MRC Clinical Trials Unit

Smarter studies
Global impact
Better health

UCL

# DATABASE DEVELOPMENT SOP

# VERSION 5.0

## APPROVALS

| **Author** | **Position** | **Signature** |
|---|---|---|
| Chiara Borg | Data Scientist | DocuSigned by: Chiara Borg 3175C8085B6D475... 22-Jun-2021 |
| Marion Hall | Database Programmer | DocuSigned by: Marion Hall 59D82208C527401... 21-Jun-2021 |
| **Reviewer(s)** | **Position** | **Signature** |
| Brendan Murphy | Data Manager | DocuSigned by: Brendan Murphy 4E85DF146265406... 22-Jun-2021 |
| Carlos Diaz Montana | Clinical Data Systems Manager | DocuSigned by: Carlos Diaz-Montana 96D24ED07E77456... 22-Jun-2021 |
| Lindsey Masters | Clinical Project Manager for Data Science | DocuSigned by: Lindsey Masters 86B2B130A1EA4E7... 23-Jun-2021 |
| Nadine Van Looy | Clinical Data Systems Manager | DocuSigned by: Nadine Van Looy D411963F4E374C6... 23-Jun-2021 |
| **Approver** | **Position** | **Signature** |
| Mary Rauchenberger | Head of Data Management Systems | DocuSigned by: Mary Rauchenberger 5DEA25C1E04841F... 23-Jun-2021 |

**All appropriate approvals must have been completed prior to uploading to SOPbox.**

## UPLOAD TO SOPBOX

| Name | Position | Signature | Date uploaded to SOPbox |
|---|---|---|---|
| Steve Townsend | SOPbox Administrator | DocuSigned by: Steve Townsend 72B77F4216C14ED... | 09-Jul-2021 |

**The effective date of this SOP is the day on which it is uploaded to SOPbox and is available to use. This is the date associated with the signature of the SOPbox Administrator.**

**For the Revision History please see the Version History Summary in SOPbox.**

# DATABASE DEVELOPMENT

## TABLE OF CONTENTS



**Note:** Glossary of terms, acronyms and abbreviations will be provided in a separate document for all SOPs and associated documents

The following symbols may be used in this SOP:

Indicates a link to a related document

Indicates instructions to document trial-specific processes elsewhere

Throughout this document 'MRC CTU' will be used to refer to the MRC Clinical Trials Unit at UCL (MRC CTU at UCL).

# 1 PURPOSE

The purpose of this SOP is:

- To provide a procedure for developing a database system in compliance with the principles of ICH GCP and any other regulatory requirements relevant to the development
- To provide a procedure which will be able to demonstrate through documented evidence that the database system is fit for its intended purpose and able to consistently maintain this state.
- To identify the documents which must be produced as part of a database system development.
- To define the roles involved in developing a database system and their respective responsibilities.

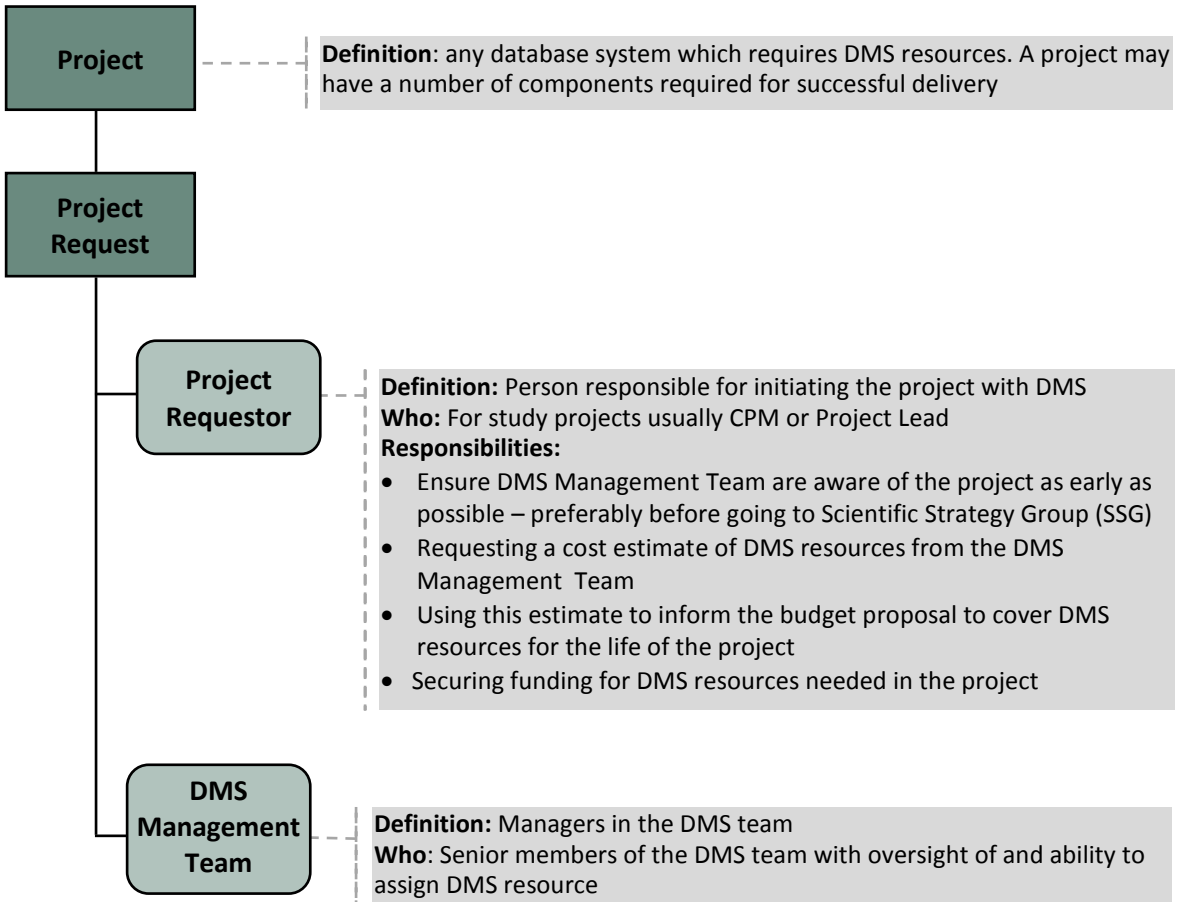
Systems developed by DMS are herein referred to as 'database systems'; these will normally include a database component, but usually one or more of the following as well: a front-end application; reports; web components; interfaces to load, extract or merge data; project-specific innovations.

