Research & Innovation Office

Standard Operating Procedure

St Luke's Research & Innovation Office

Source Data Documentation

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Approved by (name & Role)	Dr Paul Taylor Head of Research - SLH	**Date**	14th April 2025
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Standard Operating Procedure: St Luke's Hospice Research & Innovation Office.

Source Data Documentation

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Acronyms

CAG - Confidentiality Advisory Group
CI – Chief Investigator
CTIMP - Clinical Trial of an Investigational Medicinal Product
CV- Curriculum vitae
HRA – Health Research Authority
HTA – Human Tissue Act
ICHGCP - International Conference on Harmonisation of Good Clinical Practice
IRAS - Integrated Research Approval System
MHRA - Medicines & Healthcare Products Regulatory Agency
MRC - Medical Research Council
NIHR - National Institute for Health & Care Research
NRES - National Research Ethics Service
PI- Principal Investigator
REC- Research Ethics Committee
SOP – Standard Operating Procedure
SLH - St Luke's Hospice
SDV- Source Data Verification

Introduction

Appropriate documentation is an essential part of any clinical trial as it supports the work undertaken, enables the clinical management of subjects and permits the accurate reconstruction of the trial. As a result, clinical information should be recorded, handled and stored in a way that enables accurate reporting, interpretation and verification, whilst the confidentiality of the trial subject's records remain protected (Part 2(9) to Schedule 1 of SI 2004/1031).

Trial Sponsors have a responsibility for providing a GCP compliant records management system. This means implementing Electronic Health Record (EHR) systems that are robust, GCP compliant, and that source data is identifiable for each study (31A(8) UK Clinical Trials regulations 2004; CPMP/ICH/GCP/135/95)1).

In order to ensure that these requirements are fulfilled, there is a need to have clear guidance on the use of electronic/paper source data and the principles that should apply to them.

Purpose

The purpose of this SOP is to provide instruction and a process to support research personnel who are involved in recording and managing source data for research within the Hospice. This is to ensure data quality, data integrity, and compliance with GCP and all relevant legislation.

Scope of Document

Source data includes all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical investigation used for reconstructing and evaluating the investigation (E6(R2) GCP, 2016).

The scope also includes electronic systems (including instruments, software and services) used in clinical trials in the creation/capture of electronic clinical data, such as:

- Electronic Case Report Forms (eCRFs) e.g. laptop/desktop, mobile device-based programs or web-based tools, which may contain source data directly entered, transcribed data by re-keying from other sources, or both.

- Electronic patient data capture devices used to collect Patient Reported Outcome (PRO) data – e.g. mobile devices supplied to patients to record observations, rating scales, IMP use. This can be primary efficacy or supportive data.

- Instruments supplied to investigators for recording clinical data either by data entry or by automated capture of events such as biometric measures (e.g. blood pressure, respiratory measures, ECG monitoring etc.).

- Instrumentation or electronic systems to capture, generate, manipulate or store data in an environment where analysis, tests, scans, imaging, evaluations, etc. are performed in support of clinical trials.

- Electronic Health Records/e-Record.

Definitions

The following definitions have been adapted from the 'ICH GCP Integrated Addendum E6(R2) – Section 1' and the FDA's 'Guidance for Industry: Electronic Source Data in Clinical Investigations 2013':

Source Data: All information in original records and certified copies of original records of clinical findings, observations, or other activities within a trial necessary for the reconstruction and evaluation of the trial events. Source data are contained in source documents (original records or certified copies) and can be in paper format, electronic format, or a combination of the two.

Source Documents: Original documents, data, and records. Examples include: hospice/hospital records; clinical/office charts; laboratory notes; memoranda; subject diaries or evaluation checklists; pharmacy dispensing records; recorded data

from automated instruments; copies or transcriptions certified after verification as being accurate and complete; microfiches; photographic negatives; microfilm or magnetic media; x-rays; subject files and records kept at pharmacy, laboratories and/or medicotechnical departments involved in the trial.

Electronic Source Data: Data initially recorded in electronic format, including information in original records and certified copies of original records of clinical findings, observations, or other activities captured prior to or during a clinical investigation used for reconstructing and evaluating the investigation.

