Joint Research Management Office Standard Operating Procedure for:			
Data Management			
SOP Number:	**38d**	Version Number:	**3.0**
Effective Date:	**3rd February 2025**	Review Date:	**3rd February 2028**

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Purpose:

The purpose of this Standard Operating Procedure (SOP) is to outline the high-level procedures for data management in clinical trials. The SOP describes both the central procedures completed by the study coordination team and the site-level activities completed by delivery teams.

Scope:

This SOP must be followed for all Medicines and Healthcare products Regulatory Agency (MHRA)-regulated studies sponsored by Barts Health NHS Trust (Barts health) or Queen Mary University of London (Queen Mary). It is considered to be best practice and therefore is recommended by the Joint Research Management Office (JRMO) to be used for all studies where research data is being collected and analysed.

This SOP only provides a high-level overview of the requirements for an electronic data management system. For detailed information about setting up and maintaining an electronic system, see JRMO SOPs *38a*, *38b* and *38c* or contact the GCP and compliance team.

Abbreviations:

CI	Chief Investigator
CRF/eCRF	Case Report Form/Electronic Case Report Form
DMP	Data Management Plan
GCP	Good Clinical Practice
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
SOP	Standard Operating Procedure

SOP Text:		
	Responsibility	**Activity**
Prior to obtaining funding		
1.	Chief Investigator (CI)	**Include study data management in the costing of the study.** At funding application stage, include all costs associated with any management systems (data management and paper record keeping), including staff time and any purchasing of resources (Please see SOP 11a Associated Document 1 Costing MHRA regulated studies guidance more information). Confirm that the database complies with GCP requirements (please see SOP 38b Electronic data management systems for MHRA-regulated studies).
2.	CI	**Ensure that all chosen Data Management Systems comply with this SOP, ICH Good Clinical Practice (GCP), and the relevant UK laws.** Ensure there is a clear data management plan (DMP) in place (see Template 1 Data Management Plan template). A DMP will provide guidelines in the control of data management processes for the study, including the flow of data from source to analysis. A DMP is recommended for large, long-running, multi-centre studies; and is especially useful in cases where the study requires deviations from or amendments to current SOPs. In addition, the CI must ensure that the DMP is appropriately summarised in the following documents: • The protocol • The research site agreements, where sites are delegated data management by the CI. • Monitoring plan
3.	CI	**Design and develop the Study Case report Forms (CRF).** Design the CRFs to record all information required to answer the protocol aims and objectives (including all primary and secondary objectives). The CRFs must capture the required study data across all research sites and for every participant consented to take part in the study, including screening fails. The CRFs should also include any data required to demonstrate protocol and regulatory compliance. In compliance with General Data Protection Regulation and Data Protection Act, the CRFs should only capture the minimum amount of data required to

		answer the study objectives and confirm compliance to regulatory requirements The CRF must have pages/areas to capture the following information: • Inclusion & Exclusion Criteria Review • Eligibility and Principal Investigator (PI) signature • Randomisation (if applicable) • Participant Status (i.e., screen-fail, withdrawn, enrolled) • Concomitant medications • Dates of all visits / interactions with the participant must be recorded. • IMP Administration & compliance • Pharmacovigilance safety information • Study Completion • PI signoff (confirming that the data in the CRF is accurate and complete at a site level) • CI sign off as part of data lock and oversight. For detailed guidance on CRF design and structure see SOP 38b Associated Document 2 CRF Design Guidance. CRFs are **not** source documents but a tool for transcribing study data from source documents. If the CI wishes to use CRFs to record source data directly **the decision to use the CRF as a source document must be discussed with the GCP team and be recorded in the protocol, source data agreement (**SOP 45 Associated Document 5**),** DMP and risk assessment before the study starts. It is advisable that the CI designs the CRFs after the study has received *sponsorship with conditions*. Care should be taken to ensure that CRFs are not finalised until regulatory approval is obtained, to ensure that any changes to the protocol are covered by the CRF.
4.	CI & Study Statistician	**Approve the CRFs.** CI should document their final approval of the CRF. After the CI has completed the design of the CRF, the study statistician should then confirm that the CRFs contain all the data points required for the statistical analysis plan. For some studies the JRMO Clinical Trial Monitor will review the CRF prior to finalisation. This will be confirmed in the JRMO Final Governance Meeting. The CRF should then be used to create an eCRF(s) and/or a database specification document if required.
5.	CI	**Establish process for transferring data from sites to study manager/coordinator.** The data transfer process from sites to the study team/coordinator should be clearly defined in a study specific document such as the study protocol or DMP.

