from academic centers to industry context; overview of registry design and implementation

Creating the Research Plan: Primer of observational epidemiology; which research questions can/cannot be answered using observational designs; hypothesis generation and testing; approach to data analysis; maximizing research output

Creating the Commercial Plan: Using registries to build or strengthen the customer base, communicate product messages, drive product utilization; strategy vis-à-vis competing products; strategic use of sales force

Registry Technical Design: Getting the most from an advisory panel; subtleties of protocol-writing; determining site and subject criteria; selecting data instruments; prospective vs. retrospective data collection; defining and incorporating clinical, economic, and patient-reported endpoints; regulatory issues; risk management

Day Two: 8:30 a.m. – 5:00 p.m.

Study Conduct: Registry project management; site training options; streamlining investigator recruitment materials; working successfully with community investigators; cost-effective methods of monitoring and maintaining data quality; practical decision-making with respect to GCP adherence; web-based vs. paper-based methods of data collection

Providing Value to Investigators: Creating meaningful benchmark reports; using registries for clinical quality improvement efforts; setting investigator fees; data use agreements

Understanding Costs and Benefits: Estimating and managing program cost; calculating return on investment; strengths and limitations of outsourcing; making in-house programs succeed without a CRO

Putting it All Together: Interactive exercises using simulation, enabling participants to consolidate their understanding of the course material in the development and critique of mock registry programs

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



The Pharmacovigilance Audit: How to Prepare for an Inspection

Course Description

Large and small pharmaceutical companies alike face an increasingly complex set of international regulations in their commitment to patient safety and Good Pharmacovigilance Practices. The specialized operational configurations of firms present complex challenges to meeting international requirements effectively.

Pharmacovigilance audits can contribute to regulatory compliance and support industry best practices. This course will describe how to conduct a thorough drug safety and pharmacovigilance audit, including compliance with applicable worldwide laws, regulations, and guidance. In addition, attendees will learn how to compare the company's pharmacovigilance operations to applicable best practices.

Learning Objectives

- Discuss why the pharmacovigilance audit is important to ensure Good Pharmacovigilance Practice
- Explain the impact of FDA regulations on international safety reporting and review methods
- Describe the objectives and components of a pharmacovigilance audit

- Describe the requirements of all applicable regulatory bodies for the company's products
- Inspect company practices in relation to drug safety across the product lifecycle
- Review detailed documentation on AE case processing

Who Should Attend

- Clinical Safety/Pharmacovigilance Specialists
- Regulatory Affairs Professionals
- Quality Management Specialists

Instructor

Steve Jolley

Interactive Activities

- Mock Audit Case Studies
- Requirements for active surveillance
- Expedited reporting in the US and EU
- Qualified Person for Pharmacovigilance - what they must do
- Signaling and data mining: laws, regulations, and guidances in the US and EU

Course Dates and Locations

March 1, 2012

San Diego, CA 92101

Courtyard San Diego
Downtown

Course #: SVGD0312

\$800 by January 27

\$1,000 after January 27

June 20, 2012

Philadelphia, PA 19103

Club Quarters Philadelphia

Course #: SVGA0612

\$800 by May 18

\$1,000 after May 18

Academic Discount

A \$100 academic discount is available to those who qualify.

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

**For assistance,
CALL: (800) 856-2556**

Registration fees include assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation



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

Participants will receive 7 hours (0.7 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test and program evaluation. Barnett International will mail ACPE statements within three weeks of program completion. ACPE#:
778-000-09-035-L04-P.
Released: 7/09.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

The Pharmacovigilance Audit: Typical pharmacovigilance current process model; best practice approach to enhancing process model; achieving best practices through the pharmacovigilance audit; scope; company sources of information to be examined; representative findings from case study

The Pharmacovigilance Risk Profile: Knowing which gaps to close; pharmacovigilance concepts; example of an effective supporting information architecture; example of how signaling supports Good Pharmacovigilance Practice

Signaling Fundamentals: BCPNN – Bayesian Confidence Propagation Neural Network; PRR – Proportional Reporting Ratio; MGPS - Multi-item Gamma Poisson Shrinker

Preparing for a Pharmacovigilance Inspection:

Overview eight domains of pharmacovigilance; strategy; organizational structure and operating model; skills and training; quality management; SOPs/ Documentation; business processes and communication; systems; surveillance

Practical Tips: Importance of QPPV in Europe; need for oversight of the pharmacovigilance system; ensuring information on adverse events is accessible; suitability of people; requirements for SOPs; processing of ICSRs; electronic reporting; Periodic Safety Update Reports (PSURs); signal detection practical tips; quality assurance

Series of Interactive Case Studies: Based on five real-world inspections

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Pharmacovigilance in Europe: Impact of Regulatory Changes on Investigational & Marketed Products

Course Description

The ICH process has resulted in multiple initiatives aimed at harmonizing global regulatory requirements for the approval and marketing of pharmaceuticals. The EU has faced the additional challenge of harmonizing disparate regulations and practices across multiple cultures and languages. This course will cover the essential ICH pharmacovigilance guidelines for investigational and marketed products, as they are currently being implemented in Europe, together with other approaches to standardization such as CIOMS reports. The provisions and impact of Volume 9A and Volume 10 will be discussed in detail, including:

- Expedited and periodic reporting of safety information
- Pharmacovigilance and risk mitigation plans
- The role of the Qualified Person for Pharmacovigilance (QPPV)
- EU PV inspection requirements
- Use of the EudraCT and Eudravigilance databases
- Safety data exchange within licensing agreements
- Representation of safety information in the Summary of Product Characteristics

Differences from US regulatory requirements and additional local requirements will also be discussed. This course will give US pharmacovigilance personnel a working knowledge of EU pharmacovigilance requirements and an overview of the processes and procedures needed to ensure compliance with them.

Learning Objectives

- Review the regulatory reporting requirements of the EU Clinical Trials Directive (Volume 10) and Volume 9A for companies which develop or market products in Europe
- Utilize the tools and mechanisms set up by the EU to enable and assist regulatory compliance
- Review the extensive pharmacovigilance inspections now being conducted by Competent Authorities, their findings, and the sanctions that can be imposed upon companies and individuals
- Recognize the challenges facing European pharmacovigilance employees of non-EU companies

Who Should Attend

- Clinical trial safety personnel responsible for multinational clinical trials, as well as safety personnel involved with global post-marketing safety responsibilities
- Pharmacovigilance personnel involved in auditing of company compliance
- Safety personnel responsible for safety data analysis, and for updating safety in the company labels

Instructor

Sidney N Kahn, M.D., Ph.D.

Interactive Activities

- Shared experiences
- Group discussions

Course Dates and Locations

April 24-25, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SPVA0412
\$1,595 by March 23
\$1,795 after March 23

June 11-12, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SPVB0612
\$1,595 by May 11
\$1,795 after May 11

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

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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 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-004-L01-P. Released: 4/12.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.
Understanding the EU Pharmacovigilance Requirements and Current Interpretation

Day Two: 8:30 a.m. – 5:00 p.m.
Developing the Processes and Procedures Necessary for Compliance

Hold this Course at Your Company: In-person or On the Web!
Call (215) 413-2471 for more information



Pharmacokinetics: A Comprehensive Overview of Principles and Applications

Course Description

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

Learning Objectives

- Understand the anatomy and physiology of systems involved in drug absorption, distribution, and elimination

- Compute pharmacokinetic parameters after intravenous and/oral drug administration
- Design pharmacokinetic studies
- Analyze and interpret data from pharmacokinetic studies
- Evaluate bioequivalence data
- Predict the effect of physiological and formulation changes on the pharmacokinetics of drugs

Who Should Attend

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

Instructor

Anil D'Mello, Ph.D.

Interactive Exercises

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

Course Dates and Locations

March 20-21, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SCKA0312
\$1,595 by February 17
\$1,795 after February 17

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

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For assistance,
CALL: (800) 856-2556

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assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

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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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-10-015-L01-P. Released: 10/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 4:30 p.m.

Anatomy and Physiology: Anatomy and physiology of systems responsible for drug absorption, distribution, metabolism, and excretion

Intravenous Dose: Conceptual description and computation of half-life, volume of distribution, area under the plasma concentration – time curve, and clearance

Oral Absorption: Description of the phases in drug absorption, computation of half-life, volume of distribution, area under the plasma concentration – time curve, clearance, C_{max} , and t_{max} ; effect of alterations in pharmacokinetic parameters on the area under the plasma concentration – time curve, C_{max} , and t_{max} of the drug

Day Two: 8:30 a.m. – 4:30 p.m.

Bioavailability and Bioequivalence: Definition of terms and computation of bioavailability and bioequivalence; design of bioavailability studies; historical perspective of statistical techniques used to evaluate bioequivalence data

Physiological and Formulation Factors

Affecting Drug Absorption: Effect of food, drug solubility, permeability, and surface area on the rate and extent of drug absorption

Clearance Concepts: Physiological model for organ clearance and the effect of alterations in organ blood flow, intrinsic clearance, and plasma protein binding on drug pharmacokinetics

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Planning and Conducting Global Clinical Trials

Course Description

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

Learning Objectives

- Summarize the trends in globalization of clinical trials
- Explain the impetus for globalization of clinical trials
- Identify the factors supporting globalization of clinical trials
- Understand the impact of the FDA's, EMA's, and MHLW's expectations on global clinical trials

- Assess the issues critical to planning a global clinical trial
- Identify key variables for understanding local clinical research environments
- Recognize the differences among countries that may be advantageous or challenging to clinical trial sponsors
- Develop capacity for working in a multi-cultural environment
- Anticipate the challenges involved in global clinical trials
- Formulate strategies for meeting the challenges

Who Should Attend

Experienced clinical research professionals who want to develop skills in planning and conducting international clinical trials.

Instructor

Anne McDonough, M.P.H., C.C.R.A., M.I.C.R., C. Sci.

Interactive Activities

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

Course Dates and Locations

April 26-27, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SMGA0412
\$1,595 by March 23
\$1,795 after March 23

Academic Discount

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

Registration

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barnettinternational.com

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CALL: (800) 856-2556

Registration fees include
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Accreditation

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Globalization of Clinical Trials: Where are clinical trials being conducted? Why are clinical trial sites and services moving around the world?

FDA Rule on Foreign Clinical Trials/EMA Reflection Papers/MHLW Basic Principles on Global Clinical Trials: What are the impacts of these documents on the planning and conduct of global clinical trials?

Considerations for Planning Global Trials: What are the ethical, scientific, and practical considerations for global clinical trial design and country selection?

Understanding the Local Environments: What do we already know? What else do we need to find out? How do we get this information? How can we perform successfully in a multi-cultural environment?

Day Two: 8:30 a.m. – 5:00 p.m.

Regulation: How can we ensure compliance with the local clinical trial regulations?

Legal: What other kinds of laws affect clinical trials? How do we manage contracts and insurance?

Language: What needs translation or interpretation? How do we do it?

Communication: How do we communicate and train in many languages, to people of many cultures, in countries all over the globe, in time zones around the clock?

Logistics: How do we manage international differences in shipping, technology, and currency?

Clinical Trial Procedures: What are the considerations for investigational products, study supplies and equipment, informed consent, data collection, monitoring, pharmacovigilance, record retention?

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Preparing IND Submissions: How to Organize, Write, Submit, and Track Submissions

Course Description

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

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

In this practical course, approved drug labels and summary basis of approvals are used to help students acquire the knowledge and insight needed to understand and begin to construct core U.S. drug and biologics submissions, including pre-marketing (IND), and

marketing (NDA/CTD) applications. Participants also gain experience with tools that help manage timelines and sections needed from contributors.

Learning Objectives

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

Who Should Attend

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

Instructor

Meredith Brown-Tuttle, R.A.C.

Course Dates and Locations

March 15-16, 2012
San Francisco, CA 94102
Hilton San Francisco
Course #: SPDF0312
\$1,595 by February 17
\$1,795 after February 17

June 28-29, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SPDB0612
\$1,595 by May 25
\$1,795 after May 25

Academic Discount

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

Registration

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

FDA Division Information

- Submission Basics
 - Outlining the submission
 - Creating the Table of Contents
 - Timing of submission/timelines
 - Contributions from other departments
 - Editing
 - Style Guides
 - Templates
 - Supportive documents
 - QAing the submission
 - Cover Letter

Publishing the Submission

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

Tracking the Submissions

- Creating the index history
- Creating an issues log

• Day Two: 8:30 a.m. – 5:00 p.m.

Common Technical Document Format

Pre-Market

- FDA Meetings (Type A, B and C)
 - Pre-IND
 - Phase I
 - Phase II
 - End of Phase II
 - Requesting the meeting
 - Preparing the meeting package
 - Meeting minutes
- The IND Submission
- Routine IND Submissions
 - Clinical
 - Non-Clinical
 - CMC
 - Annual Reports
 - Investigator Brochure Updates
 - Protocol/Protocol Amendments
 - Investigators
- Additional IND Submissions
 - Fast Track
 - Orphan Drug
 - Special Protocol Assessment

Marketing Application

- NDA in a CTD Format

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Query Creation & 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
- Analyze edit check content
- Describe the key elements for a good query
- Identify multiple results of query resolution
- Describe options for inappropriate query responses
- Integrate/update data amendments as a result of query resolution

Who Should Attend

Clinical Data Managers who are beginning their careers and desire to grasp a better understanding of the query process.

Instructor

Denise G. Redkar-Brown

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 Locations

June 20, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SQCA0612
\$800 by May 18
\$1,000 after May 18

Academic Discount

A **\$100** academic discount is available to those who qualify.

Registration

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Module 1 - Protocol review, CRFs, and the DMP.

Activity Discussion: Queries Gone Wrong

Describe a query processing nightmare you've experienced or heard about from a reliable source. Next, share a query processing "trick of the trade" you've developed, or seen others use.

Module 2 - 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?

Assignment

Examine the edit check list in the sample protocol and compare that to the case report forms. Is the list complete? Would you add any CRFs? How would you improve the output message for this study?

Module 3 - 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?

Assignment

Develop a list of data discrepancies by creating a spreadsheet that itemizes the discrepancy, the CRF page on which it is found, the data point, and the edit check that would catch the discrepancy (a template will be provided).

Module 4 - 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.

Hold this Course at Your Company: In-person or On the Web!

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Regulatory Intelligence 101

Course Description

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

The monitoring and gathering of RI will ultimately culminate in developing a regulatory strategy which can result in decreased time to approval; potentially decreased cost of product development through strategizing risk based on current information; and maximization of target market(s).

In addition, as more companies are conducting trials and filing marketing application worldwide, the need to keep abreast of worldwide regulatory information is increasing in importance as a change in the global landscape can affect the global regulatory strategy. RI allows a regulatory professional to determine requirements for conducting global clinical trials, meet manufacturing requirements, advise personnel, answer strategic regulatory questions, and write or construct a global marketing application.

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

Hands-on class exercises help participants gain experience using a regulatory intelligence database to search and summarize regulatory intelligence information.

Learning Objectives

- Discuss what Regulatory Intelligence is and why it is important to companies
- Identify multiple sources of Regulatory Intelligence

- Monitor the constantly changing regulatory landscape
- Break down a regulatory research question in to researchable units, and conduct the research using a Regulatory Intelligence Database
- Summarize and present Regulatory Intelligence findings back to a team
- Archive and store RI
- Apply and integrate Regulatory Intelligence to current company practices and global regulatory strategy

Who Should Attend

This course is designed for seasoned regulatory affairs professionals looking to develop their skill set, as well as other research and development professionals who are interested in learning a new skill.

Instructor

Meredith Brown-Tuttle, R.A.C.

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: 8:30 a.m. – 5:00 p.m.

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

Course Dates and Locations

February 17, 2012
San Diego, CA 92101
Courtyard San Diego
Downtown
Course #: SIQD0212
\$800 by January 13
\$1,000 after January 13

April 20, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SIQA0412
\$800 by March 16
\$1,000 after March 16

Academic Discount

A **\$100** academic discount is available to those who qualify.

Registration

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Accreditation



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Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Report Writing for CRAs

Course Description

This course is designed so that the participants walk away with usable skills and invaluable knowledge in clinical trial site visit report writing and review. The course combines lecture with real life scenarios, practicum exercises involving writing, editing and mapping of findings. Both beginners and those with experience will benefit from the content.

Learning Objectives

- Locate and become familiar with industry regulations and guidelines relating to report writing
- List the rules for writing an effective report
- Identify the steps in effective report writing
- List the essential content of the four major types of monitoring visit reports
- Define the report mapping process relating to action item identification, documentation & resolution monitoring
- Identify the difference between efficient and inefficient report writing tools
- Demonstrate the ability to write a protocol deviation, onsite data query, action items, and more

Who Should Attend

- Clinical Research Monitors
- In-house and field CRAs, CRCs transitioning to CRA role
- Contract CRAs
- Anybody responsible for reviewing clinical reports including Project Managers, Quality Assurance Auditors, CRA Managers, Lead CRAs

Instructors

This course will be taught by one of the following instructors

Karen Gilbert, B.S., C.C.R.A.
Lily Romero, P.A., C.C.R.C.
Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.
Kimberly Turner, C.M.A., A.S., B.H.S., C.R.A.
Elizabeth Weeks-Rowe, L.V.N., C.C.R.A.

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 Locations

April 13, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SECA0412
\$800 by March 9
\$1,000 after March 9

Academic Discount

A \$100 academic discount is available to those who qualify.

Registration

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Report Writing Roots and Mandates: FDA requirements regarding monitoring, record and report keeping; ICH guidelines for monitoring visit reports and non-compliance

10 Rules of Effective Report Writing:

Application of good report writing practices; steps in report writing: before, during, after

Approaches to Report Writing: Objective vs. subjective, choice of tense & voice, use of abbreviations, fragments vs. full sentences, proper use of bullets, etc.

Remember Who Your Audience Is: Who reviews and has access to monitoring reports

Always Be Ready if Abducted by Aliens: Designing reports to be independent of author to smoothly handle staffing changes and/or temporary stand-ins

The Mapping and Flow of Reports: Each report depends on one another; reports and follow-up letters correlation; contact reports; mapping to action item resolution

The Major Types of Monitoring Reports: Evaluation, initiation, interim, closeout, combos and abbreviated

Use of References to Support Report Claims: Documentation of protocol sections and past correspondence, etc.

Answering the Question Right and Answering the Right Question: Comment when needed; make it mean something; document teaching and re-instruction; document what was accomplished and what was not

Compliance Plans: Development, agreement, and success!

Industry Standards: Best practice; goals and content of industry monitoring reports; regulatory authority use of report content

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



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

Course Description

Managing compliance in the research industry is critical to successful clinical trials. Regulatory authorities expect that all stakeholders identify non-compliance, correct the non-compliance through intervention, and evaluate the effectiveness of the intervention. Root cause analysis provides a process through which issues can be accurately identified and interventions can be effectively designed. Root cause analysis is invaluable for all stakeholders in clinical research including the sponsor, CRO, investigator/site, and IRB/IEC.

The corrective action process including, when appropriate, preventive action planning, should be implemented when RCA has been completed. Effective corrective action planning includes many important steps that lead to promoting improved performance for the study and for future activities. Most importantly, effective CAPA can lead to improved human subject protections and confidence in the integrity of the data. Lack of effective corrective action management can lead to repeated non-compliance, compromised subject safety, poor data quality, and/or unacceptable inspection findings with subsequent negative impact on the final submission.

Learning Objectives

- Define investigator and site non-compliance
- Describe performance management concepts and skills for effective site risk management
- Implement Gilbert's Root Cause Analysis Diagnostic Process

- Apply performance management concepts in case studies with a focus on preventive and issues management scenarios
- Recognize components of effective Corrective Action Planning
- Identify examples of Corrective Action Planning application for different levels of site non-compliance case scenarios
- Discuss successful Preventive Action Planning and implementation

Who Should Attend

- CRAs
- Project Managers/CRA Managers
- Principal Investigators
- Site Research Directors/Managers
- Clinical Research Coordinators
- QA staff

Instructors

This course will be taught by one of the following instructors

Karen Gilbert, B.S., C.C.R.A.
Lily Romero, P.A., C.C.R.C.

Interactive Exercises

- Case Study Scenarios
- Review of FDA Warning Letters identifying corrective action responses

Course Dates and Locations

March 20-21, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SRCA0312
\$1,595 by February 17
\$1,795 after February 17

June 28-29, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SRCB0612
\$1,595 by May 25
\$1,795 after May 25

Academic Discount

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Performance Management Concepts for effective site risk management to promote prevention of performance issues and to ensure adequate site issues management. Factors that promote positive performance of research sites from pre-study through close-out

Define Investigator Non-Compliance: Human subject protection; data integrity; investigational product; PI oversight

Issues Management when deficiencies are identified: Evaluate and determine if a true issue exists; communication with stakeholders; when re-training is not the only solution; timely evaluation of effectiveness

Root Cause Analysis (RCA): Timely; accurate and complete; intervention; evaluation

Apply Performance Management Concepts in case scenarios representing preventive and issues management examples. Scenario of CRA identification of site qualification issues (i.e. staffing, subject availability); scenario of CRA identification of site not performing per expectation (i.e., lack of enrollment, staffing)

Day One: 8:30 a.m. – 5:00 p.m.

Corrective and Preventive Action (CAPA)

Concepts: Evaluate deficiencies and determine if issue requires short or long term solution; communication; training, re-training, and education; enforcing standards; internal and external oversight; timely response to identification of problems; timely evaluation of effectiveness of process

Identify Examples of Corrective Action Planning application for different levels of site non-compliance case scenarios: Scenario: site non-compliance (i.e., inappropriate investigator delegation and ICF); apply the steps of CAPA; ensure the interventions are linked to root cause; identify when short term (case specific) and long term (systems improvement) should be utilized

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Signal Detection and Pharmacovigilance

Course Description

This course will describe how to implement signal detection and data mining as part of your pharmacovigilance operations. The requirement for companies to perform signal detection is mandatory in Europe and highly recommended in the U.S. Many simple techniques can be applied to the generation and review of potential signals, which can also be augmented by the application of sophisticated data mining algorithms. This course will cover signal assessment, use of signal triage algorithms, compliance with FDA guidance as specified in "Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment," March 2005, and the timing and frequency of signal detection, triage, and data mining runs.

Learning Objectives

- Describe the basic concepts and principles of signal detection
- Apply these techniques within your company
- Apply data mining techniques to analyze large volumes of adverse event report data
- Conduct signaling analyses on real-life data

Who Should Attend

- Clinical Safety/Pharmacovigilance
- Clinical Research and Development
- Risk Management

Instructor

Steve Jolley

Course Dates and Locations

April 20, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SBPA0412
\$800 by March 16
\$1,000 after March 16

Academic Discount

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Registration

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Part 1: Background to Signal Detection:

Regulatory requirements; approaches to signal detection; signal detection hierarchy; layered approach to signaling; statistical versus medical significance; signaling analyses specified by Good Pharmacovigilance Practices; components of suggested analyses; how to characterize a suspected signal

Part 2: Signaling Examples

Signaling case study; data flow; recommended data elements to be obtained prior to analysis; typical PSUR data elements; analysis by MedDRA System Organ Class, analysis by MedDRA Preferred Term; Age Range, Sex, Country, Time to Onset, Treatment Duration, AE Duration, Concomitant Medications, Dechallenge/ Rechallenge; describe signal and relate to prior signaling exercises; define correlations found via prior signaling exercises

Part 3: Data Mining

Definitions, principles, methodologies; challenges in adverse event databases; recommended approaches; components of suggested analyses; external data sources; data flow elements; Bayesian Confidence Propagation Neural Network (BCPNN); Multi-Item Gamma Poisson Shrinker (MGPS); Proportional Reporting Ratio (PRR); which data mining algorithm?; comparison of methods; relative timing

Part 4: Signal Detection Process

Signal detection and pharmacovigilance process; operational questions; sources; signal evaluation steps; signal repository and safety profiles; Product Safety Profile (PSP); risk management planning; factors to consider in signaling optimization; signal detection triage example; triage algorithms used; comprehensive signaling process elements

Hold this Course at Your Company: In-person or On the Web!
Call (215) 413-2471 for more information



Source Documentation Best Practices

Course Description

Adequate and accurate source documentation in clinical research is critical to ensuring subject safety, data integrity, and investigators meeting regulatory expectations. Appropriate monitoring of source data is also vital for the sponsor stakeholder performance. Best practices will be presented and applied as participants work through a simulated clinical research study from first subject, first visit, to site-close out - while examining source documentation from the perspective of the CRC, CRA, and the auditor. All of the regulatory required attributes of quality source data will be presented and applied using real-life case studies, simulations, and interactive group exercises. Participants, sponsors/CROs and/or research sites will gain new insights into the role source documentation plays in the clinical research process.

