MedTrials®
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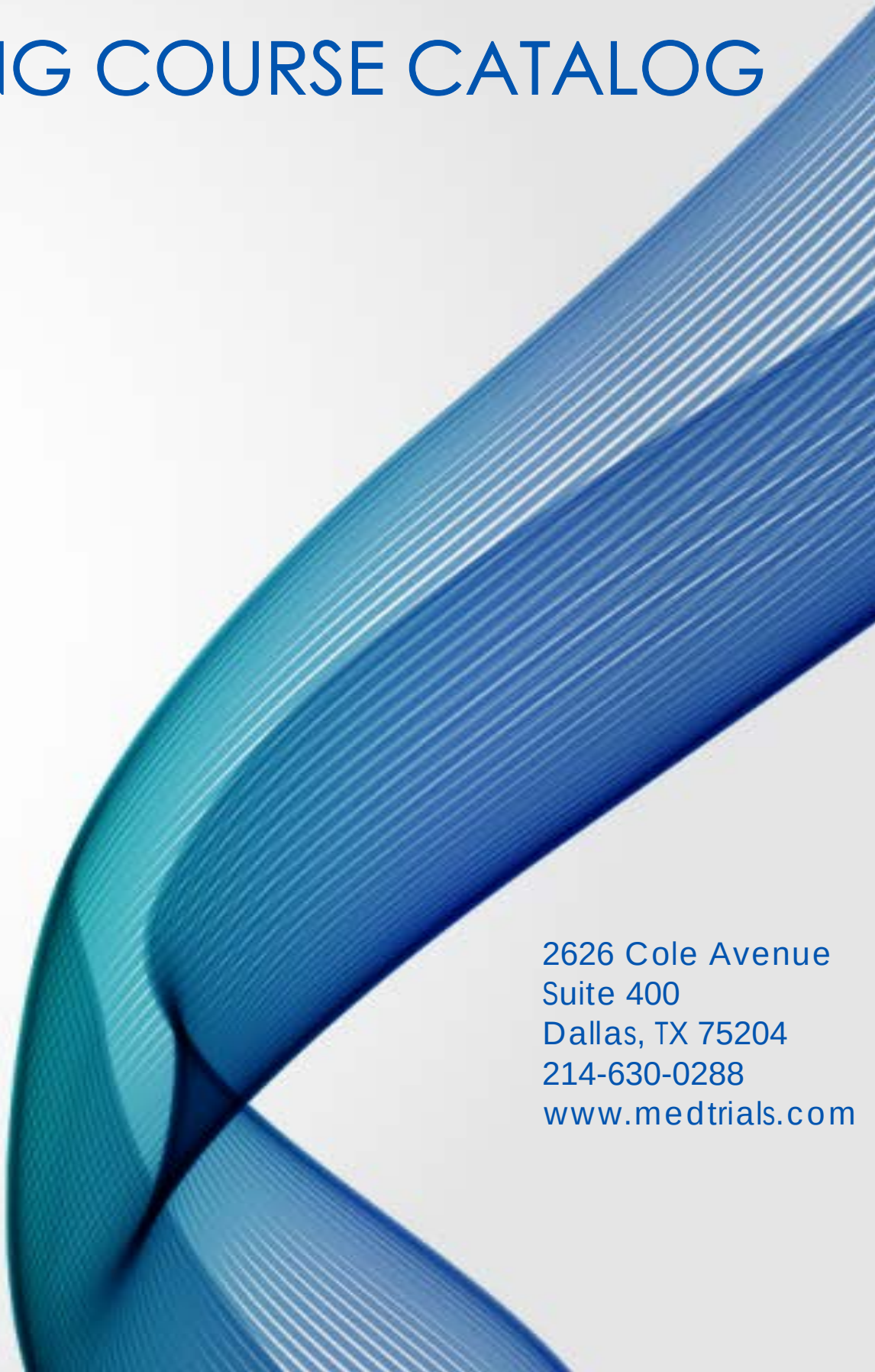
TRAINING COURSE CATALOG



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MedTrials®
INCORPORATED
Aligning the Art & Science of Clinical Research®

Aligning the Art and Science of Clinical Research® is not just our tagline; it represents our signature and collaborative approach to clinical research involving expertise, communication skills, industry insight, and relationship management.

Since 1993, MedTrials has been a recognized leader in offering a full spectrum of professional services including training, clinical trial management, clinical monitoring, data management, statistical analysis and reporting in all phases and types of clinical trials, and providing current and relevant learning and development programs to the clinical research industry. Our highly experienced trainers are well known for delivering dynamic and innovative presentations and programs throughout the world and possess in-depth understanding of clinical research, thanks in part to our hands-on experience and industry-wide leadership. MedTrials trainers are recognized as faculty and curricula developers for the Association of Clinical Research Professionals (ACRP) and are also adjunct faculty for the Graduate School of Biomedical Sciences at the University of North Texas Health Science Center.

