Joint Research Management Office Standard Operating Procedure for:			
Electronic data management systems for MHRA-regulated studies			
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Purpose:

The purpose of this Standard Operating Procedure (SOP) is to outline the procedure for the selection, design, testing, validation, implementation and management of electronic data management systems for Medicines and Healthcare products Regulatory Agency (MHRA) regulated studies that are sponsored by Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary).

The Joint Research Management Office (JRMO) acknowledges that Queen Mary and Barts Health Clinical Trials Units (CTUs) and research groups may already have data management SOPs and associated documents. Research groups may follow their own procedures and documents as long as they comply with this SOP.

Scope:

This SOP applies to all MHRA-regulated studies sponsored by Barts Health or Queen Mary. This SOP describes the processes for establishing data management systems, but the principles should also be applied to the set up and validation of other computer systems used in clinical studies.

For broader guidance on research computer systems see *SOP 38a - Use of computerised equipment, software, and systems in clinical research*.

Please see *SOP 38c Trial data management systems for interventional studies and research studies* for guidance on establishing data management systems for clinical research studies which are not regulated by the MHRA.

Abbreviations:

Barts Health	Bart's Health NHS Trust
CI	Chief Investigator
CRF	Case Report Form

CTU	Clinical Trials Unit
DMP	Data Management Plan
GCP	Good Clinical Practice
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
Queen Mary	Queen Mary University of London
SOP	Standard Operating Procedure
TMF	Trial Master File
UAT	User Acceptance Testing

SOP Text:		
	Responsibility	**Activity**
Prior to obtaining funding		
1.	Chief Investigator (CI)	**Include study database and data management in the costing of the study.** The CI must include the cost of a database and data management, including any electronic data management systems that will be used, when preparing the funding application. The researcher must specify the name of the software or system they plan to use if known. If unknown, they can provide an estimate for the cost of the database at the application stage and then select a specific database later. Please see *SOP 11a Associated document 1: Costing MHRA regulated studies guidance*.
2.	CI/Good Clinical Practice (GCP) and Governance Manager	**Assess the suitability of individuals and organisations working with the data management system.** The CI must only delegate responsibility for building or maintaining the database to suitably qualified and experienced individuals. If an external organisation or individual will be contracted then they must undergo a successful vendor assessment completed by the GCP and Governance Manger (see *SOP 40: Vendor Assessment*).
Design and develop the study Case Report Forms (CRFs) and specification.		
3.	CI	**Prepare System Requirements and Specification document.** The purpose of the Requirements and Specifications document is to provide a high-level summary of the system's requirements and to define the specific data fields required for the database. *Associated Document 1 Requirements and Specifications* should be used as a template to prepare the document.
4.	CI	**Design and develop the study CRFs or a CRF specification.** The CI must define all of the data fields and format that must be programmed into the database.

		The CRF specification must be designed to record all of the information required by the protocol in order to answer the studies aims and objectives. Only data explicitly indicated in the protocol or required to evidence compliance with the protocol and the applicable regulations should be collected. Collecting extra data can contravene the Data Protection Act and General Data Protection Regulation. When designing CRFs, refer to *Associated Document 2 (CRF guidance).*
5.	Clinical Trial Monitor	**If the study is a lone investigator study, review the CRF specification.** Confirm that the CRF correctly records all of the required information and that it is clear. This is mandatory for all studies that are not supported by a known CTU or research group, and is recommended for all study.
6.	CI & Study Statistician	**Approve the CRF specification.** The CI and study statistician must approve the CRF specifications before the database build begins. Submit the finalised specifications to the GCP and Governance Manager.
Install, develop and test the database		
7.	Database Developer	**Install the system in compliance with this specification (where required).** • Record all installation observations and tests • Maintain an access control list • Ensure all supplier installation guidelines are followed • Ensure the host computer system(s) meets the system configuration requirements • Confirm the system is functioning as intended
8.	Database Developer	**Build the database and complete internal quality control**. • The database and eCRFs must be built in line with the specifications, UK regulations and sponsor requirements. Internal QC will be done to confirm this. *It is recommended this is completed by someone other than the primary database builder.* • Confirm the database is ready for testing
9.	CI and Database Developer	**Complete risk assessment, validation plan and test scripts.** • Determine the level of testing required • Prepare a test plan (See *Associated document 3 Test Plan Template*) • Prepare a test Script (See *Associated Document 4 Test Script*) • The risk assessment, test plan and test scripts must be completed and signed by the CI prior to testing