Learning Objectives

- Employ the regulatory required attributes of quality supporting source data to case scenarios
- Describe what is required for electronic data from electronic health records and/or e-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 preventative action plans)

- Determine how best practice source documentation can be incorporated into any clinical research environment

Who Should Attend

- Clinical Research Associates
- Clinical Research Coordinators
- Site Managers
- CRA Managers
- Clinical Research Trainers
- Principles Investigators
- Clinical Research Professional looking to move into a quality assurance role

Instructors

This course will be taught by one of the following instructors

Karen Gilbert, B.S., C.C.R.A.
Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.
Jackie Stader, C.O.T., C.C.R.C.
Kimberly Turner, C.M.A., A.S., B.H.S., C.R.A.
Elizabeth Weeks-Rowe, L.V.N., C.C.R.A.

Interactive Activities

- Clinical research scenarios
- Simulations
- Critique of FDA Warning Letters
- Create a corrective and preventative action (CAPA) plan
- Source documentation best practice discovery session

Course Dates and Locations

March 9, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SBEB0312
\$800 by February 10
\$1,000 after February 10

Academic Discount

A **\$100** academic discount is available to those who qualify.

Registration

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COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

What is Source Documentation and Supporting Source Data? Interactive exercise examining which documents are classified as source data, which documents are classified as source documents, and which documents are neither.

Review Roles and Responsibilities of creation, maintenance and monitoring source.

What are Required Quality Source Document Characteristics? Interactive exercise applying the attributes.

Developing a Source Documentation Verification Plan: Sponsor vs. Site.

Collaboration.

Reviewing the Requirements of Electronic Medical Records and e-CRFs. 21 CFR Part II Compliant?

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

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Statistical Concepts for Non-Statisticians

Course Description

Designed for non-statisticians, this basic statistical concepts workshop has direct applicability to clinical research. The choice of statistical method, the application of statistical principles, and the interpretation of statistical results are the foundation of the design and analysis of clinical trials. It is therefore critical that statistical methods are fully understood before they are implemented. This course is beneficial to all clinical research professionals involved in the design, monitoring, interpretation, and reporting of clinical trials. Please note that this is not a course on statistical formulas or computations.

Learning Objectives

- Ascertain what information the statistician needs to determine the sample size
- Choose the appropriate sample statistical designs for a study
- Employ statistical terms used in clinical research
- Define the role of the statistician in the study design
- Become comfortable talking with statisticians

Who Should Attend

- Monitors who will assist in designing and evaluating studies.
- Clinical Research Associates who will be communicating with statisticians
- Clinical Project Leaders who will be designing and evaluating studies
- Regulatory Professionals who utilize statistical concepts in their reports
- Medical Writers who must interpret statistical reports

Instructor

Elkan Halpern, Ph.D.

Interactive Exercises

- Drawing Random Samples
- Constructing Confidence Intervals
- Creating and Testing with Real Data Individual and Group Hypotheses

Course Dates and Locations

April 16-17, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SSTA0412
\$1,595 by March 16
\$1,795 after March 16

June 20-21, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SSTB0612
\$1,595 by May 18
\$1,795 after May 18

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-015-L01-P. Released: 10/09.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Elements in Choice of Statistical Method

Descriptive Statistics: Distributions; mean, median, mode, standard deviation

Methods for Preserving Objectivity: Blinding; randomization; consequences of violations

Inference, Generalizing to a Population: Standard error; confidence interval; estimation and prediction

Study Design: Uncontrolled studies; parallel groups; crossover designs (patient as own control); block designs

Day Two: 8:30 a.m. – 5:00 p.m.

Hypothesis Testing: Creating hypothesis from objectives; level of significance, p-values; one-sided versus two-sided; types of errors

Power and Sample Size: Accuracy of estimates; confidence intervals; testing (effect size and variability)

Choice of Statistical Method

Specialized Topics

Interpreting the Statistical Report

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Study Site Start-Up: Opening and Managing a Successful Clinical Research Site

Course Description

The role of the clinical research site is vital in the success of the clinical trial process. The research site is the key conductor of studies, and quality research sites are in great demand in the current research environment. This course presents the core ingredients with explanation, tools and examples for a successful research site. Case scenarios will be presented throughout the course for study and benchmarking practices that lead to high performance and successful businesses.

Learning Objectives

- Identify components of a successful research site through benchmarking elite performers
- Identify the primary elements of business and marketing planning for a research site
- Review research site GCP responsibilities
- Recognize essential content of clinical research site SOPs
- Describe the staffing needs of a research site and review various models
- Review the process of contract and budget negotiations and content
- Describe the process of conducting project feasibility

- Identify effective approaches to subject recruitment
- Implement quality systems promoting audit readiness

Who Should Attend

- Research Site Managers/Directors
- Clinical Research Coordinators
- Principal Investigators
- Research Consultants
- Entrepreneurs

Instructor

Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Interactive Exercises

- Simulations/Scenarios
- Pre- and Post-Tests
- Case Scenario: Used Throughout the Course to Apply the Information to Promote Increased Understanding

Course Dates and Locations

March 9, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SSUB0312
\$800 by February 10
\$1,000 after February 10

Academic Discount

A \$100 academic discount is available to those who qualify.

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include
assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

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

Participants will receive 7 hours (0.7 CEUs) of continuing education credit for full participation, including the completion of a pre-test, post-test and program evaluation. Barnett International will mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-042-L01-P. Released: 5/10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Demonstrated Keys to Success for Research Sites: Benchmarking successful site practices; case scenario of the successful research site

Business Planning: Stakeholder buy-in and support; incorporating; liability insurance; vision and mission statements; objectives and goals

Site GCP Responsibilities: ICH GCP E6; FDA regulations 21 CFR Parts 11, 50, 54, 56; drug/biologic 21 CFR Part 312; device and combinations 21 CFR Parts 3 & 812; other GCPs, state laws and HIPAA; NIH studies, The Common Rule 45 CFR Part 46 Human Subject Protections Government Funded Research; other best practices

Content of Clinical Research SOPs: Components; training and implementation; measuring compliance

Staffing: Design of department: facilities and management models; key players; credentialing; national average salaries

Marketing a Research Site: How; to whom: customers (sponsors, participants and FDA); when; healing a bruised reputation; PR

Contracts & Budget: Negotiating; contract language; budget components; essentials to include; legal review

Project Feasibility: What it takes to run a successful study; completing a study feasibility; risk factor analysis and management

Subject Recruitment: Identifying accurate potential subject numbers; methods and strategies; formal recruitment plans

Quality Systems and Audit Readiness: FDA inspection program and site deficiencies; quality system components; establishing audit readiness

Performance Improvement: How to keep your site on top; evaluation and improving never ends; conflict resolution; root cause analysis and effective interventions; changing with the times

Hold this Course at Your Company: In-person or On the Web!

Call (215) 413-2471 for more information



Working with CROs: Building a Partnership for Project Success

Course Description

This course provides an in-depth overview of Contract Research Organization (CRO) management, starting with reviewing of bids through follow-up analysis and debriefing of the CRO partnership.

Learning Objectives

- Qualify CROs for your particular project
- Specify study requirements to optimize project results
- Analyze the significance of a partnership with your CRO
- Prepare and conduct a study initiation meeting
- Measure the performance of your CRO
- Manage and solve partnership problems
- Evaluate your CRO's performance
- Prepare and conduct an end of project meeting

Who Should Attend

- Clinical Research Coordinators, Clinical Research Associates, Data Managers, Project Managers who are changing roles from in-house study management to outsourcing projects with CROs

- Personnel who have significant interactions with CRO staff

Instructor

Natalie Currie B.Sc.

Interactive Exercises

- Identifying CRO Issues and Concerns
- Clarifying Performance Expectations
- Choosing a CRO and Establishing Communication Pathways
- Problem Solving Critical Issues

Course Dates and Locations

March 29-30, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SPSA0312
\$1,595 by February 24
\$1,795 after February 24

June 20-21, 2012
Boston, MA 02110
Club Quarters Boston
Course #: SPSB0612
\$1,595 by May 18
\$1,795 after May 18

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

 Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-004-L01-P. Released: 2/11.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

The Outsourcing Industry: Examine the reasons for the establishment and growth of the outsourcing industry; define roles of various outsourcing partners; understand CRO usage patterns and recent outsourcing trends; define the issues that can arise when using CROs; explore issues that can arise from both sponsor and CRO sides of the relationship

Qualifying CRO Candidates: Understand the importance of outsourcing philosophy and policy; how to construct a CRO database; appreciate the importance of performance metrics in selection of a CRO; understand the RFP process; how to evaluate bids and proposals; appreciate the different types of contracts and agreements between sponsor and CRO

Day Two: 8:00 a.m. – 4:30 p.m.

Establishing the Partnership: Learn techniques to enhance sponsor-CRO partnership; learn techniques for establishing effective communication; understand the importance of performance metrics and performance projections in managing a CRO; learn how to construct a productive kick-off meeting

Monitoring and Evaluating the Partnership: Establishing and monitoring project tracking; getting the project reports needed; productive project meetings; managing with performance metrics; productive CRO audits; problem solving; planning and participating in an end of study meeting; applying learning; supporting long-term partnerships

Hold this Course at Your Company: In-person or On the Web!
Call (215) 413-2471 for more information



Writing for Clinical Research

Course Description

This course provides the practical skills needed to write better sentences and paragraphs, which are the building blocks of protocols, reports, and manuscripts. Participants discover how to improve their writing skills and to create documents that meet regulatory requirements and are reader-friendly. Using as references The Code of Federal Regulations, The ICH Consolidated Guideline for Good Clinical Practice, and The ICH Guideline for the Structure and Content of Clinical Study Reports, participants gain practical experience applying the rules of grammar and punctuation.

Learning Objectives

- Integrate writing as both a structured and a creative process
- Use grammar and punctuation rules correctly
- Create clear, concise content
- Draft documents that are reader-friendly and that comply with the regulations
- Develop and use tools and checklists to promote clarity, appropriateness, and completeness in your documents

Who Should Attend

New Medical Writers, Clinical Research Associates, Medical Monitors, Biostatisticians, Clinical Scientists, and Other Clinical Research Professionals who want to learn practical techniques for more powerful writing

Instructors

This course will be taught by one of the following instructors

Karen Gilbert, B.S., C.C.R.A.
Anne A. Hurly, M.Ed., Ph.D., C.C.R.A.
Lily Romero, P.A., C.C.R.C.

Interactive Exercises

- Revising and Recasting Sentences and Paragraphs
- Selecting Appropriate Sentence Transitions
- Increasing Impact by Eliminating Labels and Fillers, Redundancies, and Jargon
- Using Punctuation Correctly and Effectively
- Avoiding Common Grammar Pitfalls

Course Dates and Locations

May 10-11, 2012
Philadelphia, PA 19103
Club Quarters Philadelphia
Course #: SWRA512
\$1,595 by April 6
\$1,795 after April 6

Academic Discount

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

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 152) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include
assorted breakfast items that will be available each day ½ hour prior to the start of the seminar. Also included is a Networking Lunch that will be served each training day.

Accreditation

 Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-016-L01-P. Released: 8/09.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:00 p.m.

Writing: Introductions and expectations; diagnostic writing pretest: biomedical communications and ICH; writing as a process (prewriting: considering the audience; gathering information and developing the content; outlining; writing)

Writing Effectively: Rewriting: grammar review (parts of speech: nouns, pronouns, verbs, clauses, conjunctions, modifiers; paragraphs; unity; coherence); word usage: wordiness, word choice

Day Two: 8:30 a.m. – 5:00 p.m.

Writing Effectively: Punctuation: commas, semicolons, colons, hyphens; logic and effectiveness: subject-verb agreement, dangling, misplaced, and confused modifiers, parallelism, faulty shifts in construction, the hierarchy of emphasis; miscellany: capitalization, numbers, lists, editing, proofreading; preparing manuscripts for publication



Barnett Interactive Web Seminars

What Is an Interactive Web Seminar?

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

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

feedback, and learn the information critical to your business needs. Upon completion, attendance certificates will be provided to all participants.

NOTE: The only exceptions to the web seminar team training is the online CRA, CRC evening series and the online CRA morning 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!

Web Seminar Archives

Unable to attend an Interactive Web Seminar? DVD archives are available and they will allow you to watch recordings of previous Interactive Web Seminars any time you want. Pricing is available for single users and site licenses. See page 141 for more details.

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!

System Requirements:

WebEx offers cross platform support, so you do not have to worry about what operating system you use. WebEx provides unmatched support for Windows, Mac, Linux, and Solaris. Browser support includes Internet Explorer, Mozilla, Firefox, Netscape, and Safari. You can always test your system at: <https://barnettwebseminars.webex.com>. In the panel on the left hand side, select Setup — Training Manager and follow the on-screen prompts.

Registration:

Registration for Barnett Web Seminars is on-line at: <https://barnettwebseminars.webex.com>. After registering, you will receive an email confirmation that provides you with the Web Seminar link and audio connection information. Upon completion, Barnett Educational Services 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 mail ACPE statements within three weeks of program completion.

Customized 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 215-413-2471 or nghanatra@barnettinternational.com.



10-Week CRA & CRC Beginner Program

Course Description

The online 10-Week CRA & CRC Beginner Program provides a comprehensive introduction to clinical research and the job functions of the Clinical Research Associate (CRA) and Clinical Research Coordinator (CRC) for both drug/biologic and device trials. This program is geared toward individuals seeking a new career or career change into clinical research, but who don't know which job track to pursue. Case studies and industry best practices are presented to underscore how the learning objectives apply directly to the responsibilities of the CRA and CRC. Upon completion, Barnett will provide resume assistance so that you can position yourself for entry into this market.

Learning Objectives

- Module 1: Investigational Product Development, the FDA, Good Clinical Practice Guidelines
- Module 2: Clinical Research Team: Roles and Responsibilities
- Module 3: The Principal Investigator, Site Selection, Budget Negotiation
- Module 4: Clinical Study Protocol Elements and Statistical Considerations
- Module 5: Institutional Review Boards, the Consent of Human Volunteers, HIPAA

- Module 6: Study Monitoring, Data Management, 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 CRAs and CRCs (This course is also appropriate for CRAs and CRCs with less than six months experience)
- College Students
- Nurses
- New College Graduates – Any Discipline

NOTE: This course is for individual registrants only.

Instructors

This course will be taught by one of the following instructors

Diana Martini, M.B.A., M.S., C.C.R.P.
Lily Romero, P.A., C.C.R.C.
Susan Torchio, R.N., B.S.N.

Course Length and Time

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

Course Dates

February 16 – April 26, 2012

Thursday nights

March 14 – May 16, 2012

Wednesday nights

May 10 – July 19, 2012

Thursday nights

No class: July 5

June 6 – August 22, 2012

Wednesday nights

No class: July 4 or July 11

Fee: \$1,895

Accreditation

 Barnett International is accredited by the ACPE® 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 pre-test, post-test, and program evaluation. Barnett International will mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-070-L01-P. Released: 9/11.

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

Course Description

The online 10-Week Clinical Research Associate (CRA) “on-boarding” training course is appropriate for individuals who have less than two years experience as a Clinical Research Associate. The course provides practical, hands-on training as it relates to the CRA job function, and covers core sponsor and research site activities that promote the successful monitoring of studies. The course follows an ICH/ISO global GCP framework, and covers how to identify specific country requirements, making it appropriate for both US and global audiences. Core Good Clinical Practice (GCP) skills are reinforced through a combination of activities, including lecture, case studies, and scenario review, as well as application-based homework assignments.

Learning Objectives

- Module 1: Drug Development Process, Good Clinical Practice (GCP) and Clinical Research Team Roles and Responsibilities
- Module 2: Clinical Study Protocol Elements and Amendments
- Module 3: Monitoring the Study: Key Activities, Types of Visits, Issues Management

- Module 4: Informed Consent
- Module 5: Investigational Product Accountability
- Module 6: Safety Reporting Definitions and Reporting Requirements
- Module 7: Source Document Verification
- Module 8 and Module 9: Monitoring Visit and Contact Report Writing
- Module 10: Regulatory Compliance and Quality Assurance: Audits and Inspections

Who Should Attend

- Clinical Research Associates with less than two years experience – In-house or Field-based
- Those currently working in the industry in a different role and seeking to change roles

NOTE: This course is for individual registrants only.

Instructors

This course will be taught by one of the following instructors

Karen L. Gilbert, B.S., C.C.R.A.
Lily Romero, P.A., C.C.R.C.
Jackie Stader, COT, C.C.R.C.

Course Length and Time

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

Course Dates

January 20 – April 6, 2012

Friday mornings

No class: March 2 or March 23

April 13 – June 22, 2012

Friday mornings

No class: June 8

Fee: \$1,895

Accreditation

 Barnett International is accredited by the ACPE® 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 pre-test, post-test, and program evaluation. Barnett International will mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-033-L01-P. Released: 3/11.



ABCs of Clinical Research for Clinical Administrative Support Staff

Course Description

This course provides the background needed to become an integral part of the clinical research team (for drugs and devices) and explores the need to understand the rationale behind quality performance and team-playing. The roles and responsibilities of Clinical Administrative Support will be discussed in terms of obligations to the study team and the importance of compliance with Standard Operating Procedures and Standard Office Practices. Although the course is designed for administrative staff with less than one year experience, those with some experience may also find this course helpful in providing the rationale for doing tasks in a specific manner, refining their skills, and sharing their experiences and helpful techniques with their colleagues.

Learning Objectives

- Recognize the importance of a knowledgeable clinical support staff
- Define the common terms used in the field of drug and device research
- Describe the basics of the drug/device development process

- Describe the basic principles of Good Clinical Practice and the regulations that govern clinical research
- Discuss the basics of clinical trial design and use of a study protocol
- List essential Standard Operating Procedures needed
- List the essential documents needed for a clinical trial and become familiar with the proper preparation of many 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

Gary B. Freeman, M.S., C.C.R.A., C.C.R.T.
Karen L. Gilbert, B.S., C.C.R.A.

Course Length and Time

2.5 hours 12:30 – 3:00 p.m. Eastern

Course Dates:

February 6, 2012

May 7, 2012

Archived Recording Available!

Fee: \$795*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-054-L01-P.
Released: 3/10.

Adequate Sponsor Monitoring Systems In Anticipation of FDA Sponsor GCP Inspections

Course Description

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

Learning Objectives

- Discuss BIMO Sponsor/CROs and monitors program
- Identify components of a sponsor monitoring system: Beyond SOPs
- Distinguish each component’s suggested elements

- Define adequate oversight of non-employee performers
- Identify other measures to ensure quality monitoring
- Evaluate gaps monitoring systems

Who Should Attend

- Sponsor Senior Management
- Project Managers
- CRA Managers
- Quality Assurance and Compliance Professionals
- CRAs

Instructors

This course will be taught by one of the following instructors

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

Course Length and Time

2 hours 12:00 – 2:00 p.m. Eastern

Course Dates:

January 13, 2012

June 11, 2012

Archived Recording Available!

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-055-L04-P.
Released: 2/10.



Adverse Event Monitoring for CRAs

Course Description

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

Learning Objectives

- Define safety concepts and reporting requirements
- Recognize the importance of verifying the subject baseline history
- Determine when to start and stop monitoring AEs

- Apply a detailed presentation of the source document verification process of AEs
- Manage challenges in monitoring AEs
- Verify appropriate credentialing for site AE evaluation of event relationship
- Appreciate the impact of monitoring on future product labeling
- Discuss reporting trends

Who Should Attend

- Device and Drug Study CRAs
- Contract CRAs
- CRA Managers
- Project Managers

Instructors

This course will be taught by one of the following instructors

Karen L. Gilbert, B.S., C.C.R.A.
Jackie Stader, C.O.T., C.C.R.C.

Course Length and Time

2 hours 12:00 – 2:00 p.m. Eastern

Course Dates

April 13, 2012

May 25, 2012

Archived Recording Available!

Fee:

\$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-008-L01-P. Released: 2/11.

Adverse Events for Medical Devices

Course Description

This course provides newcomers a detailed and thorough introduction of FDA regulations in the field of medical device safety. The course includes a comprehensive review of the requirements, current compliance approaches for professionals in the research and post-marketing areas, and opportunities to discuss the challenges facing those reporting and managing Adverse Events in the medical device industry.

Learning Objectives

- Describe current considerations in reporting Adverse Events in clinical trials: Terminology, consent, device-related versus procedural complication, and follow-up
- Differentiate between terminology related to Adverse Events and devices
- Define the objectives of documenting Adverse Events in both investigational and marketed devices
- Describe the reporting requirements for investigational and marketed devices
- Summarize the considerations required for Adverse Event reporting with combination products and in-vitro diagnostics
- Discuss the IRB's role in Adverse Event reporting

Who Should Attend

- Clinical Trial Personnel (Monitors, Managers, Research Coordinators, Support Staff) 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 Personnel involved in the investigation of Adverse Event reports
- Regulatory Affairs Personnel responsible for submitting safety reports to the FDA and other health authorities
- Medical Affairs Personnel responsible for safety-related decisions regarding product labeling, regulatory interactions, or customer communication

Instructor

Douglas Albrecht, B.S.N., C.C.R.A.

Course Length and Time

2 hours 1:00 – 3:00 p.m. Eastern

Course Dates

January 23, 2012

April 9, 2012

Archived Recording Available!

Fee:

\$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-0000-09-067-L04-P. Released: 2/10.



Approaches to Address Challenges in Vendor Management

Course Description

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

Learning Objectives

- Identify key approaches to planning and preparing to outsource to improve relationships
- Identify key components for formal study of vendor performance management
- Identify adequate oversight SOPs and other practices for the sponsor
- Employ end of project analysis to pave the way for improvement in future relationships

Who Should Attend

- Sponsors
- CROs/Vendors
- Those that choose, manage, or evaluate external service providers

Instructors

This course will be taught by one of the following instructors

Jeanne Morris, B.S., MT (ASCP)

Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time

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

Course Dates

February 13, 2012 (8:30-11)

May 11, 2012 (12-2:30)

Archived Recording Available!

Fee: \$795*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-018-L01-P. Released: 2/12.

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 course will provide an overview of auditing skills and techniques and a review of recent GCP audit findings from Clinical Investigators (Sites), Sponsors, and Institutional Review Boards (IRBs).

Learning Objectives

- Discuss how QA differs from QC 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

Instructors

This course will be taught by one of the following instructors

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

Jeanne Morris B.S. M.T. (A.S.C.P.), M.Q./O.E (A.S.Q.)

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 16, 2012 (12:30-2:30)

April 23, 2012 (9:30-11:30)

June 12, 2012 (12:30-2:30)

Archived Recording Available!

Fee: \$795*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-019-L01-P. Released: 2/12.



Case History Maintenance in Clinical Trials

Course Description

The FDA requires investigators to complete and maintain adequate and accurate case histories for every research subject, including all pertinent information that will aid in reconstructing and evaluating the trial source data. In this web seminar, we will define what pertinent data is and what the requirements are for the maintenance of the case histories. We will also review the importance of understanding and implementing the ALCOA standard, which ensures that records are attributable, legible, contemporaneous, original, and accurate, whether they are paper or electronic.

Learning Objectives

- Review what is required as pertinent source for any clinical trial
- Present the required characteristics for any case history (ALCOA)
- Identify the requirements for case history maintenance

Who Should Attend

- Site Research Managers
- Investigators
- Clinical Research Associates/Monitors
- Study/CRA Managers
- Clinical Research Coordinators
- Sponsors/CROs

Instructors

This course will be taught by one of the following instructors

Gary B. Freeman, M.S., C.C.R.A., C.C.R.T.
Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time

1.5 hours 9:00 – 10:30 a.m.
and 12:00 – 1:30 p.m. Eastern

Course Dates

February 24, 2012 (12-1:30)
May 21, 2012 (9-10:30)

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-082-L01-P. Released: 8/11.

Changes and Challenges in Foreign Clinical Research

Course Description

As the number of clinical research trials conducted outside of the United States increases, the FDA has come under new scrutiny for its ability to monitor and inspect foreign clinical trials. This course will examine the changing landscape of clinical research and how the FDA is adapting its processes to address these challenges. This course will also provide models for site selection, site oversight, and preparing foreign clinical research sites for regulatory inspections. Participants will gain a greater understanding of current FDA inspection trends of foreign clinical research sites.

Learning Objectives

- Explore the changing landscape of foreign clinical research
- Examine current FDA inspection metrics and challenges
- Review models for selection and oversight of foreign clinical research sites

Who Should Attend

This course is recommended for experienced:

- Clinical Quality Assurance Professionals
- Clinical Research Associates
- Project Managers
- Investigators
- Study Coordinators
- IRB Professionals
- Institutional Officials involved in oversight of clinical research
- GCP-Focused Regulatory Affairs Professionals

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

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

Course Dates

January 9, 2012 (12:30-2:30)
April 24, 2012 (9:30-11:30)
Archived Recording Available!

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-029-L01-P. Released: 4/11.