MedTrials learning and development programs are based on the latest clinical research guidelines, regulations, and techniques to provide a real-world understanding to research professionals including:

- Sponsor personnel
- Investigators and site personnel
- Institutional Review Board (IRB) members
- Contract Research Organization (CRO) personnel
- Field service engineers
- Medical product sales representatives

MedTrials is also able to offer continuing nursing education (CNE) contact hours for research professionals through the Texas Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.

Our team's organization and communication skills, empathy with both the sponsor and the investigative site, and relationship management are the primary discriminating factors between MedTrials and other CROs. It is these values and characteristics that allow MedTrials to deliver high quality solutions and training programs. We promise to provide exceptional service. When you select MedTrials as your partner in clinical research, you can expect to receive the highest level of professionalism and quality.

Table of Contents

2015 Training Course Catalog

MedTrials, Inc.
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https://core.medtrials.com

2-Day Training Courses

Courses are presented in-person at your location at a time convenient to you. A member of the MedTrials Training Team will contact you to further refine course content based on the needs of you and your team. All participants are eligible for "Certificates of Participation" and accreditation, provided full participation from participants and completion of course evaluation. Courses can be split, combined and/or developed into ½-day, or 1-day training events. Continuing Nursing Education (CNE) credits are available with 60 days advance notice.

Basic GCP

This two-day course offers the basics of good clinical practice (GCP). Topics covered include: Introduction to GCP, Investigational Product Development, Clinical Research Team Roles and Responsibilities, Regulatory Documents and Clinical Trial Management, Principles of Informed Consent, Sponsor Visits, AE Analysis and Reporting, and Practical Applications of GCP.

Intermediate GCP

This two-day course is a step up from our basic GCP offering. It covers the areas of: Intermediate Regulatory Review, Good Science, Understanding a Protocol, Introduction to Data Management, Subject Recruitment and Dealing with Slow Enrollment, IRB Authority and Requirements, Ensuring Compliance, Managing Site Performance Metrics, and FDA Regulatory Inspections. Prerequisite: Basic GCP or commensurate experience.

Advanced GCP

This two-day course offers high level application of the topics presented in Basic and Intermediate GCP. Topics are reinforced with multiple exercises and case studies. Specific topics include: Incorporating Principles of ICH into Clinical Research Practice, Regulatory Q&A: GCP Considerations, Managing the Impact of Electronic Systems in Clinical Trials, Quality Management Systems, Financial Accountability in Clinical Trial Management, Advanced Safety Reporting, Safety Monitoring. Prerequisite: Basic & Intermediate GCP or commensurate experience.

GCP Medical Device Training

This two-day course offers basic GCP principles with a specific emphasis on devices. It covers the topics of Introduction to Good Clinical Practice, Good Science, Investigational Product Development, Clinical Research Team Roles and Responsibilities, Regulatory Documents, Principles of Informed Consent, Process of Informed Consent, Clinical Trials Preparation, Sponsor Visits, AE Analysis & Reporting, The FDA Bioresearch Monitoring Program and Practical Applications of GCP.

Clinical Trial Monitoring

This one-day course covers the essential topics required to effectively provide monitoring oversight of clinical trials. Topics include roles & responsibilities, sponsor oversight, essential documents, monitoring informed consent, source document verification and query resolution, product accountability, writing monitoring reports, clinical trial challenges, and inspection readiness.

Project Management for Clinical Trials

This two-day course offers six modules detailing the project management cycle for clinical research trials. Topics include an introduction to project management, the project plan, human factors & project teams, project tracking & control, budgeting & accounting, close-out & lessons.

1-Day Training Courses

Courses are presented in-person at your location at a time convenient to you. A member of the MedTrials Training Team will contact you to further refine course content based on the needs of you and your team. All participants are eligible for "Certificates of Participation" and accreditation, provided full participation from participants and completion of course evaluation. Courses can be split, combined and/or developed into ½-day or 2-day training events. Continuing Nursing Education (CNE) credits are available with 60 days advance notice.

Good Clinical Practice

This one-day course provides an overview of clinical research practice from regulations to the varying obligations of the IRB, sponsors and investigators. Special emphasis is focused on safety reporting requirements for clinical trial management and the protection of human subjects.

GCP & Clinical Trial Coordination

This one-day course offers an insight into key members of the clinical research team and their respective responsibilities. It describes the purpose of regulatory documents, the process of informed consent, reporting requirements for adverse events and the different types of monitoring visits.

Investigator GCP Training

This one-day course offers GCP training geared for the investigator. It offers a regulatory review and update, clinical trial supervision and fraud prevention.