For the purpose of this SOP:

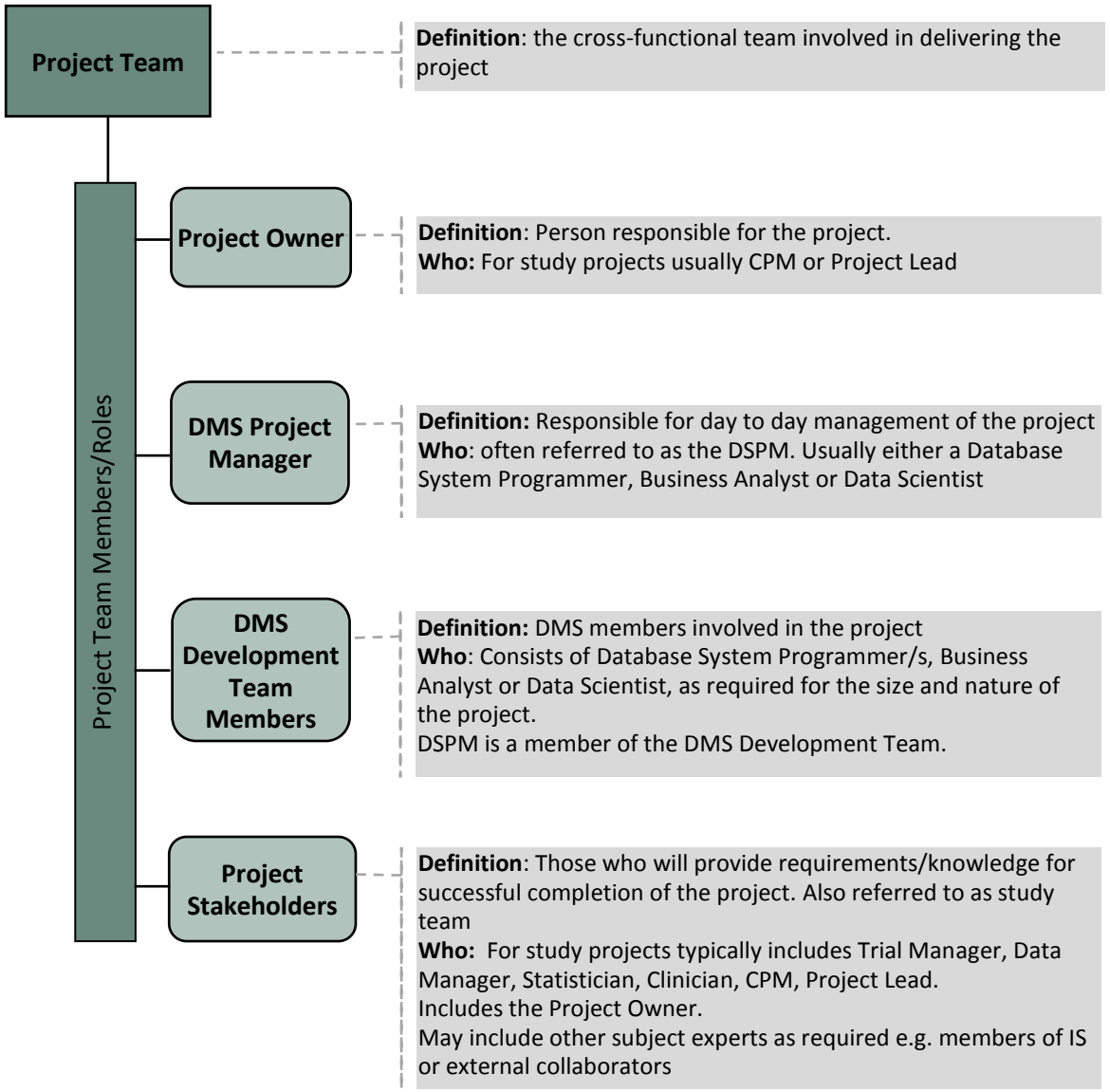
- 'paper CRF' will refer to the paper version of a CRF
- 'eCRF' refers to the electronic version a CRF in a database
- 'CRF' will be used as a blanket term when referring to both above types of forms
- 'worksheet(s)' (sometimes known as "Source data worksheets") refers to a paper document used to collect source data for the participant notes/records at site, where the primary data collection method for the study is electronic data capture (eDC). Each worksheet should be a faithful representation of the relevant eCRF(s), and updates should be made to the worksheets appropriately in the same way as paper CRFs when updates are made to the database.