Audit Trail: A process that captures additions, deletions and/or alterations of information in any record without obscuring the original record. An audit trail facilitates the reconstruction of the course of such details relating to the record.

Certified Copy: A copy (paper or electronic) of original information that has been verified, as indicated by a dated signature, as an exact copy, having all the same attributes and information as the original whilst reflecting the complete, chronological set of notes. Justification for the use of certified copies must be documented.

Case Report Form (CRF): 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.

Electronic Case Report Form (eCRF): An auditable electronic record of information that is reported to the Sponsor on each trial subject, as per the study protocol. The eCRF enables clinical investigation data to be systematically captured, reviewed, managed, stored, analysed and reported.

Validation: The process of establishing suitability for the purpose of software and systems, establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

Transcription: Process of transforming dictated or otherwise documented information from one storage medium to another (e.g. source document to CRF).

Roles & Responsibilities

This SOP applies to the Chief Investigator (CI), Principal Investigator (PI) and designated research personnel who are responsible for recording and maintaining source documentation. It also applies to any sponsor representatives and trial management teams involved in the capture, review and retention of source data.

The investigator and designated research personnel are responsible for clearly identifying the data and documents that will be maintained as source data throughout a particular study.

The PI at site is responsible for maintaining the original source documents (or the certified copies) throughout the trial (Requirement 5, ICH GCP 2.10, 5.15.1).

The PI is responsible for ensuring that research personnel involved in source data collection and management for the study are suitably qualified and adequately trained as per the trust's Clinical Record Management Policy.

Clinical research staff must ensure that they are appropriately trained and are fully aware of the requirements in the capture and management of source data. This may incorporate GCP training, SOP compliance, hospice Policy compliance, Site Initiation Visit (SIV) attendance and protocol specific training, all of which should be fully documented.

The sponsor is ultimately responsible for the quality of the study data and for ensuring that procedures, system controls and agreements are in place to protect this quality. The PI however is responsible for ensuring the accuracy, completeness, legibility and timeliness of the data reported to the sponsor (ICH GCP 4.9.1).

All staff are responsible for ensuring that source data is attributable, legible, contemporaneous, original, accurate and complete. Changes to source data should be traceable, should not obscure the original entry, and should be explained if necessary, via an audit trail (ICH GCP 4.9.0).

Source Data

The basic concept of source data is that it permits not only reporting and analysis but also verification at various steps in the process for the purposes of confirmation, quality control, audit and/or inspection.

Clinical trial data can originate from various sources depending upon the complexity of the trial design and the number of data points to be collected, the source data requirements are likely to vary.

Because of this variability, it is not always possible to have a standardised method of recording clinical source data. However, irrespective of the type of source data utilised, the principles of GCP and all relevant legislation should still be applied throughout. Similarly, practices to ensure good source documentation and data integrity should be implemented, thus permitting the reconstruction of the clinical care given to the subject and the subject specific events that have occurred throughout the trial.

The location of source documents and the associated source data should be clearly identified at all points within the data capture process (Requirement 11, ICH GCP 6.4.9). Consequently, what comprises source data should be made available and data capture methods clearly defined either in the protocol or a study specific source data agreement prior to the start of study recruitment.

This agreement (or source data log/note to file/protocol) should include details around data to be transferred (e.g. to CRFs), the origin and destination of data, parties with access to source data and transferred data, and timing of data transfers.

The source data agreement (or alternative) should be stored within the Investigator Site File (ISF).

Any instruments used to capture source data (e.g. CRF, eCRF, paper/electronic patient diaries, site designed worksheets) should ensure that the data captured complies with protocol specifications (Requirement 1, ICH GCP 2.6 & 6.4.9).

The instrument (whether paper based or electronic) should be created in a controlled manner ensuring that it conforms to applicable SOPs, the protocol and that it is validated. The instrument should include document identifiers, version numbers and associated dates, and a review date.

Where protocol amendments require changes to the instrument, appropriate change control as part of ongoing validation is needed. Records of system validation including requirements, design, installation, access and security, testing (e.g. user acceptance and performance testing), training and controlled release should be maintained.