Clinical Research Site Quality Improvement Strategies: Developing Proactive Project Study Plans

Course Description

Research sites' performance in conducting clinical trials can be improved through formalized proactive planning and management. Research sponsors commonly develop a monitoring plan for each study protocol to address the unique needs of each project to promote monitoring excellence and flexibility for protocol changes. Research sites can develop a similar plan to support departmental policies and practices to meet the demands and differences between sponsor/CRO projects. This web seminar will present components of a Proactive Compliance Plan (PCP) for research sites use in promoting high performance management of multiple research studies to meet sponsor and regulatory requirements.

Learning Objectives

- Examine challenges of meeting the compliance expectations of sponsors/CROs and regulatory authorities
- Promote performance improvement

- Design successful clinical trial site project plans: borrowing from the traditional monitoring plan, project feasibility assessments, and best practices
- Implement proactive and effective reactive project management

Who Should Attend

- Site Research Directors/Managers
- Clinical Research Coordinators
- Principal Investigators
- CRAs
- Sponsor Project Managers

Instructors

This course will be taught by one of the following instructors

Karen L. Gilbert, B.S., C.C.R.A.
Jeanne Morris, B.S., MT (ASCP)

Course Length and Time

2 hours 12:00 – 2:00 p.m. Eastern

Course Dates

May 15, 2012

Archived Recording Available!

Fee: \$595*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation

 Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-009-L01-P. Released: 2/11.

Clinical Trial Design for Medical Devices

Course Description

This web seminar 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 the FDA and sponsors to provide clear direction to support marketing of the medical device.

Learning Objectives

- Address the ethical considerations involved in conducting clinical trials
- Strategically plan for successful clinical trials
- Develop trial objectives and hypothesis testing
- Evaluate basic statistical issues relating to sample size

- Project Managers who have little or no clinical trial experience
- Project Team Leaders who will be designing clinical trials

Instructor

Douglas Albrecht, B.S.N., C.C.R.A.

Course Length and Time

2 hours 1:00 – 3:00 p.m. Eastern

Course Dates

May 7, 2012

Archived Recording Available!

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation

 Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-056-L04-P. Released: 2/10.



Comparing FDA and Health Canada Regulations: Using an ICH GCP Framework

Course Description

Protection of human research subjects and data integrity are the two central tenets of the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) worldwide. In this interactive web seminar you will learn how the U.S. Food and Drug Administration (FDA) and Health Canada have interpreted ICH GCP guidance. Case studies and other interactive techniques will be used to provide participants with a deeper understanding of clinical research requirements and best practices according to the FDA and Health Canada drug regulations. This web seminar will provide an in-depth focus on drug regulations.

Learning Objectives

- Review key guidance documents: The Belmont Report (U.S.) and the Tri-Council Policy Statement (Canada)
- Describe the similarities and differences in Institutional Review Boards and Research Ethics Boards
- Determine investigator and sponsor obligations

- Examine essential documentation; from informed consent to archiving requirements
- Discuss inspection process and recent findings
- Implement best practices in conducting clinical studies according to the FDA and Health Canada drug requirements

Who Should Attend

- Site Research Managers and Coordinators
- Investigators
- Clinical Research Monitors
- Project and CRA Managers
- Clinical Research Directors
- Regulatory Affairs Professionals

Instructor

Natalie Currie, B.Sc.

Course Length and Time

2 hours 12:00 – 2:00 p.m. Eastern

Course Dates

January 26, 2012

Fee:

\$695*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-068-L01-P. Released: 8/11.

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
- CRAs
- Project Managers/CRA Managers
- Quality Assurance Personnel

Instructors

This course will be taught by one of the following instructors

Karen L. Gilbert, B.S., C.C.R.A.
Jeanne Morris, B.S., MT (ASCP)

Course Length and Time

1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates

January 23, 2012

May 18, 2012

Archived Recording Available!

Fee:

\$795*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-069-L01-P. Released: 9/11.



CRA Current Practice Update: Impact of the FDA BIMO Program

Course Description

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

Learning Objectives

- Discuss the FDA BIMO initiative and the direct impact on sponsor monitoring
- Examine industry regulatory update impacting the role of the CRA

- Integrate strategies for determining appropriate role performance for earlier and more frequent sponsor monitoring inspections
- Apply tools and resources to implement the new required and recommended practices

Who Should Attend

- CRAs (Pharma, Biologic, or Device)
- Contract CRAs
- Sponsor Project Managers
- CRA Managers
- Recruiters

Instructor

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

Course Length and Time

2 hours 12:00 – 2:00 p.m.
and 2:30 – 4:30 p.m. Eastern

Course Dates

January 10, 2012 (12-2)

April 25, 2012 (2:30-4:30)

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



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CRC & PI Current Practice Update: Impact of the FDA BIMO Program

Course Description

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

Learning Objectives

- Examine industry regulatory updates that impact the role of the CRC
- Integrate strategies for determining appropriate role delegation and documentation specific to a study project
- Apply tools and resources

Who Should Attend

- CRCs
- Investigators
- Site Managers
- Quality Assurance Personnel
- CRAs

Instructors

This course will be taught by one of the following instructors

Karen L. Gilbert, B.S., C.C.R.A.
Jeanne Morris B.S., MT (ASCP)

Course Length and Time

2 hours 12:00 – 2:00 p.m. Eastern

Course Dates

May 1, 2012

Fee: \$595*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



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CRC Role/Responsibilities Training

Course Description

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

Learning Objectives

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

Who Should Attend

- CRCs
- Site Managers
- Principal Investigators

Instructors

This course will be taught by one of the following instructors

Gary B. Freeman, M.S., C.C.R.A., C.C.R.T.
Karen L. Gilbert, B.S., C.C.R.A.

Course Length and Time

2.5 hours 12:00 – 2:30 p.m. Eastern

Course Dates

April 24, 2012

Fee:

\$595*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.

Accreditation



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Critical Decision Points in Design & Conduct of Patient Registries

Course Description

Patient registries are based on principles of observational research and offer remarkable flexibility in design and applications. They have demonstrated value in both the biopharmaceutical and the medical device arenas. Patient registries are appealing to physician investigators, and can serve as a centerpiece or as an adjunct to a product's late-phase scientific and promotional strategy.

Although registries share some features with clinical development trials, they diverge in many important respects. Clinical, risk management, and product marketing teams can collaborate successfully to develop and implement patient registry programs. All team members should have a clear understanding of the design elements, the operational issues, and the strengths and limitations of registries.

This web seminar will focus on the most critical issues in the design and conduct of patient registries for biopharmaceutical and medical device applications. It will also cover the questions most frequently raised by clinical, risk management, and product marketing teams engaged in the development and implementation of registries.

Learning Objectives

- Discuss all the basic components of a successful registry program
- Examine when patient consent and IRB/Privacy Board approval is required
- Design benchmark reports that physicians will actually want to read
- Turn community physicians into comfortable, productive registry site investigators
- Choose study endpoints: Walking the tightrope between what is desirable and what is realistic

Who Should Attend

- Clinical Programs/Trials Professionals
- Clinical Research Professionals
- Clinical Affairs Professionals
- Medical Affairs Professionals
- Regulatory Affairs Professionals
- Project Managers
- Patient Registries Professionals
- Marketing and Business Development Professionals

Instructor

David Stier, M.D.

Course Length and Time

1.5 hours 12:30 – 2:00 p.m. Eastern

Course Dates

January 26, 2012

April 26, 2012

Archived Recording Available!

Fee:

\$795*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-021-L01-P. Released: 1/12.



De-Risk Your Protocol by Developing an Operational Advisory Board

Course Description

Scientific Advisory Boards (SABs) have long been a staple of the protocol development process. Whereas SABs focus on ensuring a scientifically sound and medically feasible protocol, they are not structured to evaluate or address all of the operational hurdles teams will inevitably face when implementing a clinical trial. Operational Advisory Boards (OABs) play a pivotal role in setting the study up for success. OABs can help you de-risk your study implementation challenges as well as avoid potential amendments and “rescue mode.” From protocol concept to successful study launch, Operational Advisory Boards can play a role in helping study teams conduct an operational analysis of the protocol, contribute ideas to optimizing the protocol to ease implementation challenges, support the development of a proactive recruitment and retention plan, aid in the development of study implementation tools, help design a strategic site communications and engagement plan, and more.

Learning Objectives

This web seminar will cover the basics of OABs:

- Define OABs and describe why they are needed
- Discuss how they can add value in the protocol design and up-front planning stages
- Determine how many members should serve on the OAB and who should be included
- Determine how often the OAB should meet
- Discuss how the OAB should be structured
- Determine what the OAB compensation package should look like
- Leverage OABs after the study start-up

Who Should Attend

- Clinical Trial Planners
- Sponsor and CRO Study Feasibility Specialists
- Clinical Team Representatives responsible for protocol design
- Project Managers

Instructor

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

Course Length and Time

1.5 hours 12:30 – 2:00 p.m. Eastern

Course Dates

March 6, 2012

June 5, 2012

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-059-L01-P. Released: 9/11.

NEW! Design Considerations for GCP Training Programs

Course Description

Regulatory authority inspection trends are identifying a need for truly effective Good Clinical Practice (GCP) training. GCP training should ensure that clinical research stakeholders not only “know GCP” but know how to apply the principles of GCP in their work lives. The decision to develop and implement a GCP Training Program is a time-consuming and expensive project for any clinical research organization. How can you maximize the effectiveness of the training to ensure return on this investment in both financial and compliance terms? By designing GCP training with a focus on engaging adult learners, which is critical to ensuring both acceptance by the learners and the transfer of knowledge into everyday professional practice. This web seminar will identify key elements to consider throughout the phases of program development and design, training deployment, and post-course assessment.

Learning Objectives

- Describe the training elements that effectively “connect” with adult learners

- Compare and contrast the pros and cons of face-to-face, web-based, and eLearning venues for GCP training
- Identify strategies for assessing training outcomes such as short-term knowledge transfer and long-term impact on the organization

Who Should Attend

- Clinical Research Training Professionals and/or Subject Matter Experts
- Pharma/Device Professionals with responsibility for internal and/or investigator GCP training
- Clinical Research Site Professionals

Instructor

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

Course Length and Time

2 hours 12:00 – 2:00 p.m. Eastern

Course Dates

February 14, 2012

May 2, 2012

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-013-L01-P. Released: 2/12.

Developing and Negotiating Research Site Clinical Study Budgets and Contracts



Course Description

Negotiating study contracts and budgets is critical for the future success of the clinical research site. This web seminar provides strategic skills and best practices for contract negotiations and budget development. Learners will also review and practice the art of negotiation.

Learning Objectives

- Prepare for negotiations: Define steps in the negotiation process; integrate strategies for effective negotiating; review success factors and risks in negotiations; discuss ethical considerations
- Review industry study start-up basic contract content: Discuss state law, institutional vs. sponsor required language; “boilerplate” terms; indemnification; other agreements including data use, confidentiality, HIPAA, master agreements
- Develop study budget presentations: Based on objective market data; subject vs. visit based
- Assess protocol feasibility and resource needs: Look for hidden costs; study start-up to final query resolution

- Go from study protocols to successful study budgets: Plan for protocol amendments and procedure changes; financial checks and balances

Who Should Attend

- Research Site Representatives that have some direct and/or indirect responsibility in contract and budget negotiations
- Site Managers/Project Managers
- Contracts and Budget Department Representatives
- CRCs/Research Nurses
- Investigators
- Sponsor Representatives working with sites on study start-up

Instructors

This course will be taught by one of the following instructors

Karen L. Gilbert, B.S., C.C.R.A.
Lily Romero, P.A., C.C.R.C.

Course Length and Time

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

Course Dates

February 2, 2012 (12-3)

April 10, 2012 (8:30-11:30)

June 28, 2012 (12-3)

Archived Recording Available!

Fee: \$795*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation

 Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-010-L01-P. Released: 3/11.

Disqualification of Clinical Investigators: Proposed Rule and FDA Transparency Initiative

Course Description

After scrutiny from the Office of Inspector General and Congressional reports, the FDA has reexamined its procedures for disqualification of Clinical Investigators and dissemination of information surrounding its processes and determinations. As a result, the FDA has issued a proposed rule that would amend the federal regulations to expand the scope of disqualifications and make information on compliance and enforcement activities more accessible. This web seminar will review the recent changes, the reasons behind them, and what they mean for Clinical Investigators, sponsors, and IRBs.

Learning Objectives

- Discuss FDA considerations for initiation of disqualification proceedings
- Examine the FDA's disqualification process (Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE), consent agreement, Notice of Opportunity for Hearing (NOOH), hearing, and final decision)
- Discuss recent disqualifications and the documented reasons for the administrative action

- Explore the FDA's Transparency Initiative and its relation to Clinical Investigator disqualifications
- Evaluate the scope of the FDA's proposed rule for disqualification of Clinical Investigators

Who Should Attend

- Professionals from Academia involved in the oversight, documentation, and conduct of clinical research
- IRB Members, IRB Professionals, and Institutional Officials involved in the oversight of clinical research
- Clinical Quality Assurance Auditors
- Clinical Quality and Compliance Professionals
- Clinical Research Associates
- Project Managers
- Regulatory Affairs Professionals
- Clinical Investigators
- 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 12:30 – 2:30 p.m. Eastern

Course Dates

January 11, 2012 (12:30-2:30)

April 27, 2012 (9:30-11:30)

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for “Certificates of Attendance,” and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation

 Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-060-L01-P. Released: 9/11.



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
- CRAs
- Auditors
- Regulatory Affairs Professionals
- Quality Assurance Personnel
- Manufacturing Personnel

Instructors

This course will be taught by one of the following instructors

Gary B. Freeman, M.S., C.C.R.A., C.C.R.T.
Albert A. Ghignone, M.S., R.A.C.
Jeanne Morris B.S., MT (ASCP)

Course Length and Time

3 hours 12:30 – 3:30 p.m. Eastern

Course Dates

January 20, 2012

April 20, 2012

Archived Recording Available!

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-0000-09-058-L01-P. Released: 2/10.

Drug Safety and Pharmacovigilance

Course Description

This web seminar will deliver an introduction to the basics of drug safety and pharmacovigilance, including regulatory requirements, Adverse Event reporting, signaling, and risk management. Successful navigation of drug safety and pharmacovigilance are keys to product longevity, consumer confidence, and regulatory compliance. This web seminar will also provide learners with the regulatory references, processes, best practices, and analysis and investigation techniques to minimize risk, avoid product recall, and meet international safety and reporting standards.

Learning Objectives

- Work to international standards by meeting regulatory requirements for product safety
- Collect, assess, report, and analyze Adverse Events
- Identify differences between U.S. and European legal requirements

Who Should Attend

- Clinical Safety/Pharmacovigilance Specialists
- Regulatory Affairs Professionals
- Quality Management Specialists

Instructor

Steve Jolley

Course Length and Time

1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates

April 11, 2012

Archived Recording Available!

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-027-L01-P. Released: 2/11.



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 electronic medical record. More and more research sites are using an EMR for all or part of their case histories for research subjects. The industry has defined the characteristics that source documents in any form must include, and 21 CFR Part 11 includes standards for electronic source data. Challenges in monitoring the original source document have been growing and unaddressed in many situations. The FDA's final guidance document for 21 CFR Part 11 supports certain characteristics that EMRs should include, but many site electronic records do not meet the requirements. This web seminar will discuss assessment of EMRs, ideal monitoring vs. contingency planning, and risk management.

Learning Objectives

- Define source documents (FDA & ICH)
- Explain required characteristics for source documents in any form
- Describe requirements of electronic source documents (21 CFR Part 11)

- Apply these concepts to electronic medical records at research sites
- Implement contingency planning for electronic source document deficiencies
- Manage site and sponsor activities regarding electronic medical records

Who Should Attend

- Investigators
- CRCs
- Device and Drug Study CRAs
- CRA Managers
- Project Managers
- Quality Assurance Personnel

Instructors

This course will be taught by one of the following instructors

Karen L. Gilbert, B.S., C.C.R.A.
Jeanne Morris, B.S., MT (ASCP)
Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A.,
C.C.R.C.

Course Length and Time

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

Course Dates

February 10, 2012 (12-2:30)

May 7, 2012 (8:30-11)

Archived Recording Available!

Fee:

\$795*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-011-L01-P. Released: 3/11.

Electronic Source Documentation: Navigating the New FDA Draft Guidance

Course Description

As the use of electronic source documentation (eSource) increases in clinical research, so does the scrutiny for ensuring the integrity of the systems used to generate and retain electronic source data. In late 2010, new draft guidance was released regarding the use of electronic source documentation, providing direction to sponsors, Contract Research Organizations (CROs), data management centers, and Clinical Investigators on capturing, using, and archiving electronic data in FDA-regulated clinical investigations. The new draft guidance focuses on the flow of data through those systems from input to analysis and "is intended to promote the capture of source data in electronic form." 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 current regulatory climate leading to the new eSource guidance
- Examine the three tiers of data management – Data Entry, Data Review, and Data Processing and Transmission

- Discuss the Clinical Investigator's responsibilities for eSource data origination, integrity, review, release for processing and retention
- Assess the implications of the guidance on current source documentation practices and policy
- Review the FDA's expectations and inspection processes for eSource

Who Should Attend

- Clinical Research Associates
- Project and CRA Managers
- Clinical Investigators and Staff
- Clinical Research Professionals involved in site and IRB assessment and/or selection
- Professionals from Academia involved in the oversight, documentation, and conduct of clinical research
- Quality Assurance and Compliance Professionals
- Data Management Professionals

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

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

Course Dates

January 10, 2012 (9:30-11:30)

June 15, 2012 (12:30-2:30)

Archived Recording Available!

Fee:

\$695*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-061-L01-P. Released: 9/11.



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
- CRAs
- Quality Assurance Personnel
- CRA Managers/Project Managers

Instructors

This course will be taught by one of the following instructors

Natalie Currie, B.Sc.

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

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

Course Length and Time

2.5 hours 12:00 – 2:30 p.m. Eastern

Course Dates

January 12, 2012

April 19, 2012

Archived Recording Available!

Fee: \$695*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.

Accreditation



Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-071-L01-P. Released: 8/11.

FDA Drug Approval Process

Course Description

This web seminar provides an overview of what is required to take a new drug from research to market. We will begin by reviewing the contents of an IND, and then follow the process of an IND submission. From there, the contents and approval process of an NDA submission will be discussed. This web seminar will also provide a foundation for those who require an understanding of the FDA new drug approval process, and help attendees become familiar with the regulatory landscape in which INDs and NDAs are developed and approved.

Learning Objectives

- Navigate the FDA approval process for a new drug
- Describe what an IND is, and identify the contents of an IND

- Describe what an NDA is, and identify the contents of an NDA
- Discuss the FDA IND and NDA review process

Who Should Attend

- Regulatory Affairs Personnel
- Quality Assurance Personnel
- Manufacturing Personnel
- Research Personnel
- Those that have to be familiar with the preparation of INDs and NDAs
- Those that have to understand the FDA new drug approval process

Instructor

Albert A. Ghignone, M.S., R.A.C.

Course Length and Time

3 hours 12:30 – 3:30 p.m. Eastern

Course Dates

April 27, 2012

Archived Recording Available!

Fee: \$695*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.

Accreditation



Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-022-L01-P. Released 2/11.



FDA Guidance: IRB Continuing Review of Clinical Investigations

Course Description

In this web seminar, the content of the new 2010 draft guidance is reviewed in detail. Perhaps more importantly, the implications of how this guidance affects the essential documentation practices and activities between the sponsor, investigator, and the reviewing IRBs are examined. Also covered is how the guidance fits in with other recent releases by the agency that promote implementing a risk-based approach for all stakeholders in performing their regulatory requirements for FDA-regulated trials. For example, we will discuss the document's suggested expansion of the current sponsor IRB information exchange practices, which clarify the sponsor's role in regard to the IRB information submission that is vaguely spelled out in the regulations.

Learning Objectives

- Describe the history of what lead to the guidance release: Risk-based focus
- Describe the recommendations regarding the criteria, process, and frequency of continuing review

- Identify how the guidance recommendations differ from current practices
- Discuss the implications of the guidance on IRB, investigator, and sponsor activities
- Review case scenarios, including recent warning letters

Who Should Attend

- Investigators and Site Managers
- Research Coordinators
- IRB Professionals
- Clinical Research Associates
- Sponsor/CRO Managers
- Quality Assurance Personnel

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates

April 23, 2012

Archived Recording Available!

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-0000-10-002-L01-P. Released: 5/10.

FDA Meetings: Drugs and Biologics

Course Description

An integral part of any successful regulatory strategy is meeting with a regulatory agency, early and often, to reach concurrence on 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 all the components of the FDA's meeting requirements as well as the elements that are not requirements but make the process smoother. 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 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 and specific requirements will be reviewed.

Learning Objectives

- Discuss types of FDA meetings
- Plan the timing of the meeting request
- Plan the timing of the meeting package
- Organize the meeting package
- Manage meeting logistics, including who should attend

- Manage meeting decorum
- Conduct meeting rehearsals
- Take meeting minutes and submit them to the agency

Who Should Attend

- Regulatory Professionals
- Quality Assurance Personnel
- Manufacturing Personnel
- Clinical Research Professionals
- Project Managers
- Pre-Clinical Personnel

Instructor

Meredith Brown-Tuttle, R.A.C.

Course Length and Time

1.5 hours 12:00 – 1:30 p.m.
and 2:30 – 4:00 p.m. Eastern

Course Dates

February 7, 2012 (12-1:30)

May 24, 2012 (2:30-4)

Archived Recording Available!

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-037-L01-P. Released 2/11.



FDA Requirements for Sponsors to Report Fraud

Course Description

This course will present the content and discuss the impact of the new FDA draft regulatory amendment to 21CFR312.56 & 21CFR812.46 regarding the sponsor responsibility for review of ongoing investigations and monitoring investigations, respectively. The web seminar will present events leading up to the draft, and include a discussion of what reporting a suspicion of fraud vs. a confirmed case of fraud means, as well as discussion of what is not in the rule that was anticipated.

Learning Objectives

- Recognize the history of the draft regulation and events leading to the release
- Review the content of the draft related to 21CFR312.56 & 21CFR812.46
- Examine implications on stakeholder activities

Who Should Attend

- Sponsors/CROs
- Project Managers
- Medical Writing Professionals
- Regulatory Professionals
- Quality Assurance Personnel
- Data Management Professionals

Instructor

Jeanne Morris, B.S., MT (ASCP)

Course Length and Time

1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates

February 13, 2012

June 18, 2012

Archived Recording Available!

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



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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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-10-028-L01-P. Released 8/10.

FDA's Bioresearch Monitoring (BIMO) Program: New Guidance for Inspection of Sponsors, CROs, and Monitors

Course Description

The FDA recently released its much-anticipated Compliance Program Guidance Manual on how agency investigators are trained to conduct inspections of sponsors, Contract Research Organizations (CROs), and monitors involved in the conduct of clinical research. This web seminar will review 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 new guidance and rules that support changes in inspection focus
- Assess the FDA's application of the guidance 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

Instructors

This course will be taught by one of the following instructors

Jeanne Morris B.S., MT (ASCP)

Elizabeth Ronk Nelson, M.P.H

Course Length and Time

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

Course Dates

January 9, 2012 (9:30-11:30)

June 14, 2012 (12:30-2:30)

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-074-L01-P. Released 9/11.



FDA's Human Subject Protection (HSP)/Bioresearch Monitoring (BIMO) Initiative: A Progress Report on New Regulations, Guidances, and Partnerships

Course Description

In response to public concern, and federal inquiry, stemming from myriad current events involving the oversight of the products it regulates, the FDA has recently developed and issued new regulations, guidance, and procedures to support the agency's mission to improve the conduct of clinical trials, assess the accuracy and reliability of clinical trial data, and secure the protection of human research participants involved in those trials. This web seminar will address some of the incidents that have led to these new developments, the federal agencies involved in overseeing the FDA, their findings, and how the FDA's response to the recommendations will impact the conduct of clinical trials.

Learning Objectives

- Describe causal factors and their relationship to the current clinical research environment
- Examine key areas of concern from Congress, the Office of the Inspector General (OIG), and the General Accounting Office (GAO)

- Identify new regulations, guidances, procedures, coalitions, working groups, and pending and proposed legislation

Who Should Attend

- Clinical Quality Assurance Professionals
- Clinical Research Associates
- Project Managers
- Investigators
- Study Coordinators
- IRB Professionals
- Institutional Officials involved in oversight of clinical research
- GCP-Focused Regulatory Affairs Professionals

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

2 hours 12:30 – 2:30 p.m. Eastern

Course Dates

April 24, 2012

Archived Recording Available!

Fee:

\$595*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-030-L04-P. Released: 8/09.

