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SOP 820 Clinical Data Management System - MAINTENANCE AND SUPPORT

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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SOP 820 Clinical Data Management System - MAINTENANCE AND SUPPORT

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
DBP	Database Programmer
DBS	Database Support
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
SU	System User
TT	Tools and Templates
UEA	University of East Anglia

3. Objectives

Once a Clinical Data Management System (CDMS) has ‘gone live’ there is a requirement for a structure within which issues arising can be dealt with, covering:

- Reporting problems
- Initial response
- A framework for solution of problems

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

This SOP describes the processes of managing bug reports and enhancement requests for CDMS that have been deployed into the Live environment at UEA and NNUH.

6. Rules

Definition of Bugs and Enhancements

- Bugs are instances of the system failing to work to the current agreed Functional Specification.
- The System User (SU) can report bugs to DBS by whatever means is convenient but this will usually be by phone or email.

- Enhancements are items of data or functionality that were not in the agreed System Specification.
- Requests must be made to the DBM by the SM.

7. Procedures

7.1 Reporting Bugs in the System

On receipt of a bug report, the DBS will attempt to reproduce the problem either in the Development environment or the Test environment.

- If the problem is reproduced, then the DBS will enter the details onto the Bug and Enhancement Request Tracker database and reply to the reporter giving the Defect number.
- If not reproduced, the DBS will inform the SU, and further discussion will determine whether the issue can be dropped or requires further investigation.

The DBS must prioritise the problem according to the following rules as far as possible and then inform the SU that the problem has been accepted as an issue and to pass on the problem ID and its priority.

Critical Bug	Where entry of all or part of the study data is halted, corrupted or subject to serious delay.
High Priority Bug	Where there is a significant breakage or loss of functionality, but work can continue until a fix is available.
Low Priority Bug	Where there is no significant loss of integrity or performance.

7.2 Requesting Enhancements to the System

- On receipt of a request for an enhancement, DBS must log the issue onto the Bug and Enhancement Request Tracker database and reply to the reporter giving the Defect Number.

The DBM must prioritise the problem according to the following rules as far as possible:

Substantial enhancement:	Needs to be treated as a project in its own right, and will require costing.
Small enhancement:	Can be treated in a similar way to a high priority bug.

- The distinction between small and substantial is a subjective judgement and must be agreed between the DBM and the SM.

7.3 Bug Fixing

- The DBP will fix the bug and test it in the Development environment.
- If appropriate, the Functional Specification and/or the associated Test Plan (see **SOP 810 Trial Data Management System - SPECIFICATION, DEVELOPMENT, TEST and DEPLOYMENT**) shall be updated to incorporate the change.
- The DBP will prepare a Release Note, based on an agreed template, giving details of the change, test instructions and any special deployment instructions.
- The DBP will install the updated software in the Test environment and run the appropriate tests. Any failures will need re-fixing, re-deployment, and re-testing.
- While the updated software is still only on the Test system, the DBP may, if required, ask the SU who reported the problem to check details of the fix, particularly where the update is complex or hard to reproduce.
- When the Test environment has been satisfactorily updated, the DBM will update the Live system and send a notification to the SU who reported the problem. This will be by email with an attached copy of the Release Note.

- The SU should check the fix in the Live system and if OK, sign the acceptance form provided with the Release note, returning it to the DBM who will file it in the CDMS file.
- Note that frequently several fixes will be done together so a coordinated correspondence with several SUs may be necessary.

- If a fix requires a change to the data structures, the user interface or special functionality then the CDMS Data Dictionary (**see SOP 810 Trial Data Management System - SPECIFICATION, DEVELOPMENT, TEST and DEPLOYMENT**) should be updated to incorporate the change.

7.4 Implementing Enhancements

- Small enhancements will be treated in the same way as bugs and documented with a Release Note.

- Substantial enhancements will need to go through the project specification, development, test and deployment process (**SOP 810 Trial Data Management System - SPECIFICATION, DEVELOPMENT, TEST and DEPLOYMENT**).

- Any changes to the data structures, the user interface or special functionality should be incorporated into an updated Functional Specification and Data Dictionary

- Any small enhancements made between large enhancements should be included in the revised Functional Specification and Data Dictionary.

8. Availability of Support

- The DBM will ensure that cover is available for standard office hours (09.00 till 17.00).

- The Trial Risk Assessment will determine whether out-of-hours support is required for any functions of the Data Management System.

9. References and Related Documents

References	
SOP No.	**SOP Title**
SOP 810	Clinical Data Management System - SPECIFICATION, DEVELOPMENT, TEST and DEPLOYMENT

10. Approval

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11. Training Implication

Training Implication	
Actions required	• Review SOP