Furthermore, the agreement or log which specifies what constitutes source data/documents should also be updated in parallel to storage medium changes (e.g. paper record system changed to electronic system). Again, any updates to the source data log or source data agreement should be evident via appropriate version controls (inclusion of document identifier with a version number and date).

Good Documentation of Source Data

The investigator and designated research personnel should maintain adequate and accurate source documents and trial records that include all pertinent observations on each of the site's trial participants. All forms of source data (whether paper or electronic) should comply with good documentation practices, i.e. be attributable, legible, contemporaneous, original, and accurate (ALCOA) and must meet the regulatory requirements for record keeping (Requirement 2, ICH GCP 1.51, 1.52, 4.9.1, 6.4.9). As such, all qualified research personnel involved in the documentation

and management of source data should apply the ALCOA standard in order to achieve data quality (see Table 1).

Table 1 - Good Documentation Practices (ALCOA)

Acronym	Title	Description
A	Attributable	All data must be attributable to the person generating the data. This can be recorded manually by initialling and dating a paper record or by an audit trail in an electronic system. Consider: • Where the data originated from • Who recorded the data (staff initials or electronic signature) • When it was recorded (date/time) If any annotations or corrections are made to the source data then this should be obvious, and they should be signed and dated with the date the entries were added (electronic entries should have clear audit trails). All 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.
L	Legible	All data must be readable and permanent. This assists with its accessibility throughout the

		entirety of the trial (including archiving). This also applies to metadata that may be recorded to support an electronic record. Consider if the data is: • Easily readable and able to be reproduced if necessary
C	Contemporaneous	Results, measurements or data should be recorded in "real time" as the data was collected. • The transcription of audio recordings should be completed during/immediately after the consultation with the subject. **Please note: source data must never be back dated.**
O	Original	Refers to the medium in which the data is recorded for the first time. In instances where a certified copy is required to replace an original document, the copy should be annotated with: • the name (printed) of the person who made the copy • their signature

		• the date and time the copy was made • the stamped or written statement to certify that this is an accurate and exact copy of the original, and that the print out represents the complete, chronological set of notes (or is verified by an electronic process). **Please note: certified copies should only be used to replace an original document and justification for use should be documented.**
A	Accurate	• A faithful, complete and reflective representation of the observation or event e.g. ensuring patient weight is recorded as 60.2kg rather than 60. • Where duplication of data is required care must be taken to ensure that transcription is accurate and consistent. Any discrepancies in transcription must be investigated in a time frame proportionate to risk.

All qualified research personnel should also ensure that source data is complete, consistent, enduring and available (CCEA) in order to ensure data integrity (Table 2).

Table 2: Data Integrity (CCEA)

Acronym	**Title**	**Description**
C	Complete	Having all necessary or appropriate parts e.g. ensuring that all 3 pages of a document are present and not just the first one. If copying or transcribing data ensuring all the information is present, accurate and legible. if read codes are used for a free text box, then they should be left blank if not applicable, otherwise that read code can be incorrectly entered into the patient's record. **Data fields in documentation must not be left blank. Not Applicable (NA), Not Known (NK) or Not Done (ND) must be entered as appropriate.**
C	Consistent	Done in the same way over time e.g. when collecting data the use of a standard template or record sheet will ensure that the same information is collected from each patient. SOPs for activities ensure everyone involved follows the same process.
E	Enduring	Lasting over a period of time e.g. using a data collection/retention system that will retain the

		information in a usable format for the duration of the study and any legislative requirements once archived. • Steps should be taken to ensure the long term preservation of source data is possible (e.g. photocopying ECG print outs).
A	Available (When needed)	Able to be used or obtained when required by study staff, auditors or regulatory bodies.

Although source data may exist in many different paper and electronic formats, they should all comply with the ALCOA and CCEA principles in order to permit the reconstruction of the clinical care provided to the subject throughout the entirety of the clinical trial whilst maintaining patient confidentiality.

Blinding and anonymity of patient identifiable information must also be maintained at all times.

Some of the key study events to be documented within source data are listed within Appendix 1, although please note that this is not an exhaustive list.

