

What is a CRF? An eCRF?

A Case Report Form, or CRF, is a research-specific document that collects all the relevant data for a given protocol.

Historically, these were completed on paper but for most current studies, data is reported into an Electronic Data Capture database (or EDC). These platforms then produce an electronic version of the Case Report Form (eCRF).

Many research staff use the terms EDC, Database, CRF, and eCRF interchangeably. The FDA outlines CRF requirements in [21 CFR Part 312.62 \(b\)](#).



Case Report Forms are created specifically to capture data related to the research study protocol. If you are on a sponsored research study, your sponsor (or CRO) will provide additional guidance on CRF completion and source documentation. They will also provide training on how to use their Electronic Data Capture platform.

If you are looking for more information, Shantala Bellary, et al. (2014) provide a good starting point for those new to CRFs in their free-access article titled "[Basics of Case Report Form Designing in Clinical Research.](#)"

Case Report Forms vs. Source Documents

Case Report Forms

- ◆ Capture the specific information related to the research study, or the “little picture”
- ◆ Ensure that the study data are comprehensively reported to answer the research question
- ◆ Use a subject number to de-identify participants and can be used by research sponsors and their statistical teams
- ◆ Ensure that the protocol is being followed
- ◆ Serve as documentation for who performed each research task

Source Documents

- ◆ Capture the “big picture” of the research subject’s medical condition, treatment, and progress throughout the study
- ◆ May be located in different places (e.g., EPIC, imaging software, etc.) and in different formats (e.g., handwritten notes, varying units, etc)
- ◆ First and original documentation of the data
- ◆ Sponsors don’t have continuous access to source documents, so they aren’t able to use them for data aggregation or analysis purposes

NOTE: Not all data in the source document will be reported on the CRF, but all data in a CRF must be verified by some kind of source document.

Many common FDA inspection findings involve CRFs or source documents:

- ◆ Source documentation missing
- ◆ Clinical significance of labs not noted
- ◆ Adverse events missing in case report forms
- ◆ Adverse events not attributed
- ◆ Multiple sources of data that differ
- ◆ Results of tests not documented
- ◆ Missing pages in quality of life questionnaires
- ◆ Discrepancies in what is in source and what is reported on case report forms
- ◆ Inaccurate medication logs
- ◆ Drug dispensing/dosing documentation missing