imarc
UNIVERSITY
CLINICAL RESEARCH EDUCATION

COURSE CATALOG

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CLINICAL RESEARCH EDUCATION

CLINICAL RESEARCH TRAINING
On Your Own Time

IMARC is a leading contract research organization that assists researchers with obtaining the approvals necessary to bring the latest medical devices, technology or pharmaceutical drugs to those who need them most.

We provide cost-effective monitoring, auditing, training and consulting services. Through IMARC University, a series of online training courses for clinical research professionals, **you can now access this training when it's most convenient for you.**

Because our staff frequently spends time at clinical research sites, we relied upon our own extensive experiences and insights in developing each course. This course catalog provides an overview of the material covered in our role-based training courses, course packages and individual courses.

We invite you to browse these course descriptions as you decide what type of training is right for you or your team.

Please note that our course catalog may change as we develop additional courses. For the most updated listing of our course offerings, visit imarcuniversity.com.

If you have questions, feel free to contact us.

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ROLE-BASED TRAINING

1 ADVANCED MONITOR PACKAGE

FOR:

Experienced monitors looking to expand their knowledge and skills.

OBJECTIVES:

Apply the quality assurance techniques of auditors to monitoring. List six core critical thinking skills and identify active processes for applying critical thinking skills in research studies. Understand risk-based monitoring approaches and best practices for developing plans. Explain approaches for effectively dealing with challenging research sites to maintain compliance.

COURSES:

a. Monitoring with an Auditing Perspective
b. Critical Thinking in Clinical Research
c. Risk-Based Monitoring (RBM) Overview
d. Developing a RBM Plan
e. Adverse Event Reporting and Classification
f. Dealing With Difficult Sites

2 PROJECT MANAGER PACKAGE

FOR:

New clinical research Project Managers or those without formal training looking to review important concepts in running compliant studies and demonstrate understanding.

OBJECTIVES:

Compare and contrast the key roles in a research study including the Project Manager, Monitor, Investigator, and Research Coordinator.

COURSES:

a. Project Manager Overview
b. Monitor Overview
c. PI Overview
d. RC Overview
e. The FAIR Shake Method
f. FDA Inspectional Findings
g. Maintaining the Sponsor TMF
h. Critical Thinking in Clinical Research
i. Dealing With Difficult Sites
j. RBM Overview
k. Developing a RBM Plan
l. Adverse Event Reporting & Classification

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ROLE-BASED TRAINING

3

RESEARCH COORDINATOR PACKAGE

FOR:

New research coordinators and those who need to review the fundamentals of clinical research regulations.

OBJECTIVES:

Introduce new or aspiring research coordinators to their roles and responsibilities within a clinical trial and provide a thorough understanding of the regulations they rely on to perform their duties. Understand how to protect research subjects and how and when to report adverse events.

COURSES:

a. Research Coordinator Overview

b. Foundation Package

c. Adverse Event Classification and Reporting

4

MONITOR PACKAGE

FOR:

New monitors and those who need to review the fundamentals of clinical research regulations

OBJECTIVES:

Provide an understanding of clinical research procedures and requirements that is based in regulations. Help monitors prioritize tasks during site visits and help the trial progress while off site. Understand what FDA inspectors need to know and be able to provide them with information as requested. Gain the confidence to answer questions or challenges regarding research procedures.

COURSES:

a. Monitoring Overview

b. Foundation Package

c. Monitoring 101 Package

d. Monitoring 102 Package

ROLE-BASED TRAINING

5

PRINCIPAL INVESTIGATOR PACKAGE

FOR:

New and experienced Investigators who need training on their research responsibilities. The Foundation Package is included to provide a solid knowledge base for conducting clinical research with human subjects.

