CT08 Clinical Trial Monitoring: Study Monitoring, Documentation and Closure

Approximate study time: 2 hours

Level: Intermediate

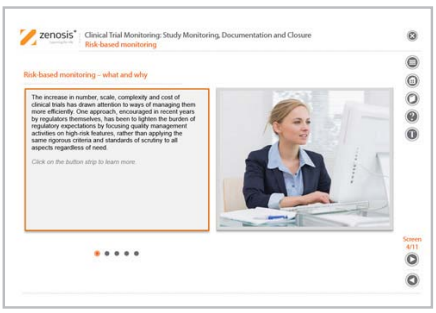
Audience: Compliance, Other

Category: Clinical

Region: USA, Europe, Other

CPD Points: 2

Module outline
- Module overview
- Site monitoring visits
- Data checking
- Close-out visit
- Risk-based monitoring
- Fraud and scientific misconduct
- Assessment



The sponsor of a clinical trial must arrange for it to be monitored throughout its duration to ensure that the rights and wellbeing of subjects are protected, the trial data are accurate, complete and verified from source documents, and the conduct of the trial complies with the study protocol, Good Clinical Practice and regulatory requirements. In this module we describe how a Clinical Research Associate (CRA) monitors an ongoing trial to its conclusion.

Who will benefit from this module?

The module is intended for those involved in clinical research and development, in particular the monitoring of clinical trials, and those who require an understanding of what this entails. It and its companion module CT06 provide a comprehensive introduction to monitoring for new CRAs, or additional training and professional development for those already working in the field. It will also be of value to clinical research coordinators, clinical investigators and other healthcare professionals involved in clinical studies.

Learning objectives

- Describe how to prepare for and carry out regular monitoring visits to investigational sites
- Describe how to review case report forms (CRFs) and verify consistency of data with source documents
- Describe how to close out a trial at a site
- Discuss the concept and implications of risk-based monitoring
- Identify warning signs that raise suspicion of scientific misconduct or fraud

Module outline

Module overview
Sets out the module's scope, objectives and notes on terminology.

Site monitoring visits
Regular visiting of investigational sites by a CRA is the front line of clinical trial monitoring. The visits allow face-to-face interaction with study site personnel and direct access to source records and site resources, providing the best opportunity for the CRA both to assess and to influence the progress and quality of a trial. In this session, we discuss monitoring tasks, the frequency and duration of visits, preparation for a visit, the kinds of deficiencies that may be found at the site, interaction with study staff, assessment of protocol compliance in a variety of areas, investigational product and subject recruitment issues, review of findings, and report and follow-up.

Data checking
Review and verification of data in CRFs and source documents is considered by many to be the CRA's principal task. It takes up most of his or her time on a monitoring visit and constitutes the primary measure taken on behalf of the sponsor to assure the quality of the data provided by the investigator. In this session, we describe how to carry out CRF review and source document verification (SDV). We discuss the extent of SDV required, outline differences between paper and electronic CRFs, identify aspects of trial conduct for which CRFs and source records should be checked, discuss on-site corrections and resolution of discrepancies, and outline data retrieval and data query procedures.

Close-out visit
Almost all clinical trials require an on-site visit to close the study at a site, irrespective of whether routine monitoring visits have been made. In addition to completing tasks typically carried out at a routine visit, the CRA will be required to perform some actions specific to the end of the trial, such as retrieving or authorising the destruction of unused supplies, retrieving some essential documents, and reminding the investigator of continuing responsibilities. In this session we describe the close-out of a trial at an investigational site.

Risk-based monitoring
Monitoring of clinical research by traditional methods, particularly as regards data checking, is time consuming and laborious. In recent years, regulatory authorities have focused attention on ways of making quality management in general, and monitoring in particular, more efficient through a risk-based approach. Implications of this approach include: increased emphasis on centralised monitoring rather than site visits; and a move away from 100% source document verification toward risk-based and statistically directed sampling of data. In this session we provide a brief introduction to principles of risk-based monitoring.

Fraud and scientific misconduct
The great majority of healthcare professionals undertaking clinical research act with honesty and integrity. However, cases of scientific misconduct and downright fraud do occur. Besides damaging the reputations of those who commit them, such actions have potentially serious consequences for the research and might even affect public health. In this session we distinguish error, misconduct and fraud, discuss the CRA's role in detecting them, and describe their consequences.

Assessment
Multiple-choice mastery assessment.