		• Create a test environment for the database to be tested in • Assign user credentials for testing
10.	Delegated testers	**Complete the first round of User Acceptance Testing (UAT).** • The tester must complete each test as defined by the test scripts and maintain a log of all testing carried out and results.
11.	CI	**Assess test results.** • Review the test results against the overall pass criteria as described in the test plan. If the database has passed testing, proceed to complete the test report (go to section 15 of this SOP). • The test results should be sent to the Database Developer who should action any minor findings as appropriate. • If the database has failed testing, send the test results to the Database Developer for action.
12.	Database Developer	**Amend database following the test results.** • Review each test fail and amend the database based on the test results. See *Associated Document 5 Database Change Control Log* • Notify the CI once the database is ready to be retested.
13.	CI	**Assess database changes and retest as appropriate.** • As a minimum, each failed test must be rerun. • Use a risk-based approach to the extent of re-testing required ensuring all retesting is documented as initial tested. • Once retesting is complete, assess whether the system has passed or failed per the test plan.
14.	CI, Testing Team and Developer	**Continue to test and update the database until the database passes testing.**
15.	CI	**Complete the test report.** *Associated Document 6 Test Report Template* should be used to complete the test report.
16.	CI & Study statistician	**Approve the database.** The CI and statistician must sign off the final build using the *SOP 38b AD 8 Data Management Systems Approval Form*. Send the complete document set to the GCP and Governance Manager for review. This must include: • All UAT documentation. • Signed test report. • Database sign-off form
17.	GCP and Governance managers or delegates	**Review database documentation.**

		Review the received documents to confirm that everything is present and that the set up and testing complies with ICH GCP. Raise any queries as required. (This is not a technical assessment). Once the review has been completed, notify the Database Developer and CI that the database can Go Live.
18.	Database Developer	**Go Live** Upon receipt of the GCP and Governance manager' Go Live notification, create a Live version of the database, distinct from the test environment.
19.	Database Developer or Study Manager	**Create user manual or guidance document.**
Study Opens		
20.	CI and Database Developer	**Ensure all relevant staff are trained, and training records are maintained for all computerised systems.** Provide training to the research team if required and arrange access to the system.
21.	CI or delegate	**Ensure data is backed up routinely.** • Documentation detailing the back-up process (including details of the backup location) should be stored in the Trial Master File (TMF). • A system to check that backups are occurring should be put in place and documented
Computer system amendments		
22.	Database Developer	**Manage change control** All changes made to a database, system, software (including version updates) or server, and the reason for the changes, should be documented on a *Database Change Control Log (Associated document 5)* A version control log must be maintained for each system being used throughout the clinical study.
23.	CI or delegate	**Re-validate the new version of the system.** Each change to the database must lead to a new round of validation and UAT. The extent of the testing should be assessed proportionate and defined in the test plan. Any component of the system affected by the change request must be re-validated in a test environment. Redundant source code and documentation must be saved in the TMF. Ensure that the following has been completed: • All errors/ test failures have been followed up to resolution • The same tests are completed after integrating any different modules. • CI can authorise go live for new versions.

24.	Database Developer	**Determine new version release date.** Following CI approval, a system release date must be agreed between the end-users and documented in the change control log. Post-installation checks must be made and documented to verify successful installations.
25.	CI	**Install the new version and provide training.** Inform end-users of the proposed change and provide training and amend any user guidance documentation as appropriate. Announce an install date to end users for the implementation of the change. Make them aware of any scheduled down time and install the required change following the validation procedure. Ensure the JRMO GCP team is informed either through the Study Monitoring Report (For non-JRMO Monitors) or directly informing the monitor at visits.
26.	CI	**Complete periodic review as required.** The CI or delegate should conduct and document a periodic review of the system to ensure the documentation is up to date, and that the validated system is functioning according to the specification, reviewing. Periodic review should be proportionate to the size and length of the study.
Study closure		
27.	CI	**Ensure that all end of study procedures are completed as per study specific Data Management Plan (DMP)(*see* *SOP 38d Data Management*) and *SOP 18a - Study closure: guidance for research staff of sponsored studies*.** The DMP should include a detailed plan of activities and the sequence of events at the end of the study, and prior to data release. For more details please *see* *Associated document 7 on End of study data activities*.
28.	Study statistician	**Ensure that full and accurate dataset is received** The designated statistician should receive a full and dated download of the database, and a complete and accurate dataset must be used for analysis. A Statistical Analysis Plan should be created and signed off prior to the start of analysis (including interim and safety analysis).
29.	CI or delegate	**Archive database as per *JRMO SOP 20 Archiving: Transferring research study records to Corporate Records Management***

Change control

This section outlines changes from version to version

Section changed	Summary and description of changes
Background	Removal of background section
Section 7 to 13	Streamline of procedures
Throughout	General administrative changes

List of appendices

There are no appendices for this SOP

List of associated documents

Appendix ref.	Appendix name
Associated Document 1	Requirements and Specification template
Associated Document 2	CRF design and structure guidance
Associated Document 3	Test Plan Template
Associated Document 4	Test Script Template
Associated Document 5	Change Control
Associated Document 6	Test Report Template
Associated Document 7	End of study Data activities