Investigator Initiated Trials

This one-day course offers a general overview of the obligations of a principal investigator and the obligations of a sponsor in the conduct of pharmaceutical and device research as required by US Code of Federal Regulations.

Focus on CRFs: Good Documentation Practices

This one-day course offers a good overview of what good documentation practices are and effective tools used to ensure protocol compliance. It also covers steps involved in query resolution and best practices for prevention.

Regulatory Document Management

This program covers the essential regulatory document requirements before, during and at the conclusion of a clinical trial. The roles and responsibilities in managing regulatory documents are reviewed along with strategies to effectively handle the most common challenges and problems in regulatory document management.

Monitoring Essentials

This one-day course covers the essential topics required to effectively provide monitoring oversight of clinical trials. Topics include roles & responsibilities, sponsor oversight, essential documents, source document verification and query resolution, and writing monitoring reports.

½ Day Training Courses

Courses are presented in-person at your location at a time convenient to you. A member of the MedTrials Training Team will contact you to further refine course content based on the needs of you and your team. All participants are eligible for "Certificates of Participation" and accreditation, provided full participation from participants and completion of course evaluation. Courses can be split, combined and/or developed into 1-day or 2-day training events. Continuing Nursing Education (CNE) credits are available with 60 days advance notice.

Basic GCP

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Certified Clinical Research Coordinator (CCRC) Exam prep Course

This is a preparatory course for the CCRC certification exam hosted by The Association of Clinical Research Professionals (ACRP). Topics covered include: Introduction to GCP, Investigational Product Development, Clinical Research Team Roles and Responsibilities, Regulatory Documents and Clinical Trial Management, Principles of Informed Consent, Sponsor Visits, AE Analysis and Reporting, and Practical Applications of GCP. (Note: This prep course is not affiliated with ACRP and/or their affiliates. CCRC exam content is the sole property of ACRP. Participation in this course does not guarantee successful completion of CCRC exam.)

Compliance Management

The clinical research environment is changing and compliance management is becoming more important than ever. Trial monitoring responsibilities extend to both sponsors, investigators and research nurses, and recent budget cuts and increased pressure to start studies faster are some of the factors that play a role in the increasing concern over compliance. This program will highlight areas of greatest concern and provide opportunity for interactive problem solving targeted toward managing challenges faced by researchers at the investigative site to ensure compliance in order to best protect the clinical research subjects and data integrity.

Compliance, Trends, and Recent News

This course offers a review of managing identifying and managing clinical research compliance at the investigator and sponsor levels. Course content also includes a review of recent BIMO inspections and findings, a review of industry trends, and a look at the most recent draft guidance and changes in US Federal Regulations as they impact clinical research practices.

CRA Roles & Responsibilities: Trial Initiation

This module includes a basic overview of initiation visits as well as preparing for an initiation visit, initiation checklists, ensuring compliance with investigator responsibilities, reviewing the protocol and CRFs, checking facilities, equipment, verifying anticipated enrollment and checking supplies and fees.

CRA Roles & Responsibilities: Interim Monitoring

This module includes a basic overview of monitoring visits including preparing for the visit, reviewing study progress, CRF review, source document verification, visit reports and tools and tracking systems.

½ Day Training Courses – continued

CRA Roles & Responsibilities: The Close-Out Visit
This module includes a basic overview of close-out visits including preparing for the visit, final review of study-related items, CRF review and closure, sponsor/investigator obligations and basic report writing.

Electronic Records and Source Documents
This program encompasses the requirements for managing, completing and maintaining electronic records and source documentation when conducting clinical research in the U.S.

FDA Inspection Readiness: Are You Ready?
This four-hour course offers a detailed overview of how to prepare for an FDA inspection. It speaks on the types of BIMO inspections, common inspection findings and their consequences, how to prepare for an FDA inspection and FDA inspection Do's and Don'ts.

Focus on CRFs: Good Documentations Practices
This program encompasses the requirements for managing, completing and maintaining case report forms (CRFs) through the implementation of good documentation practices.

Informed Consent and Investigator Liability
This four-hour course offers an insight into informed consent and the investigator's liability of such. It covers such topics as turning informed consent principles into practice, undue influence and coercion, informed consent don'ts and lessons learned from current events.

Standard Operating Procedures for the Investigative Site
This course includes information on setting up and maintaining SOPs at the investigative site. It includes how to write SOPs that are current with regulatory requirements, how to customize SOPs for your individual needs and how to implement SOPs and get staff buy-in.

Setting Standards for the Investigative Site
An in-depth analysis on setting standards for the investigative site. It includes project management, how to manage site performance problems and how to develop a Quality Assurance program.