# 2 RESPONSIBILITY AND ROLES

## 2.1 ROLES AND RESPONSIBILITIES BEFORE A PROJECT RECEIVES FUNDING



## 2.2 PROJECT TEAM ROLES DURING DATABASE SYSTEM DEVELOPMENT



## 2.3 PROJECT TEAM RESPONSIBILITIES DURING DATABASE SYSTEM DEVELOPMENT

Project Team Members/Roles

**Project Owner**

**Responsibilities:**

- Regular communication with DMS Management Team and/or DSPM on progress
- Input to and approve project documents as required
- Agreeing and approving project milestones
- Ensuring that sufficient and appropriate study team resource is available for involvement in the database systems development project
- Identifying project stakeholders and assigning individual task responsibilities as necessary
- Ensuring that all database system users request and receive training in the system, with a Delegation Log maintained in the study master file documenting this.

**DMS Project Manager**

**Responsibilities:**

- Ensuring the completion, review, and sign-off of all project documentation
- Communicating significant changes in project scope or timelines to DMS Management Team (with updates to the Project Specification if required)
- Requesting and managing resources from DMS Management Team to complete the project
- Regular communication with the Project Owner and Project Team on progress
- Ensuring requirements are gathered to enable programming of the database system
- Ensuring the completion of database programming and web development. Taking oversight when multiple programmers are involved in a project.
- Ensuring there is a process in place to grant appropriate system access to users, with access to training materials if required.
- Filing of database development documentation in the DMS Master File

**DMS Development Team Members**

**Responsibilities:**

- Input to study/project risk assessment
- Input to requirements
- Provide guidance and support to project team members as required through the database system development process
- Execution, and documentation of Unit and System Testing in accordance with the Test Plan
- Supporting the user acceptance testing (UAT) process
- Developing the database system or their assigned components where multiple programmers are working on the same project
- Input to project documentation as required

**Project Stakeholders**

**Responsibilities:**

- Providing detailed requirements (such as the Requirements Specification, Protocol Data Collection Assessment spreadsheet, CRFs, metadata, randomisation requirements)
- Ensuring input to requirements from the DMS Development Team
- Reviewing the Requirements Specification
- Providing requirements at a suitable state for programming
- Participating in User Acceptance Testing (UAT)

Note: The DMS Quality Control Reviewer is involved in the database system development process but is not considered to be part of the Project Team. This role is described in more detail in section 3.3.

# 3 PROCEDURES

## 3.1 PROJECT LIFE CYCLE

A project request should be made for a database system before the project has gained approval to proceed, for example before submission to the Scientific Strategy Group (SSG). If not, adequate resources may not be available for the project. This is usually an informal conversation between the Project Requestor and Head of DMS, to discuss high level known details of the project at that time.

Once the project has approval to proceed, the Project Requestor should ask for a DMS cost estimate. This should be done with sufficient notice before the funding proposal is due in (ideally two weeks). It is important at this early stage also to discuss any potential need for use of non-standard systems or involvement of third-party systems, as the DMS Management Team can input into the study Risk Assessment for these areas. Significant changes to these needs should be discussed with the Head of DMS as soon as they arise.

Any hardware and software required for the project that does not exist must also be included in the project budget.

