Joint Research Management Office Standard Operating Procedure for:			
Clinical Research Data Management systems for Interventional and Research Studies			
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Background:

Clinical research database systems should comply with Good Clinical Practice (GCP) guidelines to ensure that the 'data and results reported are credible and accurate and that the rights, integrity, and confidentiality of the trial subjects are protected.' (ICH GCP)

ICH-GCP has further requirements for the use of electronic systems. The sponsor should:

a. Ensure and document that the electronic data processing system(s) conforms to the sponsor requirements for completeness, accuracy, reliability, and consistent intended performance (i.e. validation).
b. Maintain Standard Operating Procedures (SOPs) for using these systems. The SOPs should cover system setup, installation, and use. The SOPs should describe system validation and functionality testing, data collection and handling, system maintenance, system security measures, change control, data backup, recovery, contingency planning, and decommissioning. The responsibilities of the sponsor, investigator, and other parties with respect to the use of these computerized systems should be clear, and the users should be provided with training in their use.
c. Ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data (i.e. maintain an audit trail).
d. Maintain a security system that prevents unauthorised access to the data.
e. Maintain a list of the individuals who are authorised to make data changes.
f. Maintain adequate backups of the data.

g. Safeguard the blinding, if any (e.g. maintain the blinding during data entry and processing)
h. Ensure the integrity of the data including any data that describe the context, content, and structure. This is particularly important when making changes to the computerized systems, such as software upgrades or migration of data.

Research data must be collected, recorded and managed in accordance with the Data Protection Act (DPA) (2018) and applicable Bart's Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary) research policies.

Purpose:

The purpose of this SOP is to outline the procedure for installing, validating and maintaining databases and electronic data capture tools for clinical research studies, which are not regulated by the Medicines and Healthcare products Regulatory Agency (MHRA).

Scope:

This SOP applies to databases and electronic data capture tools for research studies that are not regulated by the MHRA, and applies the principles of GCP in a proportionate manner. Researchers conducting MHRA-regulated clinical trials, or those who require further detail, should refer to Joint Research management Office (JRMO) SOP 38b: Electronic data management system for MHRA-Regulated studies.

Research teams and clinical trials units (CTU) may use their own procedures and documents to validate their data management systems, provided that those procedures do not contradict this SOP.

Statistical software is not considered to be a study database if it imports locked data from a separate database system.

Abbreviations:

ATMP	Advanced Therapy of Medicinal Product
Barts Health	Bart's Health NHS Trust
CA	Conformity Assessed
CI	Chief Investigator
CRF	Case Report Form
CSV	Computer Systems Validation
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit
CV	Curriculum Vitae
DPA	Data Protection Act
eCRF	Electronic Case Report Form
GCP	Good Clinical Practice
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
NICE	National Institute for Health and Care Excellence
PI	Principal Investigator
Queen Mary	Queen Mary University of London
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TMF	Trial Master File
UAT	User Acceptance Testing

Definitions:
• MHRA Regulated studies: clinical trial of an investigational medicinal product (CTIMP), advanced therapy medicinal product (ATMP), or a clinical investigation (e.g. clinical trial of non-Conformity Assessed (CA) marked medical device or medical devices used outside of their CA marking). These studies are regulated by the MHRA. • High Impact Data: Data from studies which is be submitted to a regulator, National Institute for Health and Care Excellence (NICE) or a high impact journal, or which has the potential to directly change patient care.
Relevant SOPs:
• SOP 18b Study closure for sponsored interventional and research studies and all hosted studies • SOP 20 Archiving • SOP 38b Electronic data management system for MHRA-Regulated studies.

SOP Text:		
	Responsibility	**Activity**
1.	Chief Investigator (CI)	**Include study data management in the costing of the study.** The CI should include the cost of data management, including any computer systems that will be used, in their grant application costing. This is particularly important for studies generating high impact data. The CI should specify the name of the software or system to be used. If unknown, the CI can provide an estimate figure for the cost of the database at the application stage and then select a specific database at a later time.
Assessing software suitability		
2.	CI	**Confirm whether an electronic database will be used and confirm the method of computer system validation (CSV).** When applying for sponsorship, notify the JRMO whether paper case report forms (CRFs) or an electronic database will be used to record participant data. Spreadsheets are considered to be electronic databases. If using an electronic database, confirm the method of CSV that will be followed. The Database Validation Form (AD1) along with the Guidance on completing the Database Validation Form (AD2) may be used, or the CI may follow the procedures of their research group or CTU.
3.	CI	**Select a database system and assess its suitability for the research study.** The Database Validation Form (AD 1) can be used to document an assessment of the system. If selecting Microsoft Excel or a similar product as your database, this must be clearly justified.