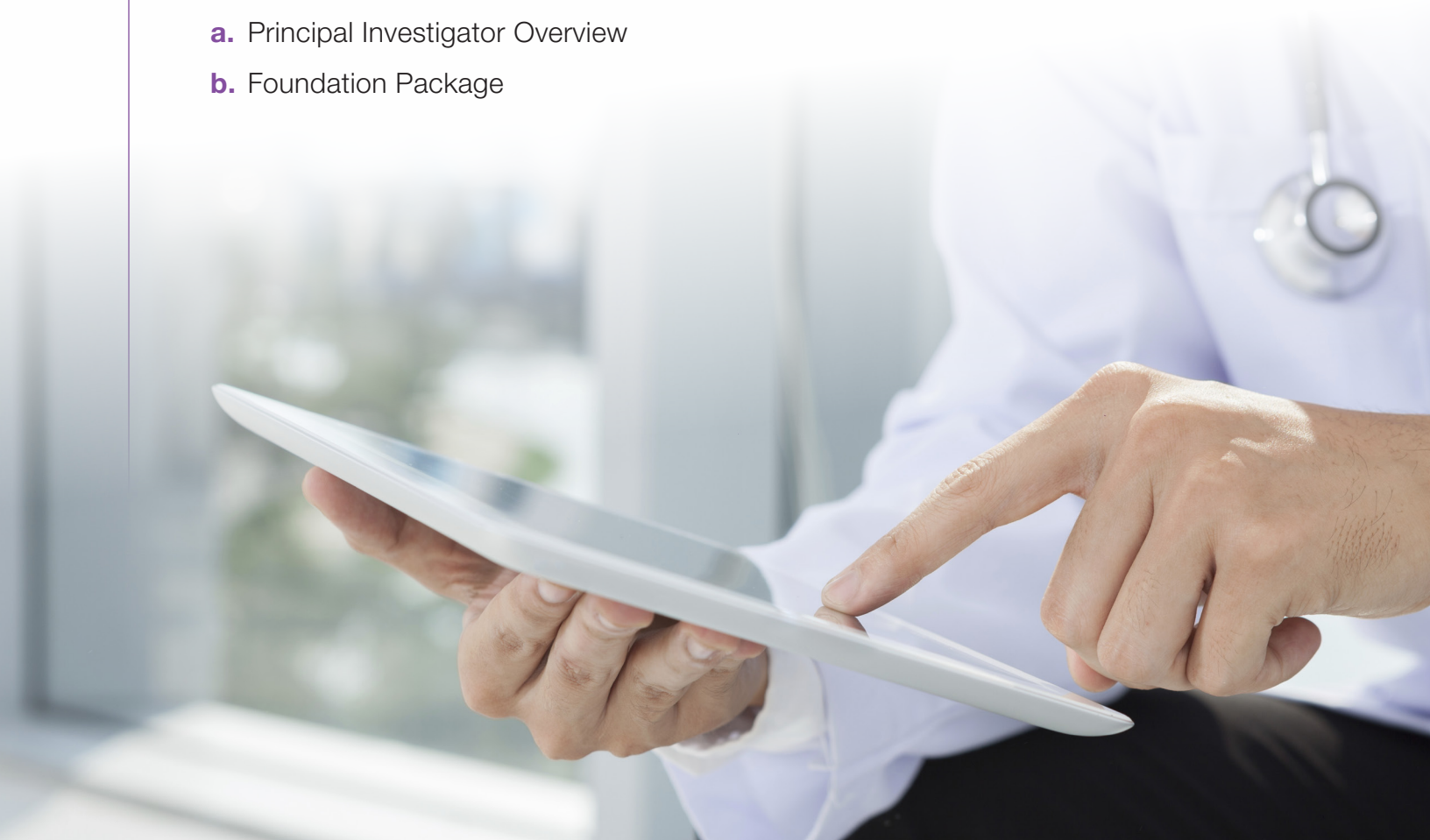
OBJECTIVES:

Learners will be able to describe the responsibilities of a principal investigator, understand the requirements they must follow when conducting a clinical study, understand how responsibilities may be delegated to other study personnel with proper oversight, and recall common warning letter findings. The Foundation Package includes two introductory courses on the FDA regulations, a good clinical practice course with an overview of the history of clinical research, a course in human subjects protection, and our signature FAIR Shake(TM) technique, which teaches the learner to take an otherwise complicated maze of requirements and break them down into four simple areas that can be applied to solving clinical research questions.

COURSES:

a. Principal Investigator Overview

b. Foundation Package



TRAINING PACKAGES

1

FOUNDATION PACKAGE

FOR:

Sponsor organizations and their project managers, sales professionals, research coordinators, monitors and anyone else involved in the clinical research process

OBJECTIVES:

Provide a solid knowledge base for conducting clinical research with human subjects. Includes two introductory courses on the FDA regulations. One covers 21 CFR Parts 312 and 812, and the other covers 21 CFR Parts 50, 56, 54, and 11. Also includes a course comparing 21 CFR Parts 312 and 812, as well as a more in-depth course on Human Subjects Protection as required under Part 50. Additionally, the Foundation Package includes courses on good clinical practice, HIPAA in research, and an overview of the history of clinical research. The Package concludes with a course on our signature FAIR Shake™ technique, which teaches the learner to take an otherwise complicated maze of requirements and break them down into four simple areas that can be applied to solving clinical research questions.