Final AE Regulatory Guidance: Reporting/Communication of Safety Information from Clinical Trials to IRBs

Course Description

This web seminar presents content and impact discussion of the new FDA and Office of Human Research Protections (OHRP) Adverse Event reporting guidance documents posted in 2007. 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: April 2007 Draft Guidance
- Describe the OHRP's response: January 2007 Final Guidance
- Recognize implications for current practices
- Examine case scenarios

Who Should Attend

- Sites: Principal Investigators, CRCs, Managers
- Sponsors: CRAs, Sponsor Clinical Operations, Safety Information Specialists, Regulatory Professionals

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates

April, 25, 2012

Archived Recording Available!

Fee:

\$595*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-10-040-L01-P. Released 9/10.



Final FDA Guidance for Supervisory Responsibilities of Investigators: What Made it Through and How It Affects Sites and Sponsors

Course Description

This web seminar presents content and impact discussion of the now FINAL FDA Human Subject Protection Guidance Document posted in May 2007 and approved in October 2009. The guidance document addresses definitions of adequate supervision, appropriate oversight and delegations, adequate training, proper credentialing by principal investigators, and reasonable medical care and access to appropriate care for study subjects. How the guidance provides long awaited counseling on activities of the principal investigator regarding working with their study team and how the guidance impacts greatly on the role of the sponsor in qualifying and monitoring the research site will also be discussed.

Learning Objectives

- Recognize the history of the guidance draft and final releases
- Analyze the two major content areas of the guidance for the clarification of certain investigator responsibilities

- Examine implications on site and sponsor activities
- Explore case scenarios: Recent warning letters and more

Who Should Attend

- Clinical Research Investigators
- Clinical Research Coordinators
- Clinical Research Associates
- Clinical Research Managers
- Quality Assurance Personnel

Instructors

This course will be taught by one of the following instructors

Gary B. Freeman, M.S., C.C.R.A., C.C.R.T.
Karen L. Gilbert, B.S., C.C.R.A.
Jeanne Morris B.S., MT (ASCP)
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates

April 26, 2012

Archived Recording Available!

Fee:

\$595*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-053-L04-P.
Released: 1/10.

Final FDA Guidance: How to Complete the FDA Form 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 and CRA Managers
- Clinical Research Directors
- Regulatory Affairs Professionals
- Sponsors/CROs
- CRAs
- CRCs

Instructors

This course will be taught by one of the following instructors

Gary B. Freeman, M.S., C.C.R.A., C.C.R.T.
Karen L. Gilbert, B.S., C.C.R.A.

Course Dates

May 16, 2012

Archived Recording Available!

Fee:

\$595*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-075-L01-P.
Released: 11/11.



Financial Disclosure: New FDA Draft Guidance for Clinical Investigator Reporting

Course Description

The requirements outlined in the federal regulations governing the disclosure of financial interests by Clinical Investigators permit sponsors and the FDA to assess the potential for bias in research by review of specific information. The integrity of data obtained from clinical research studies depends in large part on the ability to ensure that the data is free from bias or conflict of interest. Federal regulations require not only disclosure of this information, but development and implementation of plans to mitigate and manage any perceived or real conflict. This web seminar will focus on clinical research professionals' responsibilities for disclosing, reporting, and managing potential conflicts that may impact the outcome of the study and the FDA's review. Discussion will include review of sponsors' due diligence requirements, regulatory authorities' refined focus on financial information in clinical research, and the FDA's actions and recommendations for ensuring requirements are met.

Learning Objectives

- Discuss the requirements and limitations of the Form FDA 3454
- Review reporting requirements in the "real world"

- Examine acceptable management/mitigation plans
- Define and discuss Significant Payments of Other Sorts (SPOOS)
- Evaluate requirements for clinical research conducted by foreign investigators

Who Should Attend

- Clinical Research Associates
- Clinical Investigators
- Project Managers
- Clinical Research Professionals involved in site and IRB assessment and/or selection
- Professionals from Academia involved in the oversight, documentation, and conduct of clinical research
- IRB Members, IRB Professionals, and Institutional Officials involved in oversight of clinical research
- Conflict of Interest Officers and Committee Members
- GCP-Focused Regulatory Affairs Professionals

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

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

Course Dates

January 12, 2012 (12:30-2:30)
April 30, 2012 (9:30-11:30)

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-062-L01-P. Released 9/11.

Fraud in Clinical Research: An Overview

Course Description

Fraudulent activities in clinical research undermine clinical research professionals' ability to meet their obligations for ensuring credible data is obtained from protected participants. This web seminar provides an overview of fraud in clinical research and its potential impact on the industry and the public's health.

Learning Objectives

- Discuss significant and current examples of fraud in clinical research
- Describe the current focus of regulatory and Congressional bodies and their findings
- Explain the Sponsor/CRO, IRB, Clinical Investigator, and Study Staff role in detection and prevention
- Recognize the impact and consequences of fraud in clinical research
- Landmark and recent cases of fraud in clinical research
- Group discussion of best practices

Who Should Attend

- Clinical Quality Assurance Professionals
- Clinical Research Associates
- Project Managers
- Clinical Investigators
- Study Coordinators
- IRB 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 Dates

January 10, 2012 (12:30-2:30)
April 25, 2012 (9:30-11:30)
Archived Recording Available!

Fee: \$795*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-023-L04-P. Released: 8/09.



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
- Influence without authority
- Discover negotiation techniques
- Evaluate risk and develop contingency plans
- Design a process improvement plan

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 23, 2012

Fee: \$695*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.

Accreditation



Barnett International is accredited by the Accreditation Council for 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-10-029-L01-P. Released 10/10.

GCP Training for Investigators

Course Description

This web seminar provides a brief review of new drug development and the clinical trial process as it affects the investigator, and explains where Good Clinical Practice (GCP) fits in. Relevant sections of the Code of Federal Regulations (CFR), International Conference on Harmonization (ICH), and Form FDA 1572 are discussed in-depth and in relationship to the investigator's responsibilities for proper conduct of clinical trials. This course will highlight the 13 principles of ICH GCP as the foundation for all clinical studies, and demonstrate to the investigator the rationale for sponsor requirements throughout clinical development of an investigational drug.

Learning Objectives

- Identify the key stages of the drug development process
- Describe the elements involved in the clinical trial process
- Apply the principles of ICH GCP to current clinical trials

- Examine the investigator's responsibilities in the conduct of clinical trials as required in the regulations (CFR) and guidelines (ICH)
- Recognize the commitment made in executing the Form FDA 1572

Who Should Attend

- New Principal Investigators
- Seasoned Principal Investigators interested in reviewing responsibilities
- Sub-Investigators
- Physicians interested in participating in clinical research
- Site Research Managers/Directors

Instructors

This course will be taught by one of the following instructors
Gary B. Freeman, M.S., C.C.R.A., C.C.R.T.
Karen L. Gilbert, B.S., C.C.R.A.
Jeanne Morris B.S., MT (ASCP)

Course Length and Time

3 hours 12:30 – 3:30 p.m. Eastern

Course Dates

February 10, 2012

Archived Recording Available!

Fee: \$795*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.

Accreditation



Barnett International is accredited by the Accreditation Council for 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-023-L01-P. Released: 3/11.



NEW! Going Independent: Fundamentals for Independent Consultants

Course Description

Taking the steps toward becoming an independent Clinical Research Associate (CRA) or consultant can be daunting. Questions arise such as: How do I manage my business, how and where do I find contracts, what type of savings/retirement plan should I consider, do I need insurance, and who can I ask for help? This web seminar will address those questions as well as take you through the necessary steps to determine if becoming an independent contractor is right for you, or, if you are already an independent consultant, how you can manage your business more efficiently and with more stability. Some key business structures such as sole proprietorships, C- Corporations, S- Corporations, and LLCs, and the advantages/disadvantages of each, will also be addressed.

Learning Objectives

- Describe the key criteria for being a successful independent consultant
- Explain the types of business structures that should be considered and the pros/cons of each

- Describe how to find contracts and maintain a steady workload

Who Should Attend

- Those considering becoming an independent Clinical Research Associate or consultant
- Independent contractors looking to further stabilize and develop their business

Instructor

Nikki Christison, B.S.

Course Length and Time

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

Course Dates

March 27, 2012 (12:30-2:30)

June 26, 2012 (9:30-11)

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation

 Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-014-L01-P. Released: 3/12.

Good Clinical Practice: Practical Application and Implementation

Course Description

This web seminar provides an overview of the structural elements of Good Clinical Practice (GCP). Participants will learn practical application of GCP regulations and guidelines for critical components of the clinical research process. Specific attention will be given to how Quality Systems, or a lack thereof, impact overall data quality and regulatory risk. This web seminar is designed for professionals with at least two years of experience in the clinical research industry.

Learning Objectives

- Describe the elements of a functional Quality System
- Examine recent trends in non-compliance
- Discuss the role of SOPs in GCP
- Characterize the differences between the legal and procedural elements of GCP
- Recognize key differences in pharmaceutical, device, and biologics GCP

Who Should Attend

- Clinical Quality Assurance Professionals
- Clinical Research Associates
- Project Managers
- Investigators
- Study Coordinators
- GCP-Focused Regulatory Affairs Professionals

Instructors

This course will be taught by one of the following instructors

Gary B. Freeman, M.S., C.C.R.A., C.C.R.T.
Karen L. Gilbert, B.S., C.C.R.A.
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

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

Course Dates

February 17, 2012 (12:30-2:30)

April 26, 2012 (9:30-11:30)

June 13, 2012 (12:30-2:30)

Archived Recording Available!

Fee: \$795*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation

 Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-020-L04-P. Released: 8/09.



HIPAA/HITECH Requirement Changes and Enforcement: For Research Centers

Course Description

The 2009 stimulus package brought with it the HITECH Rule, which became effective February 17, 2010, and resulted in some changes to concepts and definitions within the Privacy and Security Rules impacting covered entities' responsibilities. The impact of non-compliance has increased and intensified a great deal. Come learn the expanded definitions of covered entity, business associate, unauthorized disclosures, penalties, and more. We will also discuss corrective action planning, and preparing for the increased amount of covered entity inspections, both routine and complaint driven.

Learning Objectives

- Apply the latest regulatory changes and notices impacting to the HIPAA Privacy & Security Rules specific to medical practices
- Examine covered entities compliance and the need to prepare for inspections from the Office for Civil Rights (OCR)
- Develop and respond to a gap analysis of current systems for compliance

- Implement best practices that do not contradict with the FDA and other regulatory authorities outside of research
- Examine the Enforcement Rule updates and implications

Who Should Attend

- Privacy Officers
- Site Managers
- CRCs/Research Nurses
- Investigators
- Project Managers
- CRA Managers
- CRAs
- Quality Assurance Personnel
- Regulatory Professionals

Instructors

This course will be taught by one of the following instructors

Jeanne Morris, B.S., MT (ASCP)
Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time

1.5 hours 12:00 – 1:30 p.m. Eastern

Course Dates

March 23, 2012

Archived Recording Available!

Fee:

\$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 (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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-049-L04-P.
Released: 3/10.

HIPAA Team Training: Fundamental Training Specifically for Clinical Research Settings

Course Description

By popular demand, HIPAA Team Training has been designed as a course presenting concepts and terminology of HIPAA specific to conducting clinical trials. The web seminar presents the core elements with methodologies for blending the concepts into established clinical trial best practices. The focus of the course is to train sponsors/CROs and site clinical researchers HIPAA concepts for later application in day-to-day roles.

This web seminar is ideal for new employee orientations and/or initial annual HIPAA training specific to clinical trials. Presented in understandable terms, this course is also ideal for those who never quite understood HIPAA or are confused about what their role involves. Concepts discussed include the HIPAA Privacy Rule and Enforcement Rule 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

Who Should Attend

- Research Site Managers
- CRCs/Research Nurses
- Principal Investigators and Sub-Investigators
- Project Managers and CRA Managers
- CRAs
- 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

Jeanne Morris, B.S., MT (ASCP)
Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time

3 hours 12:00 – 3:00 p.m. Eastern

Course Dates

March 22, 2012

Archived Recording Available!

Fee:

\$595*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-012-L01-P.
Released: 3/11.



NEW! How Sites Can Own the Study Process

Course Description

Relationships between sites and Clinical Research Associates (CRAs) are often strained, and frustrations can interfere with a productive relationship. By helping sites better understand the intent and application of Good Clinical Practices (GCPs) and how to apply the who, what, and why behind the regulations, sites can begin to take ownership for their own practices. With an emphasis on the why behind developing standard operating procedures and documented practices, the time, energy, and frustration around discussion of "changing" monitor and sponsor requests can be proactively and positively addressed. Real life scenarios and problem solving techniques will be discussed based on what can appear to be unreasonable monitor and sponsor requests.

Learning Objectives

- Describe a variety of approaches for interpreting and applying GCPs
- Explain the importance and practical application of developing standard clinical practices for research

- Discuss problem solving techniques based on a variety of real life scenarios

Who Should Attend

- Study Coordinators
- Site Managers
- Site Regulatory Managers
- Clinical Research Associates
- Principal Investigators

Instructor

Nikki Christison, B.S.

Course Length and Time

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

Course Dates

February 21, 2012 (9:30-11)
June 7, 2012 (1-2:30)

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-012-L01-P. Released: 2/12.

Implications of the New FDA Guideline for a Risk-Based Approach to Monitoring

Course Description

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

Learning Objectives

- Explain ways in which the regulatory climate is reflected in the new monitoring guideline
- Discuss the content of the guideline in relation to traditional monitoring plans
- Assess the implications of the guideline to current monitoring practices and relationships with oversight of Clinical Investigator

Who Should Attend

- Clinical Investigators and Staff
- Clinical Research Associates
- Study and CRA Managers
- Sponsors/CROs Clinical Operations
- Clinical Quality Compliance and Quality Assurance Professionals

Instructor

Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time

1.5 hours 9:00 – 10:30 a.m.
and 12:00 – 1:30 p.m. Eastern

Course Dates

January 20, 2012 (12-1:30)
April 13, 2012 (9-10:30)
Archived Recording Available!

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation

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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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-081-L01-P. Released: 8/11.



The IND in a CTD/eCTD Format

Course Description

The Common Technical Document (CTD) format is now the required format for all marketing applications in the U.S., EU, Japan, Canada, and Australia. Clinical Trial Applications (CTAs), the required format of INDs in most countries, are required to be in the CTD format. Currently, the U.S. does not require INDs to be in the CTD format, but rather the traditional format (per regulations in 21 CFR 312.23). However, since all marketing applications are required in the CTD format, it is more efficient to start the IND in the CTD format. If you use the traditional format, the IND and all amendment information must be converted to the CTD format prior to marketing application submission. This conversion time can impact the timeline for marketing application submission, so why not plan ahead for a successful marketing application and start the IND in the CTD format?

Currently, there is no guidance document to facilitate the transfer or mapping of information from the IND requirements contained in 21 CFR 312.23 to the CTD format. There is often a difference of opinion on where information should be stored. This web seminar will give an overview of the IND requirements and where

they can most effectively “fit” into the CTD requirements for a streamlined FDA review and building of the IND into a marketing application.

Learning Objectives

- Describe the Common Technical Document 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 is 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

Meredith Brown-Tuttle, R.A.C.

Course Length and Time

1.5 hours 12:00 – 1:30 p.m.
and 2:30 – 4:00 p.m. Eastern

Course Dates

February 7, 2012 (2:30-4)

May 24, 2012 (12:1:30)

Archived Recording Available!

Fee:

\$695*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.

Accreditation



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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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-044-L01-P. Released 2/11.

Informed Consent Content & Process Requirements

Course Description

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

Learning Objectives

- Examine required content of the Informed Consent Form (ICF): Are all stakeholders checking?
- Define the informed consent process per regulations and best practices
- Clearly define who and what determines if consent has been adequately executed
- Evaluate exceptions for obtaining consent, and the role of the research site, Institutional Review Board (IRB), and sponsor in the process

- Apply clear documentation of the informed consent process, including withdrawal of consent
- Review elements that must be included in an authorization for use and disclosure of protected health information
- Compare and contrast HIPAA authorization and the informed consent process

Who Should Attend

- Clinical Research Coordinators
- Site Research Managers
- Clinical Research Monitors
- Sponsor Project Managers
- Investigators

Instructors

This course will be taught by one of the following instructors

Gary B. Freeman, M.S., C.C.R.A., C.C.R.T.
Karen L. Gilbert, B.S., C.C.R.A.
Jeanne Morris B.S., MT (ASCP)
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

2.5 hours 12:00 – 2:30 p.m. Eastern

Course Dates

April 23, 2012

Archived Recording Available!

Fee:

\$595*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-014-L01-P. Released: 3/11.



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

Course Length and Time

3 hours 12:30 – 3:30 p.m. Eastern

Course Dates

March 15, 2012

May 15, 2012

Archived Recording Available!

Fee:

\$695*
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-072-L01-P. Released: 8/11.

Introduction to Signal Detection and Data Mining

Course Description

This web seminar will cover the fundamentals of signal detection, and how signal detection can be augmented by the use of data mining techniques. The requirement for companies to perform signal detection is now mandatory in Europe and highly recommended in the U.S. Many simple techniques can be applied to the generation and review of potential signals, which can also be augmented by the application of sophisticated data mining algorithms.

Learning Objectives

- Explain the basic concepts and principles of signal detection
- Outline how to apply these data mining techniques
- Employ data mining techniques to analyze large volumes of Adverse Event report
- Perform analysis and visualization of potential signals
- Define required data sources and formats for analysis
- Develop data mining algorithms and apply them to risk assessment

Who Should Attend

- Pharmacovigilance Professionals
- Pharmacoepidemiology Professionals
- Regulatory Affairs Professionals

Instructor

Steve Jolley

Course Length and Time

1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates

March 14, 2012

Archived Recording Available!

Fee:

\$795*
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-024-L04-P. Released: 9/09.



NEW! Investigator Selection Criteria and Strategies for Investigator Qualification

Course Description

Investigator selection is one of the most critical tasks facing clinical research professionals in today's compliance-driven environment. Yet the task is often performed with inadequate time and resources by individuals who are facing multiple competing projects and timelines. How can you better ensure the identification of the best qualified investigator candidates to ensure overall study success? By developing a strategy for an investigator selection process which includes the following: A detailed and study-specific investigator profile, a truly effective site feasibility questionnaire, leveraging existing staff members' unique skill sets, and strategies for maximizing the value of site evaluation/selection visits..

Learning Objectives

- Describe the necessary elements of an investigator profile
- Compare and contrast the traditional site interest questionnaire and the true site feasibility questionnaire

- Identify the skill sets that complement various phases of site evaluation
- Implement strategies for maximizing on-site evaluation/selection visits

Who Should Attend

- Clinical Research Associates
- Clinical Research Associate Managers
- Pharma/Device Professionals with responsibility for investigator selection
- Clinical Investigators and Site Staff

Instructor

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

Course Length and Time

2 hours 12:00 – 2:00 p.m. Eastern

Course Dates

January 31, 2012

April 18, 2012

Fee:

\$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-011-L01-P. Released: 1/12.

Investigator Initiated Trials: Roles and Responsibilities

Course Description

Investigator Initiated Trials (IITs), also referred to as Sponsor-Investigator (SI) Trials are increasing in popularity. A Sponsor-Investigator is anyone who functions as the Clinical Investigator (CI) of a given study and who also holds the investigational marketing application, i.e., the IND or IDE. How does the CI ensure compliance to both the investigator and sponsor responsibilities? This web seminar will present the responsibilities, discuss risk, and provide suggestions for compliance.

Learning Objectives

- Review the applicable federal regulations for Investigator Initiated Trials, including sponsor and investigator responsibilities
- Review the steps involved in initiating an Investigator Initiated Trial and review regulatory reporting requirement of investigators and sponsors
- Identify essential documentation for the Sponsor-Investigator: Remaining audit ready

- Minimize risks associated with IITs by avoiding common pitfalls associated with IITs
- Review examples of regulatory deficiencies to Sponsor-Investigators

Who Should Attend

- Investigators/Site Study Team Members
- Sponsor Study Team Members
- Ethics Committee Members

Instructor

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

Course Length and Time

2 hours 12:00 – 2:00 p.m. Eastern

Course Dates

February 27, 2012

May 3, 2012

Archived Recording Available!

Fee:

\$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



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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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-10-032-L01-P. Released 8/10.



Key Components of a Successful Study Site Start-up, Management, and Maintenance Strategy

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

Instructors

This course will be taught by one of the following instructors

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

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

Course Length and Time

2.5 hours 12:00 – 2:30 p.m. Eastern

Course Dates

March 29, 2012

Archived Recording Available!

Fee:

\$595*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.

Accreditation



Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-021-L01-P.

Released: 3/11.

Making Good Teams Better: Taking Your Cross-Functional Global Team to the Next Level

Course Description

Teamwork isn't easy. While most teams are highly skilled technically and scientifically, only the best teams can overcome the pressure, compressed deadlines, inevitable conflict, and unforeseeable turns of direction. Others struggle and get stuck in a loop of conflict, rework, and fire fighting, which slows down their work, and costs them precious time. What differentiates the best teams from the others? What are they doing behaviorally and operationally to navigate through the issues, and rise above the noise? A research study was conducted specifically to study teamwork in the pharmaceutical industry. More than 500 team members and team leaders participated – and the results are clear and compelling. There are strategies you can employ tomorrow to start getting your team back on track. Attend this session and find out what we learned.

Learning Objectives

- Distinguish five building blocks for high performance teams
- Harness the power of a structured team kick-off
- Identify 11 drivers of teamwork that increase trust, ownership, and higher performance

Who Should Attend

- Team Leaders
- Clinical Research Teams
- Product Development Teams
- Expert Teams
- Global Team Members
- Regulatory Teams
- Department Leaders

Instructor

Ruth Dubinsky, M.S., O.D.

Course Length and Time

1.5 hours 12:30 – 2:00 p.m. Eastern

Course Dates

March 26, 2012

June 25, 2012

Archived Recording Available!

Fee:

\$695*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.

Accreditation



Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-10-022-L01-P.

Released 8/10.



Managing CRAs to Improve Performance & 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. Effective management of CRAs' performance by sponsors is essential. Promoting improvement in overall and individual monitoring is also important. 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 CRAs
- CRA Managers

Instructor

Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time

2.5 hours 12:00 – 2:30 p.m. Eastern

Course Dates

May 18, 2012

Archived Recording Available!

Fee: \$595*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-073-L01-P. Released: 9/11.

March 2011 Compliance Program Guidance Manual (CPGM) Update: Recommendations for the Inspection of Sponsors, CROs, and Monitors

Course Description

The FDA released a significant update to the Compliance Program Guidance Manual (CPGM) chapter on Inspection of Sponsors, Contract Research Organizations (CROs), and Monitors (7348.810) in March 2011. This chapter is being revised to incorporate recommendations for improving communications among FDA staff before, during, and after an inspection, and to more clearly define the thresholds for initiating regulatory actions against non-compliant sponsors or CROs. In this web seminar, we will review the changes within the manual, and identify key areas of sponsor activities for audit readiness.

Learning Objectives

- Navigate the new regulatory climate related to the update to the CPGM: Why the new version?
- Discuss the content of the revised CPGM: What has changed?
- Present the implications of the changes in the CPGM for sponsors/CROs and monitoring: How does this impact how I conduct clinical trials?

Who Should Attend

- Clinical Operations
- Clinical Research Associates
- Project and CRA Managers
- Sponsors/CROs
- Clinical Quality Compliance and Quality Assurance Professionals

Instructor

Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time

1.5 hours 9:00 – 10:30 a.m.
and 12:00 – 1:30 p.m. Eastern

Course Dates

January 30, 2012 (9:10:30)

June 15, 2012 (12:1:30)

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-077-L01-P. Released 8/11.



Meeting HIPAA/HITECH & FDA Requirements for Case Histories

Course Description

The HIPAA Privacy Rule has been in effect for some time, but still the FDA clinical investigator's and Privacy Rule covered entities requirements in many cases are not easily harmonized, supporting adequate original source documentation and individual privacy protections. But both sets of rules can work well with one another, supporting protection for individuals on studies. This web seminar presents common misunderstandings regarding the roles and responsibilities of clinical research sponsors, sites, and IRBs regarding HIPAA and clinical trials. The course also offers sponsors, sites, and IRBs application strategies for improved clinical trial conduct post HIPAA.

Learning Objectives

- Discuss many of the frequently misunderstood components of the Privacy Rule relating to clinical research source documentation disclosure
- Answer many of the questions regarding frequently misunderstood components of the Privacy Rule relating to clinical research
- Describe the latest guidance and notices relating to the Privacy Rule impacting clinical research

Who Should Attend

- Research Site Trainers
- Sponsor/CRO Trainers
- CRAs
- CRCs
- Quality Assurance Personnel
- Other Site Study Personnel working with study records

Instructors

This course will be taught by one of the following instructors

Jeanne Morris, B.S., MT (ASCP)
Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time

2 hours 12:00 – 2:00 p.m. Eastern

Course Dates

June 29, 2012

Archived Recording Available!

Fee: \$595*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-068-L04-P.
Released: 3/10.