4.	CI	**Confirm the location of the host server.** The JRMO recommends that databases should be hosted on a Barts Health or Queen Mary server. The use of an external host must be clearly justified in the database documentation. The location of the server should be physically secure, protected from fire, flooding and vermin, have an emergency power supply, should be temperature controlled and should have antivirus software in place. If the database will store personal identifiable information about research participants then it must only be hosted on Barts Health or Queen Mary Safe Haven server. The server must be routinely backed-up to a separate location, which should also be secure. The Database Validation Form (AD1) can be used to document an assessment of the host server.
5.	CI	**Confirm the security of the selected database.** The database system must have security that prevents unauthorised access to the data. Where possible this should include *role-based access*, whereby some users will be able to enter data, while others have read-only access. The database should be password protected and, ideally, each user should have their own account with their own password. The CI should maintain a list of authorised users, with the dates that access was granted and revoked. Once a user leaves the study and is removed from the delegation log, their access to the database should be revoked. The Database Validation Form (AD1) can be used to document an assessment of the host server.
6.	CI	**Ensure that the database developer is appropriately qualified.** The database developer should demonstrate that they have appropriate knowledge and experience to set up and maintain the database. This should be documented through their signed Curriculum Vitae (CV) and can also be documented on the Database Validation form (AD1).
7.	CI	**Define source data and documentation.** The form and location of all source data should be defined before research activity starts. A source data agreement form (SOP 45 AD 5) can be used to document the location of all source data. For single centre studies, this could also be documented in the study protocol. If paper data capture tools will be used to collect data, ensure that they match the protocol and the database. If any source data will be recorded directly into the research database then this must be documented in the protocol or source data location list.

Install, develop and test the database		
8.	CI or delegate	**Complete a software risk assessment.** The risk assessment will determine the level of user acceptance testing (UAT) required for the system and the amount of detail required in the specification. Section 2 of the Database Validation form (AD1) can be used to complete a simple risk assessment.
9.	CI or delegate	**Prepare a specification for the database.** Prepare a specification to describe the features that will be required for the database, including the data fields that will be required. In accordance with the DPA, only data which is explicitly required by the protocol or by regulations should be collected. Section 3 of the Database Validation Form (AD1) can be used to document the specification.
10.	Database designer	**Build the database.** The database and Electronic Case Report Form (eCRF) must be built in line with the specification provided by the CI. Provide written confirmation to the CI when the database has been built and is ready to be validated.
11.	CI or delegate	**Prepare for UAT.** UAT involves checking that the database meets the requirements of the specification. The level of UAT required will be defined by a software risk assessment. Prepare a list of "test scripts" to describe how the database will be validated. This will include the fields and features to be tested and the expected results. Section 4 of the Database Validation Form (AD1) can be used to document the planned test scripts.
12.	CI or delegate	**Complete (UAT) of the database.** Complete each test script, documenting the date that each test was performed, the name of the person completing the test, the findings of the test and whether the feature has passed or fails. Notify the developer of each test fail and ask them to amend the database. Retest and document each failed test, until all test scripts have passed. Section 4 of the Database Validation Form (AD1) can be used to document the completed tests.
13.	CI & Study statistician	**Approve the database.** Section 5 of the Database Validation Form (AD1) can be used to document approval.

	(where appropriate)	Retain all key documentation used throughout the database development process and file it in the Trial Master File (TMF). Notify the JRMO Governance Officer by email once the database has been approved (this is a condition of Confirmation of Sponsorship).
14.	CI	**Arrange training and user support** Ensure that all staff who will be using the database are suitably trained. Training should be recorded on the study's training log. Consider arranging other kinds of support such as a user manual or a helpline.
During the study		
15.	CI or delegate	**Ensure data is routinely backed up.** Databases must be backed up routinely. For databases hosted on a Barts Health or Queen Mary server, the relevant department will generate backups in accordance with their organisational policies. The JRMO does not recommend hosting the database on a server outside of Barts Heath or Queen Mary. If the database is hosted in an external location, the CI must ensure that the database provider is making regular backups and that these backups are stored in a separate, secure location. The use of an external host must be clearly justified.
16.	Database designer	**Manage changes to the database.** Document the reason for making changes to the database (e.g. in the format of email correspondence or a 'change request form'). Update the database specification with the changes. Once the database has been updated, the database should be revalidated. The level of revalidation should be proportionate to the changes made. Where appropriate, consider retraining users. A version and change control log must be maintained throughout the research study. Database documentation must also be version controlled. Section 6 of the Database Validation Form (AD1) can be used to document changes.
17.	CI or delegate	**Validate new data management systems and system updates before they are implemented.** If the research team decide to implement a new data management system or update an existing system, it must be set up and validated prior to use. This includes implementing an electronic database to transfer data that has previously been recorded on paper case report forms. The research team may follow steps 3-14 of this procedure or follow the established procedure of their research group / clinical trials unit. Consider whether the implementation of the new data management system will require an amendment to the study.

End of study		
18.	CI	**Ensure that study data is cleaned and that all data queries are resolved.** End of study planning should commence before the end of the study. Once the End of Trial Definition has been met, the research team have 90 calendar days to enter all study data, clean the data, resolve queries and lock the data. See JRMO SOP 18b Study closure for sponsored interventional and research studies and all hosted studies for more information on study closure.
19.	CI	**Lock the database end export the final dataset.** Once the final data has been cleaned, the database should be locked to prevent further editing. The final dataset should be exported in a locked format. If spreadsheet software is being used as a database then it should be locked to editing, but an export may not be required. In multicentre studies, each site should be sent a copy of the dataset for their participants. Each Principal Investigator (PI) should review the data and confirm that this is accurate. The final dataset should be sent to the study statistician or the person responsible for analysing the study data.
20.	Study statistician	**Ensure that full and accurate dataset is received.** Confirm receipt by email.
21.	CI or delegate	**Archive the database** The database may be archived once the Clinical Study Report has been submitted to the Research Ethics Committee (REC). See JRMO SOP 20 Archiving for further information.

Change control

Minor administrative changes throughout.

List of appendices

There are no appendices for this SOP.

List of associated documents

Document ref.	Document name
Associated Document 1	Database Validation Form
Associated Document 2	Guidance on completing the Database Validation Form