Study Subject Recruitment and Retention
A practical review of issues that many clinical trials face in regards to recruitment and retention including common ethical issues found with advertisements and incentives involving special populations and other universal obstacles.

The Art of Training: Transforming Theory into Practice
This module provides an overview of the roles and responsibilities of the trainer in the learning process and techniques to employ to overcome obstacles. It also includes learning the difference between training and teaching, identifying several learning theories and the benefits and limitations of the different training modalities.

1-Hour Training (Live or Webinar)

Courses are available for live presentation or via webinar at a time convenient to you. A member of the MedTrials Training Team will contact you to further refine course content based on the needs of you and your team. All participants are eligible for "Certificates of Participation" and accreditation, provided full participation from participants and completion of course evaluation. Courses can be presented in-person at your location. Courses can be split, combined and/or developed into 1-day or 2-day training events. Continuing Nursing Education (CNE) credits are available with 60 days advance notice.

Advanced Coordinating Techniques

This module offers an advanced overview of clinical trial coordination, with an emphasis on resource utilization, time management and coordinating mechanics.

Advanced Monitoring

Focusing on how auditors review data, this module provides an overview on detecting fraud and fabrication, advanced monitoring techniques and report writing.

Advancing Medical Device Research

This module offers a regulatory review and current perspective on medical device research. Also addressed are medical device challenges ranging from regulatory rigor to subject recruitment and protocol compliance.

Adverse Device Effect Reporting

This module offers a regulatory review on medical device research. Also included are ethics, research and the law, medical device trial challenges, cultural and regulatory challenges in multi-national trials and electronic data capture.

Adverse Experience Data Collection & Reporting

This module offers an overview of adverse events and includes information on AE CRF completion, seriousness vs. severity, causality assessments and coding systems.

AE Analysis and Reporting

This module offers an overview of adverse events and includes information on making an AE diagnosis, AE terminology, anatomy of a serious AE and the who, what, when and how of reporting AEs.

Audit Principles and Practice

This module offers an overview of FDA audits. It includes an overview of the FDA Bioresearch Monitoring Program, types of FDA inspections, inspection reports and classifications, common FDA audit findings and the investigator disqualification process.

Auditing Techniques

This module offers an in-depth review on auditing techniques. It includes information on logistics & planning, tools & trackers, audit methods, interviewing strategies, conducting summary meetings and how to report findings.

Building Study Budgets

This module offers a basic overview of study budgets including identification of budget items, estimating per-patient costs and activity based training.

1-Hour Training - continued

Burnout Prevention & Stress Management
This module is designed to help define and alleviate burnout. It includes information on burnout, what causes it, who is at risk for burnout and methods in treating and preventing burnout.

Challenges in Conducting Medical Device Research
This module is designed to help identify three challenges found specifically in medical device trials as well as discuss possible resolutions to these challenges.

Clinical Research Team Roles and Responsibilities (Drugs & Devices)
This module discusses the roles and responsibilities of individuals involved in the clinical research process for device trials including: clinical investigator, research site personnel, investigator as the sponsor, CROs, Quality Assurance personnel and regulatory authorities.

Clinical Study Design Considerations
This module contains information on clinical study designs. It includes information on what constitutes a good clinical study, elements of a protocol, protocol modifications and implications of an intent-to-treat analysis.

Clinical Study Execution: CROs
This module offers a basic overview of CROs and includes transfer of obligations to CROs as well as selecting and managing CROs.

Clinical Trial Execution
This module discusses the basics of clinical trial execution and includes clinical research SOPs, documentation, investigational product accountability, confidentiality of records and record storage.

Clinical Trial Management Activities
From a clinical trial management perspective, this module offers information on clinical laboratories, regulatory files, investigational product accountability and site management, communication and documentation.

Clinical Trials Preparation
This module discusses preparing for a clinical trial. It includes topics on protocol development, clinical supplies, source documents, CRFs, financial disclosure and Form FDA 1572.

Closeout Visits
This module includes a basic overview on closeout visits as well as clinical supplies and files, record retention, report obligations and closeout visit checklists.

Common Deficiencies and FAQs for FDA Audits
This module gives a broad range of deficiencies found in FDA audits (informed consent, protocol non-adherence, inadequate/inaccurate records, inadequate product accountability) as well as answers many Frequently Asked Questions.

1-Hour Training - continued

Conducting Monitoring Visits
This module offers information on conducting monitoring visits as well as how to set up data tracking sheets, scheduling and preparing for the monitoring visit, reviewing study progress and CRFs, verifying source document data and how to monitor efficiently, timing and travel tips.

Conducting Clinical Research in a Changing Global and Regulatory Environment
This module offers a regulatory overview and historical perspective of US regulations and laws.

Conducting Quality Clinical Trials: Ensuring Success Through Team Effort
This module offers information on how to conduct a successful clinical trial through the inner workings of various individuals involved in clinical trials.