COURSES:

a. Introduction to the U.S. FDA Regulations
  - **i.** Part I: 21 CFR Parts 312 and 812
  - **ii:** Part II: 21 CFR Parts 50, 56, 54, and 11
  - **iii.** Comparing 21 CFR Parts 312 and 812

b. Introduction to Good Clinical Practice

c. Introduction to HIPAA/HITECH

d. The History of Clinical Research

e. Human Subjects Protection: Drilling Down 21 CFR Part 50

f. The FAIR Shake™ Method

2

MONITORING 101 PACKAGE

FOR:

New monitors or monitors who need to review regulations

OBJECTIVES:

Provide the learner with an overview of what it means to be a clinical research monitor. Understand the four traditional types of monitoring visits: Site Assessment, Site Initiation, Periodic, and Close-Out. Learn what to do between visits to help a clinical trial progress and remain compliant.

COURSES:

a. Site Assessment Visits
b. Site Initiation Visits
c. Periodic Monitoring Visits
d. Close-Out Visits
e. Site Management

3

MONITORING 102 PACKAGE

FOR:

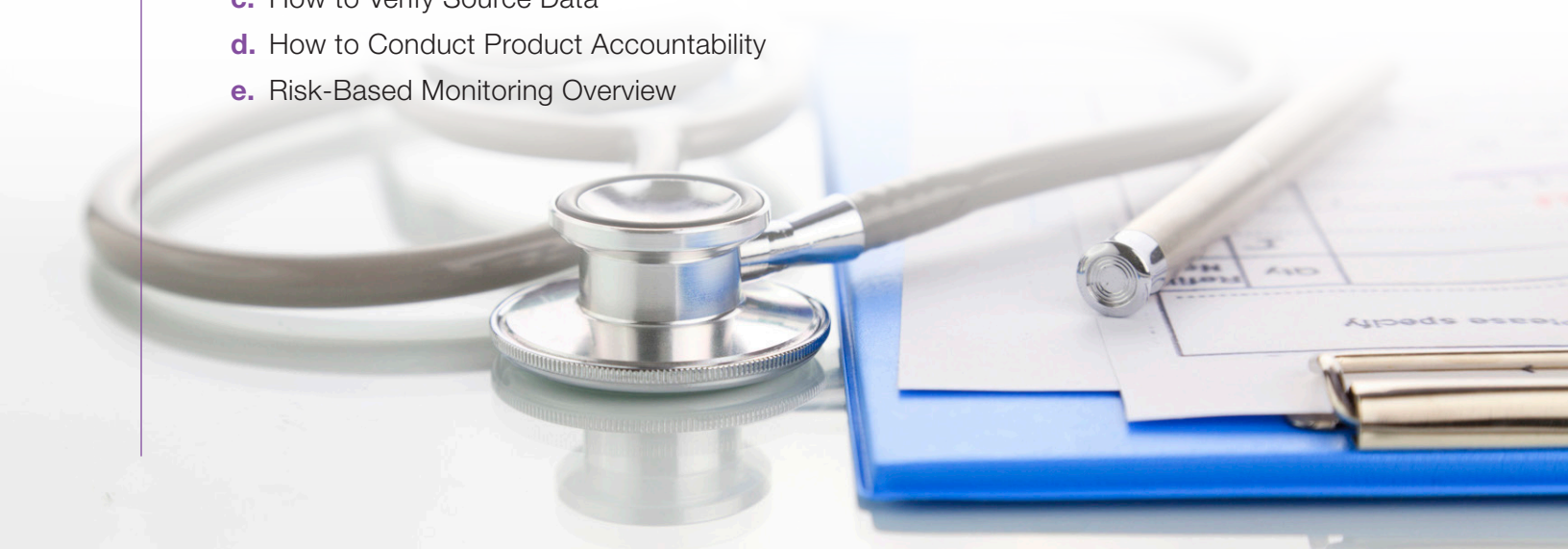
New monitors who have taken Monitoring 101 or experienced monitors who want to dive deeper into the requirements for informed consent, documents review, source data verification and more.

