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Information and guidance for primary care sites on recording research data

The purpose of this guide is to provide primary care sites with guidance on the sources of data and information collected for research studies, where it is recorded and how it is stored.

1. What data is collected for a research study?

The study protocol specifies what data to collect at each study visit and this will be dependent upon the type of study. A clinical trial of an investigational medicinal product (CTIMP) will have more visits and require more data collection than a questionnaire study.

2. How will I know what to record?

The study sponsor should arrange a site initiation meeting or visit, known as an SIV, with the Principal Investigator (PI) and local research team. At this meeting they will discuss what data needs to be collected at each participant visit and how this should be recorded on the Case Report Form (CRF) for the study.

3. What is a Case Report Form (CRF)?

CRFs are paper or electronic (eCRF) documents that are designed to record information required at each study visit. The contents of the CRF/eCRF are confidential and should be stored safely and securely on site.

4. Who can enter data on to the CRF/eCRF?

Data should only be entered onto the CRF/eCRF by local study staff who have been delegated to do this by the PI. Data that is entered on to a CRF/eCRF needs to be shown as accurate when checked against source data and source documents.

5. What is source data?

Source data is where study data is first recorded and is the original record of that information. Source data is contained in source documents and can be in paper format eg questionnaire, electronic format eg clinical record, or a combination of the two.

6. What are source documents?

Source documents are the original documents, data, and records including the CRF/eCRF. The PI and local study team should record each participant study visit using this guide:

Attributable: Signed and dated by the person making the entry (electronic entries should have clear audit trails). Entries should also include details of staff involved in the consultation and should be countersigned where decisions have been made by staff other than the person making the entry.

Legible: All data must be readable and permanent. This also applies to metadata that may be recorded to support an electronic record.

Contemporaneous: Results, measurements or data should be recorded in “real time” as the data was collected. If retrospective entries or annotations are made then this should be obvious, and they should be signed and dated with the date the entries were added.

Original: Refers to the medium in which the data is recorded for the first time. In instances where a copy is required to replace an original document, the copy must be certified i.e. verified, as indicated by a dated signature, as an exact copy, having all the same attributes and information as the original.

Accurate: A faithful, complete and reflective representation of the observation or event.

Entries must be written clearly in black ballpoint pen.

7. When should we start creating source data?

As soon as a potential participant is approached about a study and given a participant information sheet (PIS) this should be recorded in the EHR. When informed consent is obtained from the participant this is the start of their commencement in the study and this should be recorded in the CRF/eCRF and should include:

- the date and time the participant received the PIS.
- the date and extent they discussed the project and with whom.
- the date of informed consent and time.

8. What happens if I need to change or update the source data or CRF/eCRF?

Paper records

All changes should be signed and dated with the date the entries were added. Any errors should be corrected by drawing a single line through the error, initialling and dating the change, and adding a reason for the error if necessary. Incorrect entries must always be legible and never obliterated.

All data should include details of staff involved in the consultation and should be countersigned where decisions have been made by staff other than the person making the entry.

Electronic records

This type of data includes laboratory test results and Electronic Health Records (EHRs). A secure, computer generated, time stamped audit trail (or alternative methods that fulfil audit trail requirements) need to be in place to independently record the date and time that data has been updated or modified.

9. How should source data be shared?

Authorised members of the local study team should send the data to the study sponsor by the method and timescale agreed during the study's set-up.

10. Who else can have access to the source data?

In addition to members of the local study team, source data and CRF/eCRF access must be given upon request to staff from the study sponsor, auditors and regulatory bodies.

11. How should source data be stored at the end of the study?

At the end of a study, a full copy of each completed CRF/eCRF should be stored as agreed during the study's set up. This may include different storage arrangements for paper and electronic data.

12. Who do I contact if I have further questions?

For any questions, please email: rdu@shsc.nhs.uk