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

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure of managing quantitative research data on paper and/or in a Clinical Data Management Systems (CDMS), to ensure all data collected are validated, coded and reconciled in a manner that preserves the scientific integrity of the research. This SOP outlines procedures for managing research data and includes development of the Data Management Plan (DMP), describes quality control processes, query management, data export and data security.

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.

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.

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 Data Management Plan

The DMP is a document that describes and defines all data management activities for the research project (if applicable) and must be in place 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.

4.2 Data Quality Control

4.2.1 Data Review

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

4.2.2 In-house Data Entry Checks (paper)

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

The paper CRF will be compared with the data entered on to the CDMS for a random subset of participants. The extent of checking (i.e. frequency, number of cases, acceptable error rate) will be defined in the DMP based on the level of risk. 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.

4.2.3 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.

4.2.4 Data Reconciliation

The DMP will document all data reconciliation activities including variables to be reconciled and their frequency throughout the research project.

4.2.5 Source Data Verification

Source Data Verification (SDV) should be carried out in accordance with the agreed research project specific monitoring plan.

4.3 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.

4.2 Data Export and Blinding

The DMP will document the data required for oversight reporting. Any additional data exports must be requested using 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

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.

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 2004 - http://www.legislation.gov.uk/uksi/2004/1031/contents/made

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	Q-Pulse

7. Abbreviations

List of Abbreviations	
CDMS	Clinical Data Management System
CI	Chief Investigator
CRF	Case Report Form
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
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

8. Appendices

Appendix 1: Document History

Version No:	3	Effective Date:	22-Apr-2024
Description of changes:	Updated to SOP Template v5		