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To provide every patient with the care we want for those we love the most

SOP 825 Clinical Data Management System: VALIDATION

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
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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

CDMS	Clinical Data Management System
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
ICH	International Conference for Harmonisation
NCTU	Norwich Clinical Trials Unit
NNUH	Norfolk and Norwich University Hospital
PI	Principal Investigator
R&D	Research and Development
SOP	Standard Operating Procedure
TT	Tools and Templates
TMF	Trial Master File
UEA	University of East Anglia

3. Objectives

Validation of a CDMS through this set of documents:

(a) Demonstrates that a system was developed and implemented and is operated and maintained in a controlled manner throughout its life-time up to and including decommissioning
(b) Results in a high degree of assurance that the system consistently meets its specification and is therefore suitable for its intended purpose.

4. Scope

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

5. Purpose

The aims of this SOP are to give an overview of the Clinical Data Management process in terms of the people involved and the procedures that are followed.

6. Rules

All computer systems, both hardware and software, being used for the collection and analysis of clinical trial data must have undergone full validation.

- See **SOP 730 Computer System Validation** for more information
- Specialist software that has been produced 'in-house' or as a one-off application by a commercial company must be subject to rigorous validation processes, the results of which should be filed as evidence of validation in the Trial Master File (**SOP 305 Creating and Maintaining a Trial Master File**).
- Computerised laboratory information systems which capture analytical results of tests conducted during a clinical trial are also part of the data management for CTIMPs and medical device trials. CI/PIs must seek assurances at the trial planning stage that the accreditation status of the computerized system in the chosen laboratory is suitable and ensure that any documentary evidence is filed in the Trial Master File (**SOP 305 Creating and Maintaining a Trial Master File**).

7. Responsibilities

Throughout the CDMS development and support processes it is expected that people will be nominated to fulfil specific roles. These roles and their responsibilities are listed here. The DMP should name at least one individual for each role although one individual may fulfil several roles. The individual roles assigned will be recorded in the Study Delegation Log (**SOP 325 Study Start up Activities for Clinical Research Trials**) and in the Data Management Plan.

7.1 Study Team Members

CI / PI	The instigator of the study and the individual ultimately responsible for its smooth running.
Systems Manager (SM)	The individual who is responsible for the day to day running of the study, possibly including management of other study staff. Likely to be the main liaison between the Study Team and the Database Management Team.
Systems Tester (ST)	The individual who tests the system before it goes live, and checks any updates following bug fixes etc. before they are released into the live system.
Study Statistician (SS)	The individual who will be responsible for analysis of outcome data.

7.2 Data Management Team

Database Manager (DBM)	The individual who has overall responsibility for database production and support.
Database Analyst (DBA)	The individual who is assigned to the project to liaise with the Study Team to determine and document the data management requirements
Database Programmer (DBP)	The individual(s) who builds and deploys the system and fixes it if there are changes needed.
Database Tester (DBT)	The individual who produces and works through the test plan before the system is released to the Study team.
Database Support (DBS)	The individuals who provide support to users once the system has gone ‘live’.

8. Trial Documents

Trial specific documents will be based on a set of approved templates. Each trial requires a completed copy of each of these documents to be logged in the TMF (**SOP 305 Creating and Maintaining a Trial Master File OP**). If not completed, then an explanation must be provided and logged in the TMF at study close. The documents derived from standard templates are:

Data Management Plan Template	Lists key documents and processes for the development and maintenance of the CDMS
Data Dictionary template	A description of the data to be collected during the study including data types and value ranges, etc. Agreed between the Data Management Team and the Study Team including the study Statistician.
Functional Specification template	A description of the CDMS to be built, agreed between the Data Management Team and the Study Team.
Internal Test Plan, End-user Test Plan, and Report	A description of the testing to be done by the Data Management Team before the CDMS is released for evaluation by the Study Team. The Test Plan is usually based on the Functional Specification.
CDMS Users Log template	A list of users of the CDMS and their roles within the system that give them varying access rights to various parts of the system.
System Acceptance template	A letter for the Study Team to sign indicating acceptance of the system before it is released for live data entry.
Release Note template	A description of any changes made as a result of bug fixes or enhancements to the TDMS. Includes a section for sign-off indicating acceptance by the Study Team.
Emergency Unblinding Form template	A proforma to be completed by the Data Management Team when a request for emergency un-blinding has been processed by the team. Note that where a secure electronic unblinding function is included in the system this paper form will not be used. The system will retain records if any use of the unblinding function.
Data Validation Report template	A report noting the running and success/failure of Data Validation Queries.
Database Unlock Request template Database Lock Request template	Proformas to be completed by CI/PI or SM requesting that the database should be locked/unlocked.
Data Request Form template	A proforma to be completed by Study Team members, statisticians etc. requesting datasets to be produced or read-only access to the database to be granted.
Database Closedown Request template	A proforma to be completed by CI/PI authorising the closedown of the CDMS.

9. Clinical Data Management Systems Procedures

Each CDMS will be designed, built, and maintained following the latest approved Data Management Standard Operating Procedures (SOPs). The SOPs and their basic purpose are as follows:

SOP 825 Clinical Data Management System – VALIDATION	This document. Describes the high-level process of CDMS management.
SOP 805 Clinical Data Management System - TDMS SET-UP	Describes the process of beginning the development of a CDMS and setting up a Data Management Plan.
SOP 810 Clinical Data Management System - SPECIFICATION, DEVELOPMENT, TEST and DEPLOYMENT	Describes the process of designing, testing and deploying the CDMS.
SOP 815 Clinical Data Management System – LOCKING AND UNLOCKING OF DATABASES	Describes the process of locking/ unlocking the database to provide a stable basis for quality control and analysis
SOP 860 Clinical Data Management System – DATA REQUEST	Describes the process of obtaining official data sets for analysis etc. after database lock.
SOP 820 Clinical Data Management System - MAINTENANCE AND SUPPORT	Describes how bugs and enhancements are handled after the CDMS has gone ‘live’.
SOP 835 Data Management - EMERGENCY UNBLINDING	Describes how randomisation data can be revealed in an emergency, in a CTIMP or Device Trial.
SOP 840 Clinical Data Management System - DATA MANAGEMENT AND SECURITY	Describes how trial data is protected and recoverable from system failures.
SOP 850 Clinical Data Management System – CLOSEDOWN	Describes the process of decommissioning the CDMS after the trial is completed.
SOP 855 Clinical Data Management System – MANIPULATION OF DATA AFTER EXPORT	Describes the procedure for recording data manipulation after export from the clinical database

10. References and Related Documents

References
ICH GCP E6 / SI 2004/1041
EU Directive 2001/20/EC
Medicines for Human Use (Clinical Trials) Regulations 2004
Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice (E6R2), Step 4 version, dated 9 November 2016
Research Governance Framework for Health and Social Care (DH 2005)

SOP No.	SOP Title
SOP 305	Creating and Maintaining a Trial Master File
SOP 325	Study Start up Activities for Clinical Research Trials
SOP 730	Computer System Validation
SOP 805	Clinical Data Management System - TDMS SET-UP
SOP 810	Clinical Data Management System - SPECIFICATION, DEVELOPMENT, TEST and DEPLOYMENT
SOP 815	Clinical Data Management System – LOCKING AND UNLOCKING OF DATABASES
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SOP 840	Clinical Data Management System - DATA MANAGEMENT AND SECURITY
SOP 850	Clinical Data Management System – CLOSEDOWN
SOP 855	Clinical Data Management System – MANIPULATION OF DATA AFTER EXPORT

11. Approval

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12. Reason for new version and Training Implication

This SOP replaces the previous version number, 2.2

Changes made	What changes have been made to the contents of the document
Reason	• New layout • Revision in procedure
Training Implication	Yes
Actions required	• Read and Update Training Matrix