Once a request has funding approval, the Project Requestor becomes or assigns the Project Owner, and the Project Owner should schedule a meeting with members of the DMS Management Team to discuss the high-level requirements. This will include a discussion of the proposed technology solution for the project. The high-level requirements are outlined in a Project Specification (See Section 3.4). The DSPM may be assigned at this time or shortly thereafter.

Database system development occurs in a cyclic incremental fashion. The following sections detail the components of each cycle. Requirement specification, database system development and testing are iterative, and the iterations or phases continue until the scope of the project has been met.

## 3.2 PROJECT TEAM

Database systems are developed by a Project Team. The project team is made up of the Project Owner, the DSPM, the DMS Development Team and the Project Stakeholders. (See Section 2.2 for more detail on these groups and roles.)

The DMS Management Team will identify appropriate and available resource to fulfil the role of the DSPM and the DMS Development Team Members at the start of a project, as required based on the Project Specification. The DSPM is responsible for oversight and coordination of the project and whilst some of the tasks may be delegated to other DMS Development Team members, overall responsibility lies with the DSPM.

The DSPM in conjunction with the DMS Management Team will maintain oversight of the resourcing requirements of a project throughout its life cycle. Any concerns over resource, e.g. inadequately funded projects will be discussed with the Project Owner as this may affect the development of the database system.

Similarly, the Project Owner is responsible for identifying appropriate Project Stakeholders to join the Project Team and for ensuring they have appropriate and available resource to undertake their assigned tasks (requirements gathering and UAT).

It is important for the Project Team to meet and communicate regularly throughout the database system development process. This will ensure any issues which may prevent the project from meeting its timelines will be identified and can be dealt with effectively. Regular discussion will also allow the DMS Development Team to provide support and guidance to the Project Stakeholders as needed throughout the requirements gathering and testing process.

## 3.3 DMS QUALITY CONTROL (QC) REVIEWER

The DMS QC Reviewer ensures that the DMS documents adhere to the Database Development SOP. The QC review process will be performed by the DMS QC Reviewer who is a member of the DMS team but who was not involved as an author or reviewer of the document concerned.

## 3.4 PROJECT SPECIFICATION

Once assigned, the DSPM is responsible for drafting the Project Specification, to establish a high-level view of the project requirements.

The Project Specification should then be completed on the basis of input from the Project Team, the Study Protocol and/or any other documents available.

The Project Specification should contain, but is not limited to:

- Scope of Project
- High Level Requirements and deliverables
- Project Approach, including details of tasks to be performed, proposed timelines for release and any logical phased approach to the project (e.g. delivery of a system to enable screening to study enrolment in the first phase, follow up forms in the second phase, etc). This is however a forecast and subject to change during the life cycle of the project.
- Validation Plan. This details the documentation set required for the project. For a study related project, we would normally expect all the documents listed in this SOP to be produced to document the validated state.
- Project Team Members at the time of signing off the Project Specification will be listed in the document. However, during the life cycle of the project, the study team are responsible for maintaining a list of project team members in STOPOVER as team members change.

The Project Specification is reviewed by the DMS QC Reviewer and approved by the Project Owner and DMS Management at the start of the project. Significant changes in scope or timelines which impact the resources required for the project must be communicated to the DMS Management Team by the DSPM and must be re-reviewed by the DMS QC Reviewer and re-approved by the Project Owner and DMS Management. This may be an update to the original Project Specification or a separate update document. All changes are detailed in the revision history.

Once the Project Specification has been approved, the requirements gathering phase begins and the Requirements Specification can be drafted.

## 3.5 RISK ASSESSMENT

The study team should ensure that any risks that have been identified in the development or implementation of systems for a study should be included in the study risk assessment, in discussion with the DMS Development Team. Some examples of the type of risks which might be included are:

- If the study needs to capture directly identifiable data (as per the Management of Participant Personal Data SOP)
- If the study data is to be collected for regulatory purposes – this may impact on the way the data needs to be collected and managed in the database
- If the study has funding dependent timelines, which mean the database systems have to be delivered by a specific deadline
- If the study has a lack of resources (people/monetary) for collecting database system requirements and participating in the implementation of those systems
- If the study plans to open in sites that may not have adequate technical capabilities, e.g. poor internet connection to access the study database systems or low-spec PCs
- If the study requires technical innovations

Development of non-study related database systems (i.e. those that do not hold clinical data, or are not used to manage clinical data e.g. TAPP) and study related database systems that are not used for clinical data capture and management of CRFs (e.g. Drug Supply Management System), will have a project-level risk assessment in their Project Specification.

## 3.6 REQUIREMENTS SPECIFICATION

The Requirements Specification is a high-level document which summarises all the user requirements, including regulatory, technical and procedural (such as screening/randomisation/enrolment for a study system) requirements. It describes the business needs that the users require from the system in a non-technical manner. Detailed requirements are held in supporting documents, such as metadata spreadsheets, and referenced in the Requirements Specification. The DSPM is responsible for ensuring the relevant Project Team members contribute to and approve the Requirements Specification.

