LIFE SCIENCE TRAINING INSTITUTE

CRA Training Academy Curriculum

Assessment **Pre-Assessment**

The training is based on core competencies related to quality monitoring of clinical trials. The assessment includes an assessment of facilitation skills that are essential for working with sites effectively. Questions on the pre-assessment are related to critical GCP knowledge base, decision-making skills, and activities related to the role of a clinical research professional.

Module 1 **The Role of the CRA in Managing Clinical Research Sites**

Classroom, full day

The module defines the global guidelines relevant to Good Clinical Practices (GCP) in clinical research trials. Module 1 sets the stage for the remainder of the modules where core Monitoring activities are expanded upon relating to the role of the Monitor to initiate clear expectations related to site management activities. Emphasis is placed on the role of the Monitor in overall site management, including the training of sites and investigator relationship management, setting clear expectations for a study, study site performance management and how the roles and responsibilities of the Monitor impact the whole study team, and ultimately the study outcome.

Module 2 **Overview of Protocols and Monitoring Amendments**

Webinar, 3hrs

This module provides an overview of protocol elements and demonstrates how to use the protocol as a monitoring tool. The importance of a scientifically sound, clear, and detailed protocol are emphasized. The Monitor's obligation to protocol compliance includes taking responsibility for: understanding the protocol, working with their manager to obtain training in order to understand the therapeutic area and investigational product(s), and ensuring that site questions are answered and support clear job expectations. Discussions include how to identify areas where there may be potential problems for site compliance, and how to develop a plan to resolve and prevent these issues. The creation of valuable Monitoring tools is reviewed.

Module 3 **Monitoring A Study**

Webinar, 3hrs

This module includes an overview and purpose of various types of monitoring visits (MVs): Site Qualification Visit, Site Initiation Visit, Interim Monitoring Visit, and Closeout Visits. The importance of following the Monitoring Plan and preparing for each visit is discussed, including remote monitoring activities, and reviewing available data prior to a monitoring visit (e.g., electronic data capture (EDC), data management reports).

Module 4 **Monitoring the Informed Consent & Privacy Statement *(two parts)***

Webinar, 3hrs

This module's is broken into two parts. The focus for these sessions are on the Monitor's role in the monitoring of the informed consent process, including the collection, documentation, and management of informed consents at the site level. A well-managed informed consent process ensures subject understanding, creates reliable audit trails, and reduces the risk of subject withdrawal of consent. A focus of the module is the concept that the review of informed consent must be approached – and monitored – as a process, not a one-time event. In this module, learners review problematic informed consent forms, and review other mock informed consent forms. Attention is paid to the informed consent process and good documentation practice of informed consent, including circumstances involving vulnerable populations.

Practicum **Review Modules 1-4 and Supplemental Activities**

Classroom, full day

Self-Study **Independent Study Assignment**

Begins Week 4, due Week 5

Module 5 **Monitoring and Safety Reporting**

Webinar, 3hrs

Source data review/verification, reporting, and follow-up of adverse effects/events is one of the Monitor's most important responsibilities in the monitoring of clinical trials. Incorrect or inadequate reporting of adverse events can lead to inaccurate labeling, delay market applications, and risk patient safety. This course focus is on the definitions, concepts, timelines, and key criteria for adverse event reporting as noted by FDA and ICH specifically related to the role of the Monitor.

Assessment **Mid-Course Assessment**

Module 6 **Monitoring Investigational Product (IP) Accountability**

Webinar, 3hrs

Regulatory inspections frequently note investigational product (IP) accountability deficiencies, and the Monitor plays a key role in prevention of issues at site related to IP. This module addresses investigational product accountability requirements, including storage, reconciliation, and disposition. Emphasis is placed on documentation requirements, and recent trends in regulatory inspections citing product accountability deficiencies. Monitors are given strategies for proactively identifying errors or deficiencies early in the process, as well as how they can be properly addressed.

Practicum **Review Independent Study and practical application of Modules 4-6**

Module 7 **Source Data Verification & Quality Review *(two parts)***

Classroom, full day

Part 1: At about the half-way point we come together to team build, clarify questions, discuss each modules key concepts and application. Essential documentation requirements before, during and after a study are reviewed per ICH E6 Section 8. Work in groups on case studies that involve compliance issues related to challenges in the areas covered so: 1) Site evaluation and Initiation, 2) Essential Documents, 3) Proactive Protocol Compliance, 4) Informed Consent, and 5) Safety Reporting, using real industry case scenarios to practice identifying and facilitation effective issues management for assigned research sites.

Part 2: Adequate and accurate source documentation is critical to ensuring subject safety, data integrity and regulatory compliance. This module reviews the critical role of the Monitor in verifying data accuracy and integrity. Good documentation practices are expanded upon from, including strategies for identifying all supporting data sources, and strategies for supporting sites to appropriately correct data discrepancies and proactively avoid discrepancies. The module also stresses the importance of reviewing eCRF and any other available data prior to the actual visit, with the goal of identifying potential issues and promoting a more effective and efficient on-site visit. The emphasis is on the role of the Monitor in recognizing the relevance of the source data, as well as key questions to ask throughout the process (i.e., is it an adverse event? Is there a trend with data? Does it indicate compliance with the protocol? Was it obtained by a qualified individual?).

Module 8 **Managing Site Non-compliance: The CRA's Role in Preventing Inspection Findings**

Webinar, 3hrs

This module discusses the importance of quality systems and provides information regarding current data and trends on regulatory audits and inspections. The Monitor's role in responding to audit findings and inspections is applied. Key regulatory findings and trends from various regulatory authorities (i.e. FDA and EMA) are reviewed. Special attention is paid to source data review, and how the Monitor can ensure that local practices are harmonized with ICH GCP and competent authority requirements. The Monitor plays the crucial role of ensuring that follow-up actions are completed in response to audit and inspection findings. This session also focuses on the Monitor's reports as site management tools; the Monitor utilizes the reports to document issues and to describe actions including corrective and preventative actions. This section emphasizes the importance of creating continuity from one report to another, showing the corrective and preventative actions taken, how issues were escalated, and the Monitor's involvement in resolution of the issues.

Module 9 **Rules for Quality Documentation of Monitoring Activities**

Webinar, 3hrs

This module reviews the effect of poor monitoring documentation and emphasizes that the monitoring documentation is both a tool for the documentation of protocol-relevant information, and a critical site management tool for the Monitor. The visit report and other associated documents are documentation tools; it is important to know what to include, what not to include, and how to write effectively to the documentation's audience. Additionally, the writing of a scientific report and associated documents that supports the sponsor monitoring obligations are included throughout the presentation (e.g.., objectively presenting facts to writing protocol deviations).

Self-Study **Independent Study Assignment**

Begins Week 9, due Week 10

Module 10 **Source Data Review & Verification Practicum/Simulation**

Classroom, full day

Module 10 is a practicum that includes a simulation exercise to test the competency of a Monitor and verify if the information is being applied in a simulated environment. Description of the training: monitoring an abbreviated mock study that includes protocol synopsis, Monitoring Plan, ICF, delegation log, and other essential documents for the simulation.

Assessment **Final Course Assessment**