Electronic Health Records (EHRs) and Certified Copies

When original observations are entered directly in to a computerised system, the electronic record is the source document.

In the instance that electronic health records (EHR) are used as source data, it is possible that monitors may not have direct access to the system for confidentiality reasons. In such circumstances, monitors and inspectors may be permitted read only access. In most cases this is under supervision of research personnel, although this may not always be necessary.

An alternative option may be for the site to print out a copy of the patient records for the monitor to review.

It is a fundamental requirement that a source document and data can be copied (Requirement 8, ICH GCP 1.51) and that there is a practical method of copying that is complete and accurate, including relevant metadata.

When source data are copied, the process used should ensure that the copy is an exact copy preserving all of the data and metadata of the original (requirement 12, ICH GCP). Furthermore, accurate and complete copies for certification should include the meaning of the data (e.g. date format, context, electronic signatures and any relevant authorisations), as well as the full audit trail.

Consequently, where original records are printed out the site personnel should ensure that the copy includes:

- the name (printed) of the person who made the copy
- their signature
- the date and time the copy was made
- the stamped or written statement to certify that this is an accurate and exact copy of the original, and that the print out represents the complete, chronological set of notes.

Monitors and auditors should then be able to verify that the copy is a complete and accurate copy of the EHR.

EHRs may however be updated to include omitted information or input from an external source (e.g. hospice admission/discharge letters). Similarly, EHRs are likely to be updated or amended between monitoring visits. In such circumstances, the monitor may not be aware that what they have reviewed previously has been modified. Consequently, all previous print outs should be retained as these will serve as a full audit trail (by conducting comparisons of superseded versions versus the

latest print outs). Thus, if the EHR has been updated, the research team should produce any new certified copies prior to the monitoring visit so that the monitor can compare these against superseded versions. Any new information that is retrospectively added to a subject's notes (whether these are paper or electronic) must show when the entry was made and by whom, so that a full audit trail of events can be maintained.

Modifications to Source Data

Source data should only be modified with the knowledge or approval of the PI (Requirement 6, ICH GCP 4.9.3, 4.9.4 and chapter 8).

An audit trail should be maintained as part of the source documents for the original creation and subsequent modification/transformation of all source data (Requirement 3, ICH GCP 4.9.3 and 5.5.4). This is to ensure that any changes to source data are traceable.

Secure, computer generated, time stamped audit trails (or alternative methods that fulfil audit trail requirements) should be used to independently record the date and time of operator entries and actions that create, modify, or delete electronic records.

For paper-based records, any changes to source data 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 (correction fluid must not be used). Furthermore, all entries 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.

Similarly, if data are transformed during processing, it should always be possible to compare the original data and observations with processed data via an audit trail.

Such audit trail documentation should be retained as long as the subject's EHRs. Audit trails need to be readable and changes to audit trail data should be prevented

by the system. The relevant investigators, sponsors and inspectors should be able to review the audit trail.

Validation of computerised systems

Computerised systems should meet the same degree of confidence as that provided by paper systems. The study protocol should include the intended use of computerised systems during the conduct of a clinical trial, with a description of security measures and details of transmission of electronic data. Changes that exceed previous operational limits and design should also be validated.

EHRs need to facilitate regulatory compliance with UK Clinical Trials Regulations 2004, schedule 1 (as amended). SLH has an obligation to provide GCP compliant record management systems. Sponsors also have a responsibility for providing GCP compliant record management systems that are robust and that source data is identifiable for each study (Regulation 31A(8) UK Clinical Trials Regulation 2004 (amended), MHRA position statement, 2015).

Protection of Source Data

Source documents should be protected against unauthorised access in order to maintain patient confidentiality (Requirement 9, ICH GCP 2.11, 5.15.2).

The study consent form must include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. The consent form must also identify all entities who may gain access to the patient's health records/source data relating to the clinical investigation. The extent of access to other parties (e.g. Sponsors, CROs and inspectors) should also be identified.

Furthermore, any transfer of data must adhere to the protocol (as approved by sponsor and Research Ethics Committee) and Caldicott principles as defined in hospice policies.

