Data Management Guidance

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# References

* ICH-E6 R2: Good Clinical Practice Guideline (2017)
* Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)
* [European Directive for the implementation of GCP](http://www.eortc.be/Services/Doc/clinical-EU-directive-04-April-01.pdf) 2001/20/EC
* Good Clinical Data Management Practice, Version 4, SCDM, October 2005
* Good Clinical Practice Guide – MHRA (2012)
* GDPR - EU General Data Protection Regulation (May 2018)

# Introduction

Case Report Forms (CRF) are “printed, optical or electronic document designed to record all the protocol required information to be reported to the sponsor on each trial subject.” ICH GCP section 1.11.

The CRF is a data collection tool used in clinical research and can either be a paper CRF (pCRF) or electronic CRF (eCRF). It should be study protocol driven, robust in content and designed to record all of the protocol required information on each study subject and should comply with GDPR regulations.

The design of the pCRF/eCRF and its completion has a direct impact on the quality of the data collected during a clinical study. A well designed pCRF/eCRF ensures that: no essential data are missed, data queries are kept to a minimum, aids good data management practice and assists with statistical analysis and reporting.

pCRF/eCRFs should be designed for optimal collection of data in accordance with the study protocol compliance, regulatory requirements and shall enable the researcher to test the hypothesis or answer the study related questions.

Good data planning up front, with input from the research team, is key to ensuring good data output.

# Objectives of pCRF/ECRF Design

**Primary:** is to collect all the data required by the protocol in such a way that it can be analysed according to the protocol and Statistical Analysis Plan (SAP). For example, Visits, Procedures to be performed, data field/variables.
All the data elements/points within the pCRF/eCRF must support the identifiable objectives of the protocol, in the form of the primary and secondary outcomes and safety endpoints.

**Secondary:** is to reduce the number of queries to the site that ask for clarification of the data responses. For example, avoid duplicating data in data collection and eliminating missing and/or ambiguous responses.

It should also serve to ensure the safety and eligibility of the participant. It should also demonstrate compliance with study procedures and where possible, adherence to Good Clinical Practice (GCP) and Principles of Good Data Management.

In order to achieve these goals, the following points below should be adhered to when designing pCRF/eCRFs:

* Subject identifiers must not be used anywhere on the pCRF/eCRF, such as subject’s name, initials, address, hospital number etc., in order to maintain the confidentiality of the subject. This is known as Pseudonymisation.
* Do not collect the full date of birth. Consider either collecting the Month/Year or Year only. If age is an inclusion criterion, collect age instead.
* Only collect data related to the protocol
* Collect the raw data measurements rather than implied result (with the exception of age as explained above)
* Use coded entries and drop down codelist entries
* Consider the format type of each data variable and associated unit
* Minimise the use of text fields
* Avoid using abbreviations that are ambiguous or could be interpreted differently.
* When completing the pCRF/eCRF, avoid using abbreviations in text fields (other than NA - **Not Applicable**, ND - **Not Done**, NK - **Not Known** and UNK - **Unknown**) and acronyms, unless they are approved medical abbreviations known to be acceptable.

# pCRF/eCRF Design

The pCRF/eCRF can be one single form covering all aspects of the study or a collection of separate forms.

