Training and Resources for Clinical Research Professionals

Liv e 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

COURSE AND PUBLICATIONS CATALOG | JANUARY – JUNE 2010
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
January 2010

Dear Colleagues,

It is with great pleasure that we present you with our January-June 2010 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:**
- Advanced Clinical Research Coordinator (CRC) Training
- Clinical Drug Development
- Combination Products: How to Get a Product Through the FDA Approval Process
- Global IND Submissions
- Introduction to the Food and Drug Administration (FDA)
- Regulatory Intelligence 101

**New Web-Based Courses:**
- Investigator, CRC, CRA 8 Weeks Fundamentals Training for the Global Professional Working in the ICH Environment (for global attendees!)
- ABCs of Clinical Research for Clinical Administrative Support Staff
- Adequate Sponsor Monitoring Systems
- Adverse Events for Medical Devices
- Clinical Trial Design for Medical Devices
- Clinical Trials for Pharmaceuticals: Design and Development
- Drug Development and FDA Regulations
- Meeting HIPAA & FDA Requirements for Case Histories
- Navigating the FDAs New Website: Tools for the Clinical Research Professional
- Phase I Study Management
- Sponsor Management of Investigator Non-Compliance
- Strategies for Managing Difficult Clinical Research Sites
- Train-the-Trainer: Successful Web-Based Training Strategies
- Transitioning Pharmaceutical Professionals to Medical Device Professionals
- Trial Master File (TMF) for Research Sites: Set-Up and Maintenance

In addition to these new offerings, you will also find many course updates and content revisions for 2010. 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.

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

Kind regards,

Naila Ganatra
General Manager
Barnett International

Phillips Kuhl
President
Cambridge Healthtech Institute
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**Hyatt Regency Boston**

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## Philadelphia, PA  
**Renaissance Philadelphia Airport**

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- Drug Safety and Pharmacovigilance
  - February 11-12, 2010
- Fraud in Clinical Research
  - February 11-12, 2010
- Comprehensive CRC Training
  - February 11-12, 2010
- Preparing IND Submissions
  - February 11-12, 2010
- Pharmacovigilance Audit
  - February 22, 2010
- Drug Development and FDA Regulations
  - February 22-23, 2010
- Statistical Concepts for Non-Statisticians
  - February 25-26, 2010
- Working with CROs
  - February 25-26, 2010
- Monitoring Clinical Drug Studies: Advanced
  - February 25-26, 2010
- Combination Products
  - March 9-10, 2010
- Pharmacokinetics
  - March 9-10, 2010
- Advanced Good Clinical Practice
  - April 15-16, 2010
- Clinical Project Management: Intermediate
  - April 20-21, 2010
- Study Site Start-Up
  - May 21, 2010
- Report Writing for CRAs
  - May 21, 2010
- Patient Registry Programs
  - May 25-26, 2010
- Regulatory Intelligence
  - June 28, 2010
- Drug Safety and Pharmacovigilance
  - June 29-30, 2010
- Monitoring Clinical Drug Studies: Advanced
  - June 29-30, 2010
- Managing and Conducting Global Clinical Trials
  - June 29-30, 2010
- Drug Development and FDA Regulations
  - June 29-30, 2010

### San Diego, CA
**Courtyard San Diego Downtown**
- Introduction to FDA
  - February 9-10
- Mastering Cost Management for Global Clinical Trials
  - February 9-10
- Advanced Good Clinical Practice
  - February 22-23
- Global GCP Monitoring
  - February 22-23
- GMP for Pharmaceuticals
  - February 22-23
- Adverse Events: Managing and Reporting for Pharmaceuticals
  - February 25-26
- Medical Device Approval Process
  - February 25-26
- Facilitation Skills for Clinical Research Team Members
  - February 26
- Introduction to Clinical Project Management
  - March 4-5
- Drug Approval Process
  - March 16-17
- Introduction to Clinical Data Management
  - March 16-17
- Teambuilding for the Cross-Functional Global Team
  - March 16-17
- Monitoring Clinical Drug Studies: Advanced
  - March 16-17
- Developing Clinical Study Budgets
  - March 18
- Source Documentation
  - March 18
- Adverse Events: Managing and Reporting for Medical Devices
  - March 18-19
- Drug Safety and Pharmacovigilance
  - March 18-19
- Medical Device Postmarketing Vigilance Reporting
  - March 18-19
- Regulatory Intelligence
  - March 19

### San Francisco, CA
**Hilton San Francisco**
- Comprehensive Monitoring for Medical Devices
  - April 7-9
- CRA & CRC Beginner
  - April 19-21
- Pharmacovigilance Audit
  - April 20
- Auditing Techniques for Clinical Research
  - April 20-21
- Fraud in Clinical Research
  - April 20-21
- Global IND Submissions
  - April 20-21
- Institutional Review Boards (IRBs)
  - April 22-23
- Monitoring Clinical Drug Studies: Intermediate
  - April 22-23
- Medical Device GCP Overview
  - April 22-23
- Working with CROs
  - April 22-23
- Monitoring Clinical Drug Studies: Beginner
  - April 26-28
- The CRA Manager
  - April 29-30
- Preparing IND Submissions
  - April 29-30
- Statistical Concepts for Non-Statisticians
  - April 29-30
- Pharmacovigilance
  - April 29-30
- Report Writing for CRAs
  - April 30
- Clinical Project Management: Intermediate
  - May 20-21
- Advanced Clinical Research Coordinator
  - June 10
- Combination Products
  - June 10-11
- Introduction to Clinical Project Management
  - June 10-11
- Clinical Trials for Medical Devices: Design & Development
  - June 24-25
- Clinical Project Management Advanced
  - June 26-29

### Chicago, IL
**Embassy Suites Chicago-Downtown/ Lakefront**
- Monitoring Clinical Drug Studies: Beginner
  - May 17-19
NEW! 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.

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

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

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

Course Dates and Locations
March 23, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SAAA0310
$800 by February 12
$1,000 after February 12

June 10, 2010
San Francisco, CA 92101
Hilton San Francisco, CA
Course #: SAAD0610
$800 by April 30
$1,000 after April 30

Registration
ON-LINE:
barnettinternational.com
FAX or MAIL:
Submit Registration Form (page 120) 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#: 778-000-09-047-L01-P. Released: 3/10.
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 OUTLINE

Day One: 8:30 a.m. – 5:30 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. – 5:30 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

Course Dates and Locations
February 22-23, 2010
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SADD0210
$1,595 by January 15
$1,795 after January 15

April 15-16, 2010
Philadelphia, PA 19153
Sheraton Suites Philadelphia Airport
Course #: SADA0410
$1,495 by March 5
$1,695 after March 5

June 9-10, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SADB0610
$1,495 by April 30
$1,695 after April 30

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Submit Registration Form (page 120) 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#: 778-000-09-017-L01-P. Released: 7/09.
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
January 26-27, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SDAA0110
$1,595 by December 18
$1,795 after December 18

March 18-19, 2010
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SDAD0310
$1,595 by February 5
$1,795 after February 5

May 13-14, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SDAB0510
$1,595 by April 2
$1,795 after April 2

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Barnett Customer Service
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#: 778-006-001-L04. Released: 9/08.

Call (215) 413-2471 for more information

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

COURSE OUTLINE

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

Call (215) 413-2471 for more information
Course Description
This course provides an excellent introduction for newcomers to the field of drug and biologic product pharmacovigilance, 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 pharmacovigilance
• 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
This course will be taught by one of the following instructors
Natalie Currie, B.Sc.
Stephen Jolley
Sidney Khan, Ph.D.
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., 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 OUTLINE
Day One: 8:30 a.m. – 5:30 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. – 5:30 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

Registration
ON-LINE:
barnettinternational.com
FAX or MAIL:
Submit Registration Form (page 120) with Payment to Barnett Customer Service.
For assistance, CALL: (800) 856-2556

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. 778-000-07-005-L01-P. Released: 6/07.
The New Jersey State Nurses Association (NJSNA) is accredited by the American Nurses Credentialing Center (ANCC) Commission on Accreditation of the American Nurses Association as an approver of continuing education for nursing. As an accredited body, NJSNA has approved this program for 13.83 Contact Hours.

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 apply these techniques, they can better detect, correct, and prevent clinical study performance deficiencies at clinical sites and within their organizations.

Learning Objectives
- Apply auditing standards that are solidly based in current law, regulations, and guidelines
- Utilize special, not often taught, auditing techniques as part of your daily monitoring or auditing activities
- Employ techniques for auditing and monitoring the electronic clinical trial (e.g., e-trials in which electronic medical records and/or Electronic Data Capture are utilized)
- Identify the differences between monitoring and auditing and integrate auditing techniques into monitoring procedures.
- Select investigators and patient 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

Instructors
This course will be taught by one of the following instructors
Carol Cox-McClave
Barry Renaud

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 OUTLINE

Day One: 8:30 a.m. – 5:30 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

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

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

Day Two: 8:30 a.m. – 5:30 p.m.

Auditing Techniques Exercise: Perform data trend analysis; audit to determine document validity and data accuracy; 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, Auditing of Sponsors and CROs, and Managing Regulatory Authority Inspections: The compliance organizations in CDER, CBER and CDRH; FDA inspection results and consequences of adverse findings; how to conduct “in-house” audits; how to manage a regulatory authority inspection; FDA’s Application Integrity Policy

Summary of the Trial Center Audit Process: Planning, notifications, conduct, reporting, Corrective and Preventative Actions (CAPAs), and process improvement

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Submit Registration Form (page 120) 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#: 778-000-07-006-L01-P

Released: 6/07.
## Course Description

People often use the term, “Well, it’s not rocket science!”, to indicate that something is not hard or complicated. They could also use the term “Well, it’s not drug development!” The process of clinical drug development utilizes pharmacokinetic, medical, statistical, and other clinically relevant disciplines to turn a chemical compound into a safe and effective drug. These key areas will be examined and the process that utilizes them will be described in a way that draws from real examples.

While the whole process of drug development will be discussed, the focus of the course will be to examine the clinical aspects of the development process with emphasis on the clinical pharmacology and pharmacokinetic contributions to this process.

### Learning Objectives

- Describe the process of transforming a chemical into a drug product
- Describe how people from varied disciplines complement each other on a development team
- Discern the decision-making process that efficiently moves a drug through development
- Describe how pharmacokinetic principles are applied in the decision-making process
- Appreciate the importance of monitoring in clinical studies
- Discern the role of regulatory affairs to bring a drug to market

### Who Should Attend

- Individuals from outside the pharmaceutical industry who want to gain an understanding of how drugs are developed
- Pharmaceutical company employees with skills that can be applied to the drug development process

### Interactive Activities

- Craft a clinical development plan from information found in a package insert
- Role play individuals on a clinical development team as they respond to a particular challenge.
- Present a development plan to the FDA and defend it

### Course Dates and Locations

**March 25-26, 2010**  
Philadelphia, PA 19113  
Renaissance Philadelphia Airport Hotel  
Course #: SICA0310  
$1,595 by February 12  
$1,795 after February 12

**May 20-21, 2010**  
San Francisco, CA 92101  
Hilton San Francisco, CA  
Course #: SICF0510  
$1,595 by April 9  
$1,795 after April 9

### Registration

**ON-LINE:**  
barnettinternational.com

**FAX or MAIL:**  
Submit Registration Form (page 120) with Payment to Barnett Customer Service.

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

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### Accreditation

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Released: 3/10.

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### COURSE OUTLINE

#### Day One: 8:30 a.m. – 5:00 p.m.

**Organization of R & D in a pharmaceutical company as it relates to drug development**

- Dynamics of project teams and sub-project teams
- Stages of drug development
- Phase I – IV clinical studies

**Clinical development strategies**

- Review of prior drugs in a therapeutic class
- Developing the proposed label

**Regulatory submissions**

- Dynamics of interactions with regulatory agencies
- IND, NDA, sNDA, and aNDA

**Application of pharmacokinetics**

- Compartmental vs. noncompartmental analysis in the drug development process
- Applications of population pharmacokinetics
- Pharmacokinetic/pharmacodynamic (PK/PD) modeling
- Generic drugs

**Craft a clinical development plan from information found in a package insert**

#### Day Two: 8:30 a.m. – 5:00 p.m.

**Examples of strategies in specific therapeutic areas**

**Applications for drug delivery systems**

- Role play individuals on a clinical development team as they respond to a particular challenge
- Present a development plan to the FDA and defend it.

**Summary and next-steps**
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
Susan Bassion, Ph.D.
Kenny Jones
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
January 26-27, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SPM00110
$1,595 by December 18
$1,795 after December 18

March 4-5, 2010
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SPM0310
$1,595 by January 22
$1,795 after January 22

May 4-5, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SPM0510
$1,595 by March 26
$1,795 after March 26

June 10-11, 2010
San Francisco, CA 94112
Hilton San Francisco
Course #: SPM0610
$1,595 by April 30
$1,795 after April 30

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: FAX or MAIL: Barnett Customer Service.

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Accreditation
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Released: 11/07.

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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Released: 11/07.

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

Course Outline

Day One: 8:30 a.m. – 5:30 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 resolution; communication strategies; effective communication skills
Contractor – 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
Susan Bassion, Ph.D.
Madja Benhouyn
Kenny Jones
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
February 11-12, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SMIB0210
$1,595 by January 8
$1,795 after January 8

April 20-21, 2010
Philadelphia, PA 19153
Sheraton Suites Philadelphia Airport
Course #: SMIA0410
$1,595 by March 12
$1,795 after March 12

May 20-21, 2010
San Francisco, CA 94102
Hilton San Francisco
Course #: SMIF0510
$1,595 by April 9
$1,795 after April 9

Registration
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Released: 8/09.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:30 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. – 5:30 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

Instructor
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. – 5:30 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 programs 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. – 5:30 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 Global Trials
Negotiation Skills Across Cultural Barriers

Course Dates and Locations
March 2-3, 2010
Hyatt Regency Boston
Course #: SMY0310
$1,595 by January 22
$1,795 after January 22

May 10-11, 2010
Renaissance Philadelphia Airport Hotel
Course #: SMYA0510
$1,595 by April 2
$1,795 after April 2

June 28-29, 2010
Hilton San Francisco
Course #: SMYP0610
$1,595 by May 21
$1,795 after May 21

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: 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#: 778-006-08-030-L04-P.
Released: 3/09.
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.

Interactive Activities
- Ethical Issues
- Case Studies: Improving Clinical Trials
- Control Groups
- Rationale Evaluation
- Protocol Modification
- Sample Size
- Study Objectives

Course Dates and Locations
June 24-25, 2010
San Francisco, CA 94102
Hilton San Francisco
Course #: SMMF0610
$1,595 by May 14
$1,795 after May 14

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Submit Registration Form (page 120) 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#: 778-006-08-002-L04-P. Released: 12/08.

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

Day Two: 8:30 a.m. – 5:30 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

Instructors
This course will be taught by one of the following instructors
Susan Bassion, Ph.D.
Lynne Eddy, Ph.D.
Lily Romero, P.A., C.C.R.C.
Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.
Albert A. Ghignone, M.S., R.A.C.

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
March 23-24, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SCTA0310
$1,595 by February 12
$1,795 after February 12

June 24-25, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SCTA0610
$1,595 by May 14
$1,795 after May 14

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Submit Registration Form (page 120) 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#: 778-000-07-778-L01-P. Released: 5/07.

Day One: 8:30 a.m. – 5:30 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. – 5:30 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
NEW! 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
March 9-10, 2010
Philadelphia, PA 19153
Sheraton Suites Philadelphia Airport
Course #: SPOA0310
$1,595 by January 29
$1,795 after January 29

June 10-11, 2010
San Francisco, CA 92101
Hilton San Francisco, CA
Course #: SPOF0610
$1,595 by April 30
$1,795 after April 30

Registration
ON-LINE:
barrettinternational.com
FAX or MAIL:
Submit Registration Form (page 120) 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#: 778-000-09-046-L01-P. Released: 3/10.
Comprehensive CRC Training

Course Description
This course provides an in-depth survey of the roles and responsibilities of the Clinical Research Coordinator (CRC), and is designed for CRCs with less than one year of experience. CRCs with some experience also may find this course valuable for refining their skills and sharing experiences and helpful techniques with their colleagues.

Learning Objectives
• Recognize how the CRC plays a role in the development of new drugs
• Describe the responsibilities of the Investigator in clinical research
• Analyze the “letter” and the “spirit” of FDA regulations, ICH guidelines, and ethical considerations pertinent to conducting clinical trials
• Compare various sponsor interpretations of the regulations and how these impact the investigational site
• Prepare for all sponsor site visits
• Review the informed consent form and process requirements
• Develop strategies for recruiting and retaining study subjects
• Review the requirements for managing and reporting adverse events
• Employ study documentation requirements and standards for collecting and reporting clinical trials data

Who Should Attend
• Clinical Research Coordinators with limited experience in managing industry-sponsored investigational drug/device studies
• Experienced Coordinators seeking a greater understanding of federal regulations and ICH requirements and to enhance their skills to more efficiently and effectively manage their studies

Instructors
This course will be taught by one of the following instructors
Erica Elefant
Gary B. Freeman, M.S., C.C.R.A.
Beth D. Harper, B.S., M.B.A
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.
Jennifer Stanford, R.N., M.S.N.

Interactive Activities
• Adverse Events Exercise
• Time Management Exercise
• GCP Jeopardy® Game

Day One: 8:30 a.m. – 5:30 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. – 5:30 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
GCP Jeopardy® Game

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Barnett Customer Service
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#: 778-000-07-001-L01-P. Released: 3/07.

