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SOP 805 Clinical Data Management System - CDMS SET-UP

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
Key words:	Clinical Data Management System, CDMS Set-Up
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Date of approval:	20.09.2023
To be reviewed before: This document remains current after this date but will be under review	20.09.2026 (3 years, unless legislation or process changes)
Reference and / or Trust Docs ID No:	14267
Version No:	4

Version and Document Control:

Version No:	Date of update	QPulse Change Request reference (CR no.)	Change Description	Author
4	August 2023	NA	Updated logos, template	Martin Pond

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

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1. Contents

2. Definitions of Terms Used / Glossary

CI	Chief Investigator
CDMS	Clinical Data Management System
CRF	Case Report Form
CTIMP	Clinical Trial of an Investigational Medicinal Product
DBM	Database Manager
DM	Data Management
DMP	Data Management Plan
GCP	Good Clinical Practice
ICH	International Conference for Harmonisation
NNUH	Norfolk and Norwich University Hospital
PI	Principal Investigator
R&D	Research and Development
SM	Study Manager
SOP	Standard Operating Procedure
UEA	University of East Anglia

3. Objectives

The data management strategy covers the management and manipulation of the study data, and the development and / or validation of any tools used to collect, store, and process the data.

The main deliverable from this procedure is a Data Management Plan (DMP) which outlines the details of the Clinical Data Management System (CDMS) to be set up, lists relevant documents, and references relevant procedures.

4. Scope

This SOP applies to all research managed by Norwich CTU however the principles contained in this SOP shall be followed for all other trials.

5. Purpose

The purpose of this procedure is to describe the setup and agreement of a data management strategy for the study.

6. Rules

Data Management Plan Timeline
The DMP **must** be in place and approved by the Database Manager (DBM) and the Study CI by the time that study data collection begins.

7. Procedures

7.1 Initial Approach

⇩	• Once a project has been funded, the DBM will (re)establish contact with the CI or Study Manager (SM) to gather, refresh and confirm their data management requirements and to outline the Data Management processes and possibilities.
⇩	• The DBM will set up an on-line folder to store any associated documents on a server with access, security, and back-up controls in place in accordance with NNUH or UEA information systems policies.
⇩	• The DBM will set up a DMP for the new project, based on an agreed design template, refer to **SOP 825 Clinical Data Management System VALIDATION**
⇩	• To begin discussing and defining requirements the DBM must request the latest versions of all relevant documentation from the CI or SM with assistance from the R&D Office as required. These may include: Protocol, Grant Application documents, trial specific CRFs and copies or references to pre-validated questionnaires. • The documents and their locations should be referenced in the DMP. • It is recognized that earlier versions may be used to inform initial discussions, but the final versions of all documents should be provided.

7.2 Setting Up the Data Management Plan

- The development of the DMP is led by the DBM but is a collaborative process between the Data Management team and the Study team

- The information gathering process is dependent on the nature of the trial and is by its nature an iterative process. The following points need to be addressed by the CI or delegated member of staff with the advice and support of the DBM when developing the CDMS:
    a. Study team members and roles
    b. Data Management team members and roles for this study
    c. Other relevant Data Management procedures (including management of the blinding of the study where applicable)
    d. Data sources
    e. Systems
    f. Validation
    g. Query process
    h. Quality assurance
    i. Quality control
    j. Handling protocol non-compliance
    k. Pharmacovigilance
    l. Training and documentation
    m. Database users
    n. Location of data
    o. Archiving and data return to sponsor

- There will be discussion between DBM and CI to note what is possible and what is required, noting that the most stringent requirements will apply to data management systems for CTIMPs and Medical Device trials.
- This may involve tailoring the specification of the CDMS according to cost or time constraints, and consideration should be given to the possible phasing of delivery

7.3 Production and adoption of the Data Management Plan

- The DBM will be responsible for the initiation and maintenance of the DMP. All signed-off versions will be retained online in the study data management folder

- The DMP will be developed and enhanced during the period leading up to the start of recruitment and data collection.

- During development and during the period of the study, the CI or SM should keep the DBM informed of any changes to system requirements that affect the DMP and the DBM will make the necessary amendments.

- The DBM will review and if necessary, update the DMP according to an agreed schedule.
- Any revisions to the DMP during the lifetime of the study must be agreed and signed off by the DBM and the CI or SM.

8. References and Related Documents

References	
SOP No.	**SOP Title**
SOP 825	Clinical Data Management System - VALIDATION

9. Approval

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10. Training Implication

Training Implication	
Actions required	• Review SOP