Monitoring Oncology Clinical Trials

Course Description

This web seminar will provide attendees with a general overview of oncology clinical trials and their distinct characteristics. We will review how oncology clinical trials differ from those in other therapeutic areas, with a special emphasis on the unique challenges of monitoring oncology clinical trials. Distinctions will be drawn between early and later phase trials. Attention will be paid to Adverse Event (AE) and Serious Adverse Event (SAE) reporting. All aspects of oncology clinical trials and how to successfully monitor them will also be discussed.

Learning Objectives

- Identify the differences between monitoring oncology early phase clinical trials vs. later phase clinical trials
- Identify ways in which oncology clinical trials differ from those in other therapeutic areas
- Describe the complexities of AE and SAE monitoring in oncology clinical trials
- Utilize Common Terminology Criteria for Adverse Events (CTCAE) grading and apply CTCAE to AE source data
- Address common challenges in monitoring and apply tools and techniques to overcome them

Who Should Attend

- Monitors who are new to or are interested in learning more about oncology clinical trials

Instructors

This course will be taught by one of the following instructors
Jackie Earabino, R.N., B.S.N.
Kimberly Turner, C.M.A., A.S., B.H.S., M.S.

Course Length and Time

2 hours 1:00 – 3:00 p.m. Eastern

Course Dates

February 9, 2012

May 8, 2012

Archived Recording Available!

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-031-L01-P.
Released: 4/11.



Monitoring Phase I Clinical Trials

Course Description

Phase I trials require an additional monitoring skill set. The 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 certain components of this type of monitoring. Tools to support the activities will be presented, as well as case studies to apply certain concepts.

Learning Objectives

- Distinguish Phase I monitoring activities from other types of trials
- Describe the differences between Phase I research sites and others
- Identify the importance of familiarity with PKs and timed blood drawing
- Recognize the requirements in bioequivalence drug accountability and disposition
- Describe safety monitoring in Phase I trials
- Identify additional essential document requirements
- Recognize common compliance issues at Phase I research sites

Who Should Attend

- CRA Managers
- CRAs

Instructor

Erica Elefant, R.N., B.S.N., M.S.W.

Course Length and Time

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

Course Dates

January 13, 2012 (12-2:30)
May 18, 2012 (8:30-11)
Archived Recording Available!

Fee: \$795*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-022-L01-P.
Released: 1/12.

Monitoring Plan Development

Course Description

The approach to monitoring plan development can vary from sponsor to sponsor. Come to this web seminar to learn how to set up a project monitoring plan that supports traditional and unique project needs, including regulatory expectations and valuable data regarding site and CRA performance.

Learning Objectives

- Design a traditional clinical trial project monitoring plan
- Develop a monitoring plan to meet the unique needs of a project
- Develop a monitoring plan to meet the unique needs of sites
- Link the plan to performance goals to meet project goals and promote improvement from study to study

Who Should Attend

- CRAs
- Project Managers
- CRA Managers

Instructor

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

Course Length and Time

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

Course Dates

February 28, 2012 (8:30-10:30)
April 25, 2012 (12-2)
Archived Recording Available!

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-015-L01-P.
Released: 3/11.



Monitoring Reports: 10 Rules of Effective Report Writing

Course Description

The CRA creates reports that have many audiences, one being regulatory authorities reviewing essential documentation of clinical trials linked to marketing application approvals. This web seminar presents 10 categories of scientific report writing in the context of the role of the CRA and the reports that they write. The applicable reports are monitoring visit reports, e-mails, telephone reports, Memos to File, and more. The concepts of writing in a scientific voice versus first person, objective versus subjective, and many more are presented. This course is invaluable for the CRA, as well as the individual who critiques the various reports.

Learning Objectives

- Examine the impact of poor report writing
- Apply the definitions and concepts of scientific report writing
- Implement the 10 rules of quality report writing for CRAs

- Apply the 10 rules to CRA activities
- Write action items, deviations, queries
- Integrate essential document mapping within a monitoring report
- Appreciate the challenges of CRA report writing and report review

Who Should Attend

- CRAs
- Contract CRAs
- CRA Managers
- Project Managers

Instructors

This course will be taught by one of the following instructors

Gary B. Freeman, M.S., C.C.R.A., C.C.R.T.
Karen L. Gilbert, B.S., C.C.R.A.

Course Length and Time

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

Course Dates

January 9, 2012 (12-3)

April 9, 2012 (12-3)

May 11, 2012 (8:30-11:30)

Archived Recording Available!

Fee: \$795*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



Barnett International is accredited by the ACPE 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-10-042-L01-P. Released 9/10.

New FDA Guideline to Informed Consent

Course Description

The FDA has announced the release of a guideline for informed consent, "Guidance on Exculpatory Language in Informed Consent." The guidance is aligned with the Office for Human Research Protections' (OHRP) recommendations, and many useful examples are included. In this web seminar, we will review examples of Informed Consent Form (ICF) language, and discuss how to apply the recommendations of the guideline to ICFs.

Learning Objectives

- Navigate the regulatory climate related to the new guideline: Why the guidance?
- Discuss the content of the guideline: What do you need to know?
- Present the implications of the guideline on current practices and policy: How does it impact how you conduct clinical trials?

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

Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time

1.5 hours 9:00 – 10:30 a.m.
and 12:00 – 1:30 p.m. Eastern

Course Dates

January 27, 2012 (12-1:30)

April 23, 2012 (9-10:30)

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



Barnett International is accredited by the ACPE 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-078-L01-P. Released 9/11.



Pediatric Clinical Drug Development

Course Description

Fueled by the encouragement from regulatory agencies in the U.S. and Europe, the art and science of pediatric drug development has evolved rapidly in pharmaceutical companies over the last few years. Due to recent governmental initiatives such as the Pediatric Research Equity Act (PREA) in the U.S. and Pediatric Investigation Plans (PIPs) in Europe, pharmaceutical companies have been given clear pathways and incentives to develop drug indications and products for this important group of patients. This web seminar will examine these regulatory initiatives and discuss practical and effective development approaches and study designs.

Learning Objectives

- Identify recent regulatory initiatives that encourage drug development in pediatrics
- Examine the limitations of working in this population and how to overcome them
- Apply adult data to the pediatric population
- Utilize pharmacokinetic and pharmacodynamic data
- Examine study designs and approaches successfully used for approval
- Develop a pediatric plan outline

Who Should Attend

- Project Team, Clinical Team, and Study Team Members
- Individuals moving into the drug development area
- Clinical Investigators working with pharmaceutical companies

Instructor

Robert L. Kunka, Ph.D.

Course Length and Time

3 hours 12:30 – 3:30 p.m. Eastern

Course Dates

February 16, 2012

May 17, 2012

Archived Recording Available!

Fee:

\$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-10-037-L01-P. Released 9/10.

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 a Phase I Study
- Describe the attributes of an effective Phase I Unit
- List project management best practices specific for Phase I clinical trials

Who Should Attend

- Project Managers
- Study Directors
- Site Monitors

Instructor

Erica Elefant, R.N., B.S.N., M.S.W.

Course Length and Time

1.5 hours 1:00 – 2:30 p.m. Eastern

Course Date

June 8, 2012

Fee:

\$595*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



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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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-061-L04-P. Released: 6/10.

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
- CRAs/Site Managers
- Research Site Personnel

Instructors

This course will be taught by one of the following instructors

Karen L. Gilbert, B.S., C.C.R.A.
Jeanne Morris, B.S., MT (ASCP)

Course Length and Time

2.5 hours 12:00 – 2:30 p.m. Eastern

Course Dates

April 2, 2012

Fee:

\$595*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-019-L01-P. Released: 5/11.

Preparing for a Safety Inspection

Course Description

To ensure compliance, regulatory authorities routinely conduct inspections of companies' drug safety operations. To prepare for an inspection, you must perform a thorough drug safety and pharmacovigilance audit. An internal audit will assess your company's compliance with applicable worldwide laws, regulations, and guidances. Indeed, regulatory inspectors will look for evidence that such an audit has taken place. This web seminar will provide participants with practical strategies for preparing for a safety inspection at their company via an internal audit.

Learning Objectives

- Obtain the practical information needed to understand the applicable regulations and achieve compliance
- Explain the impact of global regulations on international safety reporting and review methods
- Describe the requirements of all applicable regulatory bodies for your company's products

Who Should Attend

- Clinical Safety/Pharmacovigilance Specialists
- Regulatory Affairs Professionals
- Quality Management Specialists

Instructor

Steve Jolley

Course Length and Time

1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates

May 9, 2012

Archived Recording Available!

Fee:

\$695*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-024-L01-P. Released: 2/11.



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/CRA Managers
- Clinical Research Coordinators
- Sponsors/CROs

Instructors

This course will be taught by one of the following instructors

Gary B. Freeman, M.S., C.C.R.A., C.C.R.T.,
Jeanne Morris B.S., MT (ASCP)
Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A.,
C.C.R.C.

Course Length and Time

1.5 hours 9:00 – 10:30 a.m.
and 12:00 – 1:30 p.m. Eastern

Course Dates

March 2, 2012 (9-10:30)

June 1, 2012 (12-1:30)

Archived Recording Available!

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-079-L01-P. Released 9/11.

Principal Investigator Training: Roles and Responsibilities

Course Description

The roles and responsibilities of the Principal Investigator (PI) are essential for quality data and regulatory compliant clinical trials, but the PI remains an under-trained position in the industry. Because of the critical role the PI plays during a clinical trial, there is debate within the industry of mandatory certification for the PI and/or site accreditation. Documentation of industry training is essential. This web seminar reviews the clinical trial core competencies required for the Principal Investigator in accordance with the federal regulations, ICH GCP guidelines, and industry best practices.

Learning Objectives

- Recognize GCPs and the responsibilities of the Principal Investigator
- Examine protocol content
- Identify essential documents and the regulatory binder
- Define source documentation

- Examine informed consent and HIPAA authorization
- Examine sponsor visits and reports
- Explain investigational product management
- Define safety reporting and Adverse Event documentation
- Discuss FDA audits
- Apply tools and resources

Who Should Attend

- Physicians and others interested in getting involved in research
- Experienced PIs or Site Personnel looking to take an industry investigator certification exam

Instructors

This course will be taught by one of the following instructors

Gary B. Freeman, M.S., C.C.R.A., C.C.R.T.
Karen L. Gilbert, B.S., C.C.R.A.
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

3 hours 12:00 – 3:00 p.m. Eastern

Course Dates

May 11, 2012

Archived Recording Available!

Fee: \$795*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-038-L04-P. Released: 8/09.



NEW! Proposed Changes to DHHS Human Subjects Research Protections: Enhancing Subject Protection and Reducing Ambiguity for Investigators

Course Description:

The DHHS, the United States' agency that houses both OHRP and the FDA, recently released its announcement for proposed rule changes to the regulations that govern the conduct of human subject research in an effort to streamline, modernize, and increase their effectiveness. Human subject protection regulations have not always kept pace with the evolution of clinical research. As a result, the regulatory requirements to which those involved in clinical research are held accountable are unclear, inconsistent, and outdated. This web seminar will review DHHS' proposed changes to 45 CFR 46 and 21 CFR 50 and 56 and the factors driving the transformation. Specifically, recent guidance documents and legislation will be linked to better understand how the conduct of clinical research can be utilized to enhance compliance.

Learning Objectives:

- Discuss the identified need to ensure review of protocols is equivalent to degree of risk
- Review the proposed model for more efficient IRB review
- Assess how amendments to the consent document and process can enhance subject protection

- Examine how changes in risks have necessitated alterations in how and which information is protected
- Explore the impact of risk-based monitoring on human subject protection

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)/ Academic Research Organizations (AROs)
- Clinical Quality Assurance Auditors and Compliance Professionals
- Clinical Research Associates
- Project Managers
- Institutional Review Board Staff and Members
- Regulatory Affairs Professionals
- Clinical Research Coordinators
- Sponsor-Investigators

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time:

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

Course Dates

January 11, 2012 (9:30-11:30)
March 15, 2012 (12:30-2:30)

Fee:

\$695*
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-010-L01-P.
Released: 1/12.

NEW! Quality Risk Management in Clinical Trials and Pharmacovigilance

Course Description

The ICH Q9 Quality Risk Management (QRM) guideline has become an accepted standard, facilitating the development and implementation of a systematic risk-based approach to quality management of clinical trials and pharmacovigilance. Industry and regulatory bodies, including the EMA and FDA, have recognized the need and benefits of implementing a risk-based approach to quality management. This web seminar is designed to provide a strong conceptual foundation of the principles of quality risk management with a clear focus on the application of these principles. The course will address applying QRM to support decision-making throughout the clinical trial management and pharmacovigilance process, allocating limited resources effectively to areas of high risk, and preparing the participant to become an active contributor towards risk-based quality management at his/her organization.

Learning Objectives:

- Define Quality Management System (QMS) levels for applicable areas in clinical trials and pharmacovigilance
- Build quality at key points in the process

- Apply QRM principles: Identification and quantification of key risk indicators
- Implement a quality by design approach to overcome shortcomings in quality and compliance
- Leverage existing information to support decision making in resource allocation within clinical trials
- Create a governance model to support mitigation strategies and the overall QMS infrastructure

Who Should Attend

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

Instructors

Ken Schiff B.A., M.B.A.
Randy Ramin-Wright, M.Sc.

Course Length and Time:

1.5 hours 9:00 – 10:30 a.m.
and 12:00 – 1:30 p.m. Eastern

Course Dates

February 9, 2012 (9-10:30)
April 3, 2012 (12-1:30)

Fee:

\$695*
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-015-L01-P.
Released: 2/12.



Quality Systems: A Controlled Approach to GCP Compliance

Course Description

A Quality Systems approach to establishing and maintaining regulatory compliance allows sponsors to better leverage their resources and Clinical Investigators to meet their obligations for clinical research oversight. This web seminar will review the elements of a Quality System at the Clinical Investigator site and how it functions to proactively control site-level noncompliance.

Learning Objectives

- Discuss an overview of sponsor and Clinical Investigator responsibilities
- Explain how to identify the active elements of a functional Quality System at the clinical research site
- Discuss how implementation of a Quality System can assist in the requirements for meeting obligations of sponsors and Clinical Investigators
- Determine how Quality System overlaps with FDA Guidance
- Examine recent compliance concerns and how applying the Quality System framework at the site level can address them

Who Should Attend

- Directors of Clinical Operations at clinical research sites
- Clinical Principal Investigators
- Clinical Research Coordinators
- Clinical Research Associates
- Project Managers
- All Clinical Research Personnel involved in selecting and/or overseeing clinical research sites

Instructor

Elizabeth Ronk Nelson, M.P.H.

Course Length and Time

2 hours 12:30 – 2:30 p.m. Eastern

Course Dates

April 27, 2012

Archived Recording Available!

Fee:

\$695*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-023-L01-P. Released: 4/12.

Recent Trends in Noncompliance: Critical Review and Analysis of Recent Regulatory Letters and Communications

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. The FDA's 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 preventative action plans are developed to secure compliance. This web seminar will examine the trends in recent regulatory communication (warning, NIDPOE, NOOH letters and 483s) and open discussion for review of acceptable versus unacceptable responses.

Learning Objectives

- Review recent FDA findings for Clinical Investigators (sites), sponsors, and IRBs
- Determine areas of compliance concentration for CBER, CDER, and CDRH

- 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 (e.g., a 483)

Who Should Attend

- Clinical Research Associates
- Project Managers
- Clinical Research Coordinators
- Clinical Principal Investigators
- 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 Dates

April 30, 2012

Fee:

\$695*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-024-L01-P. Released: 4/12.



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

- Correctly calculate TRG disease response
- Identify and predict common trends with tumor data
- Use working knowledge of common trends to help develop Case Report Forms for oncology trials

Who Should Attend

- Clinical Research Coordinators
- Clinical Research Associates
- Clinical Team Managers
- Primary Investigators who are interested in participating in oncology clinical trials, but who do not specialize in oncology or radiology

Instructor

Jackie Earabino, R.N., B.S.N.

Course Length and Time

2 hours 1:00 – 3:00 p.m. Eastern

Course Dates

January 30, 2012

May 21, 2012

Archived Recording Available!

Fee:

\$695*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.

Accreditation

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NEW! Re-Inventing Investigator Meetings: From “Bore and Snore” to “Engaging and Effective”

Course Description

As the old adage goes, “telling ain’t training.” Yet the biopharmaceutical and medical device industries are obsessed with PowerPoint as the standard vehicle for conducting investigative site training. Regardless of whether the investigator meeting is done via live or on-line learning modules, there are myriad techniques for enhancing the effectiveness of investigator meetings or any type of site training program. This web seminar will explore principles of adult learning theory, best practices and techniques for helping to accelerate the protocol learning curve, and setting investigative sites up for operational success. Participants will learn why presenting is one of the LEAST effective training methods, and how to move beyond “death by PowerPoint” as a training approach. Through illustrative case examples, participants will also learn both the theory and practice of alternative training strategies and their application to re-inventing investigative site training.

Learning Objectives

- Discuss the role, importance, and value of performing a site needs assessment prior to

developing the content for the investigator meeting

- Describe the elements of an effective learning objective
- Explain the “learn, reflect, apply” training model and how it can be used in structuring effective investigator meetings
- Describe an algorithm for prioritizing training topics for live meetings vs. alternate training venues
- List several techniques for developing high-impact training content

Who Should Attend

- Project Managers (Sponsors/CROs)
- Learning Specialists (Sponsors/CROs)
- Lead Clinical Research Associates
- Those involved in the planning and execution of investigator meetings/site training programs

Instructor

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

Course Length and Time

1.5 hours 9:30 – 11:00 a.m.
and 12:30 – 2:00 p.m. Eastern

Course Dates

March 8, 2012 (12:30-2)

May 10, 2012 (9:30-11)

Fee:

\$695*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-017-L01-P. Released: 3/12.



Regulatory 101: Navigating the Background, Laws, and Pertinent Regulations

Course Description

Complex regulations govern the development, manufacture, and commercialization of biomedical products. This web seminar will help participants understand the U.S. regulatory requirements for patented and generic pharmaceuticals, over-the-counter drugs, biologicals, and medical device products. Participants will gain high-level knowledge and insight into the regulatory agencies and their roles and responsibilities, regulatory applications and pathways, and post-marketing requirements. This is an important course both for those entering the biomedical profession and for those already in the profession to learn more about the laws governing this industry.

Learning Objectives

- Examine FDA laws and the history of why they came into place
- Navigate key regulations that pertain to drug, biologic, and device development
- Describe how the FDA is organized

- Describe the roles and responsibilities of the FDA
- Navigate regulatory pathways for investigational products

Who Should Attend

- Regulatory Affairs Professionals
- Clinical Research Professionals
- Research and Development Professionals
- Manufacturing Personnel
- Project Managers
- Those who want an introduction to the FDA's legislative process and background

Instructors

This course will be taught by one of the following instructors

Karen L. Gilbert, B.S., C.C.R.A.
Meredith Brown-Tuttle, R.A.C.

Course Length and Time

1.5 hours 12:00 – 1:30 p.m.
and 2:30 – 4:00 p.m. Eastern

Course Dates

February 8, 2012 (12-1:30)
June 6, 2012 (2:30-4)
Archived Recording Available!

Fee:

\$695*
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.

Accreditation

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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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-035-L01-P. Released: 2/11.

Regulatory Intelligence

Course Description

The regulatory environment is constantly 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 RI than keeping up with the latest regulations and guidelines. Regulatory precedence, industry practices, regulatory agency opinions, and competitor information are just a few of the valuable sources of information that can help regulatory affairs professionals to develop successful regulatory strategies.

This web seminar examines the scope of RI which encompasses: Information sources, monitoring the regulatory landscape (periodic vs. ongoing), using an RI database and other sources to research the regulatory question, and how to summarize, analyze, integrate, and present RI.

Learning Objectives

- Define Regulatory Intelligence and its importance to companies
- Identify multiple sources of Regulatory Intelligence

- Monitor the constantly changing regulatory landscape
- Break down a regulatory research question 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

Meredith Brown-Tuttle, R.A.C.

Course Length and Time

1.5 hours 12:00 – 1:30 p.m.
and 2:30 – 4:00 p.m. Eastern

Course Dates

February 8, 2012 (2:30-4)
June 6, 2012 (12-1:30)
Archived Recording Available!

Fee:

\$695*
*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.

Accreditation

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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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-043-L01-P. Released: 2/11.



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/CRA Managers
- Sponsors/CROs

Instructor

Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time

1.5 hours 9:00 – 10:30 a.m.
and 12:00 – 1:30 p.m. Eastern

Course Dates

February 3, 2012 (12-1:30)
June 4, 2012 (9-10:30)
Archived Recording Available!

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-080-L01-P. Released 9/11.

Risk Management Strategies for International Regulatory Requirements

Course Description

This web seminar will explain the need for risk management, describe the different regulatory requirements in the U.S. and Europe, explain how to develop Risk Evaluation and Mitigation Strategies (REMS) and Risk Management Programs (RiskMAPs), and give examples of approaches to risk assessment both pre- and post-marketing. Keeping products on the market without interruption becomes more essential with the reduced pipeline of drugs in development. Successful risk management is vital to product longevity, consumer confidence, and regulatory compliance. This web seminar will also provide learners with the regulatory references, processes, best practices, and analysis techniques to assess, minimize, and manage risk, avoid product recall, and meet international regulatory requirements.

Learning Objectives

- Work to international standards by meeting regulatory requirements for risk management
- Perform risk assessment
- Develop REMS and RiskMAPs
- Identify differences between U.S. and European legal requirements

Who Should Attend

- Drug Safety Personnel
- Regulatory Affairs Professionals
- Clinical Development Personnel

Instructor

Steve Jolley

Course Length and Time

1.5 hours 1:00 – 2:30 p.m. Eastern

Course Dates

February 15, 2012

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



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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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-063-L01-P. Released 9/11.



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. Millions of dollars are wasted yearly on ineffective interventions. This web seminar will present the scientific concepts of root cause analysis and apply them specifically in the clinical trial setting. Root cause analysis is invaluable for all stakeholders in clinical research, the sponsor, CRO, site, and Institutional Review Board (IRB).

Learning Objectives

- Define root cause analysis concepts
- Implement Gilbert's Root Cause Analysis Diagnostic Process
- Apply root cause analysis in clinical trial study site management
- Assign the right intervention for successful solutions
- Proactively use root cause analysis to manage stakeholder compliance: Research site management, CRA management, and more

Who Should Attend

- CRCs
- CRAs
- Site Managers
- CRA Managers
- Project Managers

Instructors

This course will be taught by one of the following instructors

Karen L. Gilbert, B.S., C.C.R.A.
Jeanne Morris, B.S., MT (ASCP)

Course Length and Time

2.5 hours 12:00 – 2:30 p.m. Eastern

Course Dates

April 16, 2012

Archived Recording Available!

Fee: \$595*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



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Source Documentation: What is Adequate & Accurate?

Course Description

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

Learning Objectives

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

Who Should Attend

- Site Research Directors/Managers
- Clinical Research Coordinators
- Principal Investigators
- CRAs
- Project Managers/CRA Managers
- Quality Assurance Personnel

Instructors

This course will be taught by one of the following instructors

Natalie Currie, B.Sc.
Karen L. Gilbert, B.S., C.C.R.A.

Course Length and Time

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

Course Dates

January 19, 2012 (12-2)

April 17, 2012 (12-2)

May 15, 2012 (8:30-10:30)

Archived Recording Available!

Fee: \$795*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-076-L01-P. Released: 7/11.



NEW! SOP Lunch and Learn Web Seminar Series

Attend one, attend a few, or attend them all! Buy 3, get 1 free!

Course Description

One is hard-pressed to find anyone in the drugs/biologics/medical device industry who is not aware of SOPs (Standard Operating Procedures). Unfortunately, quality and usability vary widely. Many SOPs fall short of fulfilling their role as compliance and training tools. Many in the industry view SOPs as a necessary evil; but it does not have to be so.

The goal of this web seminar series is to help attendees create user-friendly SOPs that continuously support standards for quality and validity of data, as required by the regulations, while also providing value to their users.

Fee: \$595* per session

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.

Who Should Attend:

- SOP Authors/Reviewers
- Quality Assurance Auditors
- Clinical Monitors
- Site Managers
- Line Function Heads
- Project Managers

**Please visit our website to view more details and to register:
www.barnettinternational.com**

Accreditation:



Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. For each session, 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 mail ACPE statements within three weeks of program completion.

Session 1:

ACPE#: 0778-0000-12-028-L01-P
Released: 2/12.

Session 2:

ACPE#: 0778-0000-12-029-L01-P
Released: 2/12.

Session 3:

ACPE#: 0778-0000-12-030-L01-P
Released: 3/12.

Session 4:

ACPE#: 0778-0000-12-031-L01-P
Released: 3/12.

Session 5:

ACPE#: 0778-0000-12-032-L01-P
Released: 3/12.

