STANDARD OPERATING PROCEDURE 42
Clinical Data Management System (CDMS) Planning & Maintenance

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Version number	Effective date:	Reason for change:
Version 2.0	28 March 2023	Biennial review: Changes include an update to the workflow to show parallel tasks, a new procedure to allow system owners to delegate helpdesk support requests and minor text updates to clarify existing procedures.
Version 1.0	5 June 2020	Initial version

STANDARD OPERATING PROCEDURE 42
Clinical Data Management System (CDMS) Planning & Maintenance

1. Purpose and Scope

This Standard Operating Procedure (SOP) describes WCTU's procedure for planning and maintaining a project's CDMS by outlining:

- The process for appropriately allocating resource
- The timelines for completion of pre-programming checks
- The process of ongoing maintenance of the CDMS for the lifetime of the project.

This CDMS planning and maintenance procedure has been tailored specifically to meet the needs of research teams involved in clinical trials and other research projects using the WCTU Programming Team services. If a project is partially or fully reliant on a CDMS that has not been created by the WCTU Programming Team, then this SOP should be used as a guide to create a project specific CDMS planning and maintenance procedure.

2. Definitions

Clinical Data Management System **(CDMS)**	A tool used for the collection, tracking, processing and storage of data used in clinical research.
Functional Requirement Specification **(FRS)**	A document used to define the functionality of a system i.e. what the system must do.
User Requirement Specification **(URS)**	A non-technical document written from a user's perspective detailing the requirements of the system.
User Acceptance Testing (**UAT)**	A software testing process carried out by the user(s) of the system to ensure the requested requirements have been correctly implemented and the system is working as expected.

3. Background

International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines section 1.24 states that steps should be taken to ensure that '*data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected'*. In addition to this, it is a legal requirement that any data collected is managed in a manner that is compliant with the UK General Data Protection Regulation (UK GDPR). The CDMS should be built and maintained in accordance with regulatory requirements and best practice guidelines.

4. Procedure

4.1 Responsibilities

This SOP applies to any person involved in the planning and maintenance of a WCTU managed CDMS. Specific responsibilities for Warwick CTU roles are defined below:

Chief Investigator (CI)

- Allocate accurate CDMS development costs and provision of sufficient set-up time in the grant application.
- Assess the suitability of the software being used to support the research project, ensuring compliance with all regulatory requirements.
- Review and approve the Case Report Forms (CRFs) and oversee any other CDMS user requirements.

	• **Review the URS and provide feedback** • Comply with the end of study procedures to ensure all applicable CDMS close-down actions are performed. • Appropriately delegate CDMS tasks to members of the study team.
Senior Project Manager (SPM)	• Establish the project team to include the appointment of the Trial Manager/Coordinator and the nomination of the system owner. • Arrange for access (movers/leavers) arrangements to be changed in the event of a system owner change • Define and track the CDMS planning milestones with the Programming Team for CDMS version releases. • Schedule CDMS programming priorities based on risk factors. • Oversee the System Owner's activities, providing cover for their responsibilities.
System Owner (most commonly the Trial Manager/Coordinator)	• Coordinate the completion of the user requirement specification (URS) and CRFs. • Decide on the backlog items to be added to a sprint, review prototypes/provide feedback and monitor the sprint's progress. • Complete or delegate CDMS user acceptance testing (UAT). • Formally approve each CDMS version release. Oversee access control requests e.g. setup new users, assign security roles, remove access to movers/leavers. • Oversee support requests for the creation of reports, data cleaning and reporting bugs. • Provide CDMS user training. • Manage system change requests by maintaining the URS and product backlog.
Statistician	• Specify and approve requirements for CRFs. • Specify randomisation requirements • Test relevant computer processes to include computerised randomisation systems. • Review the URS and provide feedback
Programming Team	• Estimate programming completion timeframes and resource requirements. • Provide CDMS cost estimates to the CI (or delegated study team member). These estimates will be based on requirements gathered during the initial review meetings. • Design a CDMS solution based on the URS. • Develop, document, validate and release the CDMS. • Resolve CDMS support requests. • Maintain all CDMS related documentation.

4.2 When?

4.2.1 New Projects

During the funding application process one or more CDMS review meetings should take place between the Chief Investigator or WCTU lead, the designated SPM, the Programming Team Manager (or

delegate) and any other interested stakeholders relevant to the initial setup of the project e.g., statistician, WCTU QA Team representative etc.

