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|  | **SOP Title:** Case Report Form (CRF) Design |
| **Study title**: *Give study title to which this SOP applies* |

# Scope and application

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| A Case Report Form (CRF) serves to collect all the information required by the protocol and to report this for each trial participant to the sponsor. To facilitate proper collection of trial data, a proper CRF design should be considered.  This SOP applies to all key aspects in CRF design and involves the generation, review and approval of CRFs. This SOP serves both paper and electronic CRF design. |

# Responsibilities

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| **Function** | **Activities** |
| Coordinating Investigator or delegate | * Lead the process of CRF design * Provide input on the design |
| Data Manager | * Coordinate CRF design * Provide input on the design |
| Trial statistician | * Provide input on the design * Check CRF suitability for analysis |
| Laboratory Technician | * Provide input on laboratory sections |

# Definitions

**CRF**: A case report form (or CRF) is a paper or electronic questionnaire specifically used in clinical trial research. The Case Report Form is the tool used by the sponsor of the clinical trial to collect data from each participating site. All data on each patient participating in a clinical trial are held and/or documented in the CRF, including adverse events.

**eCRF**: Electronic CRF

**pCRF**: Paper CRF

**PI**: Principal Investigator

# Procedures CRFs should collect data for each study participant in an appropriate format, in accordance with the study protocol and as intended for statistical analysis. The design of a CRF and its completion have a direct impact on the quality assurance and control during monitoring.

* 1. **General principles on data capture**

Only collect data specified in the protocol and intended for analysis.

CRF pages are arranged in order of subject visits and generally include the following in a typical trial:

* Inclusion/exclusion criteria
* Informed consent
* Baseline data and demography data
* Relevant medical history
* Study specific data as per protocol (e.g. clinical assessment data)
* Laboratory data
* (Serious) Adverse events
* Concomitant medications
* Trial medication dosing and compliance
* Withdrawal study form
* Follow-up visits
* Unscheduled visits
* End of study / Trial completion Form
  1. **General design guidelines**

CRF design should start when the protocol is close to final, or immediately thereafter. It should be made available to allow adequate time for database programming and testing before the first patient is enrolled in the study. The CRF should be designed in cooperation with the data management staff to make sure it is suitable for the database/eCRF design (if applicable). The statistician should also review the CRF to make sure that it is suitable for downstream data analysis. Experienced Clinical investigators and lab staff should also be involved to make sure that the CRF is applicable for the real life situations of the study.

A CRF can be designed in MS Word. Starting the design in MS Word allows for easier design and review. This document can then serve as a paper CRF or to design the eCRF. Approved versions or final CRFs should best be provided in PDF format to avoid any further changes.

The way the CRF is designed depends on the variables that need to be collected. The following CRF design guidelines should be considered:

* Provide study identification information in a standard page header and footer with clear reference to study name/number, Country/site name/number, Subject ID, visit dates, page number and CRF version.
* Adopt a standardised format throughout the design to ensure consistency and facilitate training.
* Design the CRF to follow the data flow from the study perspective, taking into account the flow of study procedures and routine data in a medical record.
* Separate the CRF into sections by visits to ease organisation and provide a trial schedule
* Arrange data fields clear, logical and user friendly.
* Keep free text to a minimum and provide tick box options or drop-down lists where possible.
* Use pre-coded answer sets such as yes/no, male/female, method of administration of medicine, and severity of adverse event (AE) (mild/moderate/severe) wherever possible
* Use a combination of definitive options and option to enter “other” or “specify”.
* Be consistent in questions with yes/no responses. Keep these always in the same order (e.g. yes/no) and avoid inserting a question(s) with opposite order (e.g. no/yes).
* Add a question Done/Not done with reference to the performance of visits, lab samples and lab tests: ‘Has the visit been performed? Y/N’, ‘Has a sample been taken? Y/N’, ‘Was the test done? Y/N’. If possible, avoid questions where several answers can be ticked (e.g. tick all that apply). Instead formulate such questions as: ‘Was x present? Y/N’, ‘Was y present? Y/N’, …
* Provide input masks, a set format that data collection must conform to (e.g. dd/MMM/yyyy). Provide an appropriate number of boxes for digits required and specify the position of the decimal point (e.g. \_ \_.\_ \_)
* Specify the unit of measurement (keep in mind which unit is used in routine practice, and whether these are the same for all sites)
* Make sure that all elements of the CRF are clear, especially for non-skilled personnel.
* Avoid requesting unnecessary calculations and/or conversions.
* Try to limit the use of ‘additional comments’ within CRFs as free text is more complex to analyse and should therefore be kept to a minimum.
* Use questions, prompts and provide instructions. These must be clear, concise and consistent with other CRF pages and the protocol.
* Use well-known terminology and abbreviations.
* Provide definitions when necessary.
* Avoid duplication (same data at different locations on the CRF) unless explicitly needed for confirmation such as economic based questions.
* Ensure the confidentiality of research participants’ personal information: assign a subject identification code to each trial subject. No subject names and no other direct personal identifiers should be collected on the CRF.
* Provide CRF completion guidelines document based on the design (how to deal with blank fields and visits, coding, corrections, queries, etc) as this will help minimise misinterpretations.
* Insert a CRF or section at the end for the Principal Investigator or clinician’s signature to verify that all data is complete and accurate.
  1. **Layout**

The layout of the CRF should be consistent throughout the entire CRF including alignment, page margins, spacing and fonts. The CRF should not be overly cramped and should have sufficient space in the page margin to accommodate hole punching/binding (in case of a paper CRF).

Related questions should be grouped in sections (eg. Lab data, demographics, etc)

* 1. **Review and approval**

CRFs should be reviewed and signed off by the Coordinating Investigator and the approval process should be well documented using the CRF Approval Form – see Appendix 1. It is a good practice to involve the study data manager, statistician and PIs at sites in this process. If possible, the CRF should be tested out by site staff to ensure all questions are clear.

Amendments to the CRF may be triggered by a change in study protocol, trial design or data requirements. These amendments should be tracked through version numbers and dates and approval documented in the Trial Master File.

1. **Attachments**

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| **Attachments** | |
| **Number** | **Title** |
| 1 | CRF Approval form |
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1. **Document History and References**

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| **Revision** | | | |
| **Version number** | **Author** | **Date** | **Changes** |
| 1.0 | Hanne Landuyt | 01/02/2019 | Initial version - based on the ADMIT SOP -002 from the Association for Data Management in the Tropics  Review by Fatoumatta Cole and Yusupha Njie  Approval by Bai Lamin Dondeh and Harry van Loen |
| 2.0 | Hanne Landuyt | 10/10/2019 | Lay-out updates: spacing and font |
| 3.0 | Hanne Landuyt | 20/06/2022 | Review to ensure that the SOP is appropriate within ALERRT and with current clinical research best practices. |

1. **Approval**

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| **Name and function** | **Date (dd/mm/yyyy)** | **Signature** |
| ***Author*** | | |
| *Indicate who wrote the SOP* |  |  |
| ***Review*** | | |
| *Indicate WP team members who reviewed (if applicable)* | *Date of review* |  |
| ***Approval*** | | |
| *Indicate WP Lead/Co-lead(s) who approved* | *Date of approval* |  |