* The initial design of the pCRF/eCRF can use a final draft version of the protocol provided the pCRF/eCRF design is reviewed against the final protocol once available.
* Based on the approach used and regardless of the format, the pCRF/eCRF should be version controlled during the draft process and also once it has been finalised. If there are changes, the version number and date should be updated accordingly. Versioning format should follow the sequence for draft versions 0.1, 0.2, 0.3 etc. and for final versions 1.0, 2.0, 3.0 etc.
* pCRF/eCRFs must notcontain any participant’s identifiable information (i.e. participant’s name, address etc.), the participant’s identity should remain anonymised. The participant should only be identified on the pCRF/eCRF by means of the allocated study number, participants should be allocated a Participant Identifier (PID) when enrolled/randomised onto a clinical study.
* Sufficient information should be included in the header of the pCRF/eCRF to attribute every page or form to a participant e.g. study identifier, participant number.
* The header information should detail which time point during the study each page belongs to, clearly identifying the visit or data collection time point as defined in the protocol and the date the data was collected.
* For multi-centre studies the site should also be identifiable on the pCRF/eCRF.
* All visits and study specific procedures should be recorded on the pCRF/eCRF as the protocol schedule of assessments demands.
* pCRF/eCRF pages should be arranged in chronological order as per the visit schedule.
* The arrangement of the data fields should be clear, logical, concise and user friendly.
* The use of free text in data fields should be minimised wherever possible due to the difficulty of analysing free text responses. Consider whether text data can be collected in another format i.e. selecting form a drop down codelist.
* Where appropriate, a combination of definitive answers and an option to enter ‘other’ and specify will allow for additional information to be collected.
* Avoid collecting extraneous data – if the data are not required to be collected according to the protocol and will not be analysed, do not include in the pCRF/eCRF.
* Avoid collecting derived data, to minimize calculation errors. In particular, avoid this if designing a pCRF.
* Specify decimal points and number of places required where actual values are required for certain data points.
* Unit measurements should always be specified.
* The use of tick boxes, radio buttons, multi-select and drop down list should be incorporated in the pCRF/eCRF.
* In addition, maximise the use of standard pCRF/eCRF forms/modules from the global library (which will have already been designed, developed and tested) where possible.

# Standard pCRF/eCRF Forms

In addition to the procedures listed in a protocol visit schedule, there are some types of questions that are generally required in the pCRF/eCRF. These questions collect essential data that will be used both for analysis and regulatory submissions.

Typically, these should include but are not limited to:

* Demographic data (sex or gender, ethnicity, Date of Birth\*)
* Inclusion and Exclusion Criteria – (Participant’s eligibility)
* Relevant History e.g. Medical, Medication, Surgical
* End of Treatment Information
* End of Study Information

\*Please note: The full Date of Birth should not be collected, only Month and Year, or Year, to comply with GDPR regulations.

# pCRF/eCRF Review and Approval

The pCRF/eCRF design should be reviewed at all stages and approved by the CI and Statistician (or person assigned to analyse the data) to ensure:

1. Only the appropriate data have been collected.
2. The data are consistent with the study protocol.
3. Data have been collected to answer the research questions being asked.
4. Has been reviewed for accuracy and completeness, is fit for use and has captured all the relevant data points to ensure the objectives have been met.

Any issues identified during the review process should be discussed with the research team; input will be sought from the person responsible for final statistical analysis of the study for issues which could affect data collected.

# pCRF/eCRF Amendments

If protocol amendments are required during the conduct of the study which affect the design of the pCRF/eCRF, these amendments will also need to be reflected on the pCRF/eCRF.

The new amendments to the pCRF/eCRF will require approval from the CI or delegate and all relevant personnel and must be released under version control.

# pCRF/eCRF Completion Guidelines

A study specific pCRF/eCRF completion guideline should be generated for each study. This document explains the activities involved in pCRF/eCRF completion, correction, signing and general data handling.

This document will provide page by page clear instructions for site personnel on how to accurately complete the pCRF/eCRF. It should be prepared in a way that it enables the site personnel to complete the pCRF/eCRFs with ease and legibility and to facilitate consistency of data entry across sites. The pCRF/eCRF completion guidelines document will be version controlled and amendments should be done as and when required. The CI or delegate should approve the CRF Completion guidelines document before distribution and use by participating sites.

# Using an Electronic Data Capture (EDC) System

* Never share your password with anyone or write it down.
* After a set period of inactivity, you will be automatically logged out of the system.
* It is good practice to log out once you have finished using the EDC application. This is particularly important if you are not using your own computer.
* Data entry for a completed visit should be performed in an ongoing, timely manner.
* Data entry must only be completed by authorised personnel who have received trial-specific and EDC Software training and are competent in eCRF completion.
* Data queries should be answered in an ongoing timely manner.