CT06 Clinical Trial Monitoring: Site Evaluation and Set-up

Approximate study time: 1.5 hours

Level: Intermediate

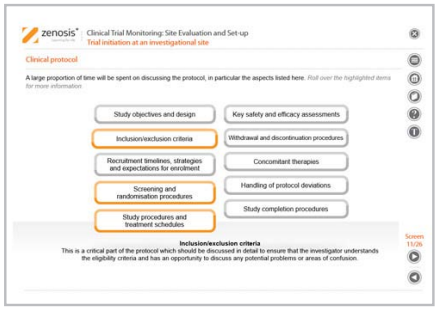
Audience: Compliance, Other

Category: Clinical

Region: USA, Europe, Other

CPD Points: 1.5

Module outline
- Module overview
- Investigational site qualification
- Preparation for trial initiation
- Trial initiation at an investigational site
- Assessment



The sponsor of a clinical trial needs to reach agreement with clinical investigators to conduct the trial. The suitability of investigators and their institutional sites, typically hospitals, has to be evaluated, and the trial has to be set up at each site. This module describes the processes involved, focusing particularly on the role of a Clinical Research Associate (CRA) employed or contracted by the sponsor to monitor the trial.

The purpose of investigational site evaluation and set-up is to ensure that the site has access to the required patient population, has appropriately qualified, trained and committed staff with adequate time and facilities, and that it is fully prepared for the safe and successful conduct of the clinical trial. In this module we set out the criteria, procedures and documentation for evaluating a site and setting up a trial there.

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 CT08 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

- State the objectives of an investigational site qualification visit and describe how to carry one out.
- Describe how to prepare for initiation of a clinical trial at an investigational site.
- State the objectives of a trial initiation visit and describe how to carry one out.

Module outline

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

Investigational site qualification
Each candidate investigational site needs to be assessed for its suitability for the trial. A CRA and/or other representatives of the sponsor will typically visit the site to discuss the trial with the potential investigator and learn about the resources that can be deployed there. In this session we describe the objectives of the visit, preparation for it, and its conduct. We set out factors that should be assessed and give examples of the sorts of issues that may arise.

Preparation for trial initiation
When one or more investigational sites are approved by the sponsor, various activities are carried out concurrently in preparation for the start of a trial. In this short session we outline the tasks leading up to site initiation.

Trial initiation at an investigational site
An initiation visit is made to ensure that the participating site is ready for the conduct of the clinical trial and that the relevant personnel have a clear and accurate understanding of how the study is to be conducted. The CRA will review the clinical protocol and procedures with the team, check that all study materials are in place and that facilities and equipment are ready, ensure that the investigator's trial master file is in order, and confirm the monitoring plan and provisions for audit and inspection. We describe the actions that should be carried out.

Assessment
Multiple-choice mastery assessment.