STU-SOP-DMS-008 – Standard Operating Procedure on Data Management

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	
CAPA	Corrective and Preventive Action
CDMS	Clinical Data Management System
CI	Chief Investigator
CRF	Case Report Form
CTIMP	Clinical Trial of an Investigational Medicinal Product
CtQ	Critical to Quality
DM	Data Manager
DMC	Data Monitoring Committee
DMP	Data Management Plan
eCRF	Electronic Case Report Form
GCP	Good Clinical Practice
PID	Participant Identifiable Data
QC	Quality Control
QbD	Quality by Design
RBQM	Risk-based quality management
SAE	Serious Adverse Event
SDV	Source Data Verification
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
TM	Trial Manager
TMF	Trial Master File
TMG	Trial Management Group
TS	Trial Statistician
TSC	Trial Steering Committee

1. Purpose

This SOP describes the end-to-end management of research data (paper, eCRF, and eSource) for Clinical Data Management Systems (CDMS), ensuring validated, coded, and reconciled data that are fit-for-purpose and preserve scientific integrity. This SOP outlines procedures for managing research data and includes development of the Data Management Plan (DMP), in line with the principles of ALCOA+ (see below) and describes risk-based quality control processes, query management, data export, data security and transparency.

2. Background

Good Clinical Practice (GCP) states that all clinical project information shall be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification. ICH GCP E6 (R3) emphasises a risk-proportionate, Quality-by-Design (QbD) approach and

introduces explicit data governance responsibilities spanning capture, review, transfer and retention. Clinical Trials Regulations 2025 reforms introduce enhanced transparency obligations (public registry registration and timely results reporting).

3. Roles and Responsibilities

Chief Investigator (CI) - Responsible for oversight and knowledge of the data management process, review of the Data Management Plan (DMP).

Data Manager (DM) – Responsible for leading the procedures outlined in this document and coordinating the DMP.

Trial Manager (TM), Trial Statistician (TS) and/or Health Economist (HE) or other members of the team – Responsible for providing input and implementation of the DMP.

All roles listed above are responsible for the identification of Critical-to-Quality (CtQ) factors and define proportionate measures consistent with fitness-for-purpose analyses.

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

4.1. Set-up of Data Management process for a study at STU

As part of project set up, the CI (or delegate) ensure data-management processes are agreed and documented – this should include the process of data collection, data clarification, data location and transfer, risk-based quality management (RBMQ) procedures, and decide the requirements of a CDMS. The data management processes will be set up to ensure the ALCOA+ principles relating to data integrity are met, defined as:

- attributable - data collection/amending is attributable to the person performing the task
- legible - data recorded is clearly legible and permanent
- contemporaneous - data collection is recorded at the time alongside the procedure
- original - original records or certified copies are available
- accurate - data being acquired is accurate and not erroneous
- complete - data being collected is without omission and any changes made to the already collected data is traceable
- consistent - data collection is in sequence to the trial events
- enduring - relevant data is recorded securely on the appropriate trial-controlled tools (e.g. not on a sticky note)
- available - data is available when required and throughout the archiving period (e.g. accessible for review/audit).

Typically the CI or DM will ensure that the data management processes are documented. The process may be documented in the protocol. For more complex projects, it is recommended that a data management plan is created, based on the project risk assessment.

4.2. Data Management Plan

The DMP is a document that describes and defines all data management activities for the

research project (if applicable) and should be approved prior to the start of recruitment (STU-AD-TMP-025). The activities described in the DMP will be dependent on the protocol and oversight reporting requirements as well any CtQ elements.

4.3. Data Quality Control

4.3.1. Data Review

Risk-based data review will be conducted in accordance with the checks documented in the data specification and/or DMP.

4.3.2. In-house Data Entry Checks

CRFs received at STU for data entry will be logged on receipt. Paper CRFs will be date stamped, Data entered inhouse onto the CDMS is then subject to data entry checks.

For paper source, perform risk-based verification against CDMS data for a defined subset informed by CtQ assessment. When eSource is used, data assimilation with appropriate logic checks should be configured and audit trails automated to minimise manual transcription and queries. For both sources document the risk -based approach in the DMP. Specific fields (e.g. primary endpoint) may have differing acceptable error rates. Where the error rate is exceeded, suitable corrective and preventative action (CAPA) should be implemented.

4.3.3. Query Management

The processes for query management will form part of the DMP. Any change or correction to a CRF should be dated, attributed, and explained (if necessary) and should not obscure the original entry; this applies to both written and electronic changes or corrections.

- Discrepancies resulting from review of the data should be flagged to sites.
- The site will respond to the discrepancy.
- A member of the research team will review the response to ensure that the discrepancy has been resolved. Then the discrepancy will either be closed or re-raised.
- Data queries can be raised for speciality areas and should be flagged to ensure that only a suitably trained person resolves/closes/re-raises the query or takes further action.
- Data queries must be carefully constructed and not leading, clearly identify the issue, and requesting resolution/clarification.

4.3.4. Data Reconciliation

The DMP will document all data reconciliation activities including variables (directly entered, externally provided), to be reconciled with a frequency defined in accordance with any specified reporting requirement or risk-based assessment throughout the research project.

4.3.5. Source Data Verification

Source Data Verification (SDV) should be carried out in accordance with the project specific risk proportionate monitoring plan, prioritising CtQ data where appropriate.

4.3.6. Data Validation & Audit trails

Data validation is proportionate to intended use and impact; the DMP will document all validation details (i.e. requirements/specifications, defined factors for CtQ functionality, change control, and training). Audit trails will be required to capture create/modify/delete with user/time stamps and will need to be readable for the whole retention period.

4.4. Data Transfer

The DMP will list all vendors, external data sources, variable names to be transferred, key contact for external sources, frequency of transfers and how discrepancies will be resolved during reconciliation. Data transfer will be carried out according to STU-SOP-TM-006 Data Protection and Confidentiality.

4.5. Data Export and Blinding

The DMP will document the data required for oversight reporting and should be fit for purpose to allow for decision-making while maintaining blinding, if required. Any additional data exports must be requested using the STU Data Release Request Form (STU-AD-FRM-027).

The DMP will document the level of blinding and the roles that must be blinded, as stipulated in the research project protocol. Any reports created or data exports must not be sent to those who are blinded unless blinded exports/reports can be produced.

4.6. Patient Identifiable Data (PID)

The DMP will list PID that are being collected, how they will be received, and where they will be stored. All PID will be handled according to STU-SOP-TM-006 Data Protection and Confidentiality.

4.7. Data retention and transparency

Data will need to be retained for up to 25 years depending on the project type in a format agreed with the CI/Sponsor. The DMP should specify datasets/tabulations for public publication noting the statutory timelines and any participant feedback processes - see Data sharing SOP STU-SOP-DMS-012.

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 (2017) - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- UK Medicine for Human Use (Clinical Trials) Regulations 2025 - https://www.legislation.gov.uk/uksi/2025/538

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

6. Associated Documents

Number	Title	Location
STU-AD-TMP-025	Data Management Plan template	QMS
STU-AD-TMP-026	Database Specification document	QMS
STU-AD-TMP-027	Data Validation Plan Template	QMS
STU-AD-FRM-027	Data Release Request Form	QMS