System development may be divided into logical delivery phases (as described in the Project Specification). All high level requirements for the first release must be detailed in the Requirements Specification. The DSPM is responsible for ensuring that the implications of the specifications are understood by the Project Team. The Requirements Specification must be reviewed by key stakeholders (such as the Statistician, Trial Manager, Project Owner and DMS representative). The Requirements Specification must be reviewed by the DMS QC Reviewer and approved by the Project Owner or delegate before testing can begin.

Failure to agree final requirements according to the proposed timelines will result in a delay to subsequent development, testing and delivery of the live system.

Sufficient confidence in the requirements detailed in the Requirements Specification as well as in the underlying requirements documents associated with it (as described in section 3.7) should exist prior to system development in order to avoid misinterpretation of requirements and wasted effort on system development. If, after signing off the Requirements Specification, requirements change that affect the content of the Requirements Specification (e.g. if during the testing phase it is found that an eCRF needs to be split into two eCRFs), this document must be updated, re-reviewed by the DMS QC Reviewer and re-approved by the Project Owner or delegate.

## 3.7 REQUIREMENTS GATHERING

The main requirements areas for a study project normally consist of:

- Protocol Data Collection Assessment spreadsheet: For study projects this will contain a detailed extract of data related items from the study protocol and will document how these data items are being collected and checked. This should be completed by the trial team, ensuring input from DMS.
- CRFs: CRFs should be developed based on requirements detailed in the Protocol Data Collection Assessment spreadsheet. The Project Stakeholders (including the statistician, clinician and trial manager) alongside DMS design, develop and maintain the CRFs based on the needs of the study protocol, including the list of CRFs and the visit schedule.

For information on CRF development refer to MRC_CTU_SOP_072 CRF and Worksheet Development and Maintenance SOP.

- Metadata: Metadata spreadsheets formally specify the implementation of the CRFs and the eligibility requirements on the database system (if applicable), including query specification (missing data and validations), visit schedule, eligibility and patient identification checks.
- Report specifications: These follow a standard template to document the need for the report, data requirements, who and where the report be run by, report layout, deployment and testing.
- Analysis File Specification will be required if a generic extract of CRF data with data definition documents is not already built into the system.

Where appropriate, the study statistician is particularly responsible for providing requirements for randomisation and data to be extracted for analysis. They also should review the Requirements Specification with respect to these areas.

The process of requirements gathering is an iterative process, involving the following steps:

a) Initial specification (i.e. early drafts of protocol data collection assessment spreadsheet, CRFs and metadata, report specifications)
b) Discussion and clarification with relevant members of the Project Team
c) Review and testing for use in real-life i.e. completing or entering dummy CRFs or Worksheets
d) Finalisation and approval

Timelines for review should be agreed amongst the Project Team, including DMS since consideration must also be given to development time. Requirements should be reviewed by key stakeholders (such as the Statistician, Clinician, Trial Manager, Project Owner and DMS representative) before development starts to ensure there is sufficient confidence in the robustness of the requirements in order to avoid misinterpretation of requirements and wasted effort on system development (e.g. at the point of development, the Protocol Data Collection Assessment spreadsheet should have been completed against a near-final copy of the protocol that has been reviewed by the key stakeholders).

## 3.8 FUNCTIONAL SPECIFICATION

The Functional Specification documents show how the requirements have been achieved at a technical level. Other documents that might be included with the Functional Specification are annotated CRFs, reports and API specifications, showing the database tables and fields used in the implementation. The Functional Specification must be finalised before database system go-live.

The Functional Specification document and any other design documents, where applicable, are developed by the DMS Development Team and are peer reviewed by another member of DMS, ideally a senior programmer.

For some projects, the Requirements Specification and Functional Specification may be combined into a single document, although still covering the content of each. In such cases, the Validation Plan in the Project Specification will explain this.

## 3.9 DATABASE SYSTEM PROGRAMMING

The database system is programmed to meet the needs of the Requirements Specification and other associated requirements gathering documents. For trial databases, this will include the protocol data collection assessment spreadsheet. Programming can only begin when detailed requirements (as listed in Section 3.7) for this phase/project have been agreed by key stakeholders. Programming standards developed within the DMS group should be followed, and where appropriate source code should be kept in a source control software system, such as SourceSafe, TFS or Git.

The Database System Programmer is responsible for completing testing of basic functionality before releasing to system testing. See section 3.10.1 for further information.

Where database systems have several components, a number of Database System Programmers may be associated with the project. The DSPM will have oversight of this.