Controlling Bias
This module offers an overview of bias in clinical research. It includes such topics as types of bias, confounding, randomization, selecting qualified subjects, blinding and adherence issues.

CRA Survival Techniques
This module offers an informative course for CRAs on how to survive their tough job. It includes office organization, time management, stress management, career management and travel savvy.

Dealing with Slow Enrollment
This two hour module is an informative module on how to deal with slow clinical trial enrollment. It describes the pitfalls of slow enrollment, identifies the stumbling blocks and challenges to subject enrollment and discusses faster, easier strategies for enrollment and subject retention.

Designing Protocols in Medical Device Trials
This module contains an overview of protocol design for medical device trials and includes general principles for clinical study design, development of the protocol and definitions of design groups.

Developing SOPs
This module offers information on how to develop SOPs from planning stages through implementation. It includes how to comply with Title 21 CFR, meeting ICH guidelines, how to comply with individual institutional policies and procedures and SOP implementation.

Developing the Study
This module offers an overview of how to develop a study from initial design through blinding. It includes how to design the ideal clinical study, groups & controls, bias, randomization, confounding, sample sizes, statistical power and blinding.

Device Dynamics: Successful Management of the Medical Device Trial
This module offers information on how to successfully manage a medical device trial. It includes a GCP and regulatory review, pharmaceutical research vs. medical device research, challenges in medical device trials, common regulatory deficiencies found in medical device trials, future trends and informative exercises.

Drug Development Process
This module offers a basic overview of the drug development process from conception through application for marketing. It offers a GCP as well as historical and regulatory review of clinical research and the phases of the drug development process.

1-Hour Training - continued

Effective Communication
This module offers tips on effective communication and conflict resolution.

Electronic Data Capture
This module offers a full review of electronic data capture. It includes information on how it relates to 21 CFR 11, electronic data management, electronic signatures, record retention requirements and auditing EDC systems.

Elements of Study Design
This module offers an overview of study design and includes information on testing a hypothesis, statistical errors, sample sizes and control groups.

Ethics Review and the Protection of Human Subjects
This module offers a basic ethics review in the protection of human subjects. It includes the role of the IRB/IEC, applying for IRB review and approval, communication and reports, record keeping and principles of informed consent.

FDA Inspection Principles and Practice
This module offers information on FDA audit principles. It includes information on the FDA Bioresearch Monitoring Program, types of FDA inspections, common audit findings, how to prepare a site for an FDA audit, how to respond to warning letters and how to set up an FDA audit plan.

FDA Bioresearch Monitoring Program
This module offers an overview of the FDA Bioresearch Monitoring Program and includes types of inspections, inspection reports and classifications, common inspection findings and the investigator disqualification process.

Financial Disclosure
This module offers an overview of financial disclosure and how it relates to clinical research. It offers information on 21 CFR Part 54, the FDA's perspective and the responsibilities of sponsors and investigators.

GCP and Coordinating Medical Device Trials
This module contains information on the coordination of medical device trials. It includes information in investigational device exemption, off-label and humanitarian use of devices, medical device trial challenges and adverse device effect reporting.

GCP and Investigative Site Responsibilities
Geared toward the investigative site personnel, this module offers a review of ethics in research, protection of vulnerable populations, principles and elements of informed consent, financial disclosure, regulatory documents and device accountability.

GCP Compliance
This module offers a basic overview of GCP and includes information on sponsor responsibilities, informed consent, financial disclosure, delegation of authority, device accountability and FDA audits at investigational sites.

1-Hour Training - continued

GCP and the Protection of Human Subjects
This course offers a review of GCP and how they relate to the protection of human subjects. It includes information on regulatory documents, drug accountability, ethics in clinical research, protection of vulnerable populations, principles and elements of informed consent as well as financial disclosure.

GCP Update
This course offers a review of recent BIMO inspections and findings, a review of industry trends, and a look at the most recent draft guidance and changes in US Federal Regulations as they impact clinical research practices.

Good Clinical Practices Applications (Devices)
This module offers a practical look at GCP and includes information on the clinical research team, regulatory documents, device accountability and common FDA audit findings.

Good Clinical Practices Applications (Drugs)
This module offers a practical look at GCP and includes information on the clinical research team, regulatory documents, drug accountability and common FDA audit findings.

Implementing SOPs
This module offers practical advice on the implementation of SOPs and how to get management and staff buy-in for the new procedures as well as training techniques and the importance of SOP documentation.

Industry Trends and the Future of Clinical Research
This module offers an up-to-date review of current monitoring issues and recent press, R&D spending, pipelines, globalization of clinical research and technology.

Informed Consent
This module offers a basic overview of the informed consent process and includes principles and elements of informed consent, writing the consent document and administering informed consent.