The New Jersey State Nurses Association (NJSNA) is accredited by the American Nurses Credentialing Center (ANCC) Commission on Accreditation of the American Nurses Association as an approver of continuing education for nursing. As an accredited body, NJSNA has approved this program for 13.75 Contact Hours. Approval Number: 6680-2/08-10.

Hyatt Regency Boston
Course #: SCRA0210
$1,595 by January 8
$1,795 after January 8

May 13-14, 2010
Boston, MA 02111

Philadelphia, PA 19153
Sheraton Suites Philadelphia Airport
Course #: SCRB0510
$1,595 by April 2
$1,795 after April 2

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 3 ways devices are characterized
- Prepare and conduct a pre-investigation visit, an investigator’s meeting, an initiation visit, a periodic, 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 “do’s and don’ts” in the event of a FDA audit

Who Should Attend
- CRAs with 1-2 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.

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

COURSE OUTLINE

Day One: 8:30 a.m. – 5:30 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. – 5:30 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. – 5:30 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

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Submit Registration Form (page 120) with Payment to Barnett Customer Service.
For assistance, CALL: (800) 856-2566

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#: 776-000-07-002-L01-P Released: 2/07.
The New Jersey State Nurses Association (NJNSA) is accredited by the American Nurses Credentialing Center (ANCC) Commission on Accreditation of the American Nurses Credentialing Center as an approver of continuing education for nursing. As an accredited body, NJNSA has approved this program for 21 Contact Hours. Approval Number: 6661-1/08-10.

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.
- Diego Glancszpiguel
- Piotr Kolataj, M.D.
- Graciela Rácaro, R.Ph., BioChem
- Sebastian Yeoh
- Karen Chu, PharmD

Interactive Activities
The workshop is based on a real case study. Attendees are requested to provide sample clinical trial protocols that will be used to customize the training to meet individual participant’s needs.

Day One: 8:30 a.m. – 5:30 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. – 12:15 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

Course Dates and Locations
March 24-25, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SDRB0310
$1,595 by February 12
$1,795 after February 12

June 9-10, 2010
Boston, MA02111
Hyatt Regency Boston
Course #: SDRB0610
$1,595 by April 30
$1,795 after April 30

Registration
ON-LINE:
barnettinternational.com
FAX or MAIL:
Submit Registration Form (page 120) 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 11 hours (1.1 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. ACPE#:
778-000-08-019-L04-P.
Released: 6/08.
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

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FAX or MAIL: Submit Registration Form (page 120) 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#: 778-000-07-004-L01-P

Released: 5/07.

Day One: 8:30 a.m. – 5:30 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. – 5:30 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

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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

Erica Elefant
Beth D. Harper, B.S., M.B.A.
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
Jennifer Stanford, R.N., M.S.N.

Interactive Activities

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

Course Dates and Locations

February 3-5, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SCOA0210
$1,695 by January 8
$1,895 after January 8

April 19-21, 2010
San Francisco, CA 94102
Hilton San Francisco
Course #: SCOF0410
$1,695 by March 12
$1,895 after March 12

June 16-18, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SCOB0610
$1,695 by May 7
$1,895 after May 7

Registration

ON-LINE: barnettinternational.com
FAX or MAIL: Submit Registration Form (page 120) 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 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#: 778-000-07-007-L01-P. Released: 6/07.

The New Jersey State Nurses Association (NJSNA) is accredited by the American Nurses Credentialing Center (ANCC) Commission on Accreditation of the American Nurses Association as an approver of continuing education for nursing. As an accredited body, NJSNA has approved this program for 21 Contact Hours. Approval Number: 6682-2/08-10.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:30 p.m.
- Acronyms & Terminology
- FDA Regulations and Guidelines for Good Clinical Practice
- Clinical Research Team: Roles & Responsibilities

Day Two: 8:30 a.m. – 5:30 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

Day Three: 8:30 a.m. – 5:30 p.m.
- Study Monitoring, Data Management and the Study Initiation Visit
- 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.
Beth D. Harper, B.S., M.B.A.
Elizabeth Ronk Nelson, M.P.H.
Lily Romero
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

January 26-27, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SCMA0110
$1,595 by December 18
$1,795 after December 18

April 29-30, 2010
San Francisco, CA 94102
Hilton San Francisco
Course #: SCMF0410
$1,595 by March 19
$1,795 after March 19

June 10-11, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SCMA0610
$1,595 by April 30
$1,795 after April 30

Registration

ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 120) 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#: 778-000-071-01-P; Released: 10/07.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:30 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. – 5:30 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 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

Interactive Activities:
• 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

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 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 2: 8:30 a.m. – 5:30 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 Court at Your Company: In-person or On the Web!
Call (215) 413-2471 for more information

Course Dates and Locations
March 24-25, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SELB0310
$1,595 by February 12
$1,795 after February 12

June 24-25, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SELA0610
$1,595 by May 14
$1,795 after May 14

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Submit Registration Form (page 120) with Payment to Barnett Customer Service.
For assistance, CALL: (800) 856-2656

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.
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
- 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:
Susan Bassion, Ph.D.
Lily Romero, P.A., C.C.R.C.

Interactive Activities
- Core Concepts
- Case Study

Course Dates and Locations
March 18, 2010
San Diego, CA 92101
Courtyard San Diego
Course #: SDBD0310
$800 by February 5
$1,000 after February 5

May 11, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SDBA0510
$800 by April 2
$1,000 after April 2

Registration
ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 120) with Payment to Barnett Customer Service.

For assistance,
CALL: (800) 856-2556

Registration fees include assorted breakfast items that will be available each day 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 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#: 778-000-07-015-L01-P.
Release: 11/07.
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
January 26-27, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SDPA0110
$1,595 by December 18
$1,795 after December 18

March 16-17, 2010
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SDPD0310
$1,595 by February 5
$1,795 after February 5

June 24-25, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SDPA0610
$1,595 by May 14
$1,795 after May 14

Registration
ON-LINE:
barnettinternational.com
FAX or MAIL:
Submit Registration Form (page 120) 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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Released: 7/07.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:30 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. – 5:30 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
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 need an overview of all areas of drug development and the interrelationship and interdependence of other departments

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

Course Dates and Locations
February 22-23, 2010
Philadelphia, PA 19153
Sheraton Suites Philadelphia Airport
Course #: SDDA0210
$1,595 by January 15
$1,795 after January 15

May 18-19, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SDDB0510
$1,595 by April 9
$1,795 after April 9

June 29-30, 2010
Philadelphia, PA 19153
Sheraton Suites Philadelphia Airport
Course #: SDDA0610
$1,595 by May 21
$1,795 after May 21

Registration
ON-LINE:
barnettinternational.com
FAX or MAIL:
Submit Registration Form (page 120) 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#: 778-000-09-19-L01-P.

Released: 10/09.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:30 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. – 5:30 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, but slow down the product approval process. Keeping products on the market without interruption becomes more essential with the reduced pipeline of drugs in development. Successful navigation of drug safety and pharmacovigilance are keys to product longevity, consumer confidence, and regulatory compliance. This course will provide learners with 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
- Avoid product recall
- 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

Course Outline
Day One: 8:30 a.m. – 5:30 p.m.
- What is Pharmacovigilance? Definition; corporate pharmacovigilance; ADR system: critical elements
- What is an ADR? Adverse Drug Reaction definition; sources of SADRs; types of ADRs; ADR reports to FDA/EMEA; serious ADR; unlabeled or unexpected ADR; expectedness “listed” vs. “unlisted”; severity/intensity; lack of efficacy; pharmacovigilance
- Regulatory References: “The Tome”; FDA suggested revisions; always expedited reports; medically significant ADRs; relationship testing; causality relationship; causality evaluation; downgrading of investigator’s causality; MedWatch 3500A
- Characteristics of a Good Case Report: How to do a narrative evaluation for follow-up; active query; investigator’s brochure; safety; interim update for investigators; FDA time/report obligations; regulatory reporting and notification
- Quality Processes: Case metrics; quality assurance audit
- Clinical Trial Safety Data Collection: Audit trail; safety data management; statistical analysis; communication of safety information

Day Two: 8:30 a.m. – 5:30 p.m.
- Coding Background/History of MedDRA: Medical Dictionary for Regulatory Activities (MedDRA)
- Signaling: What is a safety signal; safety signal generation; definition; pharmacovigilance process; risk/benefit; situations for signal detection; sources of signals; analysis and investigation of a signal; understanding safety signals; suspected signals
- Labeling: When should a label be revised; impact of label revision; placement of safety messages; box warnings; goals; safety monitor training
- Audit Issues: FDA inspections; problems and issues; encountered problems; ADR; inspection principles; inspection results (FDA 483s); potential FDA actions
- Other Regulations: International Conference on Harmonization (ICH); ICH topic codes and Reports Council of International Organizations of Medical Sciences (CIOMS); European Medicines Evaluation Agency (EMEA); Eudravigilance; EUDRA CT Database

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

Course Dates and Locations
February 11-12, 2010
Philadelphia, PA 19153
Sheraton Suites Philadelphia Airport
Course #: SSVA0210
$1,595 by January 8
$1,795 after January 8

March 18-19, 2010
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SSV0310
$1,595 by February 5
$1,795 after February 5

June 29-30, 2010
Philadelphia, PA 19153
Sheraton Suites Philadelphia Airport
Course #: SSVA0610
$1,595 by May 21, 2010
$1,795 after May 21, 2010

Registration
ON-LINE:
barnettinternational.com

FAX or MAIL:
Submit Registration Form (page 120) 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#: 778-000-09-034-L04-P. Released 9/09.
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

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

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

Course Dates and Locations
February 26, 2010
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SFSD0210
$800 by January 15
$1,000 after January 15

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: 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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Accreditation Council

Hold this Course at Your Company: In-person or On the Web!
Call (215) 413-2471 for more information
## 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 fraud is presented in controls for investigating and containing suspect clinical data.

### 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

### Instructors

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

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Location</td>
<td>Sheraton Suites Philadelphia Airport</td>
<td>Hilton San Francisco</td>
<td>Hyatt Regency Boston</td>
</tr>
<tr>
<td>Course #: SFUA0210</td>
<td>Course #: SFUF0410</td>
<td>Course #: SFUB0610</td>
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<tr>
<td>Registration Fees:</td>
<td>$1,595 by March 12, $1,795 after March 12</td>
<td>$1,595 by May 7, $1,795 after May 7</td>
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</tr>
</tbody>
</table>

## Registration

**ON-LINE:** barnettinternational.com

**FAX** or **MAIL:** 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#: 778-000-09-033-L04-P. Released: 07/09.

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### COURSE OUTLINE

<table>
<thead>
<tr>
<th>Day One: 8:30 a.m. – 5:00 p.m.</th>
<th>Day Two: 8:30 a.m. – 5:00 p.m.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fraud versus Noncompliance: Review and Identification</td>
<td>Developing the Case: Detection, Documentation, and Dissemination</td>
</tr>
<tr>
<td>Elements of Fraud</td>
<td>Regulatory Authorities: Current Focus and Findings</td>
</tr>
<tr>
<td>Everyone is Suspect: Key Players in Perpetration and Prosecution</td>
<td>Novel Approaches: Elements for Prevention of Fraud in Clinical Research</td>
</tr>
<tr>
<td>Landmark and Recent Cases of Fraud in Clinical Research</td>
<td>Interactive Case Studies</td>
</tr>
</tbody>
</table>

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**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
February 22-23, 2010
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SGMD0210
$1,595 by January 15
$1,795 after January 15

May 11-12, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SGMA0510
$1,595 by April 2
$1,795 after April 2

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Submit Registration Form (page 120) 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#: 778-000-07-008-L01-P
Released: 6/07.

The New Jersey State Nurses Association (NJSNA) is accredited by the American Nurses Credentialing Center (ANCC) Commission on Accreditation of the American Nurses Association as an approver of continuing education for nursing. As an accredited body, NJSNA has approved this program for 14 Contact Hours. Approval Number: 6660-1/08-10.

Day One: 8:30 a.m. – 5:30 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. – 5:30 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
NEW! Global IND Submissions

Course Description
As drug companies seek to penetrate global markets and get new drugs to markets more quickly, these companies 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 country/regulatory agency specific requirements.

This course will walk the participants through the country requirements, IND submission requirements, and timelines for approval in for Canada, EU, South Africa, Australia, Asia, and South America using the US 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
The goal of the course is to familiarize the student with:
- 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

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
- Team exercises
- Document reviews
- Global submissions exercise

Course Dates and Locations
April 20-21, 2010
San Francisco, CA 94102
Hilton San Francisco
Course #: SRGF0410
$1,595 by March 12
$1,795 after March 12

May 13-14, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SRGB0510
$1,595 by April 2
$1,795 after April 2

Registration
ON-LINE:
barnettinternational.com
FAX or MAIL:
Submit Registration Form (page 120) 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# 778-000-044-L01-P. Released 4/10.

COURSE OUTLINE
Day One: 8:30 a.m. – 5:30 p.m.
Review the IND like contents, submissions requirements, maintenance and end of trial documents for:
- North America – Canada
- EU and Eastern EU

Day Two: 8:30 a.m. – 5:30 p.m.
Review the IND like contents, submissions requirements, maintenance and end of trial documents for:
- Australia and South Africa
- Japan
- Other Asian Countries
- South America

Hold this Course at Your Company: In-person or On the Web!
Call (215) 413-2471 for more information
GMP for Pharmaceuticals: Basic Approaches for Understanding and Compliance

Course Description
Understanding regulations, required methods, procedures, quality programs, and documentation practices are the foundation of GMP. This hands-on, how-to seminar provides instruction in basic training for compliance. This is a perfect primer course for people new to the regulated environment or an excellent refresher course for those who need to revisit the basics for better compliance. With GMP guidelines in mind, your instructor will provide insights into defining the various elements of GMP: establishing policies, building teams, writing documents, understanding quality policy, and documenting corrective and preventive actions. Particular focus will be placed on hands-on Q&A exercises.

Learning Objectives
- Review regulatory environment and history
- Explain the importance of written procedures
- Discuss the benefits of compliance
- Do it right: do's and don'ts
- Describe the importance of good housekeeping
- Determine what to and how to document
- Implement proper maintenance techniques
- Review the importance of change control
- Review various validation approaches
- Implement strategies for proper auditing

Who Should Attend
This course is applicable to those involved in the manufacturing and operations functions in the pharmaceutical industry. It is both a primer for people new to the regulated environment or an excellent refresher course for those who need to revisit the basics for better compliance. Those who will benefit include professionals in development, quality, production, operations, engineering, and regulatory affairs.

Instructors
This course will be taught by one of the following instructors
- David R. Dills
- Miguel Montalvo

Interactive Exercises
- Section and Final Q&A
- The GMP Jeopardy® Game
- Group Discussions

Course Dates and Locations
February 22-23, 2010
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SIGD0210
$1,595 by January 15
$1,795 after January 15

June 9-10, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SIGB0610
$1,595 by April 30
$1,795 after April 30

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Submit Registration Form (page 120) 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#: 778-000-08-005-L04-P. Released: 5/08.

Day One: 8:30 a.m. – 5:30 p.m.
- Regulatory Background: History; definitions and terminology; guidelines
- Getting Started: Purpose and role of written procedures; writing and following SOPs; writing and following batch records
- Doing it Right: Determining who is involved; defining what FDA is looking for; the cost of non-compliance
- Interactive Exercises: Q&A; group discussion; self evaluation

Day Two: 8:30 a.m. – 5:30 p.m.
- Housekeeping and Maintenance: Best practices; benefits; do's and don'ts
- Documentation and Validation: Knowing why you should document; the role of validation; incorporating continuous improvement
- Change Control and Auditing: critical areas to control; external and internal audits; being proactive
- Interactive Exercises: Group discussions; final Q&A; the GMP Jeopardy® Game

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

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**Course Dates and Locations**

**February 9-10, 2010**
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SOCA0210
$1,595 by March 12
$1,795 after March 12

**April 22-23, 2010**
San Francisco, CA 94102
Hilton San Francisco
Course #: SOCF0410
$1,595 by May 7
$1,795 after May 7

**June 16-18, 2010**
Boston, MA 02111
Hyatt Regency Boston
Course #: SOC06010
$1,595 by May 7
$1,795 after May 7

**Registration**

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barnettinternational.com

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For assistance,
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**Accreditation**

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**Course Outline**

**Day One: 8:30 a.m. – 5:30 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. – 5:30 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

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

Call (215) 413-2471 for more information
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
January 28-29, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SIMA0110
$1,595 by December 18
$1,795 after December 18

March 16-17, 2010
San Diego, CA 02101
Courtyard San Diego Downtown
Course #: SIMD0310
$1,595 by February 5
$1,795 after February 5

June 1-2, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SIMB0610
$1,595 by April 23
$1,795 after April 23

Registration
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barnettinternational.com
FAX or MAIL:
barnettinternational.com
ON-LINE:
Registration

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#: 778-000-07-012-L01-P. Released: 10/07.

Hold this Course at Your Company: In-person or On the Web!
Call (215) 413-2471 for more information
NEW! 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
February 9-10, 2010
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SFDD0210
$1,595 by January 8
$1,795 after January 8

April 26-27, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport
Course #: SFDA0410
$1,595 by March 19
$1,795 after March 19

Registration
ON-LINE:
barnettinternational.com

FAX or MAIL:
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For assistance,
CALL: (800) 856-2556

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778-000-09-045-L01-P.
Released: 2/10.
Managing and Conducting Global Clinical Trials

Course Description
Increased competition for clinical trial subjects and resources has quickly spread investigational sites and vendors all over the world. The globalization of clinical trial has provided opportunities to clinical trial sponsors and in many cases has been a key component in managing the costs and timelines of drug development. At the same time, this trend has added significant new challenges to the conduct and management of clinical trials. This course provides a comprehensive overview of the considerations for conducting trials and contracting resources outside the United States. General strategies for approaching differences in language, culture, health care delivery systems, 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
- Identify the reasons for globalizing clinical trials
- Recognize the differences among countries that may be advantageous to clinical trial sponsors
- Assess the critical issues related to global implementation of a clinical trial
- Develop a framework for making decisions about trial locations
- Anticipate the challenges involved in global clinical trials
- Formulate strategies for meeting the challenges

Who Should Attend
- Experienced clinical research professionals who are new to international clinical trials

Instructor
Anne McDonough, M.P.H., C.C.R.A., M.I.C.R.