## 3.10 TESTING

The Test Plan details the scope of the tests to be carried out and how issues found during testing will be documented and retested, how updates to code will be released in a controlled manner so that it is clear which changes are in the test system and which are not. The plan will also define the tasks that need to be complete before testing can begin and the criteria that will be used to conclude that testing is complete. It is developed by the DSPM or their delegate.

The Test Plan follows the standard template and all updates to the Test Plan are recorded in the revision history. It is peer reviewed by a member of DMS, reviewed by the DMS QC Reviewer and approved by the Project Owner or delegate.

### 3.10.1 UNIT & SYSTEM AND INTEGRATION TESTING

Test conditions are written to verify that the system performs according to the Requirements Specification. It is important to ensure that tests cover all relevant functionality within a Database System, including screens, reports etc. Integration tests involving data transfer between systems may be included within the Unit & System Testing, or listed separately as Integration Tests.

Test conditions are peer reviewed by another member of DMS before testing commences. The testing is normally performed by members of the DMS Development Team but ideally not the original programmer. A second programmer will perform code review as part of unit and system testing. Test results are documented in accordance with the Test Plan. Any failed tests are documented as described in the Test Plan. Fixes are performed by the programmer and the impact of the code change is assessed so that the testers can re-test all affected areas.

Once all testing is complete, it is peer reviewed by a member of DMS and reviewed by the DMS QC Reviewer.

The results of the Unit & System and Integration Test will be summarised in the Validation Report (section 3.10.4).

### 3.10.2 User Acceptance Testing (UAT)

This is performed by users of the database system (usually Project Stakeholders possibly acting on behalf of site staff) and managed by the Project Owner (often with the support of the DMS Development Team). The aim of the test is to confirm that all the business functions, processes and workflows are supported as expected. Where the Database System includes randomisation, this must be tested, and must be approved by the statistician.

Test scripts or scenarios are written by the users of the system with assistance from a member of the DMS Development Team. Scripts are reviewed by the DSPM or delegate. The system is tested by following the steps in the script and the results are documented in accordance with the Test Plan. Any tests which fail are documented as described in the Test Plan. Fixes are performed by the programmer and the impact of the code change is assessed so that the testers can re-test all affected areas.

Once all testing is complete, the test results are peer reviewed by a member of DMS and reviewed by the DMS QC Reviewer. Any conditions that fail will be discussed by the DSPM and the Project Owner and they will decide whether the testing can be signed off as is and the database system made live or whether further updates are required.

Once UAT is complete, the test documentation will be filed in the DMS Master File for the project.

The results of the UAT will be summarised in the Validation Report (section 3.10.4).

### 3.10.3 Implementation Plan

An Implementation Plan is completed, which describes what tasks need to happen for the database system to go live. This is typically started during the migration of the system from the development environment to the test environment so that the setup parameters can be documented real time and repeated to move the system to live.

It is the responsibility of the DSPM to ensure this is written by a DMS Development Team member and approved before the Validation Report. The Implementation Plan should be reviewed by a DMS programmer. Where the system is hosted by UCL, the Implementation Plan should be reviewed by a DMS programmer with database administration rights for the system being implemented, so they are able to perform or assist with the implementation. It should also be reviewed by the DMS QC Reviewer. The plan should contain the following:

- Deployment of software, hardware and database system to live servers
- Ensuring database system training materials are in place
- Ensuring database system delegation log has been created

The Database System Programmer/s should also create any other documents which may help other programmers maintain the system if required.

### 3.10.4 Validation Report

A Validation Report, which summarises the results of all testing and details any deviations to the validation plan, is issued by the DSPM and approved by the Project Owner and a member of DMS Management team, and reviewed by the DMS QC Reviewer.

The Validation Report must be signed off before the database system can be released into the live environment. A target release date may be agreed beforehand, but it is subject to this sign-off. A member of the DMS Management Team should be one of the approvers of the Validation Report.

Any further changes to the database system are managed in accordance with the Database Change Control SOP.

#### 3.10.5 DATABASE SYSTEM GO LIVE

Once the Validation Report has been signed off the implementation can be scheduled. The release will follow the steps agreed in the Implementation Plan. The scheduling and release are dependent upon available resource.

After the Database System is live users can be provided with access. This should only be done once they have been authorised by the Project Owner or delegate and trained by the Study team or other appropriate individual.

For information on how to delegate responsibilities refer to MRC_CTU_SOP_031 Signing Study Related Documents SOP.

Evidence of authorisation and training must be recorded on a delegation log. The delegation log remains with the study team, as part of the Trial Master File. Any subsequent changes to user authorisation must be recorded on the delegation log before access is granted.

### 3.11 DMS MASTER FILE

All project documentation for a database system described in this SOP is filed within a standard file structure with version control. This is known as the DMS Master File. For a study project, the DMS Master File forms part of the Trial Master File (TMF) and DMS documentation can be referenced from the relevant sections of the TMF. Specifically, the documentation described in this SOP forms evidence for Computer Systems Validation, and should be referenced from that section of the TMF.