Informed Consent: Beyond the Basics
This one-hour module offers an advanced overview of informed consent and includes challenges such as children in research, non-native language speaking subjects, incapacitated subjects, pregnancy, re-consenting and compensation for participation.

Initiation Visit
This module includes a basic overview of initiation visits as well as preparing for an initiation visit, initiation checklists, ensuring compliance with investigator responsibilities, reviewing the protocol and CRFs, checking facilities, equipment, verifying anticipated enrollment and checking supplies and fees.

International Studies (Device)
This module offers an overview of international research studies and includes international regulatory agencies and laws and US vs. European approval processes.

Interpreting the Results
This module offers an overview of how to interpret study results. It includes information on Alpha and P value, standard deviation, standard error and conclusions following the data.

1-Hour Training - continued

Introduction to Clinical Research
As an introductory course for clinical research, this course offers information on historical and regulatory perspectives, GCP, the drug and device development processes and industry vs. NIH sponsored trials.

Introduction of Learning Theory
This module offers information on how and why adults learn through various methods.

Investigational Product Accountability (Devices)
This module contains information on investigational product accountability for devices and includes product accountability, storage and handling, randomization/preparation/dispensation, reconciliation and return/disposition.

Investigational Product Accountability (Drugs)
This module contains information on investigational product accountability for drugs and includes product accountability, storage and handling, randomization/preparation/dispensation, reconciliation and return/disposition.

Investigational Product Development Process
This 2-hour module contains information on the investigational product development process. It includes a historical and regulatory perspective, basic GCP and the drug and device development process.

Investigational Product Development Process
This one-hour module contains information the basic regulatory information on being an IRB member from the basic criteria for IRB approval, to research involving special risks, to what makes a good protocol.

Liability and Risk Management in Clinical Research
This one-hour module provides important information on liability and risk management in clinical research. It includes indemnifications and contracting, malpractice vs. misconduct, delegation of authority, research fraud, consequences and an interactive case study.

Investigator Obligations
This one-hour course is geared toward investigators and contains information on their basic responsibilities when conducting clinical research. It includes the importance of the Investigator Agreement, informed consent, AE reporting, protocol adherence, basic responsibilities and the overall investigator commitment.

Investigator Responsibilities – The Basics
This one hour module is geared toward the new investigator and covers such topics as basic responsibilities, basic GCP overview, Form FDA 1572 and its implications, investigator commitments, ensuring compliance and ensuring study quality and integrity.

Letter Writing Do's and Don'ts
This one-hour course provides valuable information on the importance of good business letter writing skills.

1-Hour Training - continued

Managing Protocol Deviations
This one-hour module offers information on how to manage protocol deviations and includes information on deviations vs. violations, most common protocol deviations and how to manage protocol deviations.

Managing Site Performance Problems
This module offers comprehensive training on how to manage site performance problems. It includes how to analyze performance problems, practical tips on how to handle sites and sponsors and real world case studies.

Medical Device GCP Overview
This one-hour course provides a basic overview of GCP as they relate to medical devices. It includes a historical and global regulatory perspective, a review of the Code of Federal Regulations, role of the FDA, sponsor and investigator obligations.

Managing Your Monitor
This one-hour course provides an overview of the roles and responsibilities of the Monitor/CRA. It includes tips on how to identify ways to meet and exceed the Monitor's expectations and how to deal with challenging monitoring situations.

Medical Device Regulatory Review
This module offers a regulatory review as it relates to medical device research. It includes historical & global perspectives, a review of the Code of Federal Regulations, International Conference on Harmonization (ICH) Consolidated Guidance, comparison of ICH and U.S. CFR, current regulatory options for medical device development and common regulatory terminology.

Meeting the Challenges of Implementing SOPs for Clinical Research
This one-hour module offers an understanding of how to meet challenges faced with implementing SOPs for clinical research. It includes information on how to get management and staff buy-in to new procedures, training techniques and the importance of documentation.

Monitoring Applications
This module contains information on essential information on monitoring. It includes a regulatory document review, CRF review, document verification and fraud detection.

Monitoring Essentials
This module focuses on the basic essentials for monitors: purpose, preparation, conduct and reports.

Monitoring for GCP Compliance
This module offers an overview of monitoring for GCP compliance. It includes a clinical research team overview, regulatory document management and clinical trial material overview.

Monitoring Report Writing
This module focuses on the basics of writing a monitoring report. It includes topics such as purpose of monitoring reports, format of the report, content of the report and the entire report writing process.

Monitoring Visits
This module includes a basic overview of monitoring visits including preparing for the visit, reviewing study progress, CRF review, source document verification, visit reports and tools and tracking systems.

