Medical Research Management

The Fundamentals of Clinical Research

Course Objectives & Overview

Learning Objectives

The Fundamentals of Clinical Research is a comprehensive CRA training program that consists of 7 self-paced modules and a 6-day live virtual training session. The objectives of the course are to:

- Identify the GCP monitoring elements of informed consent and human subject protections.
- Develop monitoring strategies to review source documents, identify differences between source types, and assess data quality using the ALCOA-C test.
- Verify adverse events, eligibility and investigational product accountability.
- Discuss corrective actions to resolve common issues regarding consent, source documentation, adverse events, product accountability and regulatory documents.
- Use a monitoring system to perform quality monitoring and generate a work product that allows for oversight.

MRM Monitoring System

Clinical trial monitoring is one of the sponsor's key responsibilities, but inadequate monitoring can be costly and time-consuming, and could even lead to significant compliance issues or FDA warning letters.

Common deficiencies in monitoring include:

- Informed consent not verified for GCP compliance.
- Adverse events not identified or properly reported.
- eCRF data not verified with original source documents.
- Systemic protocol deviations not identified or resolved.

The sponsor demonstrates oversight by reviewing monitoring reports, but this method alone may not identify serious monitor training and performance issues. The MRM Monitoring System teaches monitors to use tools that streamline the GCP compliance process, support the monitoring report, and provide a detailed work product for sponsor review.

Course Overview

The Fundamentals of Clinical Research course includes both self-paced training and a 6-day live virtual session.

During the self-paced training (which must be completed prior to the virtual session), students will be introduced the following concepts:

- What Is Clinical Research?
- Drugs, Biologics, Medical Devices & Combination Products
- ICH Good Clinical Practice Guidelines
- FDA Regulations & Guidelines
- Essential Documents & Clinical Trial Documentation
- Source Document Verification & The Monitoring Process
- Resolving Compliance Issues
- Writing Professional Monitoring Reports

During the first two days of the virtual session, students will review the critical functions of monitoring and participate in interactive drills and group discussions. The remainder of the course will consist of hands-on monitoring exercises. All monitoring exercises are based on real clinical trials and include authentic electronic medical records, symptom diaries, laboratory data and adverse event reports. Students will apply critical thinking skills to identify adverse events, resolve protocol compliance issues, and evaluate the quality of study data.

On the final day of the program, students will complete a hands-on monitoring competency exam that is designed to simulate real-world monitoring challenges. Throughout the course, students will apply systematic, standardized monitoring methods to ensure consistent performance and high-quality documentation.

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Training Agenda

Self-Paced Training

The goal of the Self-Paced Training portion of the course is to provide a solid foundation in Good Clinical Practices and prepare students for hands-on monitoring activities. Training consists of 7 modules:

- **Module 1 –** Introduction to Clinical Research: Good Clinical Practices & FDA Regulations
- **Module 2 –** Human Subject Protections: IRBs, Informed Consent & Financial Disclosure
- **Module 3 –** The Investigator Site: Coordinating a Clinical Trial
- **Module 4 –** Monitoring Method: Responsibilities, Techniques, Critical Thinking & Site Management
- **Module 5 –** Monitoring Essential Documents: The Trial Master File & Investigator Study File
- **Module 6 –** Securing Compliance & Writing Monitoring Reports
- **Module 7 –** Protocol Synopsis & Monitoring Tools (for use during Virtua Session)

Study materials will be provided to students in a digital format. Drills and quizzes can be repeated as many times as needed, but all 7 modules must be completed before the Virtual Session. Drills will be reviewed and discussed on Day 1 of the Virtual Session.

Virtual Session

The Virtual Session is a 6-day live online training program that will give students an opportunity to apply their monitoring knowledge to real-world challenges. Students will identify GCP and protocol compliance issues, document their findings, and brainstorm solutions in an interactive environment. All training materials are based on real clinical trial documents and real issues identified in the field.

