STU-SOP-DMS-009 – Standard Operating Procedure on Database Development and Maintenance

Version No:	4	**Effective Date:**	27-Mar-2026
Description of changes:	SOP reviewed in light of clinical trial regulations 2025 and GCP updates. Specific references to QPulse as the QMS have been removed. We now only refer to a QMS system.		

List of Abbreviations	
CRF	Case Report Form
CI	Chief Investigator
CDMS	Clinical Data Management System
DM	Data Manager
DT	Data Tester
eCRF	Electronic Case Report Form
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
ITO	Information Technology Officer
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University
TDG	Trial Development Group
TM	Trial Manager
TMG	Trial Management Group
TS	Trial Statistician

1. Purpose and Definitions

This Standard Operating Procedure (SOP) describes the procedure of specification, design/development and validation of a research project database in the set-up and maintenance phase.

This SOP applies to all CTIMPs hosted by STU and aligns with ICH GCP E6 (R3) Principles and Annex 1. This SOP can also be used as a guide for non-CTIMP studies and non-research databases to produce validated data when required.

Definitions	
Database	A structured set of data collected and managed for a research project in a way that allows transparency of data entry, security and an audit of changes. Aims to provide confidence that project results achieved are dependable.
Critical to Quality (CtQ)	The attributes of a clinical study that are fundamental to ensuring: 1. Participant protection and safety. 2. The reliability and interpretability of study results. 3. The ability of the study to meet its objectives (decision-making).

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2. Background

Research data should be collected, recorded and managed in accordance with applicable regulations, the principles of Good Clinical Practice (GCP), the General Data Protection Regulation (GDPR), the current Data Protection Act, and the appropriate Swansea Trials Unit (STU) and Swansea University (SU) policies.

ICH GCP E6 (R3) requires risk-proportionate computerised systems validation, enhanced data governance, and full traceability for all database actions, with responsibilities defined across the system lifecycle.

All Clinical Data Management Systems (CDMS) holding research project databases will be internally validated (detailed in STU-SOP-IT-001) and automatically capture an audit trail of user activity.

3. Roles and Responsibilities

Sponsor – responsible for ensuring that the database build and required maintenance is in accordance with the appropriate regulations and the approved protocol.

Chief Investigator (CI) – responsible for ensuring that the database specification remains aligned to the approved protocol.

Trial Management Group (TMG) – responsible for overseeing the suitability of data items and ranges collected, as required by the research project protocol.

Data Manager (DM) – Responsible for leading and coordinating database development including generating the Database Specification, building the database, drafting the testing documents and signing off the database for use once all testing is complete.

Database Tester (DT) – responsible for reviewing the requirements and expected behaviour of the database in alignment to the test specification. Testers will usually be STU staff or research team members ideally with experience of the database structure, protocol and who understand the database specification. Training will be provided as required.

Trial Manager (TM) – responsible for maintaining oversight of database delivery as per the project timelines, reviewing and approving the database development documentation and ensuring that operational aspects are covered within the database design.

Trial Statistician (TS) – responsible for ensuring the database specification is aligned to the approved protocol.

IT Officer (ITO) – responsible for the administration and validation of the DMS. Aspects of this role may be delegated.

External use of SOP: This SOP and Associated Documents (AD) may be used for research projects not adopted by STU where Swansea University (SU) staff and associated NHS organisations require guidance. In such instances, oversight responsibility for any associated tasks will not be the responsibility of STU.

4. Procedure

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4.1 Research project database design

The Database Specification Document (STU-AD-TMP-026) detailing the data items required is usually drafted as per the approved research project protocol. A system-specific data dictionary template to list the data items should be used where available.

The Database Specification Document can include:

- Critical to Quality (CtQ) elements (e.g., essential data related to the primary outcome, deviation tracking)
- visit schedule for the database
- variable name, field label, type and validation
- response coding, as appropriate
- number of repeats for a given visit, form or question
- any branching logic or alerts
- list of risk based single variable or multiple variable edit checks
- any calculations
- list of visits/forms/questions requiring authorisation
- list of visits/forms/questions requiring role specific access
- data governance elements, including metadata and tracking information
- user roles and permission, as appropriate

The database specification document must be agreed and approved by the Statistician, CI and TM prior to move to production.

4.2 Database development

A request for set-up of a research project database must be made to the ITO or delegate. Project database names must be suffixed with “Development” to distinguish between databases. The research project database should be built in accordance with the current protocol and CRF and use recognised instrument templates and naming conventions where possible.

4.3 Database testing

All research project databases must undergo a risk-based testing process prior to use in alignment with the Database Specification Document. Multiple DTs may be involved in testing.

4.3.1 Database form testing

To verify that the database build is correct, complete and aligned to the CRF and the Database Specification Document, testing should ideally be performed by different people to those who designed and set up the database using testing plan and checklist (STU-AD-TMP-028 and STU-AD-TMP-030).

4.3.2 Validation, calculations and custom function testing

To ensure that the research project database is performing as expected, all custom functions, validations, calculations and notifications must be tested and documented using STU-AD-TMP-028.

The outcomes of the testing must be reviewed and any decisions documented on the test script. The Database Specification Document will be updated as required.

The DM must complete the Testing checklist (STU-AD-FRM-030) to ensure all aspects of the research project database have been tested.

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4.4 Move to production

Following successful testing, the DM will prepare to move the database to production within the DMS by requesting approval from the ITO using the Move To Production Approval Form (STU-AD-FRM-019).

A copy of the development database should be made prior to the request to move to production so that a copy is always on file for future access.

The ITO should complete the approval form and authorise the move to production within the DMS to make the database available for project use. The DM should be notified of approval via returned return of completed MTP Approval from the ITO.

When creating project databases, the naming convention must clearly distinguish between development or production project databases.

Users, roles and permissions should be created in accordance with the Database Specification Document.

All project database development documentation must be filed in the Trial Master File.

4.5 Changes to a live database

Database changes may be required due to protocol changes or error(s) identified after the database has moved to production. If changes are required, the database specification documents will be updated as indicated in section 4.1.

A database change request form (STU-AD-FRM-020) must be completed listing all required changes and sent to the TS and TM. The changes will be reviewed and assessed for any potential impact to the existing study data. Resulting changes in data processes should be discussed with the study team and the TMG as necessary.

If a live database update is required, the ITO or delegate must notify users in advance where possible of the expected duration of downtime.

All changes should be made and checked (following section 4.3) in a test environment before updating the live database (following section 4.4). The level of testing required will be risk-based with respect to the changes requested.

5. References

- Health Research Authority website (HRA) - http://www.hra.nhs.uk/
- Medicine and Healthcare products Regulatory Agency website (MHRA) - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information
- UK policy framework for health and social care research (2025) - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- The Medicines for Human Use (Clinical Trials) Regulations 2025 - https://www.legislation.gov.uk/uksi/2025/538/contents

It is assumed that by referencing the principal regulations that all subsequent modifications are included in this citation.

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6. Associated Documents

Number	Title	Location
STU-AD-TMP-028	Database Test Plan Template	QMS
STU-AD-FRM-019	MTP Approval	QMS
STU-AD-FRM-020	Database Change Request Form	QMS
STU-AD-TMP-030	Testing Checklist Template	QMS

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