UNIVERSITY OF LEEDS

The Leeds Teaching Hospitals NHS
NHS Trust

# Source Data Management in a Clinical Trial of an Investigational Medicinal Product (CTIMP)

## 1) What is Source Data?

Source data is **where a data point is first captured** and is therefore the **original** record of information.

Source data **must be retained** regardless of where the data was captured. For example, if a trial subject's blood pressure was noted on a piece of scrap paper as their medical notes were not to hand, **the paper must be kept for audit trail purposes.**

Source data is a vital aspect of trial management and should be **attributable, legible, contemporaneous, original, accurate, and complete** (GCP E6 R2, 4.9.0) allowing the trial to be reconstructed accurately.

Poor source data management is a **common monitoring and inspection finding** as it inevitably leads to missing data and general confusion as to what data point was recorded where. It is therefore essential that thorough and complete records are kept to evidence all aspects of the trial.

***Remember: if it's not documented it didn't happen!***

## 2) Where is my trial's source data located?

The location of source data will vary between trials depending on factors such as the type of data collected and departmental systems and processes. As such, data management cannot be viewed as 'one size fits all' and requires consideration and planning from the investigator and wider team during trial set up.

**Team members must understand the data management process and be aware of what constitutes source data before working on the trial**.

Common examples of source data include ***(but are not restricted to)***:

- ✓ Annotations in paper medical notes
- ✓ Source data worksheets
- ✓ Blood results stored on an online server
- ✓ Patient diaries
- ✓ Scan images stored on equipment or servers
- ✓ Laboratory data to support analysis

**Please note:** Source data kept centrally on hospital computer systems (e.g. lab results, CT scans etc.) **must remain accessible for inspection purposes**. Evidence of investigator review of these data points must also be visible to any individual reviewing the trial data.

To aid research teams in their development of data management methods, Sponsor QA mandated **Data Management Plans and Source Data Location Sheets** for all LTHT/UoL Sponsored trials submitted for approval from 1st October 2017. Further guidance and an example source data location sheet can be found in the ***QCRES_07_Researchers Guide to Data Management*** SOP.

## 3) Documentation of Source Data

All data required by the protocol should be evident as source (unless any direct entry to the CRF has previously been agreed - see section 6).

**What does a monitor / inspector expect to see recorded at source? Examples include*:**

- ✓ Documentation of patient approach and PIS provision
- ✓ A full account of the consent process
- ✓ Clear statements of eligibility by a medically qualified Doctor
- ✓ Blood tests and scan results to support the eligibility statement, including evidence of review
- ✓ Each trial visit should be clearly signposted to allow the patient pathway to be followed
- ✓ Evidence of the investigator reviewing all trial test results
- ✓ Treatment details (including any dose modifications)
- ✓ Evidence that the patient was asked whether any adverse events (AEs) had occurred with any reported documented in full and followed up at each visit until resolution.
- ✓ A full account of any concomitant medications with any changes throughout the trial's duration clearly documented.
- ✓ Documentation of any withdrawal from the trial including the reason why.
- ✓ Documentation of the patient's end of trial participation

**Common source data related monitoring and inspection findings include:**

- × There was no documented review of lab reports, scans or x-rays prior required for confirmation of eligibility prior to a patient's inclusion on the trial
- × Start and stop dates of AEs and concomitant medications were frequently omitted and were not followed up at each visit
- × An adverse event was missed by the trial team as not all sources (e.g. PPM) had been checked by the trial team
- × There was confusion as to what constituted source within a team with source data worksheets being referred to as a 'paper CRF'. This led to duplication of data in the worksheets and medical notes before transcription onto the formal electronic CRF.
- × Source noted on scrap paper had been thrown away rather than being retained for audit trail purposes
- × The original data had been altered to match the CRF which had been transcribed incorrectly
- × Team members were not referring to the protocol to ensure that all required data points were being recorded at each visit

*For further guidance and detailed examples of the key points to be recorded at source, please refer to the ***'LTU_QM23_A Researchers Guide to Source Data'*** SOP.

## 4) What is Source Data Verification?

Source Data Verification (SDV) is the process of comparing the data entered in the CRF against the corresponding value at source to check for completeness and accuracy.

SDV is routinely carried out by monitors as part of the monitoring process to ensure that the patient pathway can be reconstructed however, research teams should also carry out checks at regular intervals.

The team should have an agreed QC process for verifying the CRF against source data. This process should include frequency of QC checks and the percentage of data to be checked (e.g. 10% data check, full data check etc.).

Regular SDV helps to ensure that:

- ✓ All protocol required assessments have been carried out in full and within any timeframes specified.
- ✓ All source data has been accurately transcribed onto the CRF.
- ✓ All data recorded in the CRF has a corresponding source (unless otherwise stated in the protocol - see section 6).
- ✓ Any deviations (e.g. out of visit windows) have been identified and reported to Sponsor for review.

- ✓ Adverse events (AEs), serious adverse events (SAEs) and concomitant medications have been recorded, reported to Sponsor (where applicable) and followed up as per the protocol's requirements.
- ✓ All trial tasks and assessments have been undertaken by an appropriately qualified individual delegated to do so on the trial's delegation log.

## 5) Using Source Data Worksheets

If a team choose to use source data worksheets **it is important these are not confused with paper CRFs.**

The CRF is the formal, anonymised record of trial participation for a clinical trial whereas **source data worksheets can be used as a method to ensure all information required by the CRF is captured at source**.

The CRF may either be paper or electronic. **On no occasion should both be used.** It is the responsibility of the CI to decide what format will be used for the CRF based on the needs of the trial and the decision must be clearly documented.

Where source data worksheets are used **these must be filed in the medical notes in a timely manner** for audit trail purposes**.** It is not acceptable to file these separately to the medical notes as they contain patient data that may be required by another department.

Where a team has concerns that there is a potential for source data worksheets to be lost from the medical notes they may wish to also scan the worksheets onto PPM for backup purposes.

## 6) What if I want to enter trial data directly onto my Case Report Form (CRF)?

During trial set up the team should identify any data points that they wish to enter directly onto the CRF. On these occasions, at least part of the CRF is considered source data (e.g. patient questionnaires recorded directly into the CRF)

**The protocol, source data location sheet and data management plan** (for trials submitted for approval from 1st October 2017) **MUST clearly document all data points that will be directly entered on the CRF**.

This step is vital in the reconstruction of the trial as it enables a reviewer to identify occasions where source to verify a CRF value will not be available during the source data verification (SDV) process.

## Key Resources & Further Reading:

| | | |
|---|---|---|
| LTU_QM23_A Researchers Guide to Source Data | *Sponsor QA (UoL / LTHT)* | http://lthweb.leedsth.nhs.uk/sites/research-and-development/research-and-development-homepage/quality-and-assurance |
| QCRES_07_Researchers Guide to Data Management | | |
| Good Clinical Practice Guide | *MHRA* | https://www.tsoshop.co.uk/MHRA/Good-Clinical-Practice-Guide/ |

*** Should you have any queries or concerns, or would like further information regarding the content of this bulletin, * then please do not hesitate to contact the Sponsor Quality Assurance Office on Tel: 0113 30 60465**