Changes or deletion of source data by unauthorised individuals, either accidental or deliberate, should be prevented. Similarly, procedures should be in place to prevent unauthorised access.

With regards to EHRs, access procedural controls should be in place to limit access to authorised users who have unique usernames and passwords. Computer system audit trails should also feature access attempts and idle periods.

Records of individuals with authorised access to the system and their respective level of access should be clearly documented. There should also be timely removal of access if this is no longer required or permitted.

Thus, in order to protect source data, the following principles should be considered: physical security; restricted access; record of roles and access rights; data protection; back-up of systems; system validation; and working processes for change control and system failure.

Storage of Source Data

Throughout the entirety of a trial and after its conclusion, existing source data should be readily available to the investigator, monitors, auditors and inspectors (Requirement 4, ICH GCP 2.11, 5.15.1).

Source documents and data should also be protected from destruction, either accidental or deliberate (Requirement 7, ICH GCP 4.9.3, 4.9.4 and chapter 8). Suitable archiving systems should be in place to safeguard the data integrity for the required archiving period.

Checks of accessibility of archived data, irrespective of format, including relevant metadata, should be undertaken to confirm that the data is enduring, and that it continues to be available, readable and understandable.

Training

The PI is responsible for ensuring that research personnel involved in source data collection and management for the study are suitably qualified and adequately trained. This includes ensuring evidence of qualifications, ensuring GCP certificates are valid or that training is undertaken prior to commencement of the study and ensuring that study specific training on the study protocol and procedures is provided. Furthermore, training regarding secure data transmission, security safeguarding and contingency plans in the event of a computer virus or cyber-attack should be considered for electronic source data.

All training and education must be documented in the ISF

References

- CDISC Clinical Research Glossary Version 19, SEPTEMBER 2024 - Glossary | CDISC
- FDA Guidance for Industry – Electronic Source Data in Clinical Investigations (2018) - Electronic Source Data in Clinical Investigations | FDA
- Indexed ICH GCP Guidelines with Integrated Addendum E6(R2), Step 4, November 2016 - GUIDELINE FOR GOOD CLINICAL PRACTICE
- MHRA Good Clinical Practice - Good Clinical Practice - Health Research Authority
- European Medicines Agency – Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials (2023) - Guideline on computerised systems and electronic data in clinical trials
- MHRA Position Statement and Guidance Electronic Heath Records, V1.0, September 2021 - Access to Electronic Health Records by Sponsor representatives in clinical trials - GOV.UK

Appendices

Appendix 1: Examples of Key events to be documented in Source Data

Examples of some key information/events to be recorded within the source data include (please note this is not a comprehensive list):

- Provision of the subject information sheet/invitation to consider the trial.
- Eligibility decision (along with any relevant supporting information not available elsewhere within the patient records). All inclusion/exclusion criteria should be signed and dated by the PI or delegated medical personnel.
- Obtaining consent.
- Randomisation/trial entry.
- Trial visits or follow up phone calls required by the protocol: All study visits should be recorded in the source documentation to include patient details, study title, the visit number and date, and the complete data set collected for the visit with rationale documented for any missing data. All entries should be signed and dated to include the person's study role for clear identification purposes. Test results should be evaluated by an appropriately trained research team member and following review must be signed and dated. The purpose of this assessment is to ascertain if any out of range results are clinically significant or not.
- Treatment and dosing decisions, including changes to concomitant medications: Source documentation must contain clear information regarding the IMP dispensed to the patient, including the date the drug was dispensed; batch numbers and containers dispensed such as bottles, syringes, infusion administration details and any dose changes.
- Adverse events (including seriousness, severity, causality, expectedness).

- Withdrawal, termination or end of trial involvement including any protocol defined follow up.

Key decisions and discussions relating to the care of trial participants as well as the management of the trial. This documentation should include the rationale behind the decision and allow reconstruction of the decision making process. Such decisions/discussions may include: treatment decisions (e.g. dose escalation or reduction); implementation of urgent safety measures; discussions regarding a protocol deviation or serious breach; rationale to support specific course of action (especially if this is not defined in the protocol).