Interactive Activities
- Brainstorming group discussions
- Troubleshooting case study
- Small group assignments
- Cross-cultural simulation

Course Dates and Locations

February 25-26, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SMGB0210
$1,595 by January 15
$1,795 after January 15

June 29-30, 2010
Philadelphia, PA 19153
Sheraton Suites Philadelphia Airport
Course #: SMGA0610
$1,595 by May 21
$1,795 after May 21

Registration
ON-LINE:
barnettinternational.com
FAX or MAIL:
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For assistance,
CALL: (800) 856-2556

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Released: 2/09.

Day One: 8:30 a.m. – 5:30 p.m.
Impetus for Globalization of Clinical Trials:
Why are clinical trial sites and services moving around the world?
Understanding the Local Environments:
What do we already know? What else do we need to find out? How do we get this information?
Considerations for Planning Global Trials:
What areas do we need to think about when we seek investigational sites or services outside the US? What advantages will we find in other countries? What are the challenges?

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

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
February 9-10, 2010
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SCSD0210
$1,595 by January 8
$1,795 after January 8

April 26-27, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SCSA0410
$1,595 by March 19
$1,795 after March 19

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Submit Registration Form (page 120) with Payment to Barnett Customer Service.

For assistance, CALL: (800) 856-2656

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

Day One: 8:30 a.m. – 5:30 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. – 5:30 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

COURSE OUTLINE

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 25-26, 2010
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SD9D0210
$1,595 by January 15
$1,795 after January 15

June 1-2, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SD9B0610
$1,595 by April 23
$1,795 after April 23

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Submit Registration Form (page 120) 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#: 778-000-07-013-L01-P. Released: 10/07.

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

Course Description
This course provides information across the full range of medical device clinical trial activities. 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
January 28-29, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SD8A0110
$1,595 by December 18
$1,795 after December 18

April 22-23, 2010
San Francisco, CA 94102
Hilton San Francisco
Course #: SD8F0410
$1,595 by March 12
$1,795 after March 12

Registration
ON-LINE:
barnettinternational.com
FAX or MAIL:
Submit Registration Form (page 120) 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#: 778-000-07-010-L01-P. Released: 7/07.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:30 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. – 5:30 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
Learning Objectives

- 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 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. For most products sold in the EU, the use of CE Marking and a Declaration of Conformity are mandatory.

Course Dates and Locations

March 18, 2010
San Diego CA 92101
Courtyard San Diego Downtown
Course #: SDVD0310
$1,595 by February 5
$1,795 after February 5

June 9, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SDVA0610
$1,595 by April 30
$1,795 after April 30

Registration

ON-LINE: barnettinternational.com
FAX or MAIL: Submit Registration Form (page 120) with Payment to Barnett Customer Service.

For assistance, CALL: (800) 856-2556

Registration fees include assorted breakfast items that will be available each day 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 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#: 778-000-08-031-L04-P. Released: 3/09.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:30 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

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

Call (215) 413-2471 for more information
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
• Prepare for pre-study visits
• Conduct study initiation visits
• Conduct routine interim monitoring visit
• Manage adverse experiences
• Discuss drug accountability
• Review study files
• Complete study close-out visits
• Identify, report, and manage site performance and study related issues

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 an in-house CRA or project assistant who supports CRA monitoring activities.

Instructors
This course will be taught by one of the following instructors
Erica Elefant
Gary B. Freeman, M.S., C.C.R.A.
Elizabeth Ronk Nelson, M.P.H.
Lily Romero, F.A., C.C.R.C.
Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

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)

Day One: 8:30 a.m. – 5:30 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
IRB/IECs and the Protocol Approval Process: Membership requirements; documents and activities

Day Two: 8:30 a.m. – 5:30 p.m.
Informed Consent Documents and Process: FDA and ICH requirements; the role of the monitor in verifying the consent process
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: Data listings, edit checks, paper based and electronic case report forms, queries

Day Three: 8:30 a.m. – 5:30 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
Monitoring Simulation Exercise: Case study; identifying and resolving discrepancies

Course Dates and Locations
February 8-10, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SSBA0210
$1,695 by January 8
$1,895 after January 8
April 26-28, 2010
San Francisco, CA 94102
Hilton San Francisco
Course #: SSBF0410
$1,695 by March 19
$1,895 after March 19
May 17-19, 2010
Chicago, IL 60611
Embassy Suites Chicago Downtown/Lakefront
Course #: SSBC0510
$1,695 by April 9
$1,895 after April 9
June 21-23, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SSB0610
$1,695 by May 14
$1,895 after May 14

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Submit Registration Form (page 120) 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 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.

The New Jersey State Nurses Association (NJSNA) is accredited by the American Nurses Credentialing Center (ANCC) Commission on Accreditation of the American Nurses Association as an approver of continuing education for nursing. As an accredited body, NJSNA has approved this program for 20.25 Contact Hours. Approval Number: 6679-2/08-10.
## Monitoring Clinical Drug Studies: Intermediate

### Course Description
This course reflects current industry trends and challenges for CRAs with a focus on developing tools and identifying current industry trends and challenges for effective monitoring. FDA 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 with more than 2 years experience seeking to update their knowledge of the GCP regulations and guidelines and fine tune their site management and monitoring skills.

### Learning Objectives
- Describe various sponsor interpretations of FDA regulations and practical application of ICH guidelines
- Evaluate and develop more efficient study tracking and management tools
- Participate in monitoring/co-monitoring assessments
- Prepare for monitoring challenges in a global clinical trial
- Identify data management data listings and edit checks
- Effectively manage your sites, and ensure their optimum performance
- Implement techniques for training and mentoring the research team
- Prepare your sites for an FDA inspection

### Interactive Activities
- Group Discussion on The Different Interpretations of FDA Regulations and ICH Guidelines for GCP
- Advanced Monitoring Skills Through a Simulation Exercise
- Sponsor-CRO-Site Interactions (Problem Solving)
- Site Performance Activity

### Course Dates and Locations

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<tr>
<th>Date</th>
<th>Location</th>
<th>Course #</th>
<th>Fee Before/After Dates</th>
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<tbody>
<tr>
<td>January 28-29, 2010</td>
<td>Philadelphia, PA</td>
<td>SSIA0110</td>
<td>$1,595 by December 18</td>
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<td>$1,795 after December 18</td>
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<tr>
<td>April 22-23, 2010</td>
<td>San Francisco, CA</td>
<td>SSIF0410</td>
<td>$1,595 by March 12</td>
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<td>$1,795 after March 12</td>
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<td>June 14-15, 2010</td>
<td>Boston, MA</td>
<td>SSIB0610</td>
<td>$1,595 by May 7</td>
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<td>$1,795 after May 7</td>
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### Registration
- **ON-LINE:** BarnettInternational.com
- **FAX or MAIL:** Barnett Customer Service.
- **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#: 778-000-09-014-L01-P.**

Released: 8/09.
The New Jersey State Nurses Association (NJSNA) is accredited by the American Nurses Credentialing Center (ANCC) Commission on Accreditation of the American Nurses Association as an approver of continuing education for nursing. As an accredited body, NJSNA has approved this program for 14 Contact Hours. Approval Number: 6884-208-10.

### 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
- Identify and assess the effectiveness of monitoring plans
- Evaluate monitoring reports
- Utilize mentoring techniques
- Assess monitoring skills
- Manage stakeholders
- Analyze complex study and site issues
- Identify, report, and manage issues (site, study, project)
- Develop, implement, and evaluate corrective and preventive action (CAPA) plans
- Detect and manage situations involving fraudulent data
- Describe current FDA/Regulatory Authority findings

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

## Interactive Exercises
- **Reviewing Reports and Study Documentation**
- **Case Studies/Scenarios: Assessing Monitoring Skills, Site Issues, Stakeholder Relations**
- **Detecting Fraudulent Data**
- **Scrutinize a Sample Monitoring Plan**
- **Detecting and Managing Situations Involving Fraudulent Data**
- **Identifying, Reporting & Managing Study Site Issues**
- **Reviewing, Writing, Evaluating, and Evaluating Corrective and Preventive Action Plans:** Post-audit activities, including developing CAPA plans
- **Co-Monitoring and Assessing Monitoring Skills:** Techniques for assessing monitors in the Sponsor/CRO environment
- **Integrating and Managing Stakeholders:** Developing and communicating realistic expectations; reaching stakeholder agreement

## Course Outline

### Day One: 8:30 a.m. – 5:30 p.m.
- **Regulatory Recap:** FDA regulations and ICH guidelines will be reviewed
- **Current “Hot” Topics:** Industry trends that are critical to the effectiveness of a clinical research professional
- **Monitoring Plans:** Writing, evaluating, implementing, and assessing effectiveness
- **Training and Mentoring Techniques:** Tips for making the most of “mentoring” opportunities
- **Co-Monitoring/Assessing Monitoring Skills:** Techniques for assessing monitors in the Sponsor/CRO environment
- **Integrating and Managing Stakeholders:** Developing and communicating realistic expectations; reaching stakeholder agreement

### Day Two: 8:30 a.m. – 5:30 p.m.
- **Identifying, Reporting & Managing Study Related Issues:** Adverse events – PSURs, SUSARs; under-performing or non-compliant sites; under-performing or non compliant project team members
- **Detecting and Managing Situations Involving Fraudulent Data**
- **Compliance Review:** Current information regarding FDA and regulatory authority inspections/audits
- **Preparing Staff and Sites for a Site Inspection/Audit:** Practical tips for preparing your site for an audit
- **Responding to Audit Findings, Developing and Evaluating Corrective and Preventive Action Plans:** Post-audit activities, including developing CAPA plans

## Course Dates and Locations
- **February 25-26, 2010**
  - Philadelphia, PA 19153
  - Sheraton Suites Philadelphia Airport
  - Course #: SSAA0210
  - $1,595 by January 15
  - $1,795 after January 15
- **March 16-17, 2010**
  - San Diego, CA 92101
  - Courtyard San Diego Downtown
  - Course #: SSSD0310
  - $1,595 by February 5
  - $1,795 after February 5
- **June 29-30, 2010**
  - Philadelphia, PA 19153
  - Sheraton Suites Philadelphia Airport
  - Course #: SSAA0610
  - $1,595 by May 21
  - $1,795 after May 21

## Registration
- **ON-LINE:** barnettinternational.com
- **FAX or MAIL:** Barnett Customer Service: Barnett International, Attention: Barnett Customer Service, 4511 Trumbull Road, Barre, VT 05641
- **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#: 778-000-025-L01-P
- Released: 2/09.

**The New Jersey State Nurses Association (NJSNA)** is accredited by the American Nurses Credentialing Center (ANCC) Commission on Accreditation of the American Nurses Association as an approver of continuing education for nursing. As an accredited body, NJSNA has approved this program for 13.5 Contact Hours. Approval Number: 8847-2/09-11.
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, participants will learn and put into practice the best practice fundamentals of negotiating. Topics will include: the critical steps for a successful negotiation, communication mastery, influencing without authority, how to prepare for a negotiation session, goal setting and good decision making, tips on identifying your negotiating parties needs and how to build rapport, negotiating on your feet, and how to effectively negotiate in difficult circumstances. Participants will practice their negotiation skills in teams throughout the two-day workshop. Case studies, scenarios, group discussion and negotiation tools will be used to enhance the participants learning experience.

Following this workshop, participants will have the theoretical knowledge and skills needed to enter into any negotiating situation with confidence.

Learning Objectives
• Describe the critical steps for a successful negotiation
• Employ key verbal and non-verbal communication strategies
• Influence without authority
• Create and analyze a negotiating party map
• Design and conduct a successful negotiation
• Effectively negotiate on your feet, under difficult circumstances
• 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 Leads
• Clinical Research Managers
• Project Managers
• Clinical Research Directors
• Clinical Research Professionals involved in procurement, resource management, and negotiations

Instructors
Natalie Currie, B.Sc.

Interactive Activities
• The Constructive Negotiation Challenge (this paper-based simulation was developed in conjunction with the American Management Association)
• Clinical research case learning scenarios
• Listening self assessment
• Small group negotiation planning
• Negotiation coaching sessions
• Small group negotiation exercises
• Customizable templates including the negotiation action plan and the post-negotiation lessons learned worksheet

Day One: 8:30 a.m. – 5:30 p.m.
The Steps Required For a Successful Negotiation
Core Negotiating Skills: Communication, understanding team dynamics, motivation theory and influencing without authority
The Constructive Negotiation Challenge
Negotiation Preparation Substance: Determining negotiation goals, developing an effective negotiation strategy and plan, creating and analyzing a negotiating party map, building rapport, defining common ground
Teams Develop their Goals and Party Map followed by a Group Debrief

Day Two: 8:30 a.m. – 5:30 p.m.
Negotiation Preparation Process: The structure of the negotiations, roles and responsibilities in the negotiations, analysis of meetings, completion of the meeting management tool
Teams Develop Their Process Negotiation Plans Followed by a Group Debrief
Negotiation Decision Making: How to make good decisions with all parties in mind, review the decision making matrix tool
Team Negotiation Practice 1: Coaching and Debrief
How to Negotiate in Challenging Situations.
How to manage conflict; dealing with impasses in negotiations, determining unexplored opportunities, and how to negotiate on your feet under pressure
Team Negotiation Practice 2: Coaching and Debrief
How to Successfully Close the Negotiation
Conducting the Negotiation Follow-up: Completing the Lessons Learned matrix.

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: 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# 778-000-09-036-L04-P. Released: 11/09.

Course Dates and Locations
April 26-27, 2010
Philadelphia, PA 19113
Hyatt Regency Philadelphia Airport Hotel
Course #: SNCA0410
$1,595 by March 19
$1,795 after March 19

June 8-9, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SNCB0610
$1,595 by April 30
$1,795 after April 30

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? 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? And how should recruitment planning 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

Instructor
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 25-26, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SPTA0310
$1,595 by February 12
$1,795 after February 12

June 9-10, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SPTB0610
$1,595 by April 30
$1,795 after April 30

Registration
ON-LINE:
barnettinternational.com
FAX or MAIL:
Submit Registration Form (page 120) with Payment to Barnett Customer Service.
For assistance, CALL: (800) 856-2656

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#: 778-000-049-L04-P. Released: 3/08.

Day One: 8:30 a.m. – 5:30 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. – 5:30 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!
Call (215) 413-2471 for more information
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 25-26, 2010
Philadelphia, PA 19153
Sheraton Suites Philadelphia Airport
Course #: SPAA0510
$1,595 by April 16
$1,795 after April 16

Registration
ON-LINE: BarnettInternational.com
FAX or MAIL: 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#: 778-000-07-017-L01-P. Released: 12/07.

Course Outline
Day One: 8:30 a.m. – 5:30 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. – 5:30 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 Exercises:
- 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

Day One: 8:30 a.m. – 5:30 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 OPPV in Europe; need for oversight of the pharmacovigilance system; ensuring oversight 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

Course Dates and Locations
February 22, 2010
Philadelphia, PA 19153
Sheraton Suites Philadelphia Airport
Course #: SVG0210
$800 by January 15
$1,000 after January 15

April 20, 2010
San Francisco, CA 94102
Hilton San Francisco
Course #: SVG0410
$800 by March 12
$1,000 after March 12

June 9, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SVG0610
$800 by April 30
$1,000 after April 30

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Barnett Customer Service.

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# 778-000-09-035-L04-P. Released: 7/09.
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 9–10, 2010
Philadelphia, PA 19153
Sheraton Suites Philadelphia Airport
Course #: SCKA0310
$1,595 by January 29
$1,795 after January 29

June 10–11, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SCKA0610
$1,595 by April 30
$1,795 after April 30

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Submit Registration Form (page 120) with Payment to Barnett Customer Service.
For assistance, CALL: (800) 856-2556

Course #:
SCKA0610

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#: 778-000-07-023-L04-P. Released: 9/07.

COURSE OUTLINE

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

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

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

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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 29-30, 2010
San Francisco, CA 94102
Hilton San Francisco
Course #: SPVF0410
$1,595 by March 19
$1,795 after March 19

June 22-23, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SPVB0610
$1,595 by May 14
$1,795 after May 14

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Submit Registration Form (page 120) with Payment to Barnett Customer Service.

For assistance, CALL: (800) 856-2556

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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
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 biologic 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.

Day One: 8:30 a.m. – 5:30 p.m.
FDA Division Information
• Submission Basics
• Outlining the submission
• Applicable regulations and guidance documents
• Information available for submission
• Building the information pyramid
• Creating the Table of Contents
• Timing of submission/timelines

Marking Application
• NDA in a CTD Format

Day Two: 8:30 a.m. – 5:30 p.m.
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

Publishing the Submission
• Submission publishing basics
• Pagination
• Volumization
• Table of Contents
• Binder Covers
• Tabs
• Labels
• Copies (how many to make and keep)
• Copies to the Agency
• Archive copy
• Review copy
• Introduction to electronic publishing requirements

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

Course Dates and Locations
February 11-12, 2010
Philadelphia, PA 19153
Sheraton Suites Philadelphia Airport
Course #: SPDA0210
$1,595 by January 8
$1,795 after January 8

April 29-30, 2010
San Francisco, CA 94102
Hilton San Francisco
Course #: SPDF0410
$1,595 by March 19
$1,795 after March 19

June 10-11, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SPDA0610
$1,595 by April 30
$1,795 after April 30

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Submit Registration Form (page 120) with Payment to Barnett Customer Service.
For assistance, CALL: (800) 856-2556
Registration fees include art of the seminar. Also included is a Networking Lunch that will be served each training day.

