SDRN: Scottish Diabetes Research Network

Monitoring a Clinical Trial Using an Electronic Case Report Form (eCRF)

Clinical S.O.P. No.: 36
Version 1

Compiled by:	Lonni M. Gray
Approved by:	Shona Brearley
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1. Introduction

Monitoring is defined as the act of overseeing the progress of a clinical trial and of ensuring that it is conducted, recorded and reported in accordance with the study protocol, GCP guidelines and applicable regulatory requirements. Guidance is to ensure that electronic records used in clinical investigations are accurate, complete, and current. These requirements are important because clinical data is used to support a product's safety and effectiveness. One of the advantages of EDC is that researchers can gain faster access to data.

Clinical trials require attention to detail and the design of the EDC (electronic data capture) should meet the specific needs of the protocol and clinical requirements, with the ability to respond to changes with speed and flexibility.

2. Objective

The purpose of this SOP is to describe the process for monitoring a clinical trial using an electronic case report form. (The eCRF is an auditable electronic record of information that generally is reported to the sponsor on each trial subject, according to a clinical investigation protocol. The eCRF enables clinical investigation data to be systematically captured, reviewed, managed, stored, analysed and reported.)

3. Background

Monitoring of a clinical trial should verify that the rights and well-being of human subjects are protected, that reported trial data are accurate, complete and verified form source documents. eCRFs should have built in intelligence to catch and correct errors in real-time, as well as validate the data. This should minimize data entry errors and lead to fewer data discrepancies requiring less back-end data cleansing. eCRFs should contain a date and time stamp.

EDC should result in cleaner data throughout the study, higher overall quality, and faster time from last data in until final database lock.

4. Responsibility

It is the responsibility of all research staff to ensure that the data they record onto the electronic CRF is true and accurate. With a paper CRF the rule is that if it was not documented then it did not happen, with an electronic case report form the rule should be if no one has reviewed the audit trail then it did not happen.

5. Procedure

- In order to support the monitoring of the electronic database the eCRF should have the capability to record who entered or generated the data and when it was entered or generated.
- When original observations are entered directly into a computerised system the electronic record is the source documents.
- The audit trail begins at the time the data are transmitted to the eCRF.
- If a paper transcription step is used then the paper documentation should be retained and made available for inspection. (This can help avoid concern that the sponsor could have altered the data in the EDC in some way.)

- If data is entered directly into an electronic database, e.g., information about an underlying illness, then during a monitoring visit a record may be requested for evidence, or corroboration, of the illness.
- The monitor should be able to see if any changes that have been made to data and the changes must not obscure the original entry.
- The monitor should be able to identify who made the change(s), when and why and a field should be provided allowing originators to describe the reason for the change (e.g., transcription error).
- Computer generated, time stamped electronic prompts, flags and data quality checks should be built into the eCRF in order to minimise errors and omissions during data entry.
- Capturing source data electronically should be associated with an authorised data originator. Authorised originators can include, but not limited to, clinical investigators, any delegated clinical study staff, clinical investigation subjects or their legally authorised representatives (identified by their unique subject identifier), consulting services (e.g., radiologist), automated laboratory reporting systems such as central laboratories, electronic health records.
- Clinical investigators should review and electronically sign the completed eCRF for each subject before the data are archived, or submitted.

6 Monitor responsibilities

- The monitor should communicate the monitoring plan to the study team. This can be done by e-mail, telephone or letter.
- The communication plan should inform the study team about the frequency/scheduling of the visits.
    - Initiation monitoring visit
    - Interim monitoring visit
    - Close out monitoring visit
- The study master/investigator file should be available for the monitor to view.
- Staff CVs and GCP certificates should be available for the monitor to look at and filed in the site investigator file.
- Paper source documentation such as consent forms should be available to the study monitor along with the participant log.
- The monitor will check electronic signatures.
- The monitor will record findings and any action to be taken.
- Before data are archived, and released, the monitor should review completed sections of the eCRF for each subject.