It is the responsibility of the DSPM to ensure the DMS Master File is maintained.

The DMS Master File contains a minimum of 9 sections, as shown in Appendix 2. Within each section, the documents required by this SOP are listed in bold. Subfolders in each section hold supporting documents; many of these are standard for study projects but may be optional – they are suggested in Appendix 2 to encourage standardisation. Additional folders (from 10 onwards) and subfolders can be created according to need.

The electronic and paper versions of the DMS Master File should follow the same structure, although all files kept electronically do not need to be printed for the paper file, but should be clearly referenced in the Table of contents or within the main documents with their location. The main documents listed in bold, which typically require sign-off, should be printed and held in the paper DMS Master File.

The following principles should be applied to the documentation:

- Documents cannot be authored and peer reviewed by the same person.
- Project team review of a document is recorded in the revision history of that document.

- Document completion may be delegated as stated throughout the SOP. Where documents are delegated to another member, it is ultimately the responsibility of the DSPM to ensure that they are completed, signed and filed in accordance with this SOP.

For information on how to delegate responsibilities refer to MRC_CTU_SOP_031 Signing Study Related Documents SOP.

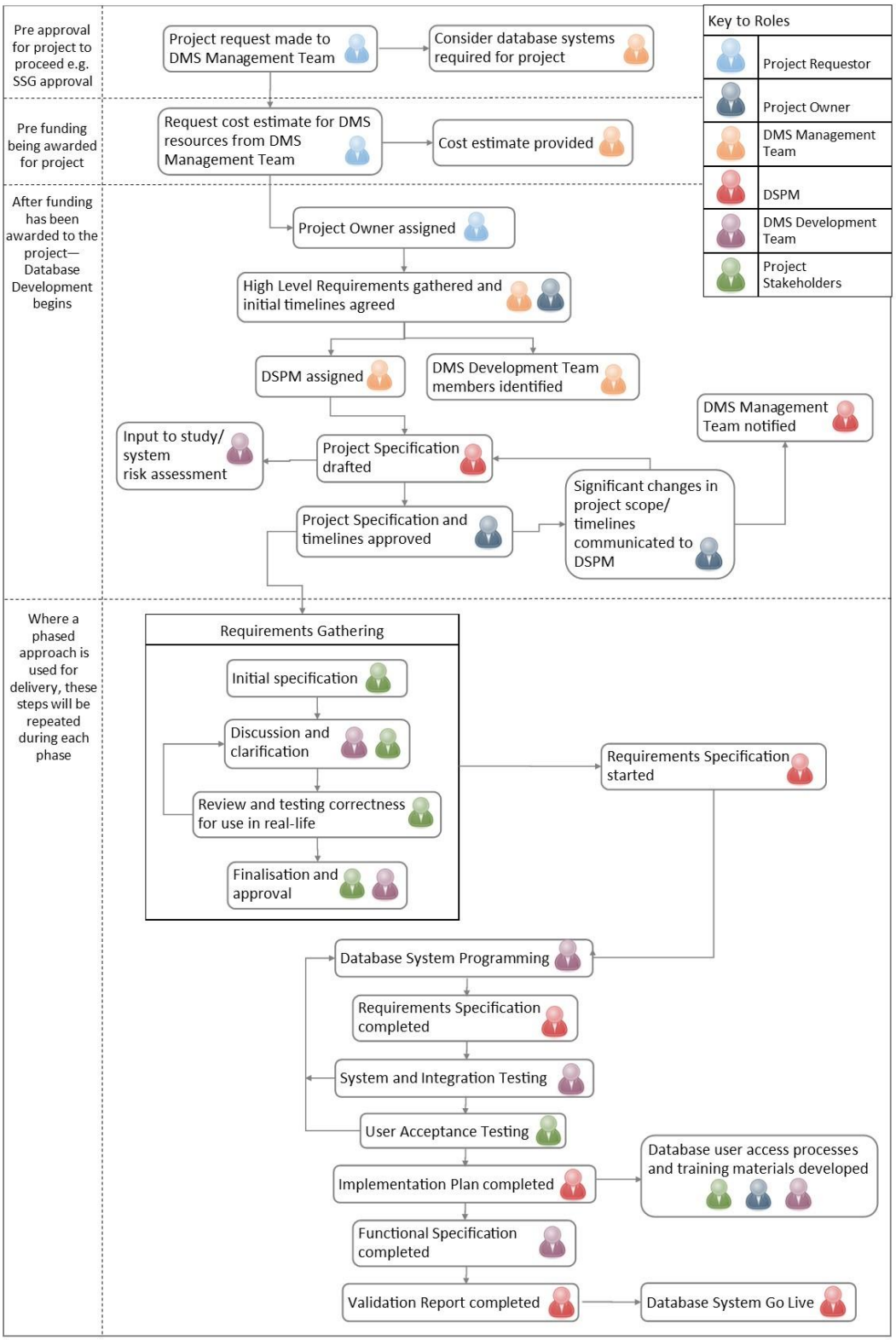
# 4 RELATED DOCUMENTS

For further information on this topic, see also:

- MRC_CTU_SOP_011 - Database Change Control
- MRC_CTU_SOP_009 – Data Management SOP
- MRC_CTU_SOP_013 – Statistical Principles SOP
- MRC_CTU_SOP_072 CRF and Worksheet Development and Maintenance SOP
- MRC_CTU_SOP_031 Signing Study Related Documents SOP

# 5 APPENDICES

## 5.1 DATABASE SYSTEM DEVELOPMENT FLOWCHART



## 5.2 APPENDIX 2 – DMS MASTER FILE STRUCTURE AND CONTENTS

Documents in bold are required to be signed off and kept in the DMS Master File
Documents not in bold are examples of the types of documents you might find in this section.

| | |
|---|---|
| 1. Project specification | |
| | **Project Specification** |
| | Project Updates where applicable |
| | Project meeting notes |
| | |
| 2. Requirements specification | |
| | **Requirements Specification** |
| | Analysis File Specification |
| | Metadata User Specification |
| | CRFs, including CRF Version History |
| | List of sites |
| | Visit schedule |
| | |
| 3. Functional specification | |
| | **Functional Specification** |
| | Annotated CRFs |
| | Front end code – Visual Studio solution files |
| | Back end code – functions, stored procedures, triggers, views, scripts |
| | Metadata – as agreed and implemented |
| | Report specifications |
| | |
| 4. Testing | |
| | **Test Plan** |
| | **Unit/Integration/System Test conditions** |
| | **UAT Test conditions** |
| | **Unit/Integration/System Test Results** |
| | **UAT Test results** |
| | Dummy CRFs |
| | |
| 5. Implementation plan | |
| | **Implementation Plan** |
| | Delegation Log (blank form only, TMT maintains list of delegated individuals) |
| | |
| 6. Validation Report | |
| | **Validation Report** |
| | |
| 7. Change Control | |
| | **Version Control Document** |
| | **Change control documents and signed Tracker tickets for each upgrade** |
| | |
| 8. User documents | |
| | User Guide (if required) |
| | |
| 9. Maintenance Procedures | |
| | **Database lock request and document** |
| | **Database unlock request and document, if required** |
| | **Database archive document** |

The DSPM is responsible for ensuring that all required documents have been completed, reviewed, and signed as required. The following table summarises who should review, approve and who should sign off documents at each stage of the life cycle. Only approvers need to sign off documents. There must be evidence of review, either in the revision history or as emails. Where specified, a signatory may delegate the act of signing to another person but delegation must be documented in the TMF (for more information please refer to MRC_CTU_SOP_031 Signing Study Related Documents SOP).

| Document | Author | Reviewer(s) | Signatory |
|---|---|---|---|
| Project Specification | DSPM | Project team members as required; for study projects this usually includes Project Lead, CPM and/or Trial Manager. DMS QC Reviewer. | Project Owner, DMS Management |
| Requirements Specification | DSPM or delegate | Project team members as required; for study projects this usually includes CPM, Trial Manager, Data Manager, and Statistician. Peer reviewed by DMS team members as required. DMS QC Reviewer. | Project Owner or delegate |
| Functional Specification | DMS Development Team | Peer reviewed by DMS team member, ideally a senior programmer | |
| Test Plan | DSPM or delegate | Project team members as required; for study projects this usually includes CPM, Trial Manager, Data Manager. Peer reviewed by DMS team members. DMS QC Reviewer. | Project Owner or delegate |
| Unit/ System/ Integration Test Conditions | DSPM or delegate | Peer reviewed by DMS team members | |
| Unit/ System/ Integration Test results | Database System Tester | Confirmation of test results from testers. Peer reviewed by DMS team members & DMS QC Reviewer | |
| UAT Test Scripts | DSPM or delegate | Peer reviewed by DMS team members /System Users | |
| UAT Test Scenarios | System Users | Reviewed by DSPM or delegate | |
| UAT results (UAT test scripts and test scenarios results) | System Users | Confirmation of test results from testers. Review by DSPM or delegate & DMS QC Reviewer | |
| Implementation Plan | DMS Development Team | A programmer who has DBA rights where necessary, DMS QC Reviewer | A DMS programmer |
| Validation Report | DSPM | Project team members as required; for study projects this usually includes Project Lead, CPM and/or Trial Manager, DMS QC Reviewer | Project Owner, DMS Management Team |