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

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 into researchable units, and conduct the research using a Regulatory Intelligence Database
• Summarize and present Regulatory Intelligence findings back to a team
• Archive and store RI
• Apply and integrate Regulatory Intelligence to current company practices and global regulatory strategy

Who Should Attend
This course is designed for seasoned regulatory affairs professionals looking to develop their skill set, as well as other research and development professionals who are interested in learning a new skill.

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 Dates and Locations
March 19, 2010
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SIQD0310
$800 by February 5
$1,000 after February 5

June 28, 2010
Philadelphia, PA 19153
Sheraton Suites Philadelphia Airport
Course #: SIQA0610
$800 by May 21
$1,000 after May 21

Registration
ON-LINE:
barnettinternational.com
FAX or MAIL:
Submit Registration Form (page 120) with Payment to Barnett Customer Service.
For assistance, CALL: (800) 856-2556
Registration fees include art 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# 778-000-09-043-L01-P. Released 3/10.

Registration fees include part of the seminar. Also included is a Networking Lunch that will be served each training day.

**NEW! Regulatory Intelligence 101**

**Course Dates and Locations**

**March 19, 2010**
San Diego, CA 92101  
Courtyard San Diego Downtown  
Course #: SIQD0310  
$800 by February 5  
$1,000 after February 5

**June 28, 2010**  
Philadelphia, PA 19153  
Sheraton Suites Philadelphia Airport  
Course #: SIQA0610  
$800 by May 21  
$1,000 after May 21

**Registration**

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barnettinternational.com
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**Accreditation**

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**Learning Objectives**
- Discuss what Regulatory Intelligence is and why it is important to companies
- Identify multiple sources of Regulatory Intelligence

**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**
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

Lily Romero, P.A., C.C.R.C.
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

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

Day One: 8:30 a.m. – 5:30 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

WHO_should_attend

Course Dates and Locations
April 30, 2010
San Francisco, CA 94102
Hilton San Francisco
Course #: SECF0410
$800 by March 19
$1,000 after March 19

May 21, 2010
Philadelphia, PA 19153
Sheraton Suites Philadelphia Airport
Course #: SECA0510
$800 by April 9
$1,000 after April 9

Registration
ON-LINE:
barnettinternational.com
FAX or MAIL:
Submit Registration Form (page 120) with Payment to Barnett Customer Service.
For assistance, CALL: (800) 856-2656

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Accreditation
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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)

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

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

Day One: 8:30 a.m. – 5:30 p.m.
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

Course Dates and Locations
March 18, 2010
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: SBED0310
$800 by February 5
$1,000 after February 5

May 11, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SBEA0510
$800 by April 2
$1,000 after April 2

Registration
ON-LINE: barnettinternational.com
FAX or MAIL: Submit Registration Form (page 120) with Payment to Barnett Customer Service.
For assistance, CALL: (800) 856-2656

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# 0778-0000-09-037-L04-P. Released 10/09.

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 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
February 25-26, 2010
Philadelphia, PA 19153
Sheraton Suites Philadelphia Airport
Course #: SSTAA0210
$1,595 by January 15
$1,795 after January 15

April 29-30, 2010
San Francisco, CA 94102
Hilton San Francisco
Course #: SSTF0410
$1,595 by March 19
$1,795 after March 19

June 22-23, 2010
Boston, MA 02111
Hyatt Regency Boston
Course #: SSTB0610
$1,595 by May 14
$1,795 after May 14

Registration
ON-LINE:
barnettinternational.com
FAX or MAIL:
Submit Registration Form (page 120) 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.

Day One: 8:30 a.m. – 5:30 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. – 5:30 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
- Describe 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

Day One: 8:30 a.m. – 5:30 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

Course Dates and Locations
May 21, 2010
Philadelphia, PA 19153
Sheraton Suites Philadelphia Airport
Course #: SSUA0510
$800 by April 9
$1,000 after April 9

Registration
ON-LINE:
barnettinternational.com
FAX or MAIL:
Submit Registration Form (page 120) 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.
Teambuilding for the Cross-Functional, Global Team: Making Good Teams Better

Course Description
Global, cross-functional teams are the primary engines of pharmaceutical product development. Pharmaceutical teams face intense pressure, compressed deadlines, inevitable conflict, and unforeseeable turns of directions. The alchemy for multidisciplinary team success is the ability of diverse individuals to build bridges across functions, integrate their efforts, and achieve their goals.

This course will provide clarity on what your team can do both operationally and behaviorally to take your team to a higher level of performance.

Learning Objectives
- Distinguish five building blocks for high performance teams
- Navigate a roadmap for team development
- Harness the power of a structured team kick-off
- Identify 11 drivers of teamwork that build trust
- Develop powerful team-owned ground rules
- Analyze the clarity of team goals
- Adopt attitudes and behaviors that accelerate team cohesiveness
- Diagnose the root cause of team dysfunction
- Enhance and simplify email communications
- Master the art of the virtual teaming

Who Should Attend
- New or experienced Team Leaders
- Professionals who participate on Clinical Teams, Product Development Teams, Expert Teams, Global Teams, or Regulatory Teams
- Project Managers with little or no experience in managing a cross functional team
- Organizations (CROs) who need better sponsor collaboration
- Managers unfamiliar with leading in a matrix team environment
- Leaders who wish to build a culture of high team performance
- New technical staff who are transitioning from an independent expert role to a collaborative, team-based role

Instructors
Ruth Dubinsky, M.S. O.D.

Interactive Activities
- Experiential exercise recreating the full range of human dynamics in teams
- Team assignments and group work
- Group discussions and brainstorming

Course Dates and Locations
March 16-17, 2010
San Diego, CA 92101
Courtyard San Diego Downtown
Course #: STBD0310
$1,595 by February 5
$1,795 after February 5

June 10-11, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: STBA0610
$1,595 by April 30
$1,795 after April 30

Registration
ON-LINE:
barnettinternational.com
FAX or MAIL:
Submit Registration Form (page 120) 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#: 778-000-09-031-L04-P.

Released: 10/09.

Day One: 8:30 a.m. – 5:30 p.m.
Orientation: Personal shields, team bests, assignment into teams, challenges of pharmaceutical teams, diversity challenges
Team Fundamentals: Examine the building blocks of teams, matrix teams, department teams, cross functional teams in the pharmaceutical industry
High Performance Team Drivers: Partnership between team leader, team members and management, 11 drivers of top team performance
Team Roadmap: Strategies for the entire life cycle of the team to accelerate work

Day Two: 8:30 a.m. – 5:30 p.m.
Team Stakeholders: Identify and gain support of internal and external stakeholders
The Team Kick-Off: Ensure your team hits the ground running
Team Goals: Going beyond SMART goals, gaining clarity on important words
Team Roles and Responsibilities: Understanding the interdependencies of the different functions on the team
Team Communications: Email tips to enhance team communications
Virtual Teaming: Making the most of remote team member contributions

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

**Interactive Exercises**
- Identifying CRO Issues and Concerns
- Clarifying Performance Expectations
- Choosing a CRO and Establishing Communication Pathways
- Problem Solving Critical Issues

**Instructors**
This course will be taught by one of the following instructors
Susan Bassion, Ph.D.
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

**Course Dates and Locations**
- **February 25-26, 2010**
  Philadelphia, PA 19153
  Sheraton Suites Philadelphia Airport
  Course #: SPSA0210
  $1,595 by January 15
  $1,795 after January 15
- **April 22-23, 2010**
  San Francisco, CA 94102
  Hilton San Francisco
  Course #: SPSF0410
  $1,595 by March 12
  $1,795 after March 12
- **June 22-23, 2010**
  Boston, MA 02111
  Hyatt Regency Boston
  Course #: SPSB0610
  $1,595 by May 14
  $1,795 after May 14

**Registration**
- **ON-LINE:** barnettinternational.com
- **FAX or MAIL:** Submit Registration Form (page 120) with Payment to Barnett Customer Service.
- **For assistance,** CALL: (800) 856-2556
- **REGISTRATION FEES:**
  - $1,595 by January 15
  - $1,795 after January 15
- **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#: 778-000-07-051-L04-P. Released: 1/08.

**Course Outline**

<table>
<thead>
<tr>
<th>Day One: 8:30 a.m. – 5:30 p.m.</th>
<th>Day Two: 8:00 a.m. – 4:30 p.m.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The Outsourcing Industry:</strong> 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</td>
<td><strong>Establishing the Partnership:</strong> 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</td>
</tr>
<tr>
<td><strong>Qualifying CRO Candidates:</strong> 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</td>
<td><strong>Monitoring and Evaluating the Partnership:</strong> 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</td>
</tr>
</tbody>
</table>

**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
Erica Elefant
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 11-12, 2010
Philadelphia, PA 19113
Renaissance Philadelphia Airport Hotel
Course #: SWRA0510
$1,595 by April 2
$1,795 after April 2

Registration
ON-LINE:
barnettinternational.com
FAX or MAIL:
Submit Registration Form (page 120) 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#: 778-000-09-016-L01-P. Released: 8/09.

COURSE OUTLINE

Day One: 8:30 a.m. – 5:30 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. – 5:30 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 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, training certificates will be provided to all participants.

NOTE: The only exception to the web seminar team training is the online CRA, CRC evening series and the Investigator, CRC, CRA morning series which is for individual registrants only.

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

What Are the Benefits?
- A seamless, secure, real-time multimedia learning experience
- No travel, no travel expenses, and no time away from the office
- Resources required are already at your fingertips — an Internet connection and a phone

- 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.

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.

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 training certificates will be provided.

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 Naiia Ganatra at 215-413-2471 or nganatra@barnettinternational.com.
**NEW! Investigator, CRC, CRA 8 Weeks Fundamentals Training for the Global Professional Working in the ICH Environment**

**Course Description**
This Internet-based, 8-Week ICH Investigator, CRC & CRA global foundations training course is appropriate for individuals anywhere in the world seeking a new career or career change within the clinical research industry. The course covers the sponsor and research site functions per international guidance and how to identify specific country requirements. Included is core good clinical practice (GCP) training, including activities, lectures, case studies, and application-based homework assignments. The resources required to take this online course are already at your fingertips - an Internet connection and a phone. After registering, you will receive an email confirmation that provides you with the Web Seminar link and audio connection information.

**Who Should Attend**
- Aspiring Clinical Research Coordinators
- Aspiring Clinical Research Associates – In-house or Field-based
- College Students
- Nurses
- New College Graduates – Any Discipline

**Instructor**
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

**Course Length and Time**
3 hours/week, 8:30 a.m. – 11:30 a.m. Eastern, 8 weeks

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**10-Week CRA & CRC: Beginner Program**

**Course Description**
The online 10-Week CRA & CRC Beginner Series is appropriate for individuals seeking a new career or career change, but who don't know which clinical research job track to pursue. The resources required to take this online course are already at your fingertips - an Internet connection and a phone. After registering, you will receive an email confirmation that provides you with the Web Seminar link and audio connection information.

**NOTE: This course is for individual registrants only and does not allow for group training.**

Before the class starts, you will receive your class books and reference guides. During the live Interactive Web Seminar, you will be able to ask questions and provide feedback. You will be required to pass both a mid-term and a final in order to receive accreditation CEUs. Upon completion, training certificates will be provided to all participants and accreditation CEUs will be requested. Following the course, Barnett will provide resume assistance so that you can position yourself for entry into this exciting market!

**Learning Objectives**
- Module 2: Discuss The Clinical Research Team: Roles & Responsibilities
- Module 3: Explain The Principal Investigator, Site Selection and Budget Negotiation
- Module 4: Examine Clinical Study Protocol Elements and Statistical Considerations
- Module 5: Define Institutional Review Boards, the Consent of Human Volunteers and HIPAA
- Module 6: Discuss Study Monitoring, Data Management and the Study Initiation Visit
- Module 7: Define Safety Reporting: Definitions and Reporting Requirements
- Module 8: Examine Accountability for the Test Article and Reporting Requirements
- Module 9: Discuss Regulatory Compliance and Quality Assurance: Audits and Inspections
- Module 10 (Summary): Discuss how to Manage Your Time and Prepare for The Interview

Each module presents the responsibilities of both CRCs and CRAs for both drug/behavioral and device trials.

**Who Should Attend**
- Aspiring Clinical Research Coordinators
- Aspiring Clinical Research Associates – In-house or Field-based
- College Students
- Nurses
- New College Graduates – Any Discipline

**Instructor**
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

**Course Length and Time**
3 hours/week, 8:30 a.m. – 9:00 p.m. Eastern, 10 weeks

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**Course Dates**
- February 3 – April 7, 2010 Wednesday nights
- March 4 – June 3, 2010 Thursday nights
  - (No class April 1, 2010 and April 8, 2010)
- April 28– June 30, 2010 Wednesday nights

**Fee:** $1,795

**Accreditation**
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 10.5 hours (1.0 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#: 778-000-08-003-L04-P. Released: 10/08.

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**Course Dates**
- February 4 - March 25, 2010
- April 15 - June 3, 2010

**Fee:** $1595.00

**Accreditation**
Barnett International is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants will receive 10.5 hours (1.0 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#: 778-000-09-059-L01-P. Released: 2/10.
NEW! 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 for a well organized Clinical Research Department
• Describe the responsibilities of various members of the clinical team
• 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
• Discuss the rationale behind building quality into the filing system
• Discuss the “do’s and don’ts” in the event of a regulatory agency audit

Who Should Attend:
Clinical Research Administrative Support Staff

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

Course Length and Time
2.5 hours 12:30 - 3:30 p.m. Eastern
NEW! Adequate Sponsor Monitoring Systems

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
- 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
- QA/Compliance
- CRAs

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

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

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. 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 adverse events 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
- Determine when to start and stop monitoring adverse events
- 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

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time
2 hours 12:30 - 2:30 p.m. Eastern
NEW! 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 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. EST

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 some review of helpful tools.

Learning Objectives
- Identify key approaches to planning and preparing to outsource to improve relationships
- Identify key components for formal study vendor performance management
- Identify adequate oversight SOP 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

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C

Course Length and Time
2 hours 1:00 – 3:00 p.m. EST
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 (CRAs)
- Project Managers
- Medical Monitors
- Regulatory Affairs Professionals
- Clinical Research Coordinators (CRCs)
- Clinical Investigators (PIs)
- IRB Administrators and Members

Instructor
Elizabeth Ronk Nelson, M.P.H.

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

Biomarkers of Drug Efficacy and Safety: Fundamentals and Applications in Preclinical and Clinical Development

Course Description
More than one-third of all Phase I-II clinical trials fail to meet the clinical objectives due to a poor study design and/or lack of defined end-points to evaluate "proof of concept" (POC) or "proof of pharmacological mechanism" (POPM). Mechanisms-based pharmacodynamics (PD) and efficacy biomarkers can offer significant advancements in meeting the objectives; however, smart strategies are needed during early preclinical development to identify, develop, and validate safety, PD, and efficacy biomarkers. Additionally, a full complementary analysis of individual patient PK and PD (biomarker) is often desirable to better evaluate the POC or POPM. This course is an entry level introductory biomarkers course designed to train people with the fundamentals of biomarkers and their applications in drug discovery and development.

Learning Objectives
- Discover, develop, and validate PD and efficacy biomarkers
- Better design early Phase I studies to include POPM biomarkers
- Evaluate biomarkers in dose selection and dose optimization
- Examine PK-PD/biomarkers strategies to identify good responders
- Discuss the use of PK-PD data to better design Phase II studies
- Identify multiple PD and efficacy endpoints
- Evaluate the maximal clinical potential of a drug
- Apply new knowledge on biomarkers of pharmacodynamics and efficacy
- Design clinical trials for Phase I trials in healthy volunteers vs. sick patients
- Select the best clinical candidate for Phase I and Phase II development

Who Should Attend
- Discovery and Preclinical Scientists
- Clinical Pharmacologists
- Medical Directors
- Phase I-II CROs
- Clinical Monitors
- Regulators
- Project Managers
- Small to middle-size new pharmaceutical companies

Instructor
Rakesh Dixit, Ph.D.

Course Length and Time
3 hours 1:00 - 4:00 p.m. Eastern
Clinical Research Site Quality Improvement Strategies: Developing Proactive Project Study Plans

Course Description
Research sites’ performance 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 course will present a PCP: Proactive Compliance Plan template and content for research sites’ use to promote 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

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

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

NEW! Clinical Trial Design for Medical Devices

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
- Evaluate basic statistical issues relating to sample size

Who Should Attend
- Clinical, Regulatory, and Development 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

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

Course Length and Time
2 hours 1:00 – 3:00 p.m. Eastern
**NEW! Clinical Trials for Pharmaceuticals: Design and Development**

**Course Description**
This course addresses the issues in the design of pharmaceutical clinical trials (including protocol development) and the interface of clinical trial design with the drug development process.

**Learning Objectives**
- Describe the clinical trial design process
- Review key ethical considerations in clinical trials
- Key components of protocol development
- Requirements for the Investigational Plan
- Describe the clinical trial phases

**Who Should Attend**
- CRAs
- Clinical Personnel
- Regulatory Personnel
- Quality Personnel
- Manufacturing Personnel
- Project managers
- Those who require an understanding of clinical trial design

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

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

**Course Dates**
February 17, 2010
April 7, 2010

**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#: 778-000-09-057-L01-P. Released: 2/10.

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**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 throughout this e-workshop to provide participants with a deeper understanding of clinical research requirements and drug regulations. This webinar will provide an in-depth focus on drug regulations.