Session 1: Procedural Document System: Organized Development

February 1, 2012, 12:00 – 1:00 p.m. Eastern,
presented by Irina Colligon

Learning Objectives:

- Develop an understanding of how different types of procedural documents can be used to improve quality, compliance and efficiency
- Perform a cross-functional process inventory
- Gain insight into how a process inventory can serve as a basis for a useful, streamlined, and manageable procedural document system

Session 2: SOP on SOPs and Procedural Document Templates

February 20, 2012, 12:00 – 1:00 p.m. Eastern,
presented by Irina Colligon

Learning Objectives:

- Identify key points about the SOP on SOPs and how this document affects other procedural documents
- Review the use of templates for and in SOPs, including SOP templates
- Identify different approaches to documenting standard materials required per SOPs

Session 3: Five Key Strategic Steps for Developing Global SOPs

March 1, 2012, 12:00 – 1:00 p.m. Eastern,
presented by Marta Jimenez-Aquino

Learning Objectives:

- Gain insight into a strategy for setting up the SOP globalization project
- Examine a methodology for developing effective global SOPs
- Discuss lessons learned by pharmaceutical organizations and common pitfalls to avoid

Session 4: Preparing for SOP Inspection: An Auditor's Perspective

March 9, 2012, 12:00 – 1:30 p.m. Eastern,
presented by Elizabeth Ronk Nelson, M.P.H.

Learning Objectives:

- Examine the true purpose of SOPs and systems for compliant development, implementation, and management
- Discuss the FDA's new expectations for SOPs from Sponsors/ CROS and Clinical Investigators (with an update on IRB requirements)
- Review recent case studies concerning issues in SOP documentation and implementation practices

Session 5: Implementation of Procedural Documents

March 16, 2012, 12:00 – 1:00 p.m. Eastern,
presented by Irina Colligon

Learning Objectives:

- Identify key components of SOP implementation
- Review approaches to training on SOPs
- Discuss approaches to implementing new and revised SOPs



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
- CRA Managers
- CRAs
- Quality Assurance/Compliance Personnel

Instructors

This course will be taught by one of the following instructors

Jeanne Morris, B.S., MT (ASCP)
Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time

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

Course Dates

April 20, 2012 (12-2)

June 8, 2012 (8:30-10:30)

Archived Recording Available!

Fee:

\$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-063-L04-P. Released: 2/10.

Strategies for Managing Difficult Clinical Research Sites

Course Description

Many 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

- Apply proactive diagnosis techniques to develop a CRA communication plan
- Describe techniques for resolving conflict and promoting successful outcomes

Who Should Attend

- CRA Managers
- CRAs
- Project Managers

Instructors

This course will be taught by one of the following instructors

Karen L. Gilbert, B.S., C.C.R.A.
Jeanne Morris, B.S., MT (ASCP)

Course Length and Time

2 hours 12:00 – 2:00 p.m. Eastern

Course Dates

February 27, 2012

June 22, 2012

Archived Recording Available!

Fee:

\$795*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



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NEW! 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.

Course Length and Time

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

Course Dates

March 29, 2012 (9:30-11)

June 27, 2012 (1-2:30)

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-009-L01-P.
Released: 03/12.

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. It's a well-documented fact that 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. Examples of the use of these novel techniques and their excellent results in practice will be provided.

Learning Objectives

- Evaluate the traditional approach to study feasibility assessment
- Examine what's working, what's not, and why not
- Re-define the concepts of study feasibility at the protocol, country and site level

- Discuss the purpose and objectives for conducting feasibility assessments
- Explore paradigm shifts in the approach and 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
- CRA Managers

Instructor

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

Course Length and Time

2 hours 12:30 – 2:30 p.m. Eastern

Course Dates

April 5, 2012

Archived Recording Available!

Fee: \$595*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-017-L01-P.
Released: 3/11.



Subject Recruitment: Proactive Project Plans & 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, and insourcing and outsourcing options. 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
- Examine keys to success: Systematic practice approaches to recruitment in clinical trials
- Employ pre-screen practices to improve screening successes

- Examine the consenting process in regard to subject recruitment and retention
- Retain quality subjects to support data integrity
- Implement strategies for managing susceptible populations
- Evaluate efforts: The recruitment report card

Who Should Attend

- Clinical Research Coordinators
- Site Research Managers
- Clinical Research Monitors
- Sponsor Project Managers

Instructor

Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time

2 hours 12:00 – 2:00 p.m. Eastern

Course Dates

May 28, 2012

Archived Recording Available!

Fee:

\$595*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-018-L01-P. Released: 5/11.

NEW! To Rejuvenate the Study or Not: The "Who, What, When, Where, and How" of Study Rejuvenation Meetings

Course Description

Widely reported industry statistics suggest that some 86% of trials fail to meet their enrollment goals. Inevitably, one intervention that is often considered is whether or not to hold a study rejuvenation meeting or site engagement meeting as a means for re-motivating investigators to accelerate enrollment. This web seminar is designed to help clarify what is an effective rejuvenation meeting, what goes into the planning, how it should be structured, and what the expected outcome looks like. At the heart of the matter is diagnosing and troubleshooting the enrollment or site engagement issues, and applying some specific parameters around the decision-making to determine whether the time and resource investment to hold a rejuvenation meeting (or series of meetings) is warranted for the potential return on investment.

Learning Objectives

- Explain what a rejuvenation or site engagement meeting is
- Describe a method for evaluating when it is appropriate to consider an engagement meeting as a suitable recruitment intervention

- List several outcomes for what a successful rejuvenation meeting might realistically achieve
- Discuss practical aspects related to the planning and organizing of a rejuvenation meeting

Who Should Attend

- Project managers (Sponsors/CROs)
- Lead Clinical Research Associates
- Recruitment Specialists
- Training and Learning Specialists
- Program Directors

Instructor

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

Course Length and Time

1.5 hours 9:30 – 11:00 a.m.
and 12:30 – 2:00 p.m. Eastern

Course Dates

February 14, 2012 (9:30-11)

May 29, 2012 (12:30-2)

Fee:

\$695*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.

Accreditation



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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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-016-L01-P. Released: 2/12.

NEW! Tools for Trainers: Clinical Research Job-Aids and Checklists



Course Description

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

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

Learning Objectives

- Discuss the considerations for determining when a job aid is appropriate to incorporate into a training presentation and when it can stand alone to accomplish the desired training objective

- Identify strategies for using tools and checklists in training programs across various audiences and venues
- Describe the elements of an effective job aid

Who Should Attend

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

Instructor

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

Course Length and Time

2 hours 12:00 – 2:00 p.m. Eastern

Course Dates

March 13, 2012

June 22, 2012

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-008-L01-P. Released: 3/12.

Train-the-Trainer: Successful Web-Based Training Strategies

Course Description

Web-based is a growing training approach in most industries, and the benefits of training a large group of people with minimum to no travel expenses has contributed to its growth. There are different definitions and approaches to web-based training, such as hosted and non-hosted events that are discussed during this web seminar. Web-based training requires an understanding of various educational and technical concepts and how to apply them for the best outcome. By attending this session, participants will walk away with ideas from educational and technical experts in the field on how to best use this platform of learning.

Learning Objectives

- Define eLearning theory and contrast approaches
- Describe various approaches to web-based training: Hosted and non-hosted
- Discuss how to plan training for a live web-based setting
- Outline how to set audience expectations and how to work the audience, facilitating learning in the e-environment
- Define course content development for presentation in a web setting

- Discuss the use of web "body language," interactive exercises, and testing effectiveness
- Review presentation logistics and technology from logging-in for sessions to service provider basic functionality orientation
- Apply audience considerations such as global attendees
- Maximize the use of live web-based interaction features and live web-based presentation considerations

Who Should Attend

- Trainers
- Training Managers and Directors
- Individuals responsible for training
- Information Technology Professionals

Instructors

This course will be taught by one of the following instructors

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

Barbara Potter

Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time

2 hours 9:00 – 11:00 a.m.
and 12:00 – 2:00 p.m. Eastern

Course Dates

January 31, 2012 (12-2)

May 24, 2012 (9-11)

Archived Recording Available!

Fee: \$795*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



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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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-066-L04-P. Released: 2/10.



Transitioning Pharmaceutical Professionals to Medical Device Professionals

Course Description

This web seminar assists study managers, program managers, CRAs, and other pharma professionals in learning more about the differences between pharma and medical device studies, including objectives, protocol creation, and Quality System Regulation. The course will help professionals learn about the most popular medical device therapeutic areas, the engineering component/R&D/preclinical, as well as the technical procedures of those therapeutic areas.

Learning Objectives

- Identify the differences between pharmaceutical and medical device studies
- Identify the key regulations of medical devices
- Explain the Quality System Regulation (QSR) process

Who Should Attend

- Professionals wanting to learn more about the medical device industry
- Pharmaceutical and other professionals who are new to the medical device industry
- CRAs
- Regulatory Professionals
- Management Professionals
- Clinical sites who will be conducting medical device trials

Instructor

Douglas Albrecht, B.S.N., C.C.R.A.

Course Length and Time

2 hours 1:00 – 3:00 p.m. Eastern

Course Dates

June 18, 2012

Archived Recording Available!

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-065-L04-P.
Released: 3/10.

Trial Master File (TMF) for Research Sites: Set-Up and Maintenance

Course Description

The investigator Trial Master File (TMF) is a collection of the essential documents for an investigator to record how they have fulfilled their regulatory obligations for a clinical trial project. This web seminar reviews the investigator TMF required and additional content for a clinical trial. The activities of set-up, maintenance, and quality control and assurance will be discussed along with common deficiencies and challenges.

Learning Objectives

- Discuss the changing regulatory climate and apply this to the essential documentation practices of an investigator of clinical trials
- Examine the required components of an investigator TMF and recommend policy
- Discuss maintenance and quality control of the TMF
- Describe CRA contributions to and adequate monitoring of the investigator TMF

Who Should Attend

- Research Site Personnel involved in the set-up and maintenance of any TMF or in charge of policy development and maintenance
- Principle Investigators
- CRCs
- CRA Managers
- CRAs
- Quality Assurance Personnel of research sites and sponsors

Instructors

This course will be taught by one of the following instructors

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

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

Course Length and Time

2 hours 12:00 – 2:00 p.m. Eastern

Course Dates

June 11, 2012

Fee: \$795*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation



Barnett International is accredited by the ACPE® 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-0000-12-033-L01-P.
Released 6/12.



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 record how they have fulfilled their obligations as sponsor for a clinical trial project. This web seminar reviews the sponsor TMF required and additional content for a clinical trial. The activities of set-up, maintenance, and quality control and assurance will be discussed along with common deficiencies and challenges.

Learning Objectives

- Discuss the changing regulatory climate and apply this to the essential documentation practices of a sponsor of clinical trials
- Examine the required components of a TMF
- Recommend policy for the TMF
- Discuss maintenance and quality control of the TMF

Who Should Attend

- Project Managers
- Quality Assurance Personnel
- Policy Development and Maintenance Personnel
- Sponsor/CRO Personnel involved in the policy, set-up, maintenance, auditing of the TMF

Instructor

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

Course Length and Time

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

Course Dates

January 17, 2012 (12-2)

March 5, 2012 (12-2)

April 2, 2012 (12-2)

June 11, 2012 (8:30-10:30)

Archived Recording Available!

Fee: \$795*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation

 Barnett International is accredited by the ACPE 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 mail ACPE statements within three weeks of program completion. ACPE#: 778-000-09-001-L04-P. Released 3/09.

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 Notes to File, the questions to ask to determine if an NTF would be beneficial, and the components of a quality NTF, if being used.

Learning Objectives

- Discuss the current overuse and misuse of NTF, including FDA Warning Letters noting deficiencies in interventions that include NTF
- Identify what is an appropriate NTF, patient and non-patient specific
- Write an effective NTF, when applicable
- Reference industry tools relating to NTF

Who Should Attend

- Quality Assurance Personnel
- CRAs
- CRCs
- Investigators
- CRA Managers
- Project Managers

Instructors

This course will be taught by one of the following instructors

Gary B. Freeman, M.S., C.C.R.A., C.C.R.T.
Karen L. Gilbert, B.S., C.C.R.A.

Course Length and Time

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

Course Dates

February 10, 2012 (8:30-10)

March 12, 2012 (12-1:30)

May 4, 2012 (12-1:30)

June 4, 2012 (12-1:30)

Archived Recording Available!

Fee: \$795*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation

 Barnett International is accredited by the ACPE 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-12-025-L01-P. Released: 2/12.



Worldwide Fast Track, Priority Review, and Accelerated Approval Options

Course Description

After spending years on the development and clinical research phase, you want to minimize the time to approval of your compound. This can be done by ensuring that your filing is complete, well written, and uses any of the available accelerated approval options, if your compound qualifies. However, Fast Track, Priority Review, or Accelerated Approval options need to be planned for and negotiated with a Health Authority well in advance of a marketing application submission. In this web seminar, we will discuss the program and/or compound qualifications needed, on a global scale; how these programs are the same or different; and how they overlap. We will also examine how these programs, if planned into the development strategy, can help reduce marketing application review time.

Learning Objectives

- Describe Fast Track, Priority Review, and Accelerated Approval options globally
- Explore the criteria that needs to be met to qualify for these options
- Discuss the similarities and differences of these programs

- Discuss the benefits of each, including time savings during the application review process
- Obtain, write, and submit the appropriate information to be granted one or many of these approval mechanisms
- Discuss what needs to be done, prior to the marketing application, to help facilitate a speedy marketing application review using Gleevec and Jevtana as case studies

Who Should Attend

- Individuals who want an introduction to accelerated approval options on a global scale
- Regulatory Affairs Professionals
- Clinical Research Professionals
- Research and Development Professionals
- Project Managers

Instructor

Meredith Brown-Tuttle, R.A.C.

Course Length and Time

1.5 hours 12:00 – 1:30 p.m. Eastern
and 2:30 – 4:00 p.m. Eastern

Course Dates

February 21, 2012 (12-1:30)
June 21, 2012 (2:30-4)

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.*

Accreditation

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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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-066-L01-P.
Released 8/11.

Worldwide Orphan Drug Designation Applications and Requirements

Course Description

Globally, there is a need for orphan drug research, development, and approval for underserved patient populations who have diseases that affect very few individuals. While this patient population has been largely ignored, some pharmaceutical companies have built their research pipeline around these patients. Receiving orphan drug designation and approval confers many benefits to the developer to compensate for the development costs of the drug. This web seminar will explore which countries allow orphan drug designations, the application requirements, population limits and how to support this number, how the applications are the same, who to submit the application to, if and when the application can be changed, and how it needs to be supported over the development process.

Learning Objectives

- Identify the countries that have orphan drug designations
- Identify, on a global basis, the differences and similarities of these applications (and how to re-use the information), including differences in population requirements

- Discuss the importance of the indication chosen for designation, and how this ultimately affects the final label and how this can differ among countries
- Examine the most difficult sections of the applications and mitigate agency concerns
- Discuss the benefits of orphan designation
- Describe how orphan drug indications and applications can be modified
- Describe the timing of the application in the drug development process

Who Should Attend

- Individuals who want an introduction to the orphan drug designation on a global scale
- Regulatory Affairs Professionals
- Clinical Research Professionals
- Research and Development Professionals
- Project Managers

Instructor

Meredith Brown-Tuttle, R.A.C.

Course Length and Time

1.5 hours 12:00 – 1:30 p.m. Eastern
and 2:30 – 4:00 p.m. Eastern

Course Dates

February 21, 2012 (2:30-4)
June 20, 2012 (12-1:30)

Fee: \$695*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-067-L01-P.
Released 8/11.



Writing and Maintaining the EU CTA (Clinical Trial Authorization)

Course Description

The Regulatory Affairs department must prepare documents that inform European Regulatory Agencies about the proposed development plan; submit a Clinical Trial Authorization (CTA) to initiate human clinical trials; answer questions about on-going investigations; and construct and submit any updates to the CTA in a concise and informative manner. Regulatory submissions are more than just writing – they encompass strategy, research, writing, organizing and leading a team, compiling, editing, publishing, and tracking of the information. When initiating a global clinical trial program, many moving parts need to be brought into harmony to ensure compliance and that timelines are met. Web seminar attendees will walk away with tools to help plan, write, and manage multiple CTAs with all their differing requirements.

Learning Objectives

- Navigate Europe's regulations, directives, and guidelines
- Describe the basic requirements of the CTA, the Investigational New Drug (IND) equivalent in the EU

- Identify the key documents that will be needed for the preparation of each country's CTA
- Identify the specific documents required by each country to support the CTA
- Determine the timelines for review by Ministry of Health and Ethics Committees
- Determine what is needed to amend and maintain the CTA including safety and annual reports

Who Should Attend

- Regulatory Associates and Managers
- Quality Assurance Personnel
- Manufacturing Personnel
- Clinical Research Professionals
- Project Managers
- Pre-clinical Personnel
- Other Members of the Drug Development Team who wish to know more about the global drug development and CTA submission process

Instructor

Meredith Brown-Tuttle, R.A.C.

Course Length and Time

3 hours 12:00 – 3:00 p.m. Eastern

Course Dates

February 22, 2012

May 29, 2012

Archived Recording Available!

Fee: \$795*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-042-L01-P. Released: 3/11.

Writing and Updating the Investigator's Brochure

Course Description

During the course of clinical research, the Investigator's Brochure (IB) is the data repository for an investigational product; effectively this is the product's "label" during the investigational stage. The IB is a dynamic document which changes as the information changes. It is critical in clinical research as physicians and Institutional Review Boards (IRBs) refer to the IB on an ongoing basis to answer questions about Serious Adverse Events, Adverse Events, dosing, manufacturing, and clinical and nonclinical study results.

To facilitate the transfer of information, the IB must be concise, well-written, and provide a summary for a physician to quickly reference. While ICH E6 provides an outline of the requirements, how companies address these requirements and the degree of information provided differs. The required contents will be reviewed in this web seminar. Tips and techniques for effective writing, including pulling together the needed information, working with a team, and writing a summary will also be discussed.

Learning Objectives

- Identify who contributes to the IB
- Determine the timing of construction of the IB
- Detail IB requirements per ICH E6 and effectively implement these requirements
- Research literature for the background section, and re-use it in other documents
- Examine how a Target Product Profile or Draft Package Insert can be drafted based on the IB
- Get a physician to read an IB: The IB Summary
- Determine when the IB should be updated, by whom, and what documents the update effects

Who Should Attend

- Regulatory Affairs Professionals
- Medical Writers
- Clinical Research Professionals
- Research and Development Personnel

Instructor

Meredith Brown-Tuttle, R.A.C.

Course Length and Time

3 hours 12:00 – 3:00 p.m. Eastern

Course Dates

February 29, 2012

May 30, 2012

Archived Recording Available!

Fee: \$795*

**Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance," and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-039-L01-P. Released: 2/11



Writing Clinical Study Protocols

Course Description

The basis and success of any drug or device development program is the clinical trial protocol. Clinical trials conducted under an IND or IDE cannot begin without a protocol, and yet there is variability between companies and individuals on how to approach writing this critical document. Clinical trials and entire programs have failed because the protocol was not scientifically sound. Knowing how to effectively research and write a clinical trial protocol is essential to a compound achieving IRB and market approval.

Over the course of a development plan, new protocols, amendments, and concept sheets will be needed. Protocols for Phases 1, 2, 3 and 4 require different writing approaches and you must know what the agency expects at every development milestone to avoid the trial being put on clinical hold. Moreover, amendments, however unwelcome, are a necessary part of the development process.

Learning Objectives

- Describe the overall structure of a protocol and regulatory requirements

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

Who Should Attend

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

Instructor

Meredith Brown-Tuttle, R.A.C.

Course Length and Time

3 hours 12:00 – 3:00 p.m. Eastern

Course Dates

March 28, 2012

June 19, 2012

Archived Recording Available!

Fee: \$795*

*Includes up to 20 participants at one site. All participants (up to 20) are eligible for "Certificates of Attendance" and accreditation, provided that accreditation requirements are met. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.

Accreditation



Barnett International is accredited by the ACPE 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 mail ACPE statements within three weeks of program completion. ACPE#: 0778-0000-11-038-L01-P. Released: 2/11.

Instructor Biographies

Douglas E. Albrecht, B.S.N., C.C.R.A., has been in the clinical research industry for 20+ years, beginning his research career with the pharmaceutical industry, and for the last 17 years in the medical device industry. He has worked for large, small, and start-up device manufacturers over the 17 years, holding numerous positions from Clinical Coordinator to Clinical Project Manager to Manager of Clinical Affairs. Through it all Doug has helped develop and manage a number of large-scaled multi-center IDE trials leading to successful marketing applications for each. Since the year 2000, along with working full time for various companies, Doug has been a trainer for Barnett International, training in areas of clinical monitoring, clinical development and trial design, and managing and reporting adverse events.

Meredith Brown-Tuttle, R.A.C., has held senior regulatory positions at Bay Area pharmaceutical companies and a full-service CRO. She has written and coordinated numerous drug and biologic submissions to US and international regulatory agencies, developed regulatory strategy for both device and drug companies, and conducted worldwide regulatory intelligence.

Majda Benhayoun, Ph.D., is currently Director of Program and Portfolio Management at Vertex Pharmaceuticals, and has been working in drug development for the past three years. Prior to joining Vertex, Majda worked in Clinical Project Management for more than 15 years, with her first 11 years at Aventis Pharma, previously Rhone-Poulenc Rorer, and then four years at PAREXEL International where she held a position of Clinical Project Director. Majda has extensive experience in project management both strategic and operational in early and late stages of drug development in various therapeutic areas, including CNS, inflammation, and immunology. As Clinical Program Manager, Majda has broad experience in the concepts of clinical trials, including planning and execution of clinical trials from single site Phase I, to large and complex multinational Phase III trials, concluding in NDA/MAA filing.

Nikki Christison, B.S., has been working in the industry for over 16 years as a study coordinator, regional CRA, managing her own research company, and consulting as an auditor, monitor, project manager, site trainer, director and regulatory specialist. Nikki has also worked for multiple sponsors in developing sites, generating corrective action plans, and educating clinicians and site staff on industry best practices and GCPs during seminars and workshops. Nikki is passionate about education and provides a wealth of experience and real-life application to the courses she teaches.

Irina Colligon is a pharmaceutical industry consultant with primary focus on compliance and process design. Prior to becoming a consultant, Irina worked in academic research as well as medical device (diagnostics) and pharmaceutical R&D. Her experience and background include developing diagnostic test kits, drug metabolism, pharmacokinetics, and bioanalysis, as well as international regulations, quality management, computer and laboratory equipment validation and implementation, records management, and laboratory safety. She has authored, co-authored, and presented on these topics at various meetings, workshops, and in several publications. Irina is a member of the SQA and MARSQA. Irina holds a Bachelor of Arts in Biology degree from the University of Pennsylvania and a Six Sigma Green Belt certification from Drexel University's Goodwin College.

Leylén Colmegna, M.D., Ph.D., studied Medicine at the University of Rosario, Argentina. Dr. Colmegna has more than 10 years of experience in Clinical Research. She has worked at an Investigative Site, and has held several positions at CROs and in the pharmaceutical industry. During

2010, she founded LAT Research, a Regional CRO with headquarters in Argentina and operations in Latin America. Dr. Colmegna is acting as CEO and COO. She is responsible for the leadership of local management teams across all operations units (Medical, Clinical, Data Management, Regulatory Affairs, Pharmacovigilance & Marketing).

Natalie Currie, B.Sc., is an instructional designer, facilitator, and learning and development consultant dedicated to Academic Research Organizations, the Pharmaceutical and Biotechnology Industries, and Clinical Research Organizations. Harnessing her 18 years of broad-based clinical research experience, Natalie is sought after as a speaker and facilitator in the United States and Canada.

Natalie's breadth of roles has spanned from Clinical Research Coordinator, Clinical Research Associate, Clinical Research Project Manager, and management roles in Government and Health Economics. She has 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) and has participated on international project teams for pivotal Phase III studies and led Canadian Phase IIb-IV studies.

Natalie holds an honors life science degree from the University of Toronto and is a member of the Society of Clinical Research Associates (SoCRA), the American and Canadian Societies of Training and Development (ASTD & CSTD), Toastmasters International, and is on the organizing committee for the World Creativity and Innovation Week in Toronto.

Natalie designs and facilitates engaging, customized corporate and public workshops in the areas of clinical research study management, good clinical practice, and communications, all with visual thinking in mind.

Anil D'Mello, Ph.D., is a Professor of Pharmaceutical Sciences at the Philadelphia College of Pharmacy at the University of the Sciences in Philadelphia. He has over 18 years experience in teaching Pharmacokinetics to Pharm.D. and Ph.D. students. Anil is the recipient of the Lindback Award for Distinguished Teaching and is listed in Who's Who Among America's Teachers. He has conducted Biopharmaceutics and Pharmacokinetics training courses at different pharmaceutical companies including Merck, Boehringer-Ingelheim, and Cephalon. His research examines the role of the maternal nutritional environment during pregnancy and lactation on the development of physiological systems in the offspring. He has numerous publications in peer reviewed journals in the area of pharmacokinetics, drug metabolism, and endocrinology. Anil is a member of the steering committee of the Delaware Valley Drug Metabolism Discussion Group.