4.2.2 Changes to an existing CDMS

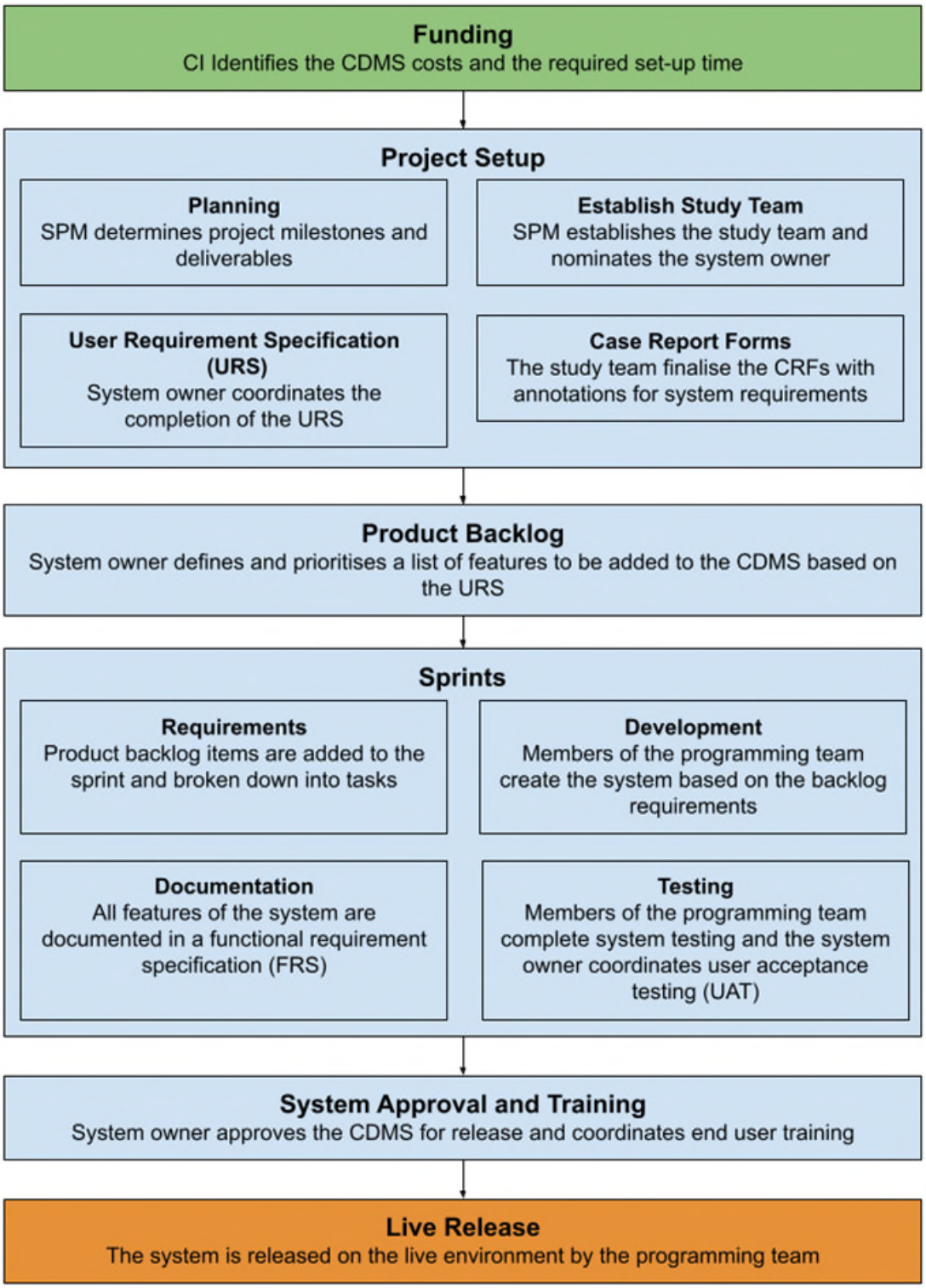
When changes to an existing CDMS are required the project team should follow the change management process detailed in section 4.3.2.

4.3 How?

4.3.1 CDMS Planning Schedule

4.3.1.1 Workflow

The workflow below illustrates the recommended CDMS planning schedule for new systems.



4.3.1.2 Funding Application

The outcome of the CDMS review meeting should provide estimates for costs and the required amount of set-up time. The amount of time allocated to program the CDMS should be agreed with the WCTU programming team at the earliest opportunity. A minimum of eight weeks should be

allocated for a new CDMS, but this could be significantly longer based on the complexity of the study design. Consideration should be given to the expected timelines of the grant application, funder response, and (if successful) grant activation date, to help with resource planning.

4.3.1.3 Project Planning

Once funding has been secured, the SPM or appropriate delegate is responsible for establishing the project milestones and deliverables. This process will be used to identify what project activities need to be accomplished to create a CDMS and to set appropriate completion targets. These activities will form part of a documented project plan and should include completion targets for the following:

- Establishment of the study team and nomination of a system owner.
- User requirement specifications (URS) approved by the system owner and a senior member of the programming team
- CRFs and non-CRF data requirements approved by the CI
- CDMS programming completion
- UAT and CDMS approval completion
- CDMS training
- CDMS live release

Any slippage in the CDMS planning schedule that could affect the release of the CDMS must be communicated between the system owner and programming team and if available recorded on the project's risk assessment e.g., delays to approve the protocol, URS and CRFs or delays in programming and testing. The Operations Committee will have oversight of programming workload and delays and risks identified in project set up.