**Learning Objectives**
- Examine essential documentation; from informed consent to archiving requirements
- Discuss inspection process and recent findings
- Implement best practices in conducting clinical studies according to 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 12:30 - 2:30 p.m. Eastern

**Course Dates**
May 25, 2010

**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#: 778-000-08-014-L04-P. Released: 12/08.
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 actions 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
- QA

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

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

Course Dates
April 29, 2010

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#: 778-000-08-008-L04-P. Released: 10/08.

CRA Current Practice Update: Impact of the FDA BIMO Initiative

Course Description
FDA announced in 2006 an initiative to modernize the regulation of clinical trials, including the BIMO inspections program. This includes 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, FDA has generated new guidance and regulation that directly affect the performance of the sponsor monitor. The initiative is a dynamic process and this course tracks the updates that directly affect the performance of the sponsor monitor. Examples are included for how to implement the agency requirements and recommendations into current practices and specific projects.

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

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

Course Dates
March 1, 2010
May 26, 2010

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#: 778-000-09-051-L04-P. Released: 3/10.
Course Description
Facilitator can be defined as an individual whose job is to help manage a process of information exchange. The role of the CRA includes facilitation, but many are not trained in this skill set, even though it is one that is considered not inherent. Facilitation is dynamic and impacts success of projects that depend on efficient information exchange. The CRAs success as a facilitator can greatly impact the success of a clinical trial, from data quality to patient recruitment. This course defines facilitation specifically relating to CRAs with a focus of successful clinical trials, including compliance and recruitment.

Learning Objectives
• Recognize the role of the CRA as facilitator
• Define facilitator: an essential soft skill for managing research sites today
• Identify facilitation core practices: effective listener, constructive feedback provider, problem solver, and more
• Apply facilitation in clinical trials and management of research sites
• Develop CRA skills for facilitation

Who Should Attend
• CRAs
• Contract CRAs
• CRA Managers
• Project Managers

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Dates
May 7, 2010

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#: 778-000-07-047-L04-P Released: 2/08.
**Course Description**

FDA announced in 2006 an initiative to modernize the regulation of clinical trials, including the BIMO inspections program. This includes 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, 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 course tracks the updates that directly affect the investigator and study staff, applying these to the session prior to each offering. Examples are included for how to implement the agency requirements and recommendations into current practices and specific projects.

**Learning Objectives**

- Examine industry regulatory update impacting 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
- QA Personnel
- CRAs

**Instructor**

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

**Course Dates**

March 31, 2010

**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. 778-000-08-060-L04-P. Released 5/09.

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**CRC Role/Responsibilities Training**

**Course Description**

The Clinical Research Coordinator (CRC) can be a key liaison between the investigator, subject, IRB, and sponsor. The CRC assists the investigator, to ensure that the clinical trial is successfully implemented and completed. This course presents the core skills and activities performed by the CRC and documentation requirements that come along within 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

**Instructor**

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

**Course Dates**

February 19, 2010

May 14, 2010

**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#: 778-000-08-033-L04-P. Released: 5/09.
**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 Interactive Web Seminar will focus on the most critical issues in the design and conduct of patient registries for biopharmaceutical and medical device applications. The seminar will 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
- Clinical Research
- Clinical Affairs
- Medical Affairs
- Regulatory Affairs
- Project Management
- Patient Registries
- Market and Business Development

**Instructor**
David Stier, M.D.

**Course Length and Time**
1.5 hours 12:30 - 2:00 p.m. Eastern

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**Current Developments and Emerging Trends in the Role of Institutional Review Boards (IRBs): Compliance Concerns and Pending Legislation**

**Course Description**
This course provides an overview of how current events are shaping the future of the Institutional Review Board and the conduct of clinical research. The content is appropriate for any professional working at or with IRBs that review, approve, and oversee clinical investigations regulated by the FDA. Best practices of IRB compliance will be addressed through interactive group discussions.

**Learning Objectives**
- Identify the new and proposed regulations, guidance, and legislation and the impact on IRB function and operation
- Review current IRB-specific compliance concerns and how they impact on Good Clinical Practice standards for Principal Investigators, Sponsors, and Contract Research Organizations (CROs)
- Discuss the evolution of the IRB’s role in protecting human research participants
- Examine new developments and emerging trends in IRB oversight and function
- Scandal and Scrutiny: Address current compliance concerns and the “ripple effect”

**Who Should Attend**
- Clinical Quality Assurance Professionals
- Clinical Research Associates
- Project Managers
- Those involved in site and IRB assessment and/or selection
- Clinical Investigators
- Study Coordinators
- IRB Members, IRB Professionals, and 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.

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

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**Course Dates**
March 18, 2010
June 24, 2010

**Fee:** $595*  
$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#: 778-000-08-023-L04-P. Released: 3/09.
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 course provides strategic skills and best practices for contract negotiations and budget development. The course also reviews and practices 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 & 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 & procedure changes; financial checks and balances

Who Should Attend
This course is designed for 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

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

Course Dates
February 9, 2010 (12:30 – 3:30)
March 29, 2010 (9:00 – 12:00)
April 28, 2010 (12:30 – 3:30)

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.

NEW! Drug Development and FDA Regulations

Course Description
This course provides an overview of the drug development process. Included are the GCP, GLP, and 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
- Those who want an understanding or greater understanding of the drug development process
- CRAs
- Auditors
- Regulatory Affairs Professionals
- Quality Personnel
- Manufacturing Personnel

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

Course Dates
February 16, 2010
April 6, 2010

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#: 778-000-09-058-L01-P. Released: 1/08.

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#: 778-000-09-058-L01-P. Released: 1/08.

Course Description
Current societal events have influenced the increased use of electronic medical records, one being the promotion of a national electronic medical record. More and more research sites are using an electronic medical record (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. FDAs release of a 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 course 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 and CRCs
• Device and Drug Study CRAs
• CRA and Project Managers
• Quality Assurance

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

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

Ensuring Compliance to MDD 93/42/EEC and Preparing for CE Marking

Course Description
The European Commission has finally released a consolidated version of the revised Medical Devices Directive. The original Directive 93/42/EEC (published in 1993) was amended in late 2007 with the publication of Directive 2007/47/EC, but a combined version of those two Directives was not published at that time, making it difficult to interpret the changes Directive 2007/47/EC had on the original MDD. Originally created July 12, 1993 and mandatory since June 14, 1998, the Directive requires that companies wishing to sell medical devices within the EU must meet the requirements under the directive. The regulations under this mandate can vary from member country to member country concerning translation of key documents to other regulatory laws specific to that region. These additions supplement the set of harmonized standards put in place by the European Commission. These harmonized standards serve to free the flow of goods from one market to another within the EU Medical Device industry. Today, all medical devices sold in the EU must have the CE Mark affixed to demonstrate compliance to this directive. If your device falls within the scope of the Medical Devices Directive, then you must meet the essential requirements of that law. This webinar will provide valuable assistance and guidance to medical device companies that are preparing for CE Mark and ensuring compliance to MDD 93/42/EEC.

Learning Objectives
• Examine the latest changes to the Directive and the impact on medical device manufacturers
• Apply and use the Conformity Assessment Procedure
• Classify your medical device correctly
• Utilize the technical file correctly
• Apply the Declaration of Conformity and review why this is critical for success
• Discuss how ISO 13485 fits in with this process as a device company
• Manage the expectations for the Essential Requirements and the certification process
• Examine the role of the Authorized Representative and the ramifications of not meeting the requirements for CE Mark and 93/42/EEC for your company

Who Should Attend
• Regulatory Affairs
• Compliance
• Quality Assurance/Quality Control
• Engineering
• Technical Services
• Marketing
• Medical Device Manufacturer Management

Instructor
David R. Dills

Course Length and Time
1.5 hours 12:30 - 2:00 p.m. Eastern
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
- QA Personnel
- CRA Managers/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 12:30 - 2:30 p.m. Eastern

Course Dates
March 15, 2010
June 1, 2010

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#: 778-000-00-010-L04-P. Released: 8/08.

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Examining the Impact of the eCTD on the Regulatory Submissions Process: Understand, Prepare, and Implement

Course Description
eCTD is definitely here, and the format is highly recommended for regulatory submissions in US, EU, Canada, and Japan. In this presentation, we will address technical issues related to its implementation across process areas based on practical experience working on over 30 eCTD submissions. The presentation will cover Authoring, Publishing, Compilation, and Management of eCTD submission, and their variations across multiple regions.

Learning Objectives
- Identify the basics of eCTD compilation
- Examine the impact on the authoring environment
- Discuss the impact on work-flow and process
- Examine the regulatory differences between US, EU, HC, and Japan
- Analyze how to handle variations
- Discuss how to manage submissions

Who Should Attend
- Regulatory Affairs
- Quality Assurance/Compliance
- Electronic Publishing/Submission
- Document Management
- Clinical

Instructor
Yolanda Hall

Course Length and Time
2.5 hours

This course is offered as a custom in-house course only

Certificates of Attendance:
All participants (up to 20) from each site are eligible for Certificates of Attendance.

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#: 778-000-07-035-L04-P. Released: 2/08.
Examining Revisions to the FDA/ORA Compliance Program Guidance Manual

Course Description
Clinical Investigator compliance has long been a key metric for assessing the credibility of data obtained from, and the protection of human participants involved in, clinical research. In an effort to increase uniformity in inspections and secure compliance, the FDA has recently reassessed and updated how its investigators inspect Clinical Investigators. This course will examine the new FDA/ORA Compliance Program Guidance Manual and highlight the recent changes and how they reflect the agency’s current focus on assessing the conduct of clinical trials.

Learning Objectives
• Examine the FDA’s revised approach to evaluating historic noncompliance issues, as well as new areas of concern
• Describe how information on electronic records and signatures will be assessed during inspections and additional requirements for U.S. Investigators inspected by foreign health authorities
• Explain how the Clinical Investigator’s responsibilities and interaction with other key clinical research team members will be evaluated

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
• GCP-Focused Regulatory Affairs Professionals

Instructor
Elizabeth Ronk Nelson, M.P.H.

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

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#: 778-000-09-022-L04-P. Released: 08/09.

Excel Spreadsheets: Step-By-Step Instructions for Compliance

Course Description
Learn how to create an Excel spreadsheet application that is GxP compliant. Critical data, such as laboratory information, are often recorded in spreadsheet applications and are subject to regulatory inspection. Understand how to validate your application with minimal documentation. Follow along as we configure Excel for audit trails, security features, and data verification. This session includes an interactive workshop so you can learn techniques that meet your own needs. This session will make you a better Excel user, saving you time and costs.

Learning Objectives
• Develop and validate spreadsheet applications that are GxP compliant
• Avoid 483s and warning letters
• Bring your laptop and use Excel for your own needs
• Apply features required for GxP environments without programming macros
• Examine built-in audit trails, how to allow multiple concurrent users to work together, data entry validation, and formulas
• Validate a spreadsheet application

Who Should Attend
• All Excel users in GxP environments
• Information Technology
• Quality Assurance
• Managers

Instructor
David Nettleton

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

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#: 778-000-09-025-L04-P. Released: 09/09.
FDA IRB Registration Requirements: 2009 Approved Final Rule

Course Description
This course presents content and impact discussion of the FDA approved regulation requiring IRB registration with the agency prior to review and approval of research activities. The approved regulation was originally proposed in 2004 and now has been amended and released. The content impacts compliance of sponsors, investigators, and IRBs to GCP requirements. The roles and responsibilities of all stakeholders will be discussed, as well as enforcement and compliance dates.

Learning Objectives
- Present the purpose of the regulation
- Compare the changes made to the original proposed regulations with the final rule
- Discuss the industry stakeholder GCP Impact: before, during, and after a study
- Outline the roles and responsibilities of IRBs, sponsors, and investigators post approved rule
- Present the new regulation compliance dates

Who Should Attend
- Sites
- Principle Investigators
- Clinical Research Coordinators
- Site Managers
- Regulatory
- Sponsor
- Project Managers
- CRAs
- Clinical Operations
- Quality Assurance
- Regulatory

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C

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

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 course 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 relation 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, guidance, procedures, coalitions, and 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 1:00 – 3:00 p.m. Eastern

Course Dates
February 12, 2010
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#: 778-000-09-002-L04-P. Released: 03/09.

Course Dates
March 8, 2010
June 21, 2010
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: 08/09.
Course Description
This course presents content and impact discussion of the new FDA and 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

Who Should Attend
• Sites: PIs, CRCs, Managers
• Sponsors: CRAs, Sponsor Clinical Operations, Safety Information Specialists, Regulatory

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time
1.5 hours 12:30 - 2:00 p.m. Eastern

Course Dates
February 15, 2010
May 17, 2010

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#: 778-000-07-026-L04-P. Released: 8/07.

NEW! Final FDA Guidance for Supervisory Responsibilities of Investigators: What Made it Through and How It Affects Sites and Sponsors

Course Description
This course presents content and impact discussion of the now FINAL FDA human subject protection guidance document posted in May 2007 and approved 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. The seminar addresses 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.

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

Who Should Attend
• Clinical Research Investigators
• Clinical Research Coordinators
• Clinical Research Associates
• Managers
• Quality Assurance

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time
1.5 hours 12:30 - 2:00 p.m. Eastern

Course Dates
January 29, 2010
April 19, 2010

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.
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 course 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
- 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
- Regulatory authorities' current focus and findings
- Group discussions 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

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Dates
January 28, 2010
May 12, 2010

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#: 778-000-023-L04-P. Released: 08/09.

GCP Training: Core Human Subject Protection Training

Course Description
This course presents history, principles, best practices, and benefit/risk analysis regarding the rights and welfare of human participants in research. Both the ethics regarding human subjects' research and the regulations for such research will be presented. Ethical case scenarios are incorporated into the training so the participant can apply various concepts. The seminar also looks at future initiatives for protection of human subjects.

Learning Objectives
- Examine the history of research ethics
- Apply principles of clinical research ethics and understanding why they are necessary
- Recognize research practices for protection of trial participants: team roles and responsibilities
- Identify susceptible populations, and specific safeguards for their protection
- Examine the effectiveness of current best practices

Who Should Attend
- Investigators
- IRB Members
- 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 Dates
May 24, 2010

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#: 778-000-043-L04-P. Released: 2/08.
Good Clinical Practice: Practical Application and Implementation

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

Learning Objectives
- Describe the elements of a functional Quality System
- Examine recent trends in non-compliance
- Discuss the role of SOPs in GCP
- Characterize the differences between the legal and procedural elements of GCP
- Recognize key differences in pharmaceutical, device, and biologics GCP

Who Should Attend
- Clinical Quality Assurance Professionals
- Clinical Research Associates
- Project Managers
- Investigators
- Study Coordinators
- GCP-Focused Regulatory Affairs Professionals

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
4 hours 12:00 - 4:00 p.m. Eastern

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 course 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.

The course is perfect for new employee orientation and/or initial annual HIPAA training specific to clinical trials. The course is presented in understandable terms, and it is great to take if you never quite understood HIPAA or are confused about what your role involves. Concepts discussed include the HIPAA Privacy Rule and Enforcement Rule specific to clinical research.

Also, check out the HIPAA Fact or Fiction course that discusses current issues and best practices. (HIPAA Fact or Fiction assumes understanding of HIPAA clinical research terminology and concepts).

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 and QA
- Others involved in use and disclosure of subject data at site or sponsor

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time
3 hours 12:30 - 3:30 p.m. Eastern
Learning Objectives
- Recognize latest guidance documents and notices relating to the HIPAA Privacy Rule
- Recognize responsibilities of the study team:
  - research site, sponsor, vendor, participant, privacy board
  - Examine multiple FAQs regarding HIPAA and uncover many myths in practices that affect clinical research
  - Utilize multiple tools & resources

Who Should Attend
- Site Managers
- CRCs/Research Nurses
- Investigators
- Project Managers
- CRA Mangers
- CRAs
- Regulatory

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

Course Description
The HIPAA Privacy Rule has been in effect for some time. You have heard the definitions and the concepts, but how do we make it work for successful clinical trials while protecting the privacy rights of the subjects we enroll? This presentation clarifies myth from fact and gives the participants application strategies for successful clinical trials post HIPAA. This course assumes understanding and application of HIPAA terminology and concepts related to conducting clinical trials.

Also, check out our introduction to HIPAA Team Training: Fundamental Training Specifically for Clinical Research Settings, presented in understandable terminology. This is a great course for new employee training or clarification on roles and responsibilities.

Learning Objectives
- Recognize latest guidance documents and notices relating to the HIPAA Privacy Rule
- Recognize responsibilities of the study team:
  - research site, sponsor, vendor, participant, privacy board
  - Examine multiple FAQs regarding HIPAA and uncover many myths in practices that affect clinical research
  - Utilize multiple tools & resources

Who Should Attend
- Site Managers
- CRCs/Research Nurses
- Investigators
- Project Managers
- CRA Mangers
- CRAs
- Regulatory

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

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

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#: 778-000-09-049-L04-P. Released 3/10

Informed Consent Content & Process Requirements

Course Description
The web seminar presents, in an interactive environment, 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 is a HIPAA authorization 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 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, 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
- Team Managers
- Site Research Managers
- Clinical Research Monitors
- Sponsor Project Managers
- Investigators

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

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

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#: 778-000-07-040-L04-P. Released 2/08

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Innovative Preclinical and Clinical Strategies to Accelerate and Optimize Phase I-II Clinical Trials

Course Description
As much as 40% of all discovery candidates are terminated in preclinical drug safety/toxicology studies due to poorly designed studies and/or unexpected toxicity-related problems. “Regulatory Holds” on clinical testing are also not uncommon due to the lack of MTD/DLTs and appropriate safety margins. To reduce toxicology-related attritions and rapidly advance an optimal discovery candidate to clinical development, unique “out of box” preclinical study designs are necessary to meet the challenges of Phase I-II clinical trials. Preclinical development strategies will be presented for initiation of “the best clinical candidate” screening exploratory IND studies, which will assure the entry of the best clinical candidate for efficacy and safety evaluation.