OBJECTIVES:

Increase competency on and off site. Be able to think critically and spot potential errors before they become violations. Learn how to perform key monitoring activities.

COURSES:

a. How to Review Informed Consent
b. How to Review Essential Documents
c. How to Verify Source Data
d. How to Conduct Product Accountability
e. Risk-Based Monitoring Overview



INDIVIDUAL COURSES

I: INTRODUCTION TO U.S. FDA REGULATIONS

This course covers the US FDA Regulations pertaining to research in Title 21 of the Code of Federal Regulations. The parts covered include 312, 812, 50, 54, 56, and 11. This course also includes comparisons between parts 312 and 812 for drug and device regulations.

COURSES:

a. Introduction to U.S. FDA Regulations Part I: 21 CFR Parts 312 and 812
b. Introduction to U.S. FDA Regulations Part II: 21 CFR Parts 50, 56, 54, and 11
c. Comparing 21 CFR Part 312 and 21 CFR Part 812

II: GOOD CLINICAL PRACTICE

This course provides an introduction to the main tenets of good clinical practice as well as a history of clinical research and the importance of research standards. The FAIR Shake Method is included to give learners a tool for applying critical thinking skills to difficult compliance questions.

COURSES:

a. The History of Clinical Research
b. Introduction to Good Clinical Practice
c. The FAIR Shake™ Method

III: HUMAN SUBJECTS PROTECTION

This course examines human subjects protection in more detail, with an in depth look at 21 CFR Part 50 as well as an introduction to the HIPAA and HITECH regulations. Learners will gain a thorough understanding of the important role of informed consent and privacy protection in clinical research.

COURSES:

a. Human Subjects Protection: Drilling Down 21 CFR Part 50
b. Introduction to HIPAA and HITECH

INDIVIDUAL COURSES

IV: FDA INSPECTIONS

This course provides learners with information about why, when, and how FDA inspections of clinical investigation sites and sponsors occur. Learners will gain a detailed understanding of the FDA's compliance program guidance manual, the items assessed by FDA inspectors, and best practices to help research teams prepare for and host inspections.

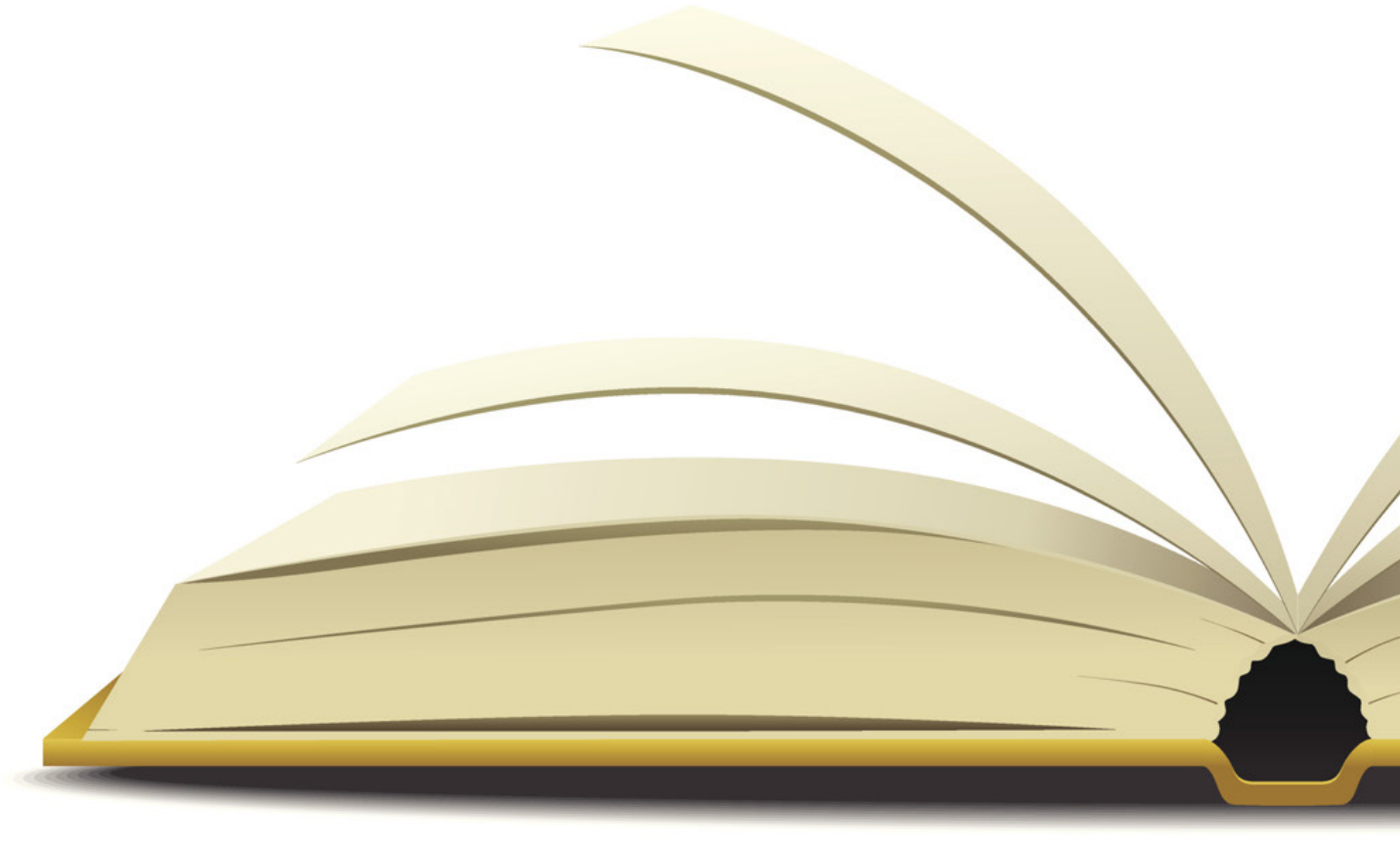
OBJECTIVES:

Learners will understand how to prepare for and host an FDA inspection, comprehend potential inspection outcomes for investigators, describe key topics assessed in the FDA's BIMO Guidelines for Site inspections and connect these with examples of evidence the FDA will review, and understand the guideline as a foundation for quality assurance activities.

COURSES:

a. FDA Inspections 101

b. FDA Inspections 102



COURSE DESCRIPTIONS

DEALING WITH DIFFICULT SITES

This course was designed as an intermediate level course to give learners an understanding of how to deal with challenging clinical trial sites as a sponsor representative. At the conclusion of this course, attendees should be able to identify common challenges that sites experience, develop an overall strategy to deal with a problematic site, and recommend specific resolutions to correct a particular problem and prevent it from recurring.

DEVELOPING A RISK-BASED MONITORING (RBM) PLAN

This course was designed as an advanced level course to give learners a roadmap to creating a monitoring plan based on careful and thorough risk-assessment of the clinical study being conducted. By the end of this course participants will be able to identify clinical study risks, and discuss how these risks may impact the monitoring plan. Learners will be able to describe important considerations for developing a Risk-Based Monitoring Plan, along with being able to verbalize understanding of how to draft a monitoring plan. Lastly, at the conclusion of the course participants will be able to discuss best practices for implementing a risk-based monitoring plan.

CRITICAL THINKING IN CLINICAL RESEARCH

This course was designed as an intermediate level course to give learners an understanding of critical thinking skills and their application to research. At the conclusion of this course learners should be able to define critical thinking, list six core critical thinking skills and identify active processes for applying critical thinking skills.

MONITORING WITH AN AUDITING PERSPECTIVE

This course was designed as an intermediate level course to give learners a perspective of the relationship between monitoring and auditing. This course examines techniques from auditing that can be applied to monitoring. At the conclusion of this course participants should be able to: identify the objective of an FDA Bioresearch Monitoring inspection, describe the differences between monitoring and auditing, and define corrective and preventive action as applied to clinical research. This presentation focuses on teaching monitors what the FDA is looking for when inspecting clinical research entities, and leveraging this information to employ auditing strategies to address site issues.

PROJECT MANAGER OVERVIEW

This course was designed as an introductory level course to give learners an overview of the role and responsibilities of a Project Manager of a clinical study. At the completion of this course learners should be able to: describe the requirements for the Sponsor and Project Manager of the oversight and management of both drug and device studies, describe the responsibilities of a Project Manager throughout the full lifecycle of a clinical investigation, and describe the qualities (inherent and learned) of a Clinical Trial Project Manager.