Holly Delaco-Smith, M.S., brings over seventeen years of management consulting experience to her clients, helping them change to be more successful. Holly's tenure in Big 4 consulting, including Accenture and IBM Global Services, grounded her with a foundation of best methodologies, leading practices, and outstanding client experience. It was these experiences that inspired and compelled her to found a management consulting organization serving the agriculture, education, financial services, pharmaceutical, and retail industries. Holly's experience includes strategic planning, process improvement, benchmarking for leading practices, organizational improvement, learning design and development, and change management. Given the critical need today for organizations to develop a talented workforce, Holly has helped her clients define and improve their learning strategies. Holly's unique collaborative approach of truly partnering with her clients and her strong focus on change management enable her to provide excellent service and results.

Instructor Biographies

David R. Dills, an independent Regulatory & Compliance Consultant with more than 20 years of hands-on experience and a proven track record within the life sciences and FDA regulated industry, has an extensive regulatory background with Class I II III and IVD devices and managing and handling activities within the global regulatory landscape. He manages quality, regulatory, and compliance projects with multiple competing priorities having a direct impact on site operations and commercial opportunities, and develops strategies for governmental approval to introduce new products to market, provides guidance on regulatory and compliance requirements, and prepares and reviews worldwide submissions, dossiers, and technical files, and addresses product registrations and submissions in other countries, including EU regulatory requirements regarding MDD and CE Mark. His background encompasses broad capabilities in quality systems, validation, regulatory affairs, compliance, auditing, interfacing with the regulatory agencies, and maximizing business performance in the devices arena. He strives to optimize business performance through proactive strategies to mitigate compliance exposure by providing strategic and tactical solutions that facilitate the achievement of regulatory milestones. David has been previously affiliated with well-known device manufacturers and service providers, and has served in various quality, regulatory, and compliance management and advisory capacities with increasing responsibilities. David is an industry speaker and author of technical and compliance related topics published in industry journals.

Ruth Dubinsky, M.S. O.D., works with pharmaceutical, biotech, device, and CRO clients, specializing in team dynamics. A former bench scientist, drug developer, and clinical researcher, she brings over 30 years of industry experience to her consulting practice. She understands the unique challenges and intense pressure on global, matrix pharma teams. Her work focuses on helping teams assess and recover from breakdowns, deal with inevitable conflict, make better, faster decisions – and accelerate their work. Teams walk away with clarity about what they can do differently – both behaviorally and operationally – that will have meaningful impact on moving their product through the pipeline. She co-led and co-authored a research study designed to identify specific behaviors and strategies of the highest performing drug development teams within J&J.

Jacqueline K. Earabino, R.N., B.S.N., has been involved in clinical research world since college where she majored in Biology and Environmental Science, earning a dual Bachelor's degree. She then went on to work for three years at Johns Hopkins School of Medicine. In this role she assisted with ongoing pre-clinical research in the department of Anesthesiology and Critical Care Medicine, afterwards earning a B.S.N. in nursing from Johns Hopkins. Therapeutic areas of expertise include medical/surgical, women's health, pediatrics/pediatric trauma, infectious disease, internal medicine, and oncology. She has also worked as a research nurse at Duke Cancer Center and Cancer Center of NC.

Jackie has worked as a CRA at several CROs including PPD, Quintiles, Novella, and Trio Clinical Research. She is currently working as a consultant, having started her own company in 2007. For the past two years she has held roles as a global trial manager on two oncology studies. This experience has included multiple trips to provide monitoring support, as well as to train project teams and clinical study sites in the UK and EU.

She also has experience working in pharmacovigilance and clinical data management for a large CRO. Jackie's wide range of background, education, and experience both as a nurse, CRA, and project manager make her a valuable clinical research resource. She continues to work in project management and training.

Erica Elefant, R.N., B.S.N., M.S.W., has close to 15 years of clinical research experience and continues to work in the pharmaceutical industry. She has worked as a study coordinator, site monitor, and clinical research project manager in multiple therapeutic areas and phases of drug development. In addition to acquiring a strong clinical research knowledge base, Ms. Elefant has obtained hands on experience writing clinical documents and SOPs. Ms. Elefant has worked as adjunct faculty at Drexel University and as a Clinical Trials Learning Manager where she has been responsible for developing and delivering trainings on various clinical research topics.

Barbara S. Fant, Pharm.D., has over 18 years experience in pharmaceutical and medical device research and development. She currently provides clinical and regulatory support services to medical device and pharmaceutical companies to bring investigational products to market. Her clients include U.S. and international companies, with a focus on start-up and incubator companies developing novel medical devices. She has worked with clients to successfully file over 30 IDEs, pre-IDEs, 510(k)s, and PMAs with the FDA in the past four years. In addition to ophthalmics, therapeutic areas of expertise include imaging technologies and/orthopedics. Prior to her consulting work, Dr. Fant spent several years directing and managing anti-infective clinical trials and pharmacokinetic studies with a major pharmaceutical company; established and directed a highly successful Phase I/Phase II academic-based pharmacology research center at the University of Cincinnati; served as the vice chairperson and associate administrator for an independent institutional review board; and, was an assistant director for clinical research for a large contract research organization. Dr. Fant is recognized as an expert in FDA regulations pertaining to medical devices with extensive experience in developing ophthalmic medical devices. Dr. Fant also serves on the board of directors for Medennium, Inc., Salpingo Medical, and several charitable and philanthropic organizations in the Cincinnati, Ohio community. She holds a B.S. in Pharmacy from Ohio Northern University and a Doctor of Pharmacy degree from the University of Cincinnati Medical Center.

Anna Filimonova, M.D., Ph.D., is Associate Director GRO, CRA/GMBA, PAREXEL International (RUS) LLC, located in Moscow, Russia. Anna has an M.D. degree and Ph.D. in Paediatrics, Allergology & Immunology, and was a university lecturer and consultant in Paediatrics for four years. Since 1998 Anna has been working for PAREXEL, first as a CRA and then holding a manager's position in Clinical Operations in Russia. She has extensive experience in the pharmaceutical industry. Her areas of expertise include clinical research and regulatory requirements in Russia, CIS, and Eastern European countries.

Gary B. Freeman, M.S., C.C.R.A., C.C.R.T., provides quality clinical monitoring, auditing, training, project management, and consulting services internationally. He has personally worked in these areas with pharmaceutical, device, healthcare, and contract research organizations for over 30 years. Mr. Freeman has been a credentialed clinical research trainer through ACRP since its inception in 2003.

Mr. Freeman holds a B.S. in Biology (pre-med program) from the University at Albany and an M.S. in Science Education from Russell Sage College. He has been actively involved in various clinical capacities for multiple therapeutic areas (Phase I-IV) for the following indications as well as devices: allergy; anti-infective; cardiovascular; critical care; dental; dermatology; endocrinology; eye care; GI; imaging/diagnostics; immunology; infectious disease; oncology; organ transplant; OTC medications; psychiatric disorders, pulmonary; sleep disorders; and STDs. This experience includes pre-clinical laboratory work, data management, protocol writing and CRF design, clinical monitoring, clinical trial management, GCP auditing, developing and presenting

Instructor Biographies

clinical training programs, regulatory affairs management and overall responsibility for Clinical Operations in several settings, including presentations at FDA Advisory meetings. Mr. Freeman has also participated as a trainer for ACRP's CRA and CRC Certification Exam Review courses and other clinical offerings, and is an active instructor for several Drug and Device courses for Barnett International for public and on-site offerings. He lectures routinely worldwide and presents training workshops for drug and device companies, as well as investigator sites in addition to conducting GCP audits at investigational sites and vendors for pharmaceutical and device studies.

Mr. Freeman is currently an active member of ACRP (Association of Clinical Research Professionals), DIA (Drug Information Association) and SQA (Society of Quality Assurance).

Albert A. Ghignone, M.S., R.A.C., has had a professional focus on regulatory affairs, quality assurance, and clinical affairs for over 25 years. He has expertise in dealing with all aspects of the FDA approval process for drugs, biologics, and medical devices. He has been responsible for regulatory submissions, registrations, FDA liaison, and compliance activities. He also has expertise in the assessment of product and facilities for due diligence relative to FDA requirements. He lectures throughout the world on numerous FDA related matters. He is a member of the Regulatory Affairs Professional Society, which awarded him as 1984's Professional of the Year. He has served the society as Vice President, President, and Chairman of the Board of Directors.

Karen L. Gilbert, B.S., C.C.R.A., has over 14 years of experience in clinical research. Her background includes pharmaceutical and medical device monitoring, regulatory affairs, site management, global study management, and clinical operations training for companies including Takeda, TAP, and Bausch and Lomb. Karen also spent five years in a research management role at a multi-specialty dedicated clinical research site, where she was responsible for over 70 clinical trials. Most recently, Karen has served as a dedicated CRA trainer and has been responsible for developing and presenting both new-hire and on-the-job training programs for CRAs. She has presented internationally for private industry and at global professional conferences, and is currently Clinical Trainer/Curriculum Manager with Barnett International.

Felicia Glover, M.P.A., B.S., R.N. A graduate of City College of New York with a Bachelor's of Science degree in nursing, Felicia worked as a nurse for several years in major medical centers in New York City, in several clinical specialities including critical care and the O.R., before transitioning to the field of Clinical Research. Felicia has earned her Master's in Public Administration with a concentration in Health Services Management from New York University Wagner School of Public Service. She has worked as a Clinical Research Associate (CRA) for big pharma and small biotech companies.

Felicia is a part time instructor in the School of Nursing and Health Sciences at La Salle University in Philadelphia, where she teaches Healthcare Terminology and Health Information Literacy to undergraduate Health Science students.

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

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 who 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.

Marta Jimenez-Aquino is a process design expert with over 20 years in the pharmaceutical industry. She was the Director of Wyeth's CR&D Procedural Compliance for several years. In that position, she led a global team in the implementation of a quality-driven methodology that enabled process improvements and the globalization of all Clinical Research & Development SOPs. As an industry consultant, Marta worked for PAREXEL Consulting leading process design projects in clinical development, medical affairs, and pharmacovigilance and facilitating strategic sessions between pharmaceutical companies and their outsourcing partners. In 2008, she retired from PAREXEL as VP of Strategic Compliance and Operational Excellence North America. Marta is currently an independent consultant specializing in GxP strategy and process design. She holds an MBA in Pharmaceutical Marketing from St. Joseph's University and a Six Sigma Green Belt certificate from Drexel University. She has been a speaker at DIA, SQA, Barnett International, and at several Henry Stewart Conferences in the UK and Washington, DC.

Steve Jolley has 23 years of experience in drug safety and pharmacovigilance. He is a specialist in global safety compliance and signal detection, and has worked with over 50 clients in the US, Europe, and Japan. Steve is a regular speaker at international industry events including DIA and MHRA, and a featured speaker with the FDA at DIA conferences and webinars on auditing, signaling, and data mining.

Sidney Kahn, M.D., Ph.D., has professional credentials that include MB, ChB (Cape Town), Ph.D. (London), FRCPath (Chemical Pathology), and MFPM. His academic career spanned 17 years in clinical laboratory medicine and basic research in neuroimmunology in the UK and USA. He spent the next 13 years at Bristol-Myers Squibb and Johnson & Johnson managing drug safety groups responsible for safety assessment of medicinal products throughout their lifecycle. Throughout his industry career, he was actively involved in US and global activities to enhance pharmacovigilance, risk assessment, and risk management, including PhRMA representation to ICH on MedDRA EWGs (M1, MedDRA MSSO Technical Evaluation Panel, Points to Consider), the U.S. National Coordinating Council for Medication Error Reporting and Prevention, the PhRMA/FDA Electronic Regulatory Submissions Task Force, and the ICH Post-Marketing EWG. He was a member of the CIOMS-VI WG, a MedDRA MSSO Blue Ribbon Panel, and the HL7 SPL Implementation Workgroup. Dr. Kahn is a frequent presenter at conferences and workshops in the USA and Europe on all aspects of pharmacovigilance, risk management, and labelling.

Hillary Kimes, R.N., M.S.N., C.C.R.A., C.C.R.C., has over 15 years experience as a CRA and CRC within the US, Europe, and Asia. Her clinical expertise is in cardiology, interventional cardiology, neurology, ED/trauma, and oncology. Her experience includes the development and conduct of clinical team, CRA, and investigator training focusing on implementing GCP compliant clinical research in the United States, Hong Kong, Singapore, and Beijing. She has conducted QA audits within the US and Asia, and developed quality improvement, site-based systems. Hillary currently monitors and provides training for drug and device studies to teams utilizing EDC for global clinical trials. Hillary is best known for her signature work on the development of "The Golden Rules of Monitoring" and focus on improving site performance.

Instructor Biographies

Robert L. Kunka, Ph.D., is an accomplished and respected scientist who contributed to the development of 27 pharmaceutical products in a seven therapeutic areas. His expertise on international product development teams produced submissions with successful clinical strategies, sound matrix management of individual study teams, and effective interactions with regulatory agencies leading to successful IND, aNDA, and NDA approvals.

Prior to starting his current career as a consultant, Bob's experience in drug development stems from 24 years in the pharmaceutical industry at GlaxoSmithKline (GSK), Chugai-Upjohn, and GD Searle. During his time at GSK, he served as secretary of the protocol review committee and chairman of the Bio Task Force that mentored young scientists during the development process. At Searle he made presentations for generic products at state formularies and reviewed potential licensing candidates. Prior to this, he was Assistant Professor at the University of Pittsburgh School of Pharmacy where he taught graduate and undergraduate courses in pharmacokinetics. He also served on the Technical Advisory Committee for the Pennsylvania Generic Drug Formulary.

Bob earned his Ph.D. in Pharmacokinetics at the University of North Carolina (UNC) at Chapel Hill and Bachelor of Science in pharmacy at the University of Illinois at the Medical Center in Chicago. While at UNC, he was honored to be named the American Foundation for Pharmaceutical Education Charles J Lynn and Syndor Barksdale Penick Memorial Fellow. Since then he has authored over 75 publications and presentations at international scientific meetings, serves as a reviewer for the Journal of Clinical Pharmacology, and received a number of scientific awards including GSK Silver and Gold Recognition Awards, the Glaxo Medical Operations Outstanding Service Award, and the GD Searle Special Unit Award.

Tim Krupa, M.S., M.B.A., is a proven leader who assists companies with their clinical development. Tim has a wealth of experience in pharmaceutical development with Big Pharma and the CRO industry. He began his career with Eli Lilly and Company where he led teams in Clinical Operations, Clinical Data Management, Medical Writing, and World Wide Regulatory Affairs. Recently, he served as Executive Director, Project Management at Quintiles, Inc. where he led teams in Project Management and Clinical Operations and gained an intimate knowledge of the Biotech industry. As a difference maker, one of Tim's key strengths is that he is a leader who builds engaged teams that execute and deliver as promised.

Diana Martini, M.B.A., M.S., C.C.R.P., is currently employed as a Manager of Clinical Operations at PRA. She has over 25 years of experience in both sponsor and Contract Research Organizations, as well as in consulting. She has experience in instruction at the university level, as well as in continuing education (classroom-based and online), community college, and high school. Her industry career spans both a preclinical and a clinical research focus, having held responsibilities as a lab assistant/research associate, senior clinical scientist, and up through director-level responsibilities in clinical operations and clinical data management. Diana is a member of DIA, ACRP, SoCRA, and SDRAN, and has been and/or is currently a local chapter board member of ACRP, AWIS, and PTA/PTSA. Diana received her M.S. in Biology (Physiology Emphasis) and B.S. in Zoology from California State Polytechnic University, Pomona, and her M.B.A. (Marketing) from National University, plus has a California Community College Instructor's Teaching Credential (Life) in Biology and Zoology.

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.

Eric Morfin, M.B.A., P.M.P., has been a project manager since 1987. A sought after speaker on the subject of Project Management, Portfolio Management, and Resource Management at North American and European symposiums and conferences, Mr. Morfin has been published many times in project management magazines and pharmaceutical publications. Currently co-author of several Project Management in Pharmaceuticals books, Mr. Morfin is an active member of several professional societies and has developed several unique seminars on Project Management in Drug Development such as "Project Management in Discovery and Preclinical" and "Project Management for Global Clinical Trials."

He has consulted with clients in a variety of industry settings throughout North America, Europe, and Asia. He has worked with the World Bank, Merck Frost, Hewlett Packard, GlaxoSmithKline, Aventis, Novartis, Bristol Myers-Squibb, and AstraZeneca to name only a few.

Prior to partnering with Chiron, Mr. Morfin managed for 10 years the project management practice of a worldwide training and consulting organization headquartered in the USA. Previously, he worked with a leading consulting group in the strategic field. In Europe, besides managing his own computer firm, dealing in digital animation, he created and managed an entire new division for Apple Computer.

Mr. Morfin is bilingual in French and English, has traveled extensively in Europe and Asia, and earned his M.B.A. in International Business in San Francisco. He currently lives in San Francisco with his wife and daughter.

Jeanne Morris, B.S., MT (ASCP), is an ASQ Certified Manager of Quality/Organizational Excellence. Ms. Morris provides GMP, GCP, GPvP, and QMS expertise to the pharmaceutical and medical device industries. She has over 20 years of experience in regulated industry, including 15 years with the United States Food and Drug Administration. Her expertise includes risk assessment and mitigation, regulatory readiness support and mock inspections, process improvement project management, and procedure review and training. Prior to consulting, Ms. Morris held varied leadership positions at Takeda Global Research and Development, Inc., most recently as Director GxP Compliance, where she ensured drug development activities were conducted in compliance with regulations, guidance, and standards. While working for the FDA, Ms. Morris conducted over 300 inspections in the United States and internationally. She was a member of FDA's national training cadre, and recipient of the prestigious FDA Commissioner's Award of Merit.

Elizabeth Ronk Nelson, M.P.H., has over 20 years of experience in medical and clinical research. During her career, she has managed clinical trial site operations as a clinical research program coordinator and researcher and has served as an IRB Quality Assurance Specialist and a Senior (GCP) Auditor, Trainer, and Compliance Director.

Her professional areas of specialization include fraud detection and prevention; mock FDA audits; customized, audit finding-specific, risk-based training; independent GCP quality systems and compliance audits; SOP and training program development and gap analysis; corrective and preventative action (CAPA) and quality systems improvement plans for GCP; customized skill-based training for clinical research professionals;

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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.

Marcellina N. Oparaoji, Ed.D., B.S.N., R.N., C.C.R.P. As a study coordinator, clinical research Monitor, Project Manager, Training Director, and clinical research administrator, Marcellina has been involved in clinical trial management, trial coordination, site monitoring, project management and coordination, budget development, training of other clinical personnel, orientation, and site management, with pharmaceutical industry, CRO and academic setting experience. Dr. Oparaoji has extensive background in curriculum development and course delivery of multi-disciplined learning experiences, to small, large, and diverse customer groups and cross-functional teams. She has also been both an academic and clinical consultant in different settings. As a Vice President of Nursing/Science Education, she managed a Practical Nursing School with a large number of adult students and staff. She has also served as a science and language teacher. She holds a Master's degree in Training and Development, a Doctorate in Educational Leadership and Policies, and degrees in Nursing, Teaching, Foreign Language, and Finance/Banking, and several certificates in clinical research practice, management (AMA), and training. She is an active member of Professional organizations like SOCRA, and the Association of Training and Development (ASTD). She is a Certified Clinical Research Professional (CCRP). Currently, Marcellina is the Director, Clinical Research Management and Training for Clinical Research Group, at Drexel University College of Medicine, Philadelphia, PA.

Gabriele Pohlig, Ph.D., is Head of Quality Management Services and Project Leader in the Department of Medicines Research at the Swiss Tropical & Public Health Institute in Basel, Switzerland. She is responsible for the Department's clinical operations and global training programs, and manages clinical trials in resource limited countries focusing on neglected diseases. She also works as a consultant for clinical trial management and quality assurance, and is an ISO 9001 accredited auditor. Gabriele is a biologist and obtained her Ph.D. at the University of Freiburg, Germany. After three postdoctoral years at the University of Oregon, USA, she joined Ciba Geigy, later Novartis AG, in Basel as senior scientist in 1989. In 1999 she became Head Manager of Clinical Research and Product Development at Medinova Ltd., Zürich, and received the EUCOR/ECPM diploma in pharmaceutical medicine in 2001. Since 2001 she has been working with the Swiss Tropical & Public Health Institute (Swiss TPH).

Barbara Potter is the Manager, Web Events for Barnett Educational Services, providing high-quality, performance-enhancing clinical education and training for all levels of staff, from novice to seasoned professional. Her most recent project includes spearheading the Web seminar product and recording lines, averaging over 70 online events quarterly that train more than 1,500 students. Ms. Potter has a Bachelor's Degree in Finance and Marketing Management, and substantial training and knowledge in information technology, including database management, data collaboration, security, data integrity, optimization, benchmarking, and reporting.

Randy Ramin-Wright, M.Sc., is a Program Manager and QRM Consultant with more than 20 years of experience in IT consulting, modeling, designing, and implementing information management systems. This expertise draws on project experience from a wide

range of industries: pharmaceutical R&D, pharmaceutical finance, pharmaceutical informatics, systems biology research, material sciences, banking, and national security. His current focus is on the development and commercialization of Quality Risk Management products and services, and the development of industry standard risk metrics to help pharmaceutical companies optimize the use of their drug development resources. Randy has an M.Sc. in Physics and B.Sc. in Astro-Physics from Michigan State University.

Denise G. Redkar-Brown began her career as a Medical Technologist working in a hospital laboratory environment. She made the transition to the pharmaceutical industry, and after more than 20 years she has held positions in basic and clinical research. She is published in the *European Journal of Pharmacology* for her work in pharmacology while at AstraZeneca, and was published in the *Good Clinical Practices Journal* in 2008. Denise has contributed to the successful submissions for Accolate® (the first leukotriene antagonist for asthma therapy) and Seroquel® (Serotonin receptor compound for treatment of Schizophrenia and bipolar disorder). Denise also worked at Dupont Pharma (Immunology), Knoll (Humira®), and Sanofi (vaccines), and at present she is the Associate Director of Scientific Affairs, Data Management for Cetero Research in Fargo, North Dakota, and is serving as a member of the Board of Trustees for the Society of Clinical Data Management (SCDM).

Lily Romero, P.A., C.C.R.C., has over 30 years of experience in clinical research. Her experience includes positions as Director of Global Development Training at Elan Pharmaceuticals, an Associate Director of Clinical Operations at Quintiles, Inc., a Clinical Research Coordinator and Research Administrator at the Allergy & Asthma Medical Group and Research Center, and a P.C. in San Diego, CA. She has worked on Phase I - IV clinical trials including pediatric studies. She was an instructor for and assisted in the development of an investigator GCP training workshop for the American Academy of Pharmaceutical Physicians. She is on the Advisory Board and an instructor for the Clinical Trials Design and Management certificate program at the University of California at San Diego (UCSD) Extension. Currently, she is a member of the Academy Board for the Associates of Clinical Research Professionals (ACRP).

Sandra "SAM" Sather, M.S., B.S.N., C.C.R.C., C.C.R.A., has over 25 years of clinical training and research experience. SAM is a clinical research consultant with a specialization in Human Performance Improvement (HPI). Her medical and science training started in nursing where she received a Bachelor's of Science in Nursing in 1983. She practiced nursing for over 10 years, intensive care to community health nursing, with much of the job in a training role. As a nurse, SAM also served as a clinical research coordinator (CRC) for intensive care cardiovascular trials. Soon after her work as a CRC, she made the transition to full time in the research industry. SAM's experience in the industry includes work for and with CROs, sponsors, and research sites of drug and device studies. In 2007, she completed her Master's in Science in Education with a specialization in Training and Performance Improvement.

She provides training, monitoring, auditing, and other services for clients in the clinical research drug and device industry. She is dual certified by ACRP, and is the chair-elect for the CCRA Exam Committee. SAM is a frequent speaker at industry conferences and has authored over 50 courses for clinical research training programs.

Ken Schiff, M.B.A., is a consultant specializing in providing risk management support to pharmaceutical and biotechnology companies around the world. In his consulting practice, he has successfully transformed traditional quality assurance and auditing methods by

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spearheading innovative quality risk management and compliance systems and driving new governance and control standards that help business partners proactively identify, manage, and mitigate risk.

