Data Management in Clinical Trials

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CHANGE HISTORY			
Date	Version Number	Change details	Approved by
05/Jan/2021	2.0	Scheduled review, Update to section 4.1.1, “Subject” wording replaced with “participant” in section 3.	Jackie Pullen
27/Mar/2023	2.1	Scheduled review, minor amendments to section 4.6	Jackie Pullen
27th October 2025	3.0	Schedule review	Ann Marie Murtagh

Table of Contents

1.0 BACKGROUND AND PURPOSE

To define the minimum standards for the collection, storage, processing, validation, and archiving of clinical trial data, ensuring compliance with applicable UK legislation, Good Clinical Practice (GCP), and data protection requirements. Only data that is relevant for the purpose of the Clinical Trial should be recorded.

2.0 SCOPE

All clinical trials sponsored by one or more of King's Health Partner Organisations or clinical trials where the sponsor responsibilities are managed by the KHP-CTO will conduct data management as described in this SOP. The standards set out in this SOP are considered as the minimum required for a Clinical Trial.

The data management process typically encompasses: the design and production of the data capture tool for the collection of trial participant data from an investigator site(s); the design and construction of databases; the processing of the data, database lock and the production of the final data set(s) for analysis. This SOP does not apply to the statistical analysis of Clinical Trial data.

Where Data Management is outsourced to an external organisation this SOP will not apply. However, vendor oversight will be maintained by the KHP-CTO on behalf of the Sponsor. This will include confirmation that the Vendor has, and adheres to, organisational SOPs that detail the principles described within this SOP to ensure compliance with GCP and UK clinical trial legislation.

3.0 RESPONSIBILITIES

Appropriately trained and delegated individuals are responsible for handling the data, verifying the data, conducting the statistical analyses, and preparing the Trial reports. The Sponsor may delegate management of the trial data to the Chief Investigator (CI) or a specialist function group such as a Clinical Trials Unit. Any delegation of data management should be clearly documented.

- Sponsor: Overall responsibility for ensuring compliant data management.
- Chief Investigator (CI): May be delegated responsibility for trial data management.
- Principal Investigator (PI): Ensures data accuracy, completeness, and timeliness at site level.
- Data Management Team: Executes processes outlined in the Data Management Plan (DMP).
- Quality Manager: Oversees compliance with SOP, validation of systems, and vendor oversight.

4.0 PROCEDURE

4.1 Data Management Process

- Data management is the collection, storage, preparation for evaluation, extraction and archiving of data collected according to a clinical trial protocol, during the conduct of a clinical trial.
- A Case Report Form is a printed, optical, or electronic document (eCRF) designed to capture or record all of the protocol required information

4.1.1 Data Management Plans

- How the data is to be managed both during and after the conduct of a clinical trial should be documented, this may be detailed within the trial protocol or in a separate Data Management Plan (DMP) (see section 5.1). It is recommended that for large multi-centre studies a separate DMP is in place.
- The DMP should be finalised and authorised by the appropriate member of staff prior to the start of trial recruitment.
- A DMP (or the data management section of a protocol) should cover an overview of the data management process including: data flow, database specifics and systems used, validation and SDV processes, query processes, QC data checks, protocol non-compliance definitions and handling, PV reconciliation, training of personnel, database lock process, data extraction procedures, data location and archiving, process for return of the trial data and documentation to the sponsor.

4.2 Data Management databases and software

- All databases must be regulatory compliant, fully validated, and approved before recruitment.

- Access rights must be role-based and logged, modifications require re-validation, and software/file formats must ensure long-term accessibility and data traceability.

4.3 Data entry, data processing and data validation

- In accordance with GCP, quality control (QC) checks should be implemented for each stage of the data handling process, to ensure that all data are reliable and have been processed correctly.
- The frequency, level and point at which a QC check is conducted should vary according to the complexity and risk level of the trial and should be determined in accordance with the trial risk assessment.
- The frequency and level of data QC checks should be included in the trial DMP.
- Adherence to the QC checks frequency and level should be documented in the Trial Master File.
- For trials not using an eCRF, the CRA should conduct a review of the database before the end of the trial at time points specified in the trial specific monitoring plan.

For electronic Clinical Trial data, the following should be maintained:

- A security system that prevents unauthorised access to the data;
- A list of individuals who are authorised to make changes;
- Adequate back up of the data;
- A fully auditable trail of data queries and corrections.

If data are transformed during processing, it should always be possible to compare the original data and observations with the processed data.

Chief Investigators should ensure that the data management team are fully aware of any amendments to a trial which may affect the data collection/management process.

4.3.1 Data entry (for paper-based data collection)

- The Principal Investigator (PI) at the site is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported to the CI/ Data Manager in the CRFs and in all required reports.
- Data reported on the CRF that are derived from source documents should be consistent with the source documents or the discrepancies should be explained.
- Data should be entered into the CRFs and database in a timely manner.