4.3.1.4 Study Team Established

The SPM is responsible for establishing the study team and nominating the system owner. The trial manager is typically appointed as the system owner or a trial coordinator that has sufficient knowledge and experience. Each study should only have one person nominated as the system owner. If there is a requirement to change the system owner permanently or temporarily, this must be first discussed and confirmed with the study team and then communicated to the programming team before the new system owner is operational.

4.3.1.5 URS

The URS should be created after the protocol has been finalised and is used as the basis for developing the CDMS. The URS is a non-technical document written from a user's perspective detailing the general requirements of the system e.g., it does not need to detail requirements for every CRF question but it should list the title of each CRF and the data collection timepoints. The nominated system owner is responsible for coordinating the creation of the URS, with support/guidance from CI and statistician as required. The URS is formally approved by the system owner and a senior member of the programming team (programming team manager or senior analyst programmer).

4.3.1.6 CRFs and Non-CRF Data Considerations

The system owner is responsible for coordinating the completion of the CRF, with support from CI and statistician, to include standardised coding, data validation checks and skip logic rules. Access requirements to data fields should also be considered, especially for identifiable data and trial-arm data used in blinded studies.

Non-CRF data considerations involve the collection of data that are not part of the CRF data collection process. This may include laboratory results, images, interview transcripts etc. The system owner must ensure that any non-CRF data collection and processing requirements are documented in the URS.

4.3.1.7 Product Backlog

The product backlog is used to document a prioritised list of features to be added to the system derived from the requirements specified in the URS. If a requirement is not documented in the URS, the URS must first be updated and approved as per the process in 4.3.1.5 before updating the product backlog.

The product backlog can be updated by the system owner or by other members of the project team that have been delegated this task by the system owner. If the system owner chooses to delegate, it remains the system owner's responsibility to control the content of the product backlog.

4.3.1.8 Sprints

CDMS programming, documentation and testing work is broken down into iterations called sprints. A sprint can only start after the work has been scheduled and the "Green Light" has been given by the SPM i.e., all planning prerequisites have been completed to include protocol, URS, CRF and any non-CRF data considerations.

SPMs together with the Deputy Head of Operations are responsible for prioritising sprints. Justification for prioritisation decisions should be documented. Where delays or changes to deliverables are likely to impact the CDMS planning schedule, prioritisation will be revisited.

Each sprint consists of items from the backlog that have been agreed between the system owner and the programming team. A deadline (sprint end date) will also be agreed by the System Owner and Programming Team for when the work should be completed. The sprint should aim to complete all committed backlog items within the specified time. If it becomes apparent that this is not feasible, a decision should be made by the system owner and the programming team to drop one or more backlog items from the sprint. If there is any outstanding work to be completed after a deadline has passed, this work should be returned to the backlog, reevaluated, and added to a subsequent sprint.

Product backlog items should be finalised before starting a sprint and therefore changes to requirements should not occur. If a change is required, then the programming team will review the change request to determine if the work can be completed within the agreed timeframe. If a change cannot be accommodated it may be necessary to remove the backlog item from the sprint or to abandon the sprint entirely.

A completed sprint results in working software that meets the requirements of the committed backlog items. Backlog items may be split into multiple sprints before a system is implemented. This is typical of complex systems that require multiple interlinked modules to be programmed before the full system is released.

4.3.1.9 CDMS Programming

Programming work on the CDMS is only carried out during a sprint. The programming team will develop the system as per the URS and the committed backlog items. All CDMS operations and

activities are documented in the Functional Requirement Specification (FRS). Throughout the sprint the programming team will provide a working prototype of the system. The system owner is responsible for reviewing the FRS and the prototype, alongside any other relevant members of the team (e.g., data entry clerk or statistician) and feeding back any issues to the programming team. Prior to releasing the system for UAT, the programming team will carry out manual and automated tests to ensure the system performs as described in the FRS.

4.3.1.10 User Acceptance Testing (UAT)

The UAT process must be assigned to a sprint and carried out by the system owner or delegate(s). The programming team will create a test plan to include test cases based on the backlogs added to the sprint and where necessary, provide training on how to use the testing software. The system owner or delegate(s) will review the test plan, relevant documentation (URS, CRF, FRS etc.) and become familiar with the system before starting the first run.

The tester will complete the test-plan by performing every step of every test case. If a test plan has failed, the programming team will resolve all issues, update the relevant documentation and implement the updated system on the test environment. The tester will then retest any failed tests and repeat the process until all tests have passed.