Ken was previously with Hoffmann LaRoche/Genentech as the Head of Quality Assurance and Quality Risk Management. Ken and his group were responsible for assessing in a systematic manner a multitude of critical quality metrics and risk indicators that leverage processes and data in the conduct of clinical trials worldwide and worked closely with study management teams to help identify and mitigate high risks. Prior to that, Ken was Manager of Worldwide Clinical Quality Assurance Resources at Merck & Co. Inc. He has specialized in the area of clinical quality assurance and has been responsible for all aspects of GCP implementation, compliance, and education. He was responsible for managing all QA aspects and was very active in process optimization initiatives and QRM.

Ken has also been an active member of the PhRMA BioResearch Monitoring Committee representing the GCP Working Group for the past seven years, working closely with the FDA on the BIMO Modernization and Critical Path Initiatives, with specific focus on QRM concepts. Mr. Schiff obtained his B.A. degree in Biological Sciences/Pre-Medicine and M.B.A. in Biopharma Innovation & Entrepreneurship from Rutgers University.

Jackie Stader, C.O.T., C.C.R.C., provides independent quality research training, monitoring, auditing, medical writing, and project management consultation services. In addition, her drug and medical device experience with both sponsors/CROs and sites has enabled Jackie to place needed focus on rescue and risk-based training, including SOP development and improved GCP. Jackie is also a sought-after international trainer and speaker, with many publications to her credit. Jackie ties in her lengthy experience as a Clinical Research Coordinator and Certified Ophthalmic Technician to her training and lecturing topics.

Jennifer Stanford, R.N., M.S.N., is the Corporate Director of the Clinical Research Department for Valley Health located in Winchester, VA. She opened this office in September 2004, which serves all physicians within the Valley Health System and the surrounding outpatient private practices. She is also responsible for the oversight of the Institutional Review Board at the medical center. Previously, Ms. Stanford was the Executive Director of Cardiopulmonary Research Science and Technology Institute (CRSTI) in Dallas, a non-profit research organization which focused on cardiology and cardiac surgery trials. Prior to her work at CRSTI, Jennifer started the Clinical Trials Office at The University of Texas Southwestern Medical Center in 1997 where she was able to build a comprehensive, successful office.

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

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.

Elizabeth Weeks-Rowe, L.V.N., C.C.R.A., has spent the last ten years in the clinical research industry working as a CRA, CRA Trainer, CRA Manager, and Medical Writer. Her initial therapeutic CRA training was in the field of oncology, and she worked as a CRA on a pivotal Phase 3 oncology trial where the compound received expedited approval. The training involved with managing oncology sites provided an impetus into her next career move, CRA training. She has worked as a CRA sign off visit leader, a CRA Trainer for internal project teams, as well as a primary CRA class-room training instructor for a large CRO.

Her creative writing and clinical research experience have enabled her to serve as a contributing writer for several international research publications. Her experience in clinical research, training, and public speaking has enabled her to make a successful transition to the role of Business Development Director for a small CRO, where she is responsible for creating web site content, email marketing campaigns, and leading bid defense meetings and therapeutic discussions with industry executives.

Edith A. Zang, Ph.D., has over 30 years of statistical consulting and teaching experience in the pharmaceutical industry and in non-profit academic research. She is an expert in designing and analyzing Phase I through Phase III clinical trials, epidemiological investigations, and basic research studies. Through her years of teaching statistics to medical professionals, she became highly effective in explaining statistical principles to individuals with little or no formal background in statistics. She is proficient in the application of both traditional and novel statistical methods to clinical study design and analysis, including the use of adaptive design in both early and late phase clinical trials. Through her work on major oncology projects in the pharmaceutical industry, Dr. Zang had frequent opportunities to successfully interact with members of both national and international regulatory agencies, which helped her develop a thorough understanding of ICH guidelines and regulatory requirements as they apply to every stage of drug development. Dr. Zang is the author of two internal harmonization documents used by pharmaceutical companies, including guidelines for the selection and definition of endpoints in late phase oncology studies, and methods for preventing bias in open label trials. In addition, she authored or co-authored over 90 abstracts and peer reviewed articles in medical and scientific journals.

Seminar Accreditation, Policies, and Procedures

Important Notice

Barnett reserves the right to change the instructors and timing of our public seminars. Efforts will be made to notify participants in either event. We will not be responsible for any costs incurred, including airfare (or penalties) and hotel, as a result of a cancellation, instructor, or date and time change of any seminar. Barnett will not be responsible for costs incurred associated with errors or omissions in this catalog.

Seminar Policies

Seminar Cancellation Policy

Your notice of cancellation must be received in writing by mail or fax to Barnett's Customer Service Department prior to the start of the seminar. Please note that Barnett does not refund your registration fee.

- Prior to 10 business days before the seminar: You will receive an Event Pass. This Event Pass may be applied toward a future Barnett seminar of equal value within six (6) months of issue date. The original Event Pass must be surrendered at the time you register for a future seminar. (This can be done by mail only. Original Barnett letterhead is required.) Event Passes are not transferable to any other type of program, such as conferences or product orders.
- Within 10 business days before seminar:
No Event Pass will be issued.

Seminar Substitution Policy

If you are unable to attend a program, you may provide a substitute person (for the same program on the same date only). Your notice of substitution must be received in writing by mail or FAX to Barnett's Customer Service Department prior to the start of the seminar.

Force Majeure

The performance of this Agreement by either party is subject to Force Majeure, government authority, disaster, strikes, civil disorders, or other emergencies, or causes beyond reasonable control of the parties hereto, any of which make it illegal or impossible to provide the facilities and/or services for your meeting. It is agreed that this Agreement may be terminated for any one or more of such reasons by written notice from one party to the other without liability.

Discounts

(Excluding Web Seminars)

Team Discounts: We provide discounts for multiple enrollments from the same company in the same program. Registrations must be received at the same time.

- 10% discount for two participants
- 15% discount for three or more participants

Team Discounts CANNOT be combined with any other offer.

Accreditation

Program participants will receive continuing education units (CEUs) as indicated on each seminar description page for full participation (complete sign-in sheet, pre- and post-test, and evaluation form). Barnett must receive all completed documentation within 30 days of program completion or CEUs will not be issued. Barnett will mail CEU statements within three weeks of participant application submission.



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

Enrollment

Seminar registration is usually limited to 30 people due to the interactive nature of our programs. Please submit your registration form well in advance to secure a seat. Full payment must accompany registration form.

Meals and Breaks

Assorted breakfast items will be available each day beginning 1/2 hour prior to the start of the seminar. Networking Lunch will be served each day from 12:00 p.m. to 1:00 p.m. There will be a 15 minute morning break and a 15 minute afternoon break on each training day.

Special Requirements

If you have any special requirements, please contact Barnett at (800) 856-2556.

Hotel Information

Following are contact details for each of Barnett's seminar locations. To make hotel reservations, Please contact the hotel directly to book your room and reference the "Barnett Corporate" or "best available" rate. Where available, the discounted rate is based upon availability and hotel reservations must be made 31 days before program start date. These rates are available to individual seminar participants and may not be available through travel agency bookings. Availability is on a first-come, first-serve basis and may fill prior to cut-off. Be sure to mention Barnett Corporate rate when contacting the hotel.

**Club Quarters has loaded Barnett Educational Services in their member database. You can book online at www.clubquarters.com, using the password: Barnett (not case sensitive) or with Member Services at 203-905-2100. Just mention Barnett.

***For Philadelphia meetings being held at The Hub Meeting Center, attendees are encouraged to make hotel arrangements at one of the following hotels: Club Quarters (see above information to request Barnett's reduced rate), the Westin Philadelphia, The Radisson Plaza-Warwick Hotel, and the Crowne Plaza. All are conveniently located within 1-2 blocks of The Hub Meeting Center.

Boston, MA

Club Quarters Boston**
161 Devonshire Street (Between Milk & Franklin Streets), Boston, MA 02110
Tel: 617-357-6400 | Fax: 617-357-6462

Hyatt Regency Boston
One Avenue de Lafayette, Boston, MA 02111
Tel: 617-912-1234 | Fax: 617-451-2198

The Park Plaza Hotel and Towers
50 Park Plaza, Boston, MA 02116
Tel: 617-426-2000

Metro Meeting Centers - Boston (this is just a meeting facility, not a hotel)
101 Federal Street, 4th Floor, Boston, MA 02110
Tel: 617-737-1200

Chicago, IL

Club Quarters Wacker at Michigan**
75 E. Wacker Drive, Chicago, IL 60601
Tel: 312-357-6400 | Fax: 312-357-9900

Philadelphia, PA

Club Quarters Philadelphia**
1628 Chestnut Street (At 17th Street),
Philadelphia, PA 19103
Tel: 215-282-5000

The Hub Meeting Center - Cityview (meeting facility, not a hotel)***
30 South 17th Street, United Plaza 14th Floor
Philadelphia, PA 19103
Tel: 215-561-8090

Sheraton Suites Philadelphia Airport
4101 B Island Avenue, Philadelphia, PA 19153
Tel: 215-365-6600 | Fax: 215-220-4626

Renaissance Philadelphia Hotel Airport
500 Stevens Drive, Philadelphia, PA 19113
Tel: 610-521-5900 or 800-HOTELS-1
Fax: 610-521-4362

San Diego, CA

Courtyard San Diego Downtown
530 Broadway Street, San Diego, CA 92101
Tel: 619-446-3000 | Fax: 619-446-3010

San Francisco, CA

Hilton San Francisco
333 O'Farrell Street, San Francisco, CA 94102
Tel: 415-771-1400 | Fax: 415-771-6807

Curriculum Compliance Assessment & Development (C-CAD) Programs

How do you ensure that your training programs can adequately withstand FDA scrutiny? Reviews of FDA 483s and warning letters indicate that the most frequently issued process deficiencies include areas that can be easily addressed with focused training programs.

Building on our deep expertise with individual training courses, 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. Services include:



Employee Satisfaction Surveying

Barnett can help you measure employee experiences and perceptions regarding your current training programs by creating and delivering a customized survey. Our survey methodology gives you the information you need to evaluate your current training situation, identify "hot spots," and plan next steps.

Curriculum Gap Analysis

Barnett works with you to identify how well your training programs are "hitting the mark" by performing a detailed assessment of the current curriculum in place and determining how well it addresses skill set and training requirements.

Curriculum Development

Barnett can work with you to define a model curriculum plan for each job type, making recommendations for training platforms, technical and leadership training integration, and frequency of training. Barnett will help you leverage your internal resources, and point you to available external training resources when necessary.

Employee Communications and Logistics Services

Barnett can help you to get the word out and generate enthusiasm about your in-house training initiatives through communications planning. Logistical support is also available, including scheduling, production services, and meeting management services.

Customized Content Development

Let Barnett put our content development expertise to work for you! Our content development teams can work with you in a wide range of topic areas to develop and design comprehensive course content that is engaging and interactive.

Let Barnett leverage our training experience and resources for your employees. To learn more and to receive a sample curriculum, contact Naila Ganatra at (215) 413-2471.

Customized 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.



Content Development Expertise

Let Barnett leverage our large base of subject matter experts for your eLearning projects. Our average trainer has over 15 years of hands-on industry experience in their specialty areas, including deep expertise and proven abilities as trainers.

Best Instructional Design Practices

Barnett understands that strong training programs start with clearly defined goals and objectives, and are rooted in best instructional design practices. 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.

Highly Interactive Features

Using a variety of interactive features including simulations, videos, games, worksheets, and interactive exercises, Barnett's modules include a high level of interactivity that is engaging and memorable for participants.

Cost Effective and Efficient

Barnett's eLearning services eliminate the need for travel, travel expenses, and time away from the office! Modules are designed as self-paced sessions that can be completed when convenient for employees.

Compatible Platform

Barnett's platform is compatible with virtually any SCORM or AICC compliant LMS or LCMS. The platform allows for numerous interactive features and offers high flexibility.

Advanced Testing Options

Barnett's testing formats include dozens of possibilities for how questions can be positioned and displayed. Test scoring is highly flexible and adaptable and supports tests and quizzes that are fun, memorable, and reinforce learning concepts.

Learn more about Barnett's eLearning services and view our product demo. For more information, contact Rachel Meyers at (413) 527-3056 or rmeyers@barnettinternational.com.



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

COMPREHENSIVE WEB-BASED TRAINING PROGRAMS

- Over 100 pre-developed web seminars that can be customized to meet your learning objectives
- Content reflects best practices, real-world examples, interactive exercises, and case study simulations - all from your location
- Materials are designed to be directly applied on the job
- Cost-effective for single and multiple sites

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

WEB-BASED PLATFORM BENEFITS

- A seamless, secure, real-time multimedia learning experience
- No travel or associated expenses, and no time away from the office
- Resources required are already at your fingertips - an Internet connection and a phone or computer headset
- Ask questions, chat, learn from industry leaders and network with fellow attendees, all from the convenience of your own office

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 are highly experienced in web-based learning environments

PERSONALIZED SERVICE

Contact Naila Ganatra at (215) 413-2471 or nganatra@barnettinternational.com for more information.

www.BarnettInternational.com

Barnett International Presents:

Mock Audit and Training Programs



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. 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. 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 Follow-up 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.

Deliverables Include:

- Detailed Audit Agenda
- Detailed audit report 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 Naila Ganatra at
nganatra@barnettinternational.com or 215-413-2471.**

www.BarnettInternational.com

Barnett International's

Good Clinical Practices (GCP) Training and Assessment Program

**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



Barnett International is pleased to offer formal Good Clinical Practices (GCP) training and assessment for global clinical research professionals. Barnett's training and assessment processes were created partly 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 test question development process and validation includes a multi-tiered approach that ensures the exam is fully vetted by industry subject matter experts, and ensures test questions go beyond the simple recall of facts and require practical knowledge demonstration and application.

For more information about Barnett's GCP Certification,
contact Naila Ganatra at (215) 413-2471 or
nganatra@barnettinternational.com



MOVING TOWARD VIRTUAL INVESTIGATOR MEETINGS

Fulfilling the Need:

It has been argued that investigator meetings are the nucleus of clinical trials — the success of the study depends on them. They are also quite involving to organize, and costs can easily skyrocket out of control. Also, there is some debate about how well information retention can be achieved in such short periods of time, and whether or not it makes more sense to offer content in “segments,” so that better adult learning practices can be built in to content and program design.

Web-based meetings offer huge cost and time savings, help with quality, and given people’s schedules and travel considerations, we are finding that they are starting to be somewhat preferred by investigators. Barnett clients are seeing higher attendance rates for virtual meetings, and the ability to present information in carve-out “focus” sessions (more sub-sessions overall) has resulted in better protocol compliance.

Key Components of Barnett's Services:

Barnett has responded to this need by creating a “virtual investigator meeting” platform, where clients are provided with web hosting solutions that are seamless, ensure interactivity, and maximize the use of the web platform to create a memorable and outcomes-focused session.

Core services that Barnett offers include:

- Meeting set-up, including website development and branding
- Management of promotional activities including invitations, communications and confirmations
- Pre- and Post- assessments and evaluation
- Subject Matter Expert orientation and speaker training
- Assistance with the development of interactive components and audience polling
- Event hosting, including pre-event customer service, login support, facilitation and moderation and recording
- Reporting of pre- and post-event registration, evaluation and interactivity results

Logistical Components:

Barnett utilizes the WebEx “training center” product as our foundation and creates a seamless, “branded to your company” experience for your attendees. All that is required of attendees is a computer, high speed internet connection and a telephone line. WebEx has many unique features built in that make the user experience a very easy logistical experience.

Getting Started:

To get started, we would suggest starting with a demonstration of our services, and allow us to walk you through the experience that your investigators would have during a virtual meeting. From there, we can further custom-tailor the experience, and create a “mock” session for your planning group. To plan a session, contact Naila Ganatra at (215) 413-2471 or nghanatra@barnettinternational.com.

SOP Development and Training

Has your organization recently merged with, acquired, or divested from another company? Have you experienced a change in organizational structure? If yes, 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. Barnett's 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.



Choose Barnett and benefit from:

- A proven SOP development methodology that gains buy-in from stakeholders and end users
- Deep expertise in the clinical drug development process and incorporation of industry best practices into your procedures
- A continuous focus on regulatory compliance
- Alleviation of this workload from your staff
- Accurate, customized, SOP documents that are easy to read and follow
- Memorable training for adult learners

Meet company deadlines and maintain regulatory compliance...

Contact Barnett for Assistance!

For more information on Barnett's SOP Development and Training Services,
contact Naila Ganatra at (215) 413-2471 or
nganatra@barnettinternational.com

ACQUISITION INTEGRATION

Strategy & 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?

Given the critical need for a successful and swift acquisition, why are so many organizations failing to derive the full benefits of the acquisition? Ask any executive and they will tell you that the issues begin the minute their organizations attempt to integrate, issues which include:

- Wasted time and resources due to a lack of clear acquisition strategy
- Lack of clearly defined priorities
- Misalignment of leaders resulting in the delivery of inconsistent messages
- Unclear decision making process
- Teams not communicating with each other resulting in organizational churn, misalignment, and opportunities lost
- Newly acquired employees not doing what they are supposed to do
- Newly acquired employees leaving within six months of the acquisition and all the knowledge they possess leaves with them
- And so on...



BARNETT EDUCATIONAL SERVICES
A Division of Cambridge Healthtech Institute

Barnett helps drive the integration process with a proven methodology that includes:

- Developing an acquisition integration strategy
- Forming and driving an Integration Steering Committee so that the big questions can be answered and the rest of the organization is aligned:
 - What are the integration goals for our organization?
 - How will we know we've been successful?
 - What is our approach: integration of processes and best practices or assimilation or something else?
 - How will we handle the acquired company's studies in progress?
 - What newly acquired employees will be transitioned to our organization and how does that affect our structure?
 - How do we remain compliant?
 - How will we handle SOPs, training, and systems?
 - How will we align with and leverage shared services?
 - How will we ensure those responsible for the integration are working in concert?
 - How will we communicate about the acquisition to our organization?
 - How do we minimize resistance and foster resilience to the change?
- Liaising with other organizations to ensure alignment
- Developing an implementation road map that includes plans to transition people, processes, and technology
- Executing the road map



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 a successful acquisition integration.

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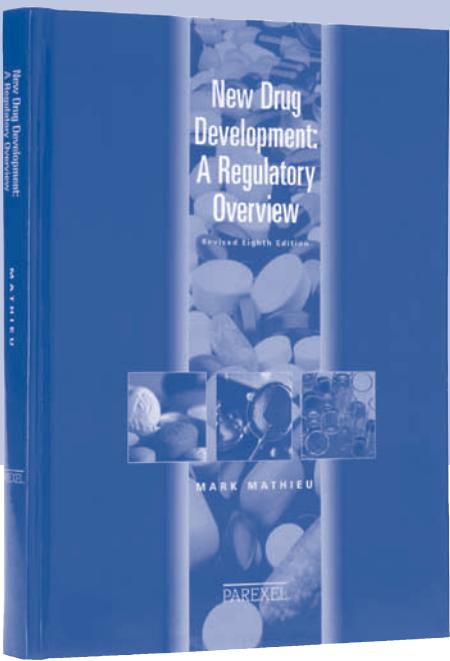
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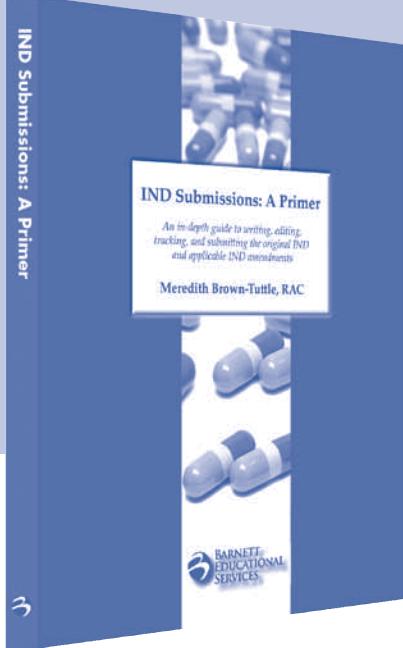
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Jonathan S. Kahan, Partner
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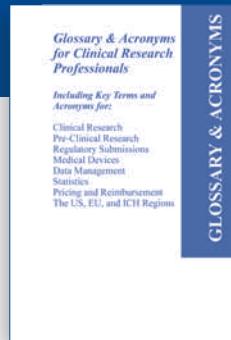
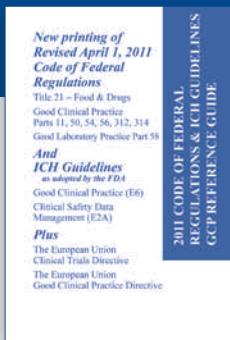
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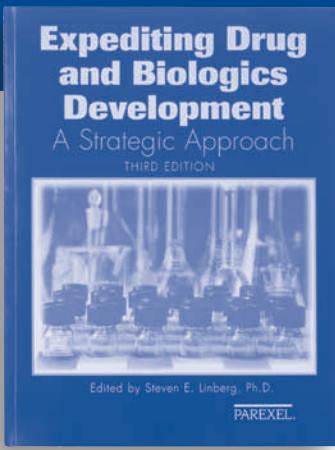
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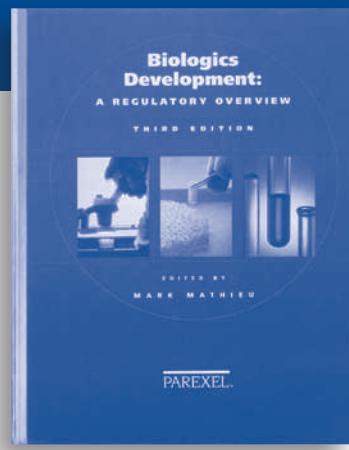
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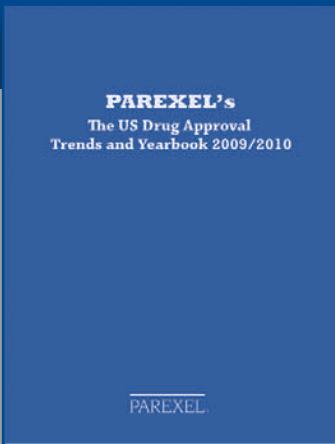
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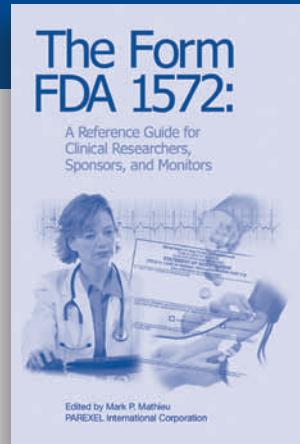
— Munish Mehra, Ph.D., Managing Director,
Global Drug Development Experts

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Good Clinical Practice: A Q&A Reference Guide (2011) Electronic Edition	GCP11E	\$45.95		
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2011 CFR/ICH GCP Reference Guide (Drug Version, Spiral Bound)	CFRS11	\$13.95		
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State-by-State Clinical Trial Requirements Reference Guide (2006)	CT07	\$49.95		
HIPAA and Human Subjects Research: A Q&A Reference Guide (2003)	HIP03	\$24.95		
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Biologics Development: A Regulatory Overview 3 rd Edition (2004)	BIODEV3	\$145.00		
The Global GCP Compliance Report 2006: US, EU, and Japan	MMGCR	\$95.00		
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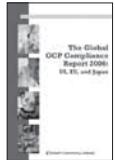
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Part 11 & Drug Development: A Q&A Reference Guide (2004)



Developed by industry experts, this guide addresses the most common and difficult questions regarding the day-to-day interpretation and implementation of the all new Part 11 standard today.

State-by-State Clinical Trial Requirements Reference Guide (2006)

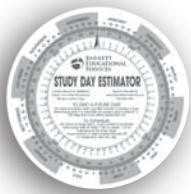


This guide covers updated and expanded profiles of the clinical trial standards in all 50 states. In addition, it breaks down each state's requirements in more than a dozen practical areas critical to specific clinical research programs.

HIPAA and Human Subjects Research: A Q&A Reference Guide (2003)



Quickly and conveniently access all the essential clinical-trial related HIPAA regulations and guidance documents – and analysis and perspectives from the two leading HIPAA experts – all in one pocket-sized handbook.



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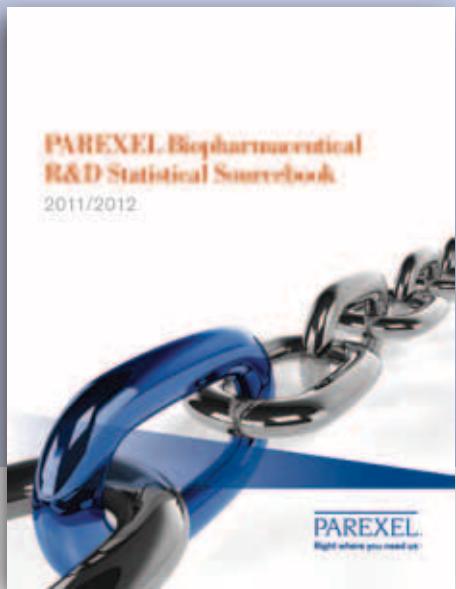
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