4.3.2 Data Protection

- All data must comply with the Data Protection Act 2018, GDPR, and the NHS Data Security and Protection Toolkit. Personal data must be pseudonymised.
- Protected Personal Information must be encrypted in transit and at rest.
- Remote access is permitted only on encrypted devices.
- Any data breach must be reported immediately to the Sponsor and site institution.

4*.3.3 Data Processing*

The following procedures should be followed when processing Clinical Trial data:

- All transactions to the database (insert, update, delete) should have a clear and complete audit trial. For some software this may necessitate the printing of data and the certification and dating of the data as an accurate record of the previous and current versions of the database;
- Data should only be accessible to authorised personnel;
- The Data Handler must comply with GCP and is responsible for keeping data secure and confidential at all times;
- Coding should be performed using appropriate dictionaries;

- Where autocoding is not possible, manual coding may be performed.

4.3.4 Data querying

A process for raising and resolving data queries throughout the Clinical Trial should be included in the DMP.

4.3.5 Source Data Verification (SDV)

- An essential aspect of data management is the process of data verification. This process should be designed to ensure that the most accurate set of data is provided for statistical analysis.
- The type and level of data verification should vary according to the trial risk assessment.
- The data verification and SDV processes should be decided prior to the trial opening and should be documented in the DMP (or protocol) and trial specific monitoring plan.
- Data verification can take place at certain points during the trial but should be completed before the data is released for statistical analysis. Data verification should continue until all missing values and inconsistencies are corrected or clarified.

4.4 Data Back-up

- Robust back-up systems are required to guard against loss of data due to software or environmental disasters.

4.5 Database Lock

- The final database should be "locked" to ensure access to the final dataset to add or edit entries is permanently removed for all users before extraction or final analysis.
- The process used to lock the database should be described in the DMP.
- Depending on the trial, a staged locking process may be appropriate. For example, a two-stage locking process may be employed, where access is initially restricted to a (pre-defined) limited group, before the final lock is performed. If staged locking is utilised the procedure for staged locking processes should be described in the DMP.
- Evidence of when and how the lock(s) was/were performed should be documented. The same standards of security should be upheld for any final dataset files.
- Confirmation that database lock has occurred should be confirmed in writing, email is acceptable, to CI or delegate prior to the release of treatment blinding codes.
- The final dataset and analysis codes should be archived as detailed in KHP-CTO Archiving SOP 4.0.

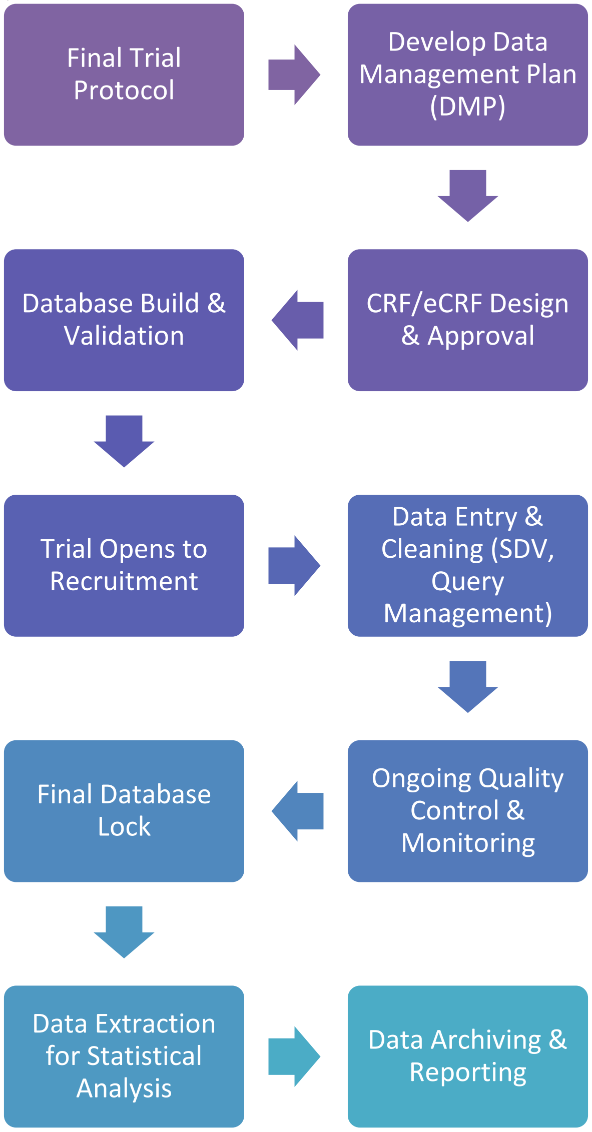
4.6 Data Release and Post Lock Changes

- Data extraction for final analysis is permitted only after database lock.

- Post-lock corrections require documented justification, prior approval, and a controlled unlock/re-lock process.
- All changes post-lock must be reported in the Clinical Study Report.