MAINTAINING THE SPONSOR TMF

This course has been designed as an intermediate level course to give learners insight into maintaining the Sponsor Trial Master File. This course will provide the learner with an understanding of the documents required as well as tips for maintaining a successful Trial Master File. At the conclusion of this course, learners should be able to recall the essential documents to be included in the trial master file (or, TMF), understand how to maintain a successful TMF, and compare the electronic approach to the TMF with traditional paper TMFs.

FDA INSPECTIONAL FINDINGS

This course has been designed as an intermediate level course to familiarize learners with FDA warning letters and the FDA Form 483. In addition, this course will describe best practices to avoid receiving citations or warning letters from FDA. At the completion of this course, learners should be able to demonstrate familiarity with FDA regulations cited in recent Warning Letters, demonstrate familiarity with the structure and language of FDA Warning Letters, understand the purpose of FDA Form 483, describe the best practices to avoid receiving a 483 or FDA Warning Letter.

RESEARCH COORDINATOR OVERVIEW

This course has been designed as an introductory level course to give learners an overview of the role of a clinical research coordinator. Learners will be able to describe the typical activities and responsibilities of a CRC, and understand the requirements they must abide by when conducting a clinical research study.

ADVERSE EVENT CLASSIFICATION AND REPORTING

This course has been designed as an introductory level course to give learners a basic understanding of what adverse events are, and how they are classified and reported. Learners will be able to define serious adverse events, and indicate whether or not they are required to be reported based on whether or not they are considered related, expected, or serious.

MONITORING OVERVIEW

This course has been designed as an introductory level course to give learners an overview of monitoring activities, and how they are performed. Learners will be able to explain why monitoring is performed, recall what a monitoring plan is, and identify the four types of monitoring visits.

SITE ASSESSMENT VISITS

This course has been designed as an intermediate level course to give learners an explanation of the activities that sponsor representatives, including monitors, may be asked to conduct during a site assessment visit. Learners will be able to describe site assessment activities and explain their significance, describe tools and best practices used for Site Assessments, and outline the steps for conducting Site Assessment visits.

SITE INITIATION VISITS

This course has been designed as an intermediate level course to give learners an understanding of how to prepare for and conduct a site initiation visit. Learners will understand how to prepare for a site initiation visit, be able to summarize study training and important items of discussion that should take place, and list documents to be collected during the visit.

PERIODIC MONITORING VISITS

This course has been designed as an intermediate level course to give learners an introduction to conducting periodic monitoring visits. Learners will understand how to plan and prepare for a periodic monitoring visit, describe what takes place during a visit, and comprehend how visit activities are documented.

CLOSE-OUT VISITS

This course has been designed as an intermediate level course to give learners an understanding of how to prepare for and conduct a close-out visit. Learners will understand how to plan and prepare for a close-out visit, describe what takes place during a visit, and comprehend how visit activities are documented.

SITE MANAGEMENT

This course has been designed as an introductory level course to give learners an understanding of the activities a monitor routinely performs during the course of an investigation between monitoring visits. Learners will be able to determine best practices for documenting site communication, manage activities that take place in between monitoring visits such as data retrieval and query resolution, and measure the progress of action items to ensure their resolution.

HOW TO REVIEW INFORMED CONSENT

This course has been designed as an intermediate level course to give learners information regarding how a monitor reviews subject informed consent forms during a monitoring visit to ensure they have been consented properly.

HOW TO VERIFY SOURCE DATA

This course has been designed as an intermediate level course to give learners an explanation of how to verify source data during a monitoring visit. Learners will be able to define Source Data, identify where Source Data can be found, describe tools and best practices used by monitors for Source Data Verification, and develop queries that are clear and objective.

HOW TO REVIEW ESSENTIAL DOCUMENTS

This course has been designed as an intermediate level course to give learners an understanding of how a monitor reviews an investigative site's study files to ensure they are accurate, current, and complete. Learners will be able to identify essential documents, recall how a monitor should document the essential documents review process, and comprehend how a table of notes can be used to review IRB correspondence.

HOW TO CONDUCT PRODUCT ACCOUNTABILITY

This course has been designed as an intermediate level course to give learners an understanding of how a monitor helps to ensure that the investigational products supplied by the Sponsor to an Investigator are accounted for during a clinical research study. Learners will be able to identify product accountability requirements for Investigators, recall items needed to perform product accountability, and recall examples of inadequate accountability that have resulted in FDA warning letters.