Learning Objectives
- Design a tailor-made preclinical program to meet your Phase I-II objectives
- Better select safety species, dosages, and schedules for GLP toxicity studies
- Examine immunotoxicity testing, testing for drug impurity
- Not kill a good drug due to toxicity problems
- Review mechanistic toxicology strategies
- Conduct multiple Phase I clinical trials using a single IND
- Remove regulatory holds
- Develop a preclinical plan to optimize preclinical and clinical formulations and dosages
- Prepare “winning” IMPD and INDs to initiate clinical trials without many delays
- Explore new knowledge on the preclinical and clinical strategies

Who Should Attend
- Discovery and Preclinical Scientists
- Clinical Pharmacologists
- Medical Directors
- Phase I-II CROs
- Clinical Monitors
- Regulators
- Project Managers
- Small to mid-sized new pharmaceutical companies

Instructor
Rakesh Dixit, Ph.D.

Course Dates
May 21, 2010
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#: 778-000-08-022-L04-P. Released: 3/09.

Introduction to Data Management

Course Description
This course 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
- Sponsor/CRO staff whose function is to review, correct, enter, or manage data, with less than one year of experience
- Individuals who desire a basic understanding of the function of the clinical data management

Instructor
Denise G. Redkar-Brown

Course Dates
May 19, 2010
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
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#: 778-000-08-009-L04-P. Released: 8/08.
Introduction to Signal Detection and Data Mining

Course Description
This course 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 US. 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 techniques within their company
- 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
- Pharmacoepidemiology
- Regulatory affairs

Instructor
Steve Jolley

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

Course Dates
March 2, 2010
June 28, 2010

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#: 778-000-09-024-L04-P Released: 09/09.

Investigational Product Accountability Training for Research Site Personnel

Course Description
Regulatory inspections results frequently note investigational product accountability deficiencies. This web seminar will present the regulatory requirements for a research site for both drug and device trials. Accountability concepts such as storage, dispensing, reconciliation, and disposition will be discussed. Exercises in product accountability calculations will be conducted. Common challenges in both drug and device will be also discussed.

Learning Objectives
- Define the responsibilities of the research site in test article accountability
- Define the process for documenting test article accountability: beginning, during, and end of trial
- Implement best practices in drug and device accountability
- Integrate essential documentation for investigational product accountability
- Recognize the challenges of accountability

Who Should Attend
- Clinical Research Coordinators
- Investigators
- Pharmacists
- CRAs
- Site Managers

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

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

Course Dates
March 25, 2010

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#: 778-000-09-024-L04-P Released: 09/09.
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 course presents an overview of the core components for a successful research site. Examples of successful sites for benchmarking will be included as well as resources for more information.

Learning Objectives
• Identify components of a successful research site through benchmarking elite performers
• Identify the primary elements of business and marketing planning for a research site
• Discuss the importance of site GCPs and components of SOPs
• Discuss marketing, staffing, recruitment, contracting, and budgeting concepts key to research sites

Who Should Attend
• Clinical Research Site Managers/Directors
• Clinical Research Coordinators
• Industry Consultants
• Principal Investigators or Potential Principal Investigators
• Entrepreneurs

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

Course Length and Time
2.5 hours 12:30 - 3:00 p.m. Eastern

Course Dates
March 22, 2010

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#: 778-000-07-027-L04-P. Released: 9/07.

Managing CRAs to Improve Performance & Study Outcomes

Course Description
Monitoring of a clinical trial is a required activity completed by sponsors of FDA regulated research that significantly affects the outcomes of product development and approval. Sponsors need to effectively manage CRAs’ performance. Promoting improvement in overall performance and individual monitoring is important. Performance Management and Improvement is a Science involving logical processes and applications. This course will present the concepts of Human Performance Improvement (HPI) and apply it directly to the management of the CRA to promote improvements. The HPI CRA Management Model will be presented and applied in 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 hours 12:30 – 2:30 p.m. Eastern

Course Dates
March 26, 2010

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#: 778-000-08-012-L04-P. Released: 8/08.
NEW! Meeting HIPAA & 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 session presents common misunderstandings regarding the roles and responsibilities of clinical research sponsors, sites, and IRBs regarding HIPAA & 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
• CRC
• Quality Assurance
• Other site study personnel working with study records

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

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

Meeting International Safety Reporting Requirements: Addressing the Challenge for Both Large and Small Organizations

Course Description
Large and small pharmaceutical companies alike face an increasingly complex set of safety regulations to maintain compliance. However, the size of their organizations leads to differing challenges and therefore differing methods to meet international requirements most effectively. Small companies with even just a single product in multi-national clinical trials can be overwhelmed with reporting regulations from the EU Clinical Trials Directive combined with individual country requirements. In large global companies, the worldwide matrix of investigative site, CRO, and sponsor personnel can lead to delays in expedited reporting.

Learning Objectives
• Examine the challenges of international safety reporting
• Review the ICH standards that impact reporting
• Explore the requirements from Americas, EMEA, and Asia
• Discuss the benefits of centralized reporting
• Review architecture of electronic submissions in the US and EMEA, including EudraVigilance
• Review the benefits of electronic submissions

Who Should Attend
• Drug Safety
• Regulatory Affairs
• Data Management

Instructor
Christopher Metzler, D.P.M.

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

Course Dates
March 8, 2010
June 2, 2010

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#: 778-000-09-021-L04-P. Released 3/10.
Monitoring Informed Consent: The Process and Document

Course Description
Monitoring is one form of checks and balances that research sponsors conduct to help ensure human subject protections and data integrity for their studies. The process of monitoring informed consent is presented, including monitoring the: ICF template content, proper completion, and documentation of the ICF process. Case examples are presented to promote understanding and stimulate questions for discussion.

Learning Objectives
- Identify required informed consent template content per regulations, including basic and additional elements
- Monitor the ICF: Clearly define who and what determines if consent has been adequately executed
- Monitor the informed consent process documentation throughout the subjects’ time on study

Who Should Attend
- Clinical Research Associates
- Research Assistants
- Project Managers
- CRA Managers

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C

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

Course Dates
March 29, 2010

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#: 778-000-08-015-L04-P. Released: 7/08.

Monitoring Phase I Clinical Trials

Course Description
Phase I trials require an additional monitoring skills set. The CRA assessment focus changes in many monitoring practices, from ICF 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 course 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
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C

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

Course Dates
January 20, 2010 (12:30 – 3:00)
May 3, 2010 (9:00 – 11:30)
June 3, 2010 (12:30 – 3:00)

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#: 778-000-08-027-L04-P. Released: 2/09.
Monitoring Plan Development

Course Description
The approach to monitoring plan development can vary from sponsor to sponsor. Come to this 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
Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

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

Course Dates
February 22, 2010
May 25, 2010

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
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#: 778-000-07-048-L04-P. Released: 2/08.

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 for the review of clinical trials linked to marketing application approvals. This course 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: audiences include regulatory authorities
- Apply definitions and concepts of scientific report writing
- Implement the 10 rules of quality report writing for CRAs
- Apply the 10 rules to the 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

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

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

Course Dates
February 5, 2010 (12:30 - 3:30)
March 15, 2010 (9:00 - 12:00)
May 10, 2010 (12:30 - 3:30)

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 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#: 778-000-07-022-L04-P. Released: 8/07.
NEW! Navigating the FDA’s New Website: Tools for the Clinical Research Professional

Course Description
The FDA recently revamped its website in an effort to help make information more readily available to users. To speed the process of accessing information, it has now been classified by subject matter for easier retrieval, with associated subjects combined in sections. The site's updated design and navigation allow uniformity across the site and content has been reviewed for relevance, with unnecessary and obsolete information removed. In addition, new information that is useful for clinical research professionals is now accessible.

This session will review the FDA website for information that will be useful for the clinical research professional in conducting their daily activities. Particular focus will be placed on facilitating location of key information, discussion of its relevance, and utilization of identified information as a tool for enhancing research compliance.

Learning Objectives
• Identify and locate the websites for the Food and Drug Administration’s (FDAs) different Centers and Offices and discuss the role of each as it pertains to human subject research.
• Review FDA databases for information on regulations, guidance, enforcement actions, updates, and FAQs.
• Discuss how these resources can be used to develop and strengthen your role in initiating and conducting clinical research.

Who Should Attend
• Clinical Quality Assurance Professionals
• Clinical Research Associates
• Project Managers
• Investigators
• Study Coordinators
• GCP-Focused Regulatory Affairs Professionals

Instructor
Elizabeth Ronk Nelson, M.P.H.

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

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#: 778-000-09-060-L04-P. Released 10/08.

Fee: $595*
*Includes up to 20 participants at one site. For groups larger than 20 or for additional sites, call 1-800-856-2556 for pricing.
Operational Modeling and Simulation in Clinical Trials

Course Description
This course is designed for clinical research operations personnel responsible for and involved with country allocation, site selection, and monitor resource planning, as well as troubleshooting study, site, and enrollment performance issues. While sophisticated modeling and simulation tools have had a significant impact on identifying viable candidates during the drug discovery phase, until recently there have been limited to no tools available to model and predict clinical trials performance at the operational level. This session will explore the principles of operational modeling and highlight new tools and capabilities for improving study planning and conduct through modeling and simulation techniques.

Learning Objectives
- Define the concept of operational modeling, core principles, and the role of modeling and simulation in other industries
- Review the basics of operational modeling, simulation, forecasting, and trade-off analysis
- Enhance study planning and execution with operational modeling and simulation
- Interpret the results of the modeling scenarios to make better informed country allocation, site selection, and study performance aiding decisions
- Engage in an interactive demonstration of a modeling and simulation tool
- Navigate a Mock trial and explore a modeling and simulation tool in action
- Discuss case studies that will be used to illustrate how simulation tools can: Determine the best location and mix of sites for a given protocol as well as across multiple protocols and programs
- Identify the best operational scenarios (mix of countries, sites, monitors and patients) to achieve optimum performance
- Proactively identify, diagnose and treat study, site or country-level performance problems across multiple protocols and programs
- Conduct trade-off analysis between study performance solutions and predict the effect of these interventions
- Help aid in decisions to reallocate resources across multiple protocols and programs on a real-time basis
- Analyze and interpret the outcome of the simulation scenarios and suggest “what if” scenarios on a real-time basis to evaluate the effect of various decisions and interventions

Who Should Attend
- Clinical Research Operations Directors
- Program Managers
- Therapeutic Area Heads
- Clinical Project Managers
- Site Selection Specialists

Instructors
Beth D. Harper, M.B.A.
Rob Andes

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

NEW! 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 session will examine the importance of Phase I studies in drug development, the issues commonly associated with conducting a Phase I study from both 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 to 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 Dates
April 14, 2010
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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Course Dates
June 22, 2010
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#: 778-000-09-061-L04-P. Released: 6/10.
Preparing Clinical Research Sites for FDA Inspections

Course Description
This course is designed for participants that are sponsors/CROs and research site representatives preparing for a research site FDA inspection.

Learning Objectives
• Recognize 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

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

Course Length and Time
2.5 hours 12:30 - 3:00 p.m. Eastern

Preparation Dates
April 20, 2010

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#: 778-000-09-052-L04-P. Released: 4/10.

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 course reviews the clinical trial core competencies required for the principal investigator in accordance to 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 investigator visits and reports
• Explain investigational product management
• Define safety reporting and adverse event documentation
• Discuss FDA audits
• Apply tools and resources

Who Should Attend
The course is great training for physicians and others interested in getting involved in research as well as experienced PIs or site personnel looking to take an industry investigator certification exam.

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

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

Course Dates
March 24, 2010

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: 08/09.
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 course 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 Investigators (PIs)
- Clinical Research Coordinators (CRCs)
- Clinical Research Associates (CRAs)
- 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 1:00 - 3:00 p.m. Eastern

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 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 ensure compliance. This course will examine the trends in recent regulatory communication (warning, NIDPOE, and 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 institutional review boards (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 (CRAs)
- Project Managers
- Clinical Research Coordinators (CRCs)
- Clinical Investigators (PIs)
- IRB Administrators and Members
- Clinical Quality Assurance Auditors
- All other personnel responsible for ensuring compliance with GCP regulations

Instructor
Elizabeth Ronk Nelson, M.P.H.

Course Length and Time
2.0 hours 1:00 - 3:00 p.m. Eastern

Course Dates
January 25, 2010
May 20, 2010

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
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#: 778-000-09-062-L04-P.

Released: 3/09.

Course Dates
January 26, 2010
May 10, 2010

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
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#: 778-000-09-062-L04-P.

Released: 3/10.
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 course 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 IRB.

Learning Objectives
- Define root cause analysis concepts
- Implement Gilbert's Root Cause Analysis Diagnostic Process
- Apply root cause 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

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Length and Time
2.5 hours 12:30 - 3:00 p.m. Eastern

Course Dates
February 8, 2010

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#: 778-000-07-021-L04-P. Released: 9/07.

Site Relationship Management: Principles and Practical Considerations for Productive Sponsor-Site Relationships

Course Description
This course is designed for Sponsor and CRO personnel responsible for and involved with developing and managing successful site relationships. As the industry evolves from viewing investigative sites as merely “transaction agents” to recognizing the need for long-term collaborative partnerships with sites, the role of the CRA and Project Manager is being transformed. This session will cover supply-chain management principles and customer relationship management techniques that can be readily implemented to build and enhance productive site relationships.

Learning Objectives
- Discuss the ABCs of Supply Chain and Customer Relationship Management in the Clinical Trials Industry
- Discuss an overview of the basic principles and why you should care
- Integrate the Eight Principles of Successful Site Relationships
- Examine the CRA as a site advocate: Transforming the role of the CRA
- Collaborate: To create “super supplier” relationships
- Negotiate: Re-thinking collaborate approaches to budget development and preferred site agreements
- Educate: Re-inventing investigator meetings to accelerate the protocol learning curve
- Motivate: Practical applications of motivational theory to enhance site performance
- Evaluate: Measuring site performance – what metrics really matter
- Communicate: What sites value most in terms of sponsor-site communications
- Appreciate: Valuing the role of the supplier in today’s highly regulated environment
- Define and Improve Your Customer Service Skills
- Review lessons learned from the Disney Institute of “Guestology”

Who Should Attend
- Clinical Project Managers
- Site Selection Specialists
- Clinical Research Associates (CRAs)
- 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
May 11, 2010

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#: 778-000-06-030-L04-P. Released: 1/07.
**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 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)

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**NEW! 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 investigators’ 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
- QA/Compliance
- CRAs

**Instructor**
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

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

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**Course Dates**
February 2, 2010
April 15, 2010

**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#: 778-000-08-016-L04-P. Released: 10/08.

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**Who Should Attend**
- Site Research Directors/Managers
- Clinical Research Coordinators
- Principal Investigators
- CRAs
- Project Managers/CRA Managers
- QA

**Instructor**
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

**Course Dates**
February 23, 2010
May 3, 2010

**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#: 778-000-09-063-L04-P. Released: 2/10.
NEW! Strategies for Managing Difficult Clinical Research Sites

Course Description
Many CRAs ask: “How do I best handle a difficult site?” In this session the question is addressed through real life case scenarios that deal with the different kinds of “difficult” sites, for example: the overwhelmed site, the unmotivated site, the passive aggressive site, the research naive site. All of these types of behaviors at sites can lead to poor performance that does not respond to typical CRA action item management. Hear ideas on how to successfully work with the difficult site to promote efficiency and positive study outcomes that include helpful job aids, soft skill coaching, and diagnostic techniques to help improve approaches to interventions and management of the “difficult” site.

Learning Objectives
- Define the causes of why sites can be “difficult”
- Discuss approaches for dealing with the different kinds 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
- CRAs
- Project Managers
- CRA Managers

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

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

Course Dates
January 15, 2010
March 19, 2010

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#: 778-000-09-064-L04-P. Released 1/10.
Study Feasibility: Eliminating Low and Late Enrollment

Course Description
This course presents an overview of the patient recruitment arena today, and focuses on strategies for successful clinical trials including systematic protocol feasibility, pre-screening approaches, and in-sourcing and outsourcing options. Included in the program are discussions for handling in-sourcing and outsourcing options. Included are protocols feasibility, pre-screening approaches, and strategies for successful clinical trials including systematic recruitment.

Learning Objectives
- Explore updated 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.

Who Should Attend
- Directors of Clinical Operations
- Clinical Project Managers
- Site Selection Specialists
- Clinical Research Associates (CRAs)
- CRA Managers

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

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

Subject Recruitment: Proactive Project Plans & Issues Management

Course Description
This course is designed for sponsor and CRO personnel responsible for protocol design and development, country allocation, site selection, and study feasibility assessments. It is a well-documented fact that the current study feasibility assessment process is inefficient and incapable of identifying the best investigative sites to conduct a clinical trial typically 35% of study sites fail to enroll more than one participant. Feasibility questionnaires and the current process undertaken by most sponsors and CROs are not effective in predicting site success in implementing a given clinical trial. This session will challenge the conventional wisdom regarding study feasibility assessment practices. It 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
- Understand 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
- Discuss case study examples

Who Should Attend
- Directors of Clinical Operations
- Regional Medical Directors
- Clinical Project Managers
- Site Selection Specialists
- Clinical Research Associates (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 hours 12:30 - 2:30 p.m. Eastern

Course Dates
June 23, 2010

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#: 778-000-07-780-L01-P. Released: 5/08.

