SOP-QA-12 V5

Title: Case Report Forms

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Document History

Version	Description of update	Date Effective
4	Scheduled review at three years. Change of author and updated scope and process at 3.3, 3.4.2	3-12-20
5	Additional information added to point 1 and 2 section 3.1 Section 3.6.2 added Removal of amendments as not reference in SOP – Section 5	20-12-23

1. Scope

1.1 This SOP applies to case report forms (CRFs) in all Clinical Trials of Investigational Medicinal Product (CTIMP) and Medical Device Clinical Investigation (MDCI) sponsored or co-sponsored by the University of Aberdeen (UoA) and/or NHS Grampian (NHSG). This SOP should also be considered best practice for any other clinical research activity.

2. Responsibilities

Chief Investigator (CI) Design of the CRFs to comply with GCP and the protocol.

3. Procedure

3.1 General

- Clinical research data shall be collected using CRFs. Patient completed questionnaires are considered to be part of the CRF within a study as they collect essential data.
- CRFs shall not be accepted as source documents without prior approval of Sponsor. If the CRF is considered the source document, this must be clearly documented in the protocol.
- CRFs shall be designed to collect only the information required to meet the aims of the study and to ensure the eligibility and safety of the participant.
- CRFs shall be version controlled and dated (on every page).
- All versions of the CRF shall be filed in the Trial Master File.
- All CRFs shall be completed in accordance with GCP.
- There shall be clear evidence that the CI and statistician have approved the CRF.
- CRFs shall be stored in a secure location when the trial is active.
- CRFs shall be archived as required by Sponsor (see SOP-QA-32 - Archiving).
- CRFs shall be available for inspection by Sponsor representative and regulators.
- CRFs shall at all times match with source data; discrepancies shall be clearly noted and the reason explained.

3.2 CRF Design

- CRF design shall be dependent on the data to be collected.
- The CRF shall be consistent with the protocol.
- The Inclusion/Exclusion criterion shall be clear and unambiguous.
- The data fields shall be clear, logical and not open to misinterpretation.
- Consideration shall be given to CRF layout in relation to database entry.
- Space for free text is discouraged unless a specific requirement of the protocol.
- For variables where the actual value is captured, the number of boxes provided shall be adequate and, if appropriate, reflect the number of decimal places.
- Laboratory results shall be entered without conversion from printed reports. If conversion is necessary (eg multi centre sites where units of measurement differ) space shall be made available on the CRF for the original value, conversion factor and converted result.
- Each CRF page shall include study identifier.
- Each CRF page shall include version number, date of version and page number.
- Each CRF page shall include the participant Identification Code number.

3.3 The data to be collected could include, but not be limited to:

- Participant unique ID number (on every page).
- Date of birth **and** age at consent.
- Demographic as per protocol requirements (ensure no identifiable information is used).
- Medical history.
- Primary and secondary outcomes.
- Dosing and compliance.
- Randomisation.
- Adverse Event Form.
- Concomitant medications.
- Withdrawal form.
- End of treatment form.
- Participant eligibility shall be clearly indicated.

3.4 Recording of Data:

3.4.1 Data shall be complete, without omissions.

3.4.2 CRFs shall only be completed only by those delegated the task to do so.

- CRFs shall be completed as soon as possible after each participant assessment.
- Any missing data shall have an explanation in source documents.
- Entries shall be accurate, legible and verifiable against source data (ie medical notes or other agreed documentation).
- Values outside normal, or expected reference ranges, shall have a comment (eg the significance) noted in the source data.
- Data queries shall be addressed quickly and an audit trail exist to detail outcome.

3.4.3 Corrections to entries on CRFs shall be made in compliance with SOP-QA-27 – Good documentation practice:

- Cross out the incorrect entry with a single line, leaving the incorrect entry readable.
- Enter the correct value.
- Date and initial the change, and provide an explanation of the correction.
- Correction fluid shall never be used.

3.5 Training in CRF completion

- The CRF design shall be reviewed and approved by the CI, or delegate, before use.
- Study staff shall receive training on the completion of CRFs to ensure that data is collected in a consistent manner.
- Clear instructions shall be given at all participating sites.
- CRF training shall be documented in a training log and/or study meeting minutes.

3.6 Electronic CRF Completion (eCRF)

3.6.1 eCRFs shall be completed using software and information downloaded, as agreed in the protocol, or a web-based application may be used to access the eCRF.

3.6.2 If the eCRF is considered the source document, this must be agreed by the Sponsor and clearly documented in the protocol.

3.6.3 An audit trail of all entries and data amendments must be captured.

3.6.4 Electronic data shall be archived when the study has finished according to Sponsor archiving procedures (see SOP-QA-32 – Archiving).

4. Abbreviations and definitions

CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
MDCI	Medical Device Clinical Investigation

5. Related documentation and references

SOP-QA-27	Good documentation practice
SOP-QA-32	Archiving