On the final day of the Virtual Session, students will complete a comprehensive Monitoring Competency Exam

Virtual training sessions will be conducted via the Zoom online meeting platform, so students will require a computer that supports Zoom's audio and video features. Additional course handouts, PowerPoints, and tools are provided in a download file. The proprietary case studies and competency test will be provided in a real-only format via Google Drive (see access information below).

Google Classroom

Your daily assignments, class schedules and tests will be available through Google Classroom. Access Google Classroom at https://classroom.google.com/. Click the + symbol in the top corner and select "Join Class." We will provide the class code to access.

You will be taken to the FOCR Classroom main screen. On the "Stream" tab, you can see the latest class updates and conversations. Go to the "Classwork" tab for your daily assignments and to-do lists.

The "Classwork" tab also includes links to a custom Google Calendar and to your Google Drive. Class documents can be accessed through the "Shared With Me" link in your Google Drive.

Google Drive

The documents the participants need to complete the assignments are available on Google Drive. Each participant will receive an email invitation to view the folder. After accepting the invitation, access the class files through the "Shared With Me" link in the Google Drive sidebar.

Occasionally, using your internet browser's "back" button may cause some of these folders to disappear. If this should occur, refresh the page. Participants will need a browser that is capable of viewing PDF files.

All participants have shared access to Google Drive, there will assignments provided with attached tools to perform monitoring activities. Everyone will need to work their own monitoring toolkit (excel notebook), sent via the assignment. Once assignment is received, select the 3 vertical dots on the right hand side, select open new window, then select "Open with Google Sheets", select file and then "Save as Google Sheets."

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Training Agenda

Virtual Training Session Agenda

Day One / Monday

Class Introduction

- Learning Objectives
- Access to Case Studies
- Examination Review & Implementation

Assignments & Drills

The assignments and learning drills completed during the Self-Paced Training Modules will be discussed. Students will review the monitoring methods and tools that will be used for the duration of the virtual session.

Day Two / Tuesday

Hormone Replacement Therapy (HRT) Study Initiation

The instructor will review the protocol, visit schedule, and Case Report Form that will be used in subsequent monitoring exercises. Students will participate in an interactive study review. The instructor will also provide an orientation to electronic medical records and source documents.

Hands-On Monitoring Exercise

Participants will monitor the first HRT Study subject case file. This case is designed to reinforce basic monitoring techniques: source document verification, informed consent verification, and adverse event identification. A full review of subject files is estimated to take 4-5 hours.

Day Three / Wednesday

Hands-On Monitoring Exercise

Participants and the instructor will meet to discuss their findings from the first monitoring exercise.

Participants will then monitor the second HRT Study subject case file. This case will involve more complex errors and demand a higher level of critical thinking. Monitoring is estimated to take 4-5 hours, after which there will be a group discussion to compare findings.

Day Four / Thursday

Hands-On Monitoring Exercise

Participants will monitor the third HRT Study subject case file. This challenging case will build on the monitoring skills acquired over the previous two exercises. Monitoring is estimated to take 3-4 hours, and will be followed by a group discussion.

Report Content Review

Participants will review the contents of a typical monitoring report, with a focus on professional written communication.

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Training Agenda

Virtual Training Session Agenda

Day Five / Friday

HRT Study Binder Review

The instructor will review the contents and purpose of essential documents contained in the Investigator Study File.

Hands-On Monitoring Exercise

Students will monitor the HRT Study Binder to identify regulatory issues. The class will discuss strategies to manage document changes, version history and re-consents.

Day Six / Monday

Monitoring Competency and General FDA/GCP Knowledge Exam

The exam has two parts: a general FDA and GCP knowledge test based on the self-paced training, and a hands-on Monitoring Competency Exam. The Competency Exam will involve monitoring a new subject case file and regulatory documents. The exam is estimated to take 3 hours in total and is designed to test the student's ability to identify and mitigate real-world monitoring issues. Students may refer to the HRT Study protocol and CRF completion guidelines during the exam.