RISK-BASED MONITORING OVERVIEW

This course has been designed as an intermediate level course to give learners a basic understanding of risk based monitoring. Learners will be able to define Risk Based Monitoring, list the approaches used in Risk Based Monitoring, and explain a risk-based approach for a hypothetical medical device trial.

INTRODUCTION TO U.S. FDA REGULATIONS PART I: 21 CFR PARTS 312 AND 812

This course has been designed as an introductory level course to give learners an overview of these parts of the Code of Federal Regulations Title 21 that pertain to investigational new drugs and investigational device exemptions. Learners will understand regulation of investigational new drugs and investigational devices by the FDA, and explain the responsibilities of Sponsors and Investigators in Investigational New Drug and Investigational Device Exemption studies.

INTRODUCTION TO U.S. FDA REGULATIONS PART II: 21 CFR PARTS 50, 56, 54, AND 11

This course has been designed as an introductory level course to give learners an overview of these parts of the Code of Federal Regulations Title 21 that apply when conducting an investigational new drug or investigational device exemption clinical research trial. Learners will understand the role of informed consent in ensuring human subject protection, the required elements of and documentation process for informed consent, the requirements for IRB composition, operation and compliance, the goals of disclosing financial interest, and required controls for electronic records and signatures.

COMPARING 21 CFR PART 312 AND 21 CFR PART 812

This course has been designed as an intermediate level course to give learners an understanding of the similarities and differences between these parts of the code of federal regulations related to clinical studies of investigational drugs and devices. Learners will review the key requirements of 21 CFR Parts 312 and 812, identify the primary similarities and differences, and understand the development pathways of new drugs and new devices.

THE HISTORY OF CLINICAL RESEARCH

This course has been designed as an introductory level course to give learners a deeper understanding of the events in history, both good and bad, that helped shape the clinical research industry. Learners will be able to recall significant events in history that influenced clinical research, match significant advances in regulation to what caused them, and explain the continued importance of research regulations.

INTRODUCTION TO GOOD CLINICAL PRACTICE

This course has been designed as an introductory level course on the concept of good clinical practice to give learners information about conducting clinical research in accordance with international guidelines. Learners will be able to define and explain Good Clinical Practice, identify the various guidelines and standards that comprise GCP, and describe the principles of the Belmont Report.

FAIR SHAKE™

This course has been designed as an introductory level course to give learners a tool for answering compliance concerns and questions. Using the acronym F-A-I-R, members of the research team will understand how to determine whether an issue is a true violation of research requirements. Learners will be able to recall the elements of the FAIR Shake Method, apply the method to potential compliance concerns, and understand the importance of supporting recommendations with the FAIR Shake Method.

INTRODUCTION TO HIPAA AND HITECH

This course has been designed as an introductory level course to give learners an overview of Private Health Information and protection of individual confidentiality as governed by HIPAA and HITECH. Learners will be able to describe HIPAA and HITECH legislative acts, list individually identifiable data elements that are protected under HIPAA and HITECH, and explain the impact that HIPAA and HITECH have on clinical research.

HUMAN SUBJECTS PROTECTION: DRILLING DOWN 21 CFR PART 50

This course is designed to provide the learner with an in-depth analysis of the requirements of 21 CFR Part 50 that pertain to informed consent of human subjects.

FDA INSPECTIONS 101

This course has been designed as an introductory level course to give learners information about why, when, and how FDA inspections of clinical investigative sites and Sponsors occur. Learners will be able to find the Bioresearch Monitoring Program (BIMO) inspectional guides, understand how to prepare for an FDA inspection, recall the mechanics of an FDA inspection, and comprehend potential inspection outcomes.

FDA INSPECTIONS 102: WALKING THROUGH THE BIMO INSPECTIONAL GUIDANCE FOR INVESTIGATIVE SITES

This course has been designed as an intermediate level course to give learners a detailed understanding of the FDA's compliance program guidance manual and the items assessed by FDA inspectors. Learners will be able to describe key topics assessed in FDA's BIMO guidance for site inspections, connect key topics with examples of evidence the FDA will review, and understand the guide as a foundation for quality assurance activities.

PRINCIPAL INVESTIGATOR OVERVIEW

This course has been designed as an introductory level course to give learners an overview of the role and responsibilities of a Principal Investigator of a clinical study. Learners will be able to describe the responsibilities of a Principal Investigator, understand the requirements they must follow when conducting a clinical study, understand how responsibilities may be delegated to other study personnel with proper oversight, and recall common warning letter findings.

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