If for any reason a tester is not able to complete the testing process a new tester can be assigned. However, incomplete runs should not be swapped between testers. If the testing process is in mid-run, the run should be restarted by the new tester.

4.3.1.11 User Acceptance (UA)

UA requires the system owner to formally confirm that the CDMS is ready for release. This may involve seeking input from other members of the team (e.g., CI or statistician) to confirm all requirements have been implemented before release. The system owner will sign a system release approval form if satisfied that the committed backlog items have been completed and the software will be released by the programming team. If for any reason the system owner is not satisfied, the CDMS will not be released. The project's risk assessment should be updated if the process will exceed the planned timeline and/or the level of risk changes.

4.3.2 Change Management

After a system has been released it may be necessary to alter a requirement e.g., change the data validation rules on a form. The content of the product backlog is to be periodically updated as and when new requirements or changes are identified. Only changes that fall within the scope of the URS can be added to the product backlog. Changes outside the scope of the URS first require the URS to be updated before any CDMS changes are implemented e.g., requesting an Interactive Voice Response (IVRS) randomisation system when the initial URS only specified an online randomisation system.

4.3.3 System Support

Requests for support should always be made to the programming team's helpdesk page (WCTU IT Support) available from using the Self-Service facility within Service-now (https://warwick.service-now.com/). If an urgent incident has occurred, a direct call to a member of the programming team should be made. All helpdesk requests must be made by either a system owner, a documented delegate, or an appropriate senior manager e.g., a SPM or a senior member of the operations team.

Helpdesk support should only be used for requests concerning the current system, not requests for new features or changes to existing functionality. The short description on the helpdesk form should be used to specify the name of the project and to indicate the nature of the request e.g., data clean, user access etc. The description box should be used to provide a detailed overview of the request. The question "Which area is your call related to?" should be set to "Reports" for all Reporting Services requests and "Software" for all other requests.

Details for specific types of requests are as follows:

- **Bugs**
  A software bug is a fault in the system that causes it to produce incorrect or unexpected results or behave in an unexpected way. Bugs should be reported immediately via the HelpDesk after the incident occurred. The short description should be used to specify the name of the project and to indicate that a bug is being reported. The helpdesk description should be used to describe what activity the user was performing immediately before the bug was triggered. The programming team will evaluate each reported bug and if necessary, apply a fix to the CDMS at the earliest opportunity.

- **Data Cleaning**
  Data cleaning requests can be submitted individually via the HelpDesk or batched. For individual data cleaning requests, the helpdesk description should be used to specify the type of data cleaning required e.g. the deletion of a record that was entered incorrectly and the necessary details to identify the record or field. Batched data cleaning requests should be stored in a spreadsheet and added as an attachment.

  It is the responsibility of the user making the request to check that the data change was carried out correctly and any data cleaning logging documentation is updated. This process should normally be documented within the Data Management Plan (DMP) (see SOP 15 Information Handling part 1 Data Management).

- **User Access**
  Requests to grant/revoke access to a system should always be submitted to the helpdesk in addition to completing the WCTU movers/leavers form if the user is a WCTU staff member (not applicable for site users). The short description should be used to specify the name of the project and to indicate that a user access request is being made. Requests to grant/revoke access to analysis datasets can be made directly by the project's nominated statistician or health economist.

4.3.4 Reports

Reports that use CDMS databases are created by the programming team outside of a sprint. The helpdesk request should include a description of the report's content, the data to be used and any deadline requirements for its completion. The programming team will then contact the person who submitted the request to schedule a time for the report to be created and to further clarify requirements. Reports must be validated by the study team to ensure the correct data are returned and then approved by the system owner before being used.

4.3.5 CDMS Study Completion

The CDMS study completion process starts when the system owner or another senior WCTU staff member notifies the programming team via the helpdesk. Once a study completion request has been

received, a member of the programming team will revoke all user access rights to the CDMS and remove the application.

Access to the data for statisticians is maintained until the programming team is notified via the helpdesk to archive the database. Unless specifically requested otherwise, all archived databases will remain on the server with read-only mode configured and all user access rights revoked. It is the study team's responsibility to inform the programming team of any pre-archiving requirements e.g., the removal of participant identifiable data.

List of abbreviations

CDMS	Clinical Data Management System
CI	Chief Investigator
CRF	Case Report Form
DMP	Data Management Plan
DPA	Data Protection Act
FRS	Functional Requirements Specification
GDPR	General Data Protection Regulation
ICH GCP	International Conference Harmonisation Good Clinical Practice
IVR	Interactive Voice Recognition
QA	Quality Assurance
R&IS	Research & Impact Services
SOP	Standard Operating Procedure
SPM	Senior Project Manager
TMG	Trial Management Group
UA	User Acceptance
UAT	User Acceptance Testing
URS	User Requirements Specification
WCTU	Warwick Clinical Trials Unit