Subject Recruitment: Proactive Project Plans & Issues Management

Course Description
This course presents an overview of the patient recruitment arena today, and focuses on strategies for successful clinical trials including systematic protocol feasibility, pre-screening approaches, and in-sourcing and outsourcing options. Included in the program are discussions for handling in-sourcing and outsourcing options. Included are protocols feasibility, pre-screening approaches, and strategies for successful clinical trials including systematic recruitment.

Learning Objectives
- Examine real-world examples and return on investment analysis of new approaches
- Evaluate what’s broken in the traditional approach to study feasibility assessments and why
- 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
- Discuss how these novel approaches have translated to improved study performance through real-world case examples

Who Should Attend
- Directors of Clinical Operations
- Clinical Project Managers
- Site Selection Specialists
- Clinical Research Associates (CRAs)
- 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
March 16, 2010

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#: 778-000-07-031-L04-P. Released: 3/08.
NEW! **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 course. Web-based training requires 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 planning training for a web setting
- Outline how to set audience expectations and how to working 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 log-in logistics for sessions to service provider basic functionality orientation
- Apply audience considerations such as global attendees
- Maximize the use of web-platform interaction features and web-based presentation considerations

**Who Should Attend**
- Trainers, training managers and directors
- Individuals responsible for training
- Information technology professionals

**Instructor**
Sandra "SAM" Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.
Barbara Potter

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

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NEW! **Transitioning Pharmaceutical Professionals to Medical Device Professionals**

**Course Description**
This course 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 systems regulations. 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 QSR process
- Discuss the differences between pharmaceutical and medical device studies
- Identify professional responsibility for training
- Information technology professionals

**Who Should Attend**
- Professionals wanting to learn more about the medical device industry
- Pharmaceutical professionals who are new to medical device industry
- Other professionals who are new to medical device industry
- CRAs
- Regulatory professionals
- Management professionals
- Clinical sites who will be conducting medical device trials

**Instructor**
Kenny Jones, Ph.D.

**Course Length and Time**
2 hours 1:00 – 3:00 p.m. Eastern
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 course 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, as well as 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 & 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 set-up and maintenance of any trial TMF
- Principle Investigators/CRCs
- CRAs/CRA Managers
- Quality Assurance of Research Sites and Sponsors
- Research Site Personnel in Charge of Policy Development and Maintenance

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C

Course Dates
March 30, 2010 (12:30 – 2:30)
May 24, 2010 (9:00 – 11:00)
June 4, 2010 (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
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#: 778-000-09-001-L04-P. Released: 1/09.

NEW! 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 course 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, as well as 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
- Policy Development and Maintenance
- Sponsor/CRO Personnel involved in the policy, set-up, maintenance, auditing of the trial master file

Instructor
Sandra “SAM” Sather, M.S., B.S.N., C.C.R.A., C.C.R.C.

Course Dates
January 14, 2010 (12:30 – 2:30)
February 22, 2010 (9:00 – 11:00)
May 18, 2010 (12:30 – 2:30)
June 28, 2010 (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 2.0 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#: 778-000-09-062-L04-P. Released: 3/10.
Update on Medical Device Postmarketing Vigilance Reporting

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) was published in April 2007 by the European Commission. This new guideline came into force on 1 January 2008 after a nine-month transitional period to allow manufacturers, distributors, and authorized representatives time to implement the necessary revisions to their operating procedures. The 2007 update provides significantly more guidance than the previous 2001 version and 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. This seminar will cover all the major revisions, point by point.

Learning Objectives
• Examine the latest changes and new terms relating to MEDDEV and Medical Device Vigilance
• Recognize the extended scope of the new guidelines

Who Should Attend
• Regulatory Affairs
• Compliance
• Management Representatives
• Marketing and Sales
• Consultants
• Distributors and Representatives
• Operations

Instructor
David R. Dills

Course Length and Time
1 hour 12:30 – 1:30 p.m. Eastern

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 NTF’s content does not serve the purpose for use or serve no purpose at all. This course will discuss the appropriate and inappropriate uses of Notes to File, questions to ask to determine if a note to file would be beneficial, and what are the components of a quality note to file, if being used.

Learning Objectives
• Discuss the current overuse and misuse of NTF, including FDA WLs noting deficiencies in interventions that include NTF
• Identify what is an appropriate NTF, patient and non-patient specific
• Write effective NTF, when applicable
• Reference industry tools relating to NTF

Who Should Attend
• Quality Assurance
• CRAs
• CRCs
• Investigators
• CRA Managers/PMs

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 12:30 – 2:00 p.m. and 2:30 - 4:00 p.m. Eastern
Vendor Management for the Clinical Data Manager

**Course Description**
This course will provide the Data Manager at either the sponsor or vendor site who will be performing project management of outsourced studies the rationale for assessing outsourcing needs, the vendor selection process, and the tools to facilitate communication and consultation to enhance the sponsor/vendor relationship. Specific topics will include:
- Determining outsourced tasks: Who, what, when, where, why
- Selecting potential vendors: Specialty based, previous experience, word of mouth reports, and/or services/costs/timeliness
- Preparing for "bid defense": Understanding company philosophy in choosing, assessing compatibility
- Final selection/getting started: Determining data management "scope of work," timelines, communication plan, interfacing with project manager (sponsor & CRO), data manager project managing their portion of the study
- Post-project evaluation: Lessons learned meeting, corrective action

**Learning Objectives**
- Discuss the strategy utilized in determining outsourcing needs
- Identify the deliverables/expertise of potential vendors
- Evaluate tools for facilitating project management tasks
- Discuss the rationale for a “Lessons Learned” or “Post Mortem” review meeting

**Who Should Attend**
- Clinical Data Managers who are involved in determining outsourcing partners or are outsourcing providers.
- Clinical Data Managers
- Contract Administrators

**Instructor**
Denise G. Redkar-Brown

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

**Course Dates**
March 2, 2010
June 10, 2010

**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#: 778-000-09-009-L04-P. Released: 6/09.
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-scale 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.

Rob Andes currently serves as EVP of Engineering and Operations Core Concept, Inc., a software product and services company providing software solutions for pharmaceutical clinical trial management and analysis of studies as dynamic systems.

Beginning in systems R&D, Mr. Andes has developed advanced technology solutions based on original work in artificial intelligence and cognitive engineering applied as software solutions. A technology leader and innovator, he has held positions as a key executive and lead team member of software applications companies, from successful start-ups to public companies. These postings have included the successful turnaround of a software unit at a Fortune 100 company and new technology developments in the medical field.

A member of the IEEE Systems, Man, and Cybernetics Society and the Association of Computing Machinery, he is a frequent speaker and has published multiple scientific and business publications, including journal articles and technical book chapters. Mr. Andes holds a B.S. in Applied Psychology and an M.S. in Industrial and Systems Engineering (Human-Machine Systems) from the Georgia Institute of Technology.

Susan Bassion, Ph.D., has over 20 years of clinical, research and business management experience. She is currently an independent clinical research consultant and trainer. She has been Director of Clinical Operations and was responsible for the oversight of multiple Phase I-III projects across the therapeutic disciplines. She was also Director, Product Development and Regulatory Affairs. Her responsibilities included providing consultation on clinical drug development, including strategy, trial design and coordination of regulatory submissions.

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 3 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 4 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, some of them being CNS, inflammation, or immunology. As Clinical Program Manager, Majda has a 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.

E. Carol Cox-McClave is the founder and Vice President of Intercoast Quality Assurance (IQA). Ms. Cox-McClave has extensive expertise in clinical research including clinical monitoring, quality assurance and Phase I research. She has worked in pharmaceutical research for over 20 years and in the quality assurance area for over 20 years. Ms. Cox-McClave has performed investigational site, sponsor-monitor, clinical report, submission, computer validation and systems audits. She has initiated and/or managed Quality Assurance departments for several major pharmaceutical companies. Ms. Cox-McClave holds a Masters degree in mathematics and computer science.

Natalie Currie is an instructional designer, facilitator and founder of Natalie Currie, Clinical Research Consulting Inc. a learning and development organization 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 Jansen-Ortho Inc. (a division of Johnson and Johnson) and has participated on international project teams for pivotal Phase III studies and led Canadian Phase IIIb-IV studies.

Natalie holds an honors life science degree from the University of Toronto and is a member of the Society of Clinical Research Associates (SoCRA), the American and Canadian Societies of Training and Development (ASTD & CSTD), Toastmasters International and is on the organizing committee for the World Creativity and Innovation Week in Toronto.

Natalie designs and facilitates engaging, customized corporate and public workshops in the areas of clinical research study management, good clinical practice and communications all with visual thinking in mind.

Anil D’Mello 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.

David R. Dills is a consultant on technical and regulatory affairs and compliance to pharmaceutical, Class I, II, and III medical device, and biologics/biotech companies with an emphasis on establishing sustainable compliance and validation environments. Through his work, Mr. Dills has been affiliated within the FDA-regulated industry for more than nineteen years in the areas of QA, Quality Engineering, Validation, Regulatory Affairs/Compliance, and Corporate/Operations Management and employed on behalf of well-known, globally recognized manufacturers and service providers. Mr. Dills has authored...
Instructor Biographies

Rakesh Dixit has a PhD in Toxicology-Biochemistry and is board certified in Toxicology from the American Board of Toxicology, Inc. since 1992. He conducted his pre-doctoral to post-doctoral training in biochemical mechanisms of toxicity, chemical carcinogenesis, and cancer chemoprevention at the University of Lucknow (M.S.) Industrial Toxicology Research Center, India, and Case Western Reserve University, Ohio, USA, and the Medical College of Ohio, USA. Subsequently, he joined the faculty of University of Nebraska Medical Center, Creighton Institute for Cancer Research, and Allied Diseases in Omaha, NE. Dr. Dixit has over 20 years of experience in developing drugs with an extensive publication record. He spent 13 years at Merck and Co., Inc. at various senior level positions in the department of safety assessment. Dr. Dixit joined Johnson and Johnson as a Senior Director in Toxicology in 2005. He recently joined MedImmune, Inc. in Gaithersburg, Maryland as Senior Director and Head of Toxicology. Dr. Dixit is responsible for managing various drug development projects and biomarker projects.

Ruth Dubinsky, M.S. O.D., founder of Clarity Consulting, Inc., 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.

Randy Dunson has 18 years of combined project management and clinical development experience at both public and private pharmaceutical and contract research organization companies. Randy has successfully built and led local and global project teams of varying sizes and complexities at companies such as PAREXEL International and GlaxoSmithKline. He possesses a strong working knowledge of contemporary project management standards and practices, and is a certified Project Management Professional. Randy has also been involved in several corporate and organizational initiatives involving strategic business change and alliances that have served to build partnerships with multiple stakeholders. He heads U.S. Operations for Harpum Consulting Ltd, a multidisciplinary project management consulting firm.

Lynne Eddy received her Ph.D. in Physiology and Biophysics from the University of Alabama at Birmingham. She has extensive experience in research and teaching in a university environment, having been a faculty member at Florida State University, the University of South Alabama College of Medicine, and the University of Southern California. She also has a broad base of experience in clinical research in both the pharmaceutical industry and in contract research organizations. She most recently was Director, Clinical Research Practices, at Alliance Pharmaceutical Corp. in San Diego and was responsible for assurance that clinical studies were being conducted in accordance with company, federal, and other agency guidelines and laws. She is currently serving as a consultant to the pharmaceutical and medical device industry in clinical research, compliance, and training and continues her teaching at UCSD Extension in several programs relating to clinical research where she has taught GCPs to over 1000 students over the past 10 years.

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. CRC is an independent consulting firm that provides clinical and regulatory support services to medical device and pharmaceutical companies to bring investigational products to market. CRC's client base includes U.S. and international companies with a focus on start-up and incubator companies developing novel medical devices. CRC has successfully filed 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. Dr. Fant is the principle regulatory consultant and owner of CRC. Prior to founding CRC, 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 clinical 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., Associate Director GRO, CRA/GMBA, PAREXEL International (RUS) LLC, located in Moscow, Russia. Anna has MD degree and PhD in Paediatrics, Allergology & Immunology, was a university lecturer and consultant in Paediatrics for 4 years. Since 1998 Anna has been working for PAREXEL, first as CRA and than holding 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., is President of The Freeman Group, a niche service provider of quality clinical monitoring, auditing, training, project management and consulting services internationally. He has personally worked in these areas with pharmaceutical, device, healthcare and contract research organizations for over 30 years. Mr. Freeman has been a credentialed clinical research trainer through ACRP since its inception in 2003. Mr. Freeman holds a B.S. in Biology (pre-med program) from the University at Albany and an M.S. in Science Education from Russell Sage College. He has been actively involved in various clinical capacities for multiple therapeutic areas (Phase I-IV) for the following indications as well as devices: allergy; anti-infective; cardiovascular; critical care; dental; dermatology; endocrinology; eye care; GI; imaging/diagnostics; immunology; infectious disease; oncology; organ transplant; OTC medications; psychiatric disorders, pulmonary; sleep disorders; and STDs. This experience includes pre-clinical laboratory work, data...
management, protocol writing and CRF design, clinical monitoring, clinical trial management, GCP auditing, developing and presenting clinical training programs, regulatory affairs management and overall responsibility for Clinical Operations in several settings, including presentations at FDA Advisory meetings. Mr. Freeman has also participated as a trainer for ACRP's CRA and CRC Certification Exam Review courses and other clinical offerings and is an active instructor for several Drug and Device courses for Barnett International for public and on-site offerings. He lectures routinely worldwide and presents training workshops for drug and device companies, as well as investigator sites 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. Ghigone, M.S., R.A.C., is the CEO/President of AAG Incorporated. For more than 25 years, his professional focus has been in regulatory affairs, quality assurance, and clinical affairs. 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.

Diego Glancszpigel is an expert in designing and developing strategies for clinical trials in Latin America. He has been working for 14 years for the CRO Industry in Latin America and he is currently responsible for PAREXEL operations in Latin America. He regularly speaks at international conferences about Clinical Trials in Latin America and has expertise in study design, regulatory considerations, and cultural considerations.

Yolanda Hall possesses a Masters in Regulatory Affairs and Health Policy. She currently holds the title of Director of Regulatory Affairs at Datafarm where she brings over 15 years of life science and healthcare regulatory experience to her position. Her primary responsibilities include supporting sponsors in implementing electronic submission filing strategies of all types to global regulatory bodies. She supervises the day to day activities of the Professional Services group which encompasses coordinating eCTD application and related software deployment, training and support. Additionally, she provides oversight for publishing, compilation tasks, and quality assurance compliancy for electronic submission procedures and processes.

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., is the President of Clinical Performance Partners, Inc., a clinical research consulting firm focused on preventing, diagnosing and treating site and enrollment performance problems. In addition to her 25 years of clinical research experience, Beth is also an adjunct Assistant Professor, School of Medicine and Health Care Sciences, Clinical Research Administration Programs with the George Washington University.

Steve Jolley is Principal of SJ Pharma Consulting and has 23 years of experience in drug safety & 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.

Kenny Jones holds a degree in nursing, business administration, a master’s degree in business management and is currently completing work on his doctorate degree in clinical psychology. He started working in the pharmaceutical industry in 1988. He worked in several roles that allowed him experiences to include good manufacturing practices, good clinical practices, monitoring, auditing, clinical project management, and many others. He has worked on national and global, phase 11 and III, adult and pediatric studies, in the areas of neuro/psyche and infectious diseases. In 2005 Kenny began work in the Medical Device industry developing and managing clinical research studies in the endovascular and drug eluting stents environment.

Sidney Khan, Ph.D., professional credentials include MB, ChB (Cape Town), Ph.D. (London), FRCPath (Chemical Pathology), and MFPMP. 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 before establishing Pharmacovigilance & Risk Management Inc. in 2002. 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 MS SO 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.

Piotr Kolataj, M.D., practiced clinical medicine (internal medicine and dialysis) in Warsaw, Poland for more than 10 years. Dr. Kolataj graduated from Warsaw Medical School and became board certified in internal medicine in 1992. The same year, while continuing his work as a hospital clinician, he joined PAREXEL International in its endeavors to develop the CRO industry in Poland and the CEE region. In 1995 Dr. Kolataj was appointed to the position of Country Manager of PAREXEL’s fast-growing Polish office. In 1998 Dr. Kolataj co-founded the Polish GCP Association and served several years as a board member, and President from 2000-2002. As a result of his successes in expanding the company’s
structure and growing the number of international clinical trials coming into the CEE region, Dr. Piotr was appointed PAREXEL’s Director of Clinical Operations—Eastern European Region in 2002 where he has responsibility for countries such as Russia, the Ukraine, the Baltic’s, Poland and Georgia. In 2003 he achieved a master degree in business administration from French Institute of Management in Warsaw. Besides his management work at the PAREXEL, Piotr is a regular speaker on international meetings and seminars promoting clinical trials in emerging regions especially CEE by sharing his own experience and observations on developing clinical trials.

Robert L. Kunka, Ph.D. is an acclaimed scientist who has a long history of getting drug approvals quickly. Bob has contributed to the development of 27 pharmaceutical products in a seven therapeutic areas including Advair, Flovent, Fiasone, Retrovir, Valtrex, Imitrex, Combivir, Zofran, Maxaquin, Zofran, and Calan. His expertise on international product development teams produced submissions with successful clinical pharmacology strategies, sound matrix management of individual study teams, and effective interactions with regulatory agencies leading to successful IND/aNDA/sNDA/NDA approvals. Prior to starting a 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. Prior to this, he was Assistant Professor in the Pharmaceutics Department at the University of Pittsburgh School of Pharmacy where he taught graduate and undergraduate courses in pharmacokinetics and pharmacy posology. 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 in pharmacokinetics and pharmacy posology. He also served on the exam committee for the EU and ICH CCRA exams (Association of Pharmaceutical Education) and he is certified by the American Board of Podiatric Orthopedics.