5.0 CLINICAL TRIAL DATA MANAGEMENT FLOW DIAGRAM

This simplified flow diagram outlines the key steps in the clinical trial data lifecycle:



6.0 RELATED TEMPLATES

6.1 Data Management Plan template

7.0 APPROVAL AND SIGNATURE

Ann-Marie Murtagh

Ann Maria Murtagh
Director,
King's Health Partners Clinical Trials Office

Date 27/10/2025

KING'S College LONDON

Guy's and St Thomas' NHS
NHS Foundation Trust

King's College Hospital NHS
NHS Foundation Trust

South London and Maudsley NHS
NHS Foundation Trust

APPENDIX 1

GLOSSARY

Case Record 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 trial participant.

Chief Investigator (CI) - The chief investigator is the overall lead researcher for a research project (Outside the UK the term Coordinating Investigator or Investigator may be used). In addition to their responsibilities if they are members of a research team, chief investigators are responsible for the overall conduct of a research project.

Clinical Research Associates (CRAs) – A professional who organises and monitors clinical trials to assess the safety and effectiveness of new or existing drugs, medical devices, or treatments. CRAs play a vital role in ensuring that clinical trials are conducted ethically, safely, and in accordance with established protocols and regulations. CTO CRA's monitor compliance, for clinical trials where regulatory oversight has been delegated to the KHP CTO

Clinical Trial of an Investigational Medicinal Product (CTIMP)- a type of clinical trial that investigates the safety and efficacy of a drug or other medicinal product that is not yet authorised for general use. It can also involve studying how the drug is absorbed, distributed, metabolised, and excreted, or identifying any adverse reactions.

Data - Facts, figures and statistics collected together for reference or analysis.

Data Management Plan (DMP) – A document, detailing how the data management activities for the trial should be carried out.

Good Clinical Practice (GCP) – an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials. It ensures the safety, well-being, and rights of trial participants are protected while maintaining the credibility and accuracy of trial data. GCP is crucial for safeguarding trial participants and ensuring clinical trials produce reliable, scientifically valid results

Investigational Medicinal Products (IMP) – a pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial. This includes products with marketing authorisation when used in a way different from the approved form, for an unapproved indication, or to gain further information about an approved use.

KHP-CTO Standard Operating Procedures (SOPs) - Detailed, written instructions to achieve uniformity of the performance of a specific function. SOPs are the basis on which Quality Systems and Processes are conducted and monitored

King's Health Partners (KHP) - King's Health Partners brings together research, education and clinical practice across three NHS Foundation Trusts - Guy's and St Thomas', King's College Hospital and South London and Maudsley - and a world-leading university, King's College London.

King's Health Partners Clinical Trials Office (KHP-CTO) – Established in 2006 by King's College London, Guy's & St Thomas' NHS Foundation Trust, South London and Maudsley NHS Foundation Trust and King's College Hospital NHS Foundation Trust to provide a streamlined approach for all aspects of trial administration. The King's Health Partners CTO has two sections: the Commercial Team which provides a single interface for those wishing to conduct trials sponsored by the pharmaceutical industries and the Quality Team that supports investigators at King's Health Partners institutions who undertake CTIMP trials where King's Health Partners are the sponsor or co-sponsor.

Personal Data - Any recorded information about a living individual who can be identified from that data or from that data and other available data.

Principal Investigator (PI) - the individual primarily responsible for the conduct of a research study at a specific research site

Protected Personal Information - Protected personal information is:

a) any information that links an identifiable individual with information that, if released, would put them at significant risk of harm or distress;
or
b) any source of information relating to 1,000 or more individuals not in the public domain, even if the information is not considered likely to cause harm or distress.

Research & Development Dept. (R&D) – NHS department responsible for confirmation of capacity and capability for all clinical research.

Source data - 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.

Electronic Source (eSource) Data - Source data captured initially into a permanent electronic record.

Source documents - Source documents are original documents, data (including relevant meta data) and records.

eSource documents - The electronic record used to aggregate a particular instance of eSource data items for capture, transmission, storage, and/or display, and serving as a source document for a CTIMP.

Source Data Verification (SDV) - refers to the process of checking the reliability of the data recorded in the data collection tool against the source documents.

The Regulations - The Medicines for Human Use (Clinical Trial) Regulations 2004 which transposed the EU Clinical Trials Directive into UK legislation, as Statutory Instrument 2004 no 1031. An amendment to implement Directive 2005/28/EC was made to the Regulations as Statutory Instrument 2006 no 1928. As amended from time to time.

Trial Master File (TMF) - a standard filing system which allows the effective storage and location of essential documents, that is the large volume of regulatory documents and approvals needed for clinical research. The filing system can be in the form of a single project file or a number of files/filing cabinets, depending on what is deemed most appropriate for a particular clinical trial given its size and complexity. The regulatory documents and approvals within the TMF will be maintained alongside case report forms and source documentation.