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HEALTH+MEDICAL RESEARCH

Source data and case report form completion

Standard Operating Procedure



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1. Purpose

To describe the process for generating, handling and correcting case report forms and source data. To ensure that sites conducting clinical trials take appropriate account of the Guidelines for Good Clinical Practice based on sponsor requirements¹.

2. Scope

All clinical trials (except Teletrials)² conducted at NSW Public Health Organisations.

3. Applicable to

The principal investigator (PI) and all site staff involved in a clinical trial.

All support departments holding source documents.

4. Definitions

Refer to SOP-G-01: Glossary of terms.

5. Background

Source data are defined as:

All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.

Collection of accurate source data (contained in source documents) is essential for compliance with GCP. The format used (whether paper or electronic) should permit the reconstruction of the clinical care given to the participant and describe any significant participant-related events that may occur during the conduct of the trial.

The case report form (CRF) is defined in ICH GCP as:

A printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

The data collected in the CRF is used as the basis of the trial report and any publications*, as well as making up part of the data for regulatory approval for the unapproved therapeutic goods. The PI has ultimate responsibility for the content of the CRF but may delegate the task to suitably qualified individuals. The PI should; however, maintain oversight of the quality of the data provided to the sponsor.

** For some pragmatic trials a CRF may not be utilised (e.g. trials collecting minimal data directly from a registry).*

Certain source data may be recorded directly into the sponsor's CRF if predefined in the protocol or other document. Irrespective of the location, the PI should retain control of all source data (the sponsor should not have exclusive control).

The location of source data and their respective capture methods should be clearly established at the start of the trial. The following points generally apply:

When trial participants are patients of the organisation, all data generated that is pertinent to their clinical care must be contained in the medical records. If this is achieved by making copies/transcriptions from another source, it should be clear which document is the source. If large amounts of data need to be transcribed to the medical records, the following should be considered to minimise the chance of transcription error:

- Where a trial-specific worksheet is the source document for any clinically-relevant data, it should be retained in the participant's medical records (if permitted by local policy).
- Where the CRF is the source document for any clinically-relevant data, a printout/copy of any relevant CRF pages should be retained in the participant's medical records (if permitted by local policy). This should not be commonplace as clinically relevant data should; wherever possible, be recorded first in the medical records (or worksheet stored in the medical records).

Where the participant does not have a medical record within the organisation (e.g. healthy volunteers), an appropriate record or file should be created in accordance with protocol requirements and local policy.

CRF completion

Most CRFs are now in the form of electronic data capture (EDC) where data is entered directly into a web-based database. Site staff delegated the task of CRF completion should be familiar with any CRF Completion Guidelines (if provided by the sponsor) and have adequate training on its completion. Most electronic CRFs have in-built edit checks but when paper CRFs are used, the following good practice should apply:

¹ All trials must comply with the principles of GCP (Section 2 of ICH GCP (E6 R2) or Clause 4 of ISO 14155) however sponsors submitting data to regulatory authorities will normally require full compliance with ICH GCP (E6 R2) or ISO 14155 GCP Guidelines.

² NSW Health have published an annotated version of these SOPs for sites utilising a Teletrials model.

- Unless indicated otherwise, no fields should be left blank - not done (ND), not known (NK) or not applicable (NA) should be used as applicable along with an explanation.
- Corrections should be made by drawing a single line through the incorrect item; dating and initialling and where the reason for the change is not obvious, adding an explanation.
- CRFs entries should be signed and dated by the person making the entries and the overall quality and accuracy of the completed CRF checked by the PI.

6. Procedure

Principal Investigator (PI)

Supervise any individual delegated responsibility for any of the requirements in this SOP

Ensure that adequate and accurate source documents are maintained including all key observations on each of the site's trial participants.

Ensure the accuracy, completeness, legibility and timeliness of the data reported in the CRF for each participant entered into the trial.

Ensure trial information is recorded, handled and stored in a way that maintains data integrity and allows its accurate reporting, interpretation and verification.

PI or delegate

Clearly establish (usually in liaison with the sponsor's staff) where all source data pertinent to the trial will be located (e.g. through the use of a source document identification log).

Ensure that any uncertainties in the completion of the CRF (e.g. unclear conventions) are resolved with the sponsor.

Complete the CRFs in a timely fashion and where specified, in line with any contractual requirements.

Ensure data entry is as complete as possible and ensure all entries are accurate, legible and verifiable with the source data (unless the CRF has been defined as the source) and any discrepancies are explained.

Keep a full audit trail of all changes and correction made during initial completion and also once the CRF has been provided to the sponsor (e.g. through data query forms).

Ensure data queries made by the sponsor are resolved in a timely fashion.

7. References

[ICH GCP \(E6 R2\): Good Clinical Practice Guidelines – Annotated by the TGA](#)

[EMA Guideline on the content, management and archiving of the clinical trial master file \(paper and/or electronic\)](#)

8. Associated documents

Source data location plan – available in the Standard Operating Procedures templates [zip file](#)