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SOP 810 Clinical Data Management System
SPECIFICATION, DEVELOPMENT, TEST and DEPLOYMENT

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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1. Contents

2. Definitions of Terms Used / Glossary

CI	Chief Investigator
CDMS	Clinical Data Management System
CTIMP	Clinical Trial of an Investigational Medicinal Product
DBA	Database Analyst
DBM	Database Manager
DBP	Database Programmer
DBT	Database Tester
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
ST	Systems Tester
UEA	University of East Anglia

3. Objectives

A clinical data management system or CDMS is a tool used in clinical research to manage the data of a clinical trial. The objective is to set out the minimum requirements for the specification development testing and deployment of the CDMS to ensure it meets the required standards for managing clinical trial data.

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 process of producing a Clinical Data Management System (CDMS), once initial discussions have been concluded.

6. Rules

Producing a Clinical Data Management System (CDMS)

There are four main phases to this process:

- Specification
- Implementation
- Test
- Deployment

Each of the above phases is subject to review, approval and repeat if necessary.

7. Procedures

7.1 Data Dictionary and Functional Specification

- Once a study funding application has been approved the DBA will begin work on producing a Data Dictionary and a System Specification using the current approved templates.

- The Data Dictionary is a by-product of development, so cannot be considered final until the database complete.
- The Functional Specification must be approved before the CDMS goes live.

- Both the Data Dictionary and the Functional Specification are working documents which may change during the development of the CDMS.
- Any significant changes should be discussed with the appropriate study team members.

Data Dictionary

- Contains a description of all the data items to be collected, their data types and ranges of valid values.
- Describes how data is divided into categorized sets and the relationship

between these sets.

- **Must** be approved by the Study Statistician, and if appropriate the Health Economist and anyone else likely to be analysing outcomes.

Functional Specification

- The Functional Specification Contains:
  - Description with illustrations of the user interface, where data is entered, reviewed and updated.
  - Description of standard data validation to be performed.
  - Description of any data transformations that take place.

  Description of any non-standard functionality and the circumstances where it occurs.
- Is a descriptive document to be used as a guide by programmers implementing the system, consideration should be given to the fact that the approvers are unlikely to be computer experts and therefore computing jargon **must** be avoided.
- Detailed technical notes, if required, **must** be put into a separate document, and referenced from the Functional Specification.
- Should also be usable as a user reference and training manual for data entry staff.
- Should be approved by the Study Manager responsible for data entry.

7.2 Quality Assurance and Validation

- When the Data Dictionary and the Functional Specification have been approved by all reviewers the DBP will produce Test Plans which can be based on the Functional Specification
  - One test for internal testing by Data Management
  - One test for user testing
- 'Standard' tests such as navigation between pages working correctly, and data loading and saving should be included.
- Each specific operation in the specification (e.g. checking that a follow-up date is within a certain range related to the randomization date) will be subject to its own tests.

- The Test Plan will, by default, be produced by copying the relevant sections of the Functional Specification and adding for each function a box to indicate that it has been tested correctly, or a note to state the nature of the failure:

PASSED	FAILED	Notes
☐	☐	

- The DBT will use the Development environment to work through the test plan noting the success or failure of each test. Any failures must be fixed and those tests re-run.

- All test plans and associated results should be stored in the CTU Data Management file system.

8. DEPLOYMENT

8.1 Test System Deployment

When the Data Dictionary and the Functional Specification have been approved by all reviewers, and the system has been built and undergone initial development testing, the Database programmer (DBP) will deploy the system for user testing:

- The DBP will install the system in the Test Environment.
- The DBT will work through the test plan noting the success or failure of each test, using the Test Environment – producing a System Test Report as a result. Any failures must be fixed and tested in the Development Environment and the system re-installed with the appropriate tests re-run in the Test Environment
- The DBP will obtain the name and contact details of one or more System Tester (ST), from the CI or SM, and setup a login account on the test system for this person.
- The ST will be given a copy of the completed System Test Report, which they can follow through alone and run whatever tests are wished.

8.2 System Acceptance

- When the ST is happy with the performance of the Test System the SM should sign the System Acceptance document.

- The System Acceptance document must also be signed by the Study Statistician to indicate approval of the database design.

8.3 Live System Deployment

- On receipt of the signed System Acceptance Form, the DBP will arrange for deployment to the Live environment, check that it is ready for use and notify the SM.

- The SM **must** provide the DBM with a list of Users and the roles to which they should be assigned in the CDMS. This will form the initial CDMS Users Log, which must be kept up-to-date through the lifetime of the study.

- The DBM will set up the required accounts and send details to the individual users. Passwords must only be sent to the user in question with a reminder that they must not be divulged.

- The system will now be under Change Control. DBM will set up a Tracker Database for the trial, this is used to record bugs reported and enhancements requested each with an ID and status.

9. References and Related Documents

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

10. Approval

Author	Martin Pond
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11. 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 • Numerous change requests raised
Training Implication	Yes
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