

STU-SOP-DMS-007 – Standard Operating Procedure on Case Report Form Development

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	
CI	Chief Investigator
CRF	Case Report Form
CTIMP	Clinical Trial of an Investigational Medicinal Product
CtQ	Critical to Quality
DM	Data Manager
GCP	Good Clinical Practice
QMS	Quality Management System
STU	Swansea Trials Unit
TM	Trial Manager/Trial Co-ordinator/Project Manager
TMF	Trial Master File
TS	Trial Statistician

Definitions	
Critical to Quality (CtQ)	The attributes of a clinical study that are fundamental to ensuring: <ol style="list-style-type: none"> Participant protection and safety. The reliability and interpretability of study results. The ability of the study to meet its objectives (decision-making).

1. Purpose and Definitions

This Standard Operating Procedure (SOP) describes the procedure of developing, managing and modifying paper or electronic Case Report Forms (CRF or eCRF) which align to the ethically approved protocol for a research project. For the purposes of this document CRFs and eCRFs will be considered as equivalent unless stated otherwise.

2. Background

Project CRFs will be developed to capture data required by the research protocol which has received required ethical and regulatory approvals. Subsequent modifications to CRFs will follow a standardised procedure to ensure that data collection is accurate and consistent across all participants.

Clinical Trials of Investigational Medicinal Products (CTIMPs) must also adhere to the Medicines for Human Use (Clinical Trials) regulations which includes the principles of Good Clinical Practice (GCP).

3. Roles and Responsibilities

The **Sponsor** is responsible for overseeing the CRF design process adheres to GCP. It is usual for CRF design to be delegated to the Chief Investigator.

The **Chief Investigator** (CI) collaborating with the research team is responsible for assuring the design of CRFs complies with GCP and the approved protocol. The CI is responsible for CRF approval.

The **Trial Manager** (TM) is responsible for coordinating the implementation of the project CRF. This includes ensuring site staff have access to current CRFs and training in their completion for the research project.

The **Data Manager** (DM) with the research team is responsible for ensuring that the CRFs are designed, finalised and approved prior to the database build. In some instances, this be in conjunction with database build. The DM should have a role in training in the completion of the project CRFs.

The **Trial Statistician** (TS) is responsible for advising on CRF design to ensure that all data required for project analysis are captured.

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

Research data shall be collected using CRFs, designed to collect accurate and complete data aligned to the approved research project protocol.

CRF development will usually start in parallel with protocol development.

When designing CRFs it is advisable to follow the principles outlined in the CRF Design Guidelines document (STU-AD-GDN-007) and to consult the EQUATOR Network website.

Templates of commonly used CRFs in the STU CRF Library (STU-AD-TMP-023) should be adapted as required.

4.1 General Principles

- All CRF fields must be justified by protocol-level Critical to Quality (CtQ) mapping and referenced in the Data Management Plan.
- CRFs should be based on the project protocol's CtQ data i.e. essential items only that are linked to the project's endpoints/objectives, safety or regulatory requirements.
- CRFs must be available prior to the initiation of the research project and any site is open for recruitment.
- CRFs are required to be approved (along with all other data acquisition tools) prior to release.

- CRFs shall not be accepted as source documents without prior consultation and approval by the sponsor or delegate.
- Any changes required to the CRF must be discussed with the research project team before they are implemented.
- CRFs (and modifications) should be documented on a CRF Approval Form (STU-AD-FRM-017).
- CRFs must be version controlled and dated whether available as electronic, paper or both.
- A CRF library is available for DMs to ensure standardisation of data items collected across multiple trials e.g. medical history, SAE reports (STU-AD-TMP-023).
- The CRF Completion template (STU-AD-TMP-024) should be adapted as required to ensure that clear, standardised instructions are given to all participating sites.
- The Data Management Plan (STU-AD-TMP-025) and the CRF completion guidelines (STU-AD-TMP-024) must be reviewed following every modification and, updated where necessary.
- Completed and approved CRFs are used to create a specification and database development (STU-SOP-DMS-009).
- Projects that use eCRFs only are required to meet the following expectations:
 - system audit trail and associated metadata that includes validation, security, data changes.
 - developed within a system that assures data integrity, security, disaster/recovery, transfer and archiving.
 - permissions and role access for specific elements as detailed in the Data Management Plan and database specification document.
- If problems arise with CRF completion:
 - New guidelines or training should be given to all those completing the CRF to ensure that requirements are clear.
 - Any problems and corrective actions should be recorded within the Quality Management System (QMS) and filed within the Trial Master File (TMF).

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 – updated 2025) - <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/ukxi/2025/538/contents>
- UK Medical Devices Regulations 2025 - <https://www.legislation.gov.uk/ukdsi/2025/9780348269529>

- EQUATOR Network <http://www.equator-network.org/>

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

6. Associated Documents

Number	Title	Location
STU-AD-GDN-007	CRF Design Guidelines	QMS
STU-AD-FRM-017	CRF Approval Form	QMS
STU-AD-TMP-023	CRF Library	QMS
STU-AD-TMP-024	CRF Completion Guidelines	QMS
STU-AD-TMP-025	Data Management Plan	QMS