1-Hour Training - continued

Patient Recruitment
This module offers strategies for successful patient recruitment. It includes rules for recruitment, making the most of the local media, challenges in recruitment, techniques and confidentiality.

Pharmacovigilance Overview
This module offers and overview of pharmacovigilance. It contains information on Volume 9A, ICH Consolidated Guidance, regulations governing AE reporting, pharmacoepidemiology and post-marketing surveillance.

Practical Applications of GCP I
This module contains multiple real world examples and class exercises with GCP in mind.

Practical Applications of GCP II
As a continuation of Practical Applications of GCP I, this module offers a basic review of GCP, then reviews real world examples and class exercises.

Preparation for Medical Device Trials
This module includes an overview for preparing for medical device trials. Also included are protocol development, clinical supplies, CRFs, source documents, regulatory documents, responsibilities of the investigator and financial disclosure.

Pre-Study Visits
This module includes a basic overview of pre-study visits including evaluating an investigator's experience, qualifications and capabilities, evaluating investigator's staff and facilities, evaluating interest and availability and a pre-study checklist.

Principles of Documentation for Field Monitors
This module includes basic documentation principles for field monitors and includes information on effective writing of reports and letters, how to present data and the Who, What, When, Where and Why of monitoring reports.

Process of Investigator Selection
This module covers the entire process of selecting investigators for research studies. It includes what makes an ideal investigator, resources for potential investigators, evaluating experience and qualifications, the importance of timing for finding qualified investigators and how they relate to the remainder of the industry and CROs.

Protocol Design
This module offers an overview of protocol design and includes information on topics such as general principals of clinical study design, development of the protocol and design groups defined.

Protocol Non-Compliance
This module offers an opportunity for participants to be able to identify potential risks to subjects due to protocol non-compliance as well as list possible strategies that can be implemented in order to minimize subject risk due to protocol non-compliance.

Query Management
This module offers an overview of query management and includes topics that include the data management process, query resolution strategies and obligations for queries from sites and sponsors.

1-Hour Training - continued

Query Generation and Management
This presentation covers the life of a query from origination through the flow of how they are managed. Strategies to effectively minimize queries are reviewed and highlighted.

Query Resolution
This module offers an overview of query resolution by defining the query process, describing query resolution by site personnel and discussing the monitor's role in the query resolution process.

Queries: Make Them Stop!
A review of the types of queries, their importance to sponsor and data management companies and strategies that a coordinator can do to ensure that a query is resolved in an appropriate and timely manner.

Recruiting Strategies and Hazards
This module offers strategies for successful patient recruitment and reviews potential hazards. It includes rules for recruitment, making the most of the local media, challenges in recruitment, techniques and confidentiality.

Recruitment and Retention
This module covers barriers to clinical research subject recruitment and retention as well as how to create effective recruitment and retention plans.

Research from the Subject's Perspective
This module discuss society's misconceptions toward clinical research, reasons that subjects choose to participate, three key aspects of subject participation in clinical research, and several tips for culturally competent care.

Research Fundamentals
This one-hour session cover the basics of clinical research and includes an introduction to the scientific method, differentiating between medicine and research and investigational plan vs. a protocol.

Safety Reporting Mechanics
This module offers an overview of the mechanics of safety reporting. It includes the who, what, when and how of reporting AEs, expedited reporting, routing and annual reporting.

Special Considerations: Customizing SOPs
This module offers in-depth information on how to customize SOPs. It includes navigating your way through SOPs in a changing regulatory environment, evaluating current SOPs and deciding which ones are needed and when and how to update SOPs.

Sponsor Visits
This module includes a basic overview of all forms of sponsor visits including pre-study, initiation, monitoring and close-out.

Study Management Guidelines and Techniques
This module offers tips on study management guidelines and visits. It includes pre-study, initiation, monitoring and close-out visits as well as coordinating strategies for successful trials.

1-Hour Training - continued

Supplemental Study Specific Documents
This module offers information on specific regulatory documents required for clinical research. It includes informed consent documents, issues in CRF designs and study table, time lines and tools.

Training Options
This module offers information on a variety of training methods. It includes how to choose a pre-packaged course, examining and critiquing training techniques and developing training skills.

Test Article Accountability
This module includes basic information of test article accountability and includes product accountability, storage and handling, randomization, preparation and dispensation, reconciliation, return and disposition.

Transition Planning: Don't Let Turnover Threaten Your Project
This presentation is designed to address prospective strategies that can be taken by the project team to ensure continuity and timely transition during a key staff change. Whether it is a CRC or CRA who is leaving the project, active steps can and should be taken. Researchers need to include turnover in their risk management plans. A working model will be presented with recommended transition tools. Knowing how to effectively manage through staff transition can reduce delays, prevent non-compliance, and promote strong working relationships on a go forward basis for both the site and sponsor personnel.