Miguel Montalvo has over 22 years of experience and, as part of his current role within AAC Consulting Group, Inc., he provides specialized compliance-focused consulting and management of validation projects for customers around the world.

Before joining AAC in 1999, Mr. Montalvo held positions of increasing responsibility in the areas of Validation, Technical Services and Quality Operations in companies such as Millipore Corporation, Raytheon Engineers and Constructors, Mova Pharmaceutical Corp., Bristol-Myers Squibb, and Baxter Healthcare Corporation. He has managed the validation efforts for several facilities under start-ups and major renovations with processes including bulk API’s, solid-dosage, parenterals, topicals, liquids, and medical devices for customers in the pharmaceutical and biotechnology segments.

He holds an MBA and a BS in Chemical Engineering from Rensselaer Polytechnic Institute. His expertise includes areas such as Process and Cleaning Validation, Use of Statistics in different applications, Facility and Equipment Qualification with focus on Sterile Operations, and Validation of Sterilization/Depyrogenation Processes. He has been a speaker at validation and quality related conferences around the world for such groups as IIR, IVT, and Barnett International and his articles/papers have been published in the American Pharmaceutical Review and the Journal of Validation Technology publications. He is a member of the Journal of Validation Technology editorial board.

Eric Morfin, M.B.A., P.M.P., is a partner with Critical Skills Inc. whose mission is to increase organizational effectiveness through the establishment of Superior Thinking Skills as a company’s most sustainable competitive advantage. Critical Skills Inc.’s primary focus is in applying project management best practices to the Pharmaceutical / Biotech / Life Sciences industries.

Eric Morfin, PMP, 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 PM 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 is the Chair of the PMNorcal PharmaLIG and the Chair of the PMI Pharmaceutical SIG (www.pharmasig.org).

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...
Instructor Biographies

John J. Needham is the Chief Operating Officer of Patient Recruitment Strategies, LLC, a consulting firm focused on global strategies for patient recruitment, enrollment, compliance, adherence, and retention. The firm advises pharmaceutical drug development, biotech, medical device, and contract support organizations. Prior to establishing this organization, John was the head of Global Patient Recruitment Strategies for Phase II and III trials at Johnson and Johnson Pharmaceutical Research and Development, LLC. John has held senior leadership positions within the healthcare industry at Acurian, Alliance Health Information, PatientQuest, Telerx Marketing, TeleSpectrum Worldwide, and PharmaKinetics Laboratories.

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; 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.

David Nettleton is a 21 CFR Part 11, Annex 11, HIPAA, software validation, and computer system validation consultant involved with the development, purchase, installation, operation and maintenance of computerized systems used in FDA compliant applications. Services include compliance related to product features, vendor audits, software validation, SOPs, training, gap analysis, remediation plans, and project management.

He has completed more than 180 mission critical software implementation projects involving: medical devices, blood bank, clinical trial, corrective action, document control, electronic data capture, Excel spreadsheets, laboratory instruments, laboratory information management (LIMS), manufacturing, enterprise resource planning, toxicology systems, and VMware.

His latest book is “Risk Based Software Validation - Ten easy Steps” which provides fill-in-the-blank templates for completing a COTS software validation project.

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 experience, CROs and academic settings. 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 Masters 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, etc and also the Association of Training and Development (ASTD). She is a Certified clinical research professional (CCRP).

Currently, Marcellina is the Associate Director, Clinical Research Management and Training for Clinical Research Group, at Drexel University College of Medicine, Philadelphia, PA.

Graciela Rácaro has more than 8 years of experience in Drug Development between Non Clinical and Clinical Research working for the Pharma industry, PAREXEL and a multinational Biotech company. Her experience in therapeutic areas includes dermatology, reproductive health, endocrine/metabolism, cystic fibrosis, neurology, cardiovascular, bone diseases and anesthesia. Phase experience in Phase II-IV trials.

For the last 5 years she has been in charge of the implementation of the studies in Latin America within all what this may imply (i.e. running the importation and storing of drugs, proposing sites and Investigators for new studies, managing study related financial issues and resources, etc.). Furthermore, she has also supervised Local Authorities submissions for study approvals in several Latin-American countries, including Argentina, Brazil, Chile, Mexico, Uruguay and Venezuela, having always a special concern to follow all Local, FDA and EMEA regulations.

Experience in clinical trials monitoring, site evaluation and initiation, data collection and quality control review of data collected at trial sites to ensure compliance with multiple protocols, FDA/EMEA regulations and GCP guidelines. Experience as Primary CRA with responsibility for managing and training CRAs team. Experience as Project Manager in Latin-American stand alone projects and Regional Project Manager for global projects. Experience as Line Manager for CRAs, Clinical Operations Managers and Regulatory staff, coaching and mentoring of new CRAs, training and mentoring of New Managers and EDC Super User in Latin-America.

Graciela Rácaro also has a strong experience on external/internal audits as well as local and international (FDA) inspections, all of them with successful results.

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 recently published in the Good Clinical Practices Journal in 2008. Denise has contributed to the successful submissions for Accolate® (the first leukotriene antagonist for asthma therapy) and Seroquel® (Serotonin receptor compound for treatment of Schizophrenia and bi-polar disorder). Denise also worked at Dupont Pharma (Immunology), Knoll (Humira®), and Sanofi (vaccines), and at present...
she is the Associate Director of Scientific Affairs, Data Management for Cetero Research in Fargo, North Dakota. Denise has been an Instructor for Barnett International/Cambridge Healthtech Institute for 11 years specializing in Clinical Data Management delivering training programs and interactive webinars for multiple clients in the pharmaceutical and biotech industry.

Barry Renaud is the founder and President of Quality Assurance Systems, Inc. (QAS). Since 1990, he and his firm have served more than 160 biomedical research companies, law firms, and research institutions worldwide and have performed investigational site, sponsor-monitor, database, clinical report, submission, Computer System Validation, computer systems, process, and other types of audits. Mr. Renaud has also provided discovery and expert testimony in court cases and has served as an Application Integrity Policy consultant. In addition, he often provides Quality System consulting, which includes the development of Quality Management Systems and Standard Operating Procedures and their supporting documentation. Before founding QAS, he directed Clinical Quality Assurance departments at a major pharmaceutical company and a Contract Research Organization.

Lily Romero, P.A., C.C.R.C., has over thirty years 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., and a Clinical Research Coordinator and Research Administrator at the Allergy & Asthma Medical Group and Research Center, 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 of Science in Nursing in 1983 and 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. SAMs 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 in Science in Education with a specialization in Training and Performance Improvement.

SAM Sather is currently the vice-president of Clinical Pathways, a consulting team out of North Carolina that 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.

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 research trials. Prior to her work at CRSTI, Jennifer started the Clinical Trials Office at The University of Texas Southwestern Medical Center in 1997 and was able to build a comprehensive, successful office.

David M. Stier, M.D., is President of EUREKA RESEARCH, which provides study design and data analysis for outcomes studies, clinical trials, and patient registry programs. Prior to founding EUREKA RESEARCH, 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 2 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 Operation. 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.
Important Notice
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The NJSNA is accredited by the American Nurses Credentialing Center Commission (ANCC) on Accreditation of the American Nurses Association as an approver of continuing education for nursing.

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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.

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- **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.

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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.

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• 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.

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New Drug Development: A Regulatory Overview is considered an authoritative, critical, and ‘go-to’ resource to navigate the FDA’s drug development approval process. The 400-page reference book addresses the most-cutting edge developments redefining how new drugs are developed and regulated today, including:

- How the FDA Amendments Act of 2007 affects everything from drug reviews to postmarketing requirements.
- How CDER’s efforts to integrate a “culture of drug safety” has affected the center’s structure and its new drug review and approval processes.
- How CDER’s much-anticipated January 2008 transition to the eCTD as the “only valid e-submission format” will affect the FDA’s drug submission and review process.
- How the FDA and industry are already integrating pharmacogenomics, computer simulation, and other emerging technologies to inform key decisions.
- Which drug development strategies are fulfilling their promise and offering optimal returns for industry, given the explosion of accelerated development/approval programs and pilot programs to speed the drug development and review process.

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IND Submissions: A Primer
An in-depth guide to writing, editing, tracking, and submitting the original IND and applicable IND amendments

For each submission type, the book outlines:

- Regulations and guidance documents
- Overview and background on why the submission is required
- Submission structure
- Who contributes to the submission
- Where to pull, re-use, or get the information needed in the submission
- How biologics differ
- Applicable FDA Form(s) information
- Electronic CTD sections, where applicable
- Real-life examples from the media and approved NDAs, when available
- Electronic examples and content templates that can be utilized to begin working on the submission immediately

“For those in Regulatory Affairs, IND Submissions: A Primer is a must. Whether one is new to Regulatory Affairs or a seasoned veteran, this book will provide you with the information you require to file a proper IND.”

— Albert A. Ghignone, M.S., R.A.C. CEO/President, AAG, Inc.
Medical Device Development: Regulation and Law

Medical Device Development: Regulation and Law is the ‘must-have’ resource for the novice or veteran medical device regulatory affairs professional. This reference book provides the most comprehensive and updated analysis of US medical device and diagnostics development and approval requirements, along with in-depth analysis on how emerging developments and trends are reshaping medical device and combination product regulations in the US. The second edition addresses the latest regulatory and legal developments that guide how medical devices are developed today:

- The Medical Device User Fee and Modernization Act of 2002, including user fees, third party inspections, reprocessed single use devices, and the establishment of the Office of Combination Products.
- The Food and Drug Administration Amendments Act of 2007, including unique device identifiers, ClinicalTrials.gov registration, pediatric device promotion, and postmarket surveillance and medical device reporting changes.
- The current and future landscape of electronic 510(k) and PMA submissions.

New chapters in the second edition include:
- Medical Device Compliance and Postmarket Surveillance requirements.
- Quality System Regulation, including management controls, design controls, risk analysis and corrective and preventive action, and other QSR provisions.
- In Vitro Diagnostics, including IVD clinical studies, ASR regulation, LDTs, CLIA, and IUO/RUO requirements.
- Combination Products and Product Jurisdiction, including a description of FDA’s jurisdictional decision-making for single entity products, the establishment of the Office of Combination Products and its jurisdiction and processes, with a detailed discussion of the new definition of the “primary mode of action.”

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This is one of the best books written on the subject of regulatory affairs for the medical device industry. The book is a great tool whether you are a seasoned regulatory professional or a front line supervisor. Kahan is in my opinion on his way to becoming the Juran of the regulatory field.”

— Scott Baker, CQT, CQE, CQA, Supplier Quality Engineer II, Smith & Nephew, Inc.
2009 CFR/ICH GCP Reference Guide

Updated each year, this convenient pocket guide puts the most commonly referenced US regulations and international guidelines at your fingertips:

- Good Laboratory Practice Part 58
- ICH Guideline Good Clinical Practice (E6)
- ICH Guideline Clinical Safety Data Management (E2A)
- The European Union Clinical Trials Directive
- The European Union Good Clinical Practice Directive
- New feature in 2009! Editor’s Notes that alert you to changes to the Federal Register that will take place after the April 1, 2009 publication date.

Glossary & Acronyms for Clinical Research Professionals

Newly updated and expanded in 2009! Do you ever wish you had the quickly-evolving terminology of the clinical research industry at your fingertips? This easy to use “back-pocket” reference guide helps you to navigate more than 900 key terms and over 500 acronyms that are commonly used in the clinical research and regulatory environment. This all-new edition has been expanded and includes terms and acronyms for:

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- Pre-Clinical Research
- Regulatory Submissions
- Medical Devices
- Data Management
- Statistics
- Pricing and Reimbursement
- The US, EU, and ICH Regions

2009 CFR Reference Guide for Medical Devices

Newly updated in 2009, the spiral bound pocket guide is designed specifically for the medical device and combination product industry and covers the:

- FDA Code of Federal Regulations, Good Clinical Practice Parts 11, 50, 54, and 56
- Medical Devices and Quality Systems Parts 801, 803, 806, 807, 812, 814, 820, and 822
- Product Jurisdiction Part 3 for Combination Products
- ICH Guideline Good Clinical Practice (E6)

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- Apply the very latest and most advanced project management techniques directly to challenges presented by the drug development process.
- Critically evaluate the needs of the package insert and marketing application up front, before getting deeply into clinical trials.
- Leverage standardization to drive and expedite the entire development process, from the development of clinical trial protocols to the development of clinical data presentations.
- Critically assess the needs of the final report before developing the clinical protocol.
- Use draft case report forms (CRFs) to dictate the content of the procedures section of the clinical protocol.
- Constructively consider the methods for data analysis in developing the clinical protocol.
- Provide direct access to the expertise and recommendations of dozens of the most experienced and forward-thinking experts in the pharmaceutical and biotechnology industries today.

Biologics Development: A Regulatory Overview

Written by CDER and CBER officials and industry experts, *Biologics Development: A Regulatory Overview* offers an expansive examination of the FDA’s regulation of biologic products, from preclinical testing to post-marketing regulatory requirements, and from user fees to electronic submissions. The book also provides the first detailed look inside the re-invented FDA that will regulate and approve today’s biological products along with a detailed analysis of each stage of the biological product development process available anywhere, including:

- CDER’s emerging organization and processes for regulating and reviewing therapeutic biological products.
- CDER’s processes for regulating and reviewing cellular and gene therapies, vaccines, and blood products.
- How CDER and CBER are evolving their procedures and requirements to address new challenges presented by the user-fee program, risk management priorities, and internal agency initiatives.
- Emerging standards for the clinical and nonclinical testing of biological products.

"Authored by FDA and industry officials, *Biologics Development: A Regulatory Overview* is the first text to provide a detailed analysis of the FDA’s regulation of the development process for… biological products. [It] gives special emphasis to the recent wave of organizational, management, and operating initiatives within… CBER… including lot release, user fees, and promotional labeling policies."

— RAPS News (on the first edition)

“A first-rate information source on the biologics approval process! This text provides an up-to-date reference for the expert, and an excellent overview for the novice. More important, it is one of the precious few sources for obtaining the detailed thoughts of current CBER officials.”

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The largest compendium of drug approval performance metrics ever compiled! This is a comprehensive source for the very latest performance metrics and trend analysis on every key aspect of the new drug approval process. The 2008/2009 edition examines hundreds of key trends and metrics to provide industry with all-new benchmarks and metrics on which to assess their own performance, to plan their own R&D projects, and to assess the various drug approval options and strategies available to them:

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Based on data compiled through internal studies, Freedom of Information requests to the FDA, and other public and private sources, our proprietary analyses will provide you with unique insights, benchmarks, and performance metrics in areas critical to the success of your R&D projects.

US Regulatory Reporter Newsletter

No other publication monitors the FDA offices and divisions that review your products more closely than the US Regulatory Reporter. Each month, you can read cutting-edge data for the pharmaceutical, medical, and allied industries, such as:

• A steady flow of hard regulatory information, one-on-one interviews with CDER’s review division directors, the latest regulatory statistics, and in-depth analysis on emerging issues and processes associated with drug development and approval.
• The information you need to benchmark your own regulatory activities and to gear your regulatory strategies to address emerging FDA issues and concerns.
• The people and issues most critical to you and your company’s products.

From IND reform to regulatory performance benchmarking, and from accelerated drug review case studies to ANDAs, the US Regulatory Reporter gives you the issues before they become issues! Available in one- and two-year subscriptions.

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Good Clinical Practice: A Question & Answer Reference Guide 2009

Newly updated and expanded for 2009, this industry-leading GCP training and reference guide answers 700 of the most common and difficult questions regarding the day-to-day interpretation and implementation of GCP standards for drugs and biologics.

The pocket reference guide provides information on not just U.S. GCP, but International GCP issues in such regions and countries as the European Union, India, Latin America, and Russia. In addition, the 2009 edition covers how the FDA will be focusing more intently on sponsors’ “quality systems” when significant problems are discovered at the clinical study site, why the rate of significant non-compliance is being discovered at clinical trial sites, and how increasing numbers of new drug reviews are being delayed due to GCP compliance issues.

The GCP guide provides clinical research professionals authoritative answers to hundreds of common and emerging questions, including over 100 Q&As specifically on informed consent. Leading pharma and biotech companies are using this reference guide to educate their clinical professionals, trial auditors, and site staff on the many emerging complexities of GCP standards.

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“This book should be mandatory reading for every person involved in clinical research.”

— Munish Mehra, Ph.D., Managing Director, Global Drug Development Experts

“This book is already a leader among GCP references and one that offers an immediate return for readers.”

— William Hirschhorn, Drexel University College of Medicine

The Form FDA 1572: A Reference Guide for Clinical Researchers, Sponsors, and Monitors

This state-of-the-art reference guide addresses an emerging reality in clinical research today: As the number of FDA-issued warning letters to clinical investigators has risen in recent years, so too have citations regarding investigators’ failure to complete the 1572 appropriately and correctly.

The Form FDA 1572 book was developed to help not only experienced clinical investigators who struggle to address the 1572 in the emerging complexities of modern clinical trials, but also the growing number of investigators who are conducting their first FDA-regulated trial each year. The reference guide addresses new 1572-related challenges facing clinical investigators and industry trial sponsors, as well as the most often-asked—but never answered—questions related to the growing complexity of today’s clinical trials.

“The Form 1572: A Reference Guide for Clinical Researchers, Sponsors, and Monitors answers the difficult questions that real life creates from even the simplest regulations. The core of this book is a section-by-section guide to completing the 1572 form.”

— Norman M. Goldfarb, Managing Director, First Clinical Research LLC

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