

CASE REPORT FORM COMPLETION STANDARDS

Introduction and Purpose

The case report form (CRF) is a paper or electronic document or series of documents designed to record all of the protocol-required information and results for each clinical trial participant. Accurate and timely entry of data into the CRF is important for the sponsor to ensure proper conduct of the trial, and for the assessment of safety and efficacy endpoints. The data collected on the CRF is the groundwork for any trial related reports or publications and therefore study teams must follow International Council on Harmonization (ICH) GCP guidelines for CRF completion. The purpose of this SOP is to establish standards for the accurate and timely entry of data into the CRF for clinical trials. These standards should be followed unless there are more specific requirements detailed in the study contract or clinical trial agreement (CTA).

Definitions and Acronyms

Clinical Research: Clinical research includes all research involving human participants. It does not include secondary studies using existing biological specimens or data collected without identifiers or data that are publicly available.

Clinical Trial: Clinical trials are clinical research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome.

CRF:	Case Report Form
CRO:	Contract Research Organization
CTA:	Clinical Trial Agreement
GCP:	Good Clinical Practice
OSP:	Office of Sponsored Projects
PI:	Principal Investigator
SOP:	Standard Operating Procedure

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Procedure

1. Case Report Form Data Entry

- 1.1. Appropriately delegated research staff, such as study coordinators, will identify, collect, record, maintain and make available all requisite clinical trial data in the CRF. All data entered on the CRF must have available source documentation except for instances when source is directly transmitted into the CRF. The data entry process begins following study initiation and enrollment of study participants and should be completed prospectively thereafter.
- 1.2. Source documentation (clinic notes, procedure reports, test results, entries on source forms, etc.) should be created contemporaneously with the study visit, or available within 2 – 3 business days in the Electronic Health Record system.
- 1.3. **All available data should be entered into the CRF within 10 business days of the study visit from which the data was generated.**
 - If data availability is delayed, the PI and study personnel will attempt to acquire and enter it into the CRF as soon as possible.
 - If the study contract or CTA specify and require different data entry requirements, those should be followed in preference to this SOP.
 - The PI should ensure the accuracy, completeness, legibility, and timeliness of data collected in the CRF to ensure the data adheres to the protocol.
- 1.4. Each field in the CRF should be completed and blanks should be avoided. If CRF's are in paper format, blue or black ink should be used and never pencil.

2. Queries and Corrections

- 2.1. Queries and other requests for changes to CRF entries are common following sponsor or CRO monitoring visits, or can be issued from the sponsor or CRO data management or pharmacovigilance teams.
- 2.2. Any change or correction to a CRF should be dated, initialed and explained (if necessary) and should not obscure the original entry (maintain an audit trail). An audit trail is important to maintain for both paper and electronic CRF's.

CASE REPORT FORM COMPLETION STANDARDS

2.3. Each query should be addressed, corrected, or appropriately responded to within 10 business days of notification or issuance of the query.

3. Contracts and Clinical Trial Agreements

3.1. For new clinical trials in the feasibility and contract negotiation phase, the study coordinator or appropriate study team member should inform the Office of Sponsored Projects (OSP) program officer of the 10 business day data entry requirement set forth in this SOP to prevent shorter data entry requirements from being included in the contract or CTA.

Materials Required

- Access to the study's paper or electronic CRF database (this often requires user training and issuance of logon credentials)
- IRB-approved clinical trial protocol
- Access to the study contract or CTA, or the contact information for the responsible OSP program officer
- Access to the Electronic Health Record and all other study source data

References

- 21 CFR Part 312.62: Investigator Recordkeeping and Record Retention
- 21 CFR Part 312.68 Inspection of investigator's records and reports
- ICH Guidance for Industry E6(R2): Good Clinical Practice 4.9

Document Approval



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DATE

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Revision History

Version Date	Change Summary
17Oct2019	Original Version
26Jun2020	Version #2 – minor updates for clarity and ease of reading

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