6.	CI /Study Coordinator	**Define source data and documentation.** A high-level definition of all source data should be defined in the protocol with the precise location of where the information is held (i.e., a specific tab within patient's electronic notes). The study manager/coordinator should work with site staff to complete a source data agreement (SOP 45 associated document 5) to confirm the location of source data at each site as this will often vary from site to site. Any paper source documentation (i.e., x-ray images) that are kept should be anonymised with only the subject ID number used as identification and be signed as a certified copy.
Plan site set-up		
7.	CI	**Assess suitability and training of site staff.** Site staff handling clinical records and study data must have relevant qualifications and training, assessed against the role they are to perform. All staff must be trained on the specifics of the study and their role in the data management system and associated guidance documents. Staff must keep their training up to date and maintain training records.
8.	CI	**Provide study specific CRF guidance.** If a CRF guidance document is required, this should be produced alongside the CRF and discussed at the Site Initiation Visit (SIV). All members of the study who enter and/or review study data must confirm that they have read the guidance document. The CRF guidance document should detail the acceptable time frame for data to be completed and should include specifics such as date and time formats and how to complete unknown, not applicable, or not recorded information.
Study opens		
9.	Site Staff	**Collect source data in accordance with the protocol.** No study specific data may be collected about a participant until they have given informed consent to participate in the study. Record source data in the participants' medical records or as otherwise described in the protocol and source data agreement. Certain data may only be recorded by certain professional groups. For example, the causality of adverse events may only be documented by a qualified study medic or dentist. Where data is held on electronic systems, the system must comply with the MHRA's guidance on electronic health records. If the system does not comply, a certified copy of the original source data must be made. This can be done by printing the data, writing on the printout that it is a true copy of the original, then signing and dating the statement.
10.	PI	**Obtain any missing data where possible.** Identify any missing data and obtain it wherever permitted. For example, it may be possible to complete CT scan RECIST measurements

		retrospectively, but it would not be possible to measure a patient's vital signs after their visit. Wherever data is recorded retrospectively, it must be separately signed and dated. Where required data is held by other organisations, for example the patient's GP surgery, a request should be made for the data. Data must only be transferred via a secure method, for example via two nhs.net email addresses.
11.	PI	**Transcribe data from source documents to case report forms and submit to study manager/coordinator.** Submit study data in the agreed method to the coordination team.
12.	Study Manager/ Coordinator	**Review submitted data, enter into database (if eCRF not in use) and raise queries on any omissions, discrepancies, or spurious data.** For data entered centrally by the coordinating team, a process should be set up to ensure that all data sets sent by the site are received. Quality checks should be completed by someone other than the person entering the data. These quality control checks should be defined in the DMP. The data sets should be entered in a timely manner. The study manager/coordinator should perform regular data cleaning. Data cleaning procedures must be defined in the DMP. Once any issues have been identified, these should then be passed on to the relevant PI and site team for rectification.
13.	Clinical Trial monitor	**During site visits, review source documents against case report forms and query any discrepancies.** See SOP 28 Monitoring for further information.
14.	PI	**Respond to data queries.** If updating data on a paper case report forms or source documents, the original datum should be crossed through with a single line, the update should be written next to it and the change should be initialled and dated. Any corrections to source data must be made by appropriately qualified individuals. Updated case report forms and responses to data queries should be sent to the trial manager/coordinator.
15.	CI or delegate	**Manage change control.** Case report forms may need to be updated due to protocol amendments. New versions should be developed and approved as above, and then sent to research sites. Maintain a version control log for all case report forms with the dates that they were active and the reason for each update. Please see SOP 45 Study Specific Essential File Documentation for the management of Superseded documents. For further details see SOP 29 Document control and creating JRMO SOPs and SOP 38b AD 2 CRF design guidance.

16.	CI and Study statistician	**Review updated CRF.** With each amendment, the CI must review to confirm that it still matches the protocol and will collect sufficient information. Similarly, the study statistician must confirm that the CRFs collect all the data points required for analysis.
17.	CI	**Maintain oversight of data** Collection and transcription of study data is often delegated to the Investigator's teams. The CI must put processes in place to ensure that they maintain oversight of all study data, and each PI must maintain oversight of data at their site.
18.	CI or delegate	**Ensure that all required data is present and clean in time for data locks.** Prior to planned data locks, each PI must review their data and sign to confirm that it is true and accurate.
19.	CI	**Ensure that all End of Trial procedures are completed as per DMP and SOP 18a Study closure for sponsored regulated studies.**
20.	CI or delegate	**Data lock procedures should be fully documented in the DMP.** Data lock procedures should ensure that the data set used for analysis is clearly identified. The data lock procedure should be followed as per agreed DMP. If it may be necessary to unlock the database after it has been locked, then contact the GCP manager for approval.
21.	Study statistician	**Ensure that full and accurate dataset is received.** The designated statistician should receive a full and dated download of the database or computer systems, with a complete and accurate dataset used for analysis. The statistician should ensure that they are able to read the dataset and should check the export for completeness and that all the fields required for the analysis have been filled. If the statistician has access to the locked study database, then they can check that the data in the report matched the database.
22.	Study Statistician	**Data Analysis** Analyse the study dataset in accordance with the clinical trial protocol and statistical analysis plan. All analyses should be pre-defined in the protocol.
23.	CI or delegate	**Patient dissemination** If outlined in the study protocol, information about the study's conclusion and results in a lay format should be passed onto the patient groups.

24.	CI or delegate	**Publication, Archiving and Provision of data to sites** Once data lock has occurred please follow JRMO Publication Policy ,JRMO SOP 20 Archiving procedures and SOP 18a Study closure for sponsored regulated studies. The CI or delegate must ensure sites have access to the required data for retention processes as detailed in the study protocol.

Change control

This section outlines changes from version 2.0 to 3.0

Section changed	Summary and description of changes
Section 24 Template 1	Requirements to have provisions to return data to site at the end of the study
Throughout	General administrative changes

List of associated documents

There are no associated documents for this SOP

List of templates

Document ref.	Document name
Template 1	Data management plan template