The CRA's Role in Human Subject Protection
This module includes information on how research personnel can and need to protect the rights and welfare of the subject's enrolled in clinical trials.

Vendor Management
This module offers a basic overview of incorporating deliverables, metrics and deadlines into vendor contracts to ensure quality. It includes how to adequately articulate quality expectations, clinical vendor escalation plans, and defining expectations for QC/QA activities.

What to Measure
This module offers a basic overview of variables in clinical research. It includes the topics of primary outcome variable, nature of the variable and whether or not the variable can be measured.

Writing for Science
This module offers an overview of writing for science and includes an introduction to the scientific method, valid scientific method, investigational plan vs. the protocol, putting it down on paper and tips to improve your writing.

Study Portal

MedTrials CORE™ is a secure, interactive online environment designed to provide shared learning and facilitate cross-functional collaboration and clinical trial support. It will increase the efficiency and execution of your clinical trial by providing specific clinical trial elements such as:

- Protocol/Amendment(s) and quick reference links
- Study-specific templates and forms
- Regulatory document share portal
- Interactive study-specific training modules with certificates of completion
- Video tutorials on study-specific tasks such as case report form completion, data/imaging submissions, product administration, etc.
- News and announcements
- Calendar for important study time points/events
- Study-specific evaluation tools
- Other helpful information

Online interaction through CORE™ improves consistency and cohesiveness across study personnel and enables your study team to share metrics and ideas to help improve the overall clinical trial process. CORE™ features online chat rooms, interactive FAQ pages, question and answer forums, and other unique tools that allow the global sharing of information.

Site training, consistency and interpretation of information, availability of resources, and site turnover are all major challenges for clinical trials. CORE™ provides a secure online environment where site personnel can access and share important study information through an interactive and well-defined experience, and can reduce inconsistencies commonly seen across sites while enhancing the opportunity for learning. In addition, CORE™ can be utilized to provide new site personnel with study and industry-specific training and information, gather helpful tips and suggestions for other project members, and view the history of the clinical study and documents previously shared by their site, all in one place.

Flexibility and adaptability are a must to effectively manage and execute a clinical trial. Any of the features, materials, content, and design elements can be modified as required or needed. Often times, these changes occur during crucial study time points such as study-startup, query deadlines, and study closure. CORE™ adapts through the life-cycle of a study to provide team members with current and relevant information and resources.

Options for MedTrials CORE™ Study Portal

Basic portal

- Unlimited users
- 20 general documents
- Q&A forum
- Study announcements
- Quarterly newsletters posted
- Study-specific training modules
  - ✓ Real-time tracking of progress and completion
  - ✓ Automatic generation and distribution of Certificates of Completion

Premium portal

- Custom colors and portal design
- Custom use of logo and project graphics
- 200 general documents
- Regulatory Document Upload Module
- Quarterly design of multimedia newsletter
- Q&A forum
- Study Announcements
  - ✓ Study-specific training modules
  - ✓ Real-time tracking of progress and completion
  - ✓ Automatic generation and distribution of Certificates of Completion

For more information, visit https://core.medtrials.com or for online demonstration of a CORE™ study portal, please contact the CORE™ team at core@medtrials.com or call 214-630-0288.

Fast On-Boarding and Continuing Education Solutions

Consistency is crucial when training new employees to internal processes. Providing each individual with access to the most relevant and updated information reduces the risk of mistakes and provides each individual with the opportunity to quickly become an effective employee. MedTrials On-boarding solution takes the latest in professional clinical research training and combines it with your site-specific training materials and resources into one seamless online package.

New employees complete the online, self-paced on-boarding training courses. Managers track progress and completion in real-time. Documentation is generated and automatically distributed and stored. Employees can refer back to materials at any time, as needed. From small to large organizations, MedTrials On-boarding solution provides consistent and effective training and gives employees easy access to the resources they need in order to be successful the first time.

- Standard package includes MedTrials' Industry-leading training courses for new clinical research professionals *
- 24/7 access to your own secure, Virtual Library **
  - ✓ Access to site-specific templates and other internal resources
  - ✓ Access and storage of training documentation
  - ✓ Standard Operating Procedures review and sign-off
- Custom production **
  - ✓ Interactive, online training courses of your internal processes
  - ✓ Video and audio tutorials demonstrating use of internal resources

* MedTrials' Industry-leading training courses for new clinical research professionals include:

- Good Clinical Practices
- Human Subject Protection
- Informed Consent development, approval and execution
- Roles and Responsibilities
- Essential Document and Records Management
- Investigator Oversight
- Preparing for Audits and Inspections

** Additional fees may apply

For more information, visit https://core.medtrials.com or contact the CORE™ team at core@medtrials.com or call 214-630-0288.