Case Report Forms

According to ICH GCP EC 1.11, a case report form is a printed, optical, or electronic document designed to record all of the protocol required information to be reported on each trial subject. CRFs are designed by the sponsor or sponsor-investigator and maintained at the investigative site. Information documented on the CRF (or eCRF) must be supported by source documentation.

One of the most essential tasks performed by the CRC is completing and/or ensuring the completion of the subject’s CRF. Most sponsors will provide instructions or a guide for CRF completion. Handwriting must be legible and should be completed in black ink. All data points must be addressed and for fields that cannot be completed, “not available,” “not done,” or “unknown” should be marked in accordance with the sponsor’s instructions.

The CRC will ensure that all required data are collected and entered on the CRF as soon as possible after, if not during, the visit. All CRFs should be checked for completeness and legibility. The CRFs should be reviewed and signed by the investigator prior to submission, if required. Only those physicians identified on the 1572 may sign CRFs.

When making a correction on a CRF, a single line should be drawn through the incorrect entry and the correct data should be entered above or next to the incorrect entry. The correction should be dated and initialed. White-out or eraser should never be used to correct an error. Blanks identified prior to the investigator’s review and sign-off on the CRF can simply be completed. Those identified after sign-off must be dated and initialed.

Sometimes, CRCs are required to create case report forms (eg, investigator-initiated studies).

To create your own CRFs, these are the steps to be followed:

- Perform an in-depth protocol review – carefully consider the schedule of events and workflows. This review will also include determining what data points need to be captured at which time points.
- If available, consult the statistical analysis plan (SAP) to perform the same determinations as above. The SAP will provide information on key output data needed from the study for analysis during and after the study has been completed. These data points need to be incorporated in the eCRFs so they are captured for analysis.
- When developing the CRFs, the current standards (Clinical Data Acquisition Standards Harmonization - CDASH) need to be referenced. These standards establish a standard way to collect data.
- Create Standard CRF Specifications which detail how the CRFs should be completed and what data is needed to complete the CRFs. These specifications should be as detailed as possible so anybody can read the specifications and create the CRFs without having to reference the protocol. Standard CRF Specifications Example
- Understand the difference between a source document and a CRF:
  - Per ICH E6, section 1.52, Source Documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects’ diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).
  - Understanding the difference can “cut the fat” from CRFs – unnecessary data that do not need to be collected can be removed. All data in the CRFs must be present in the source docs but not all data in the source docs need to be present in the CRFs.

In most cases, study sponsors provide paper CRFs or have an electronic data capture (EDC) system where electronic CRFs are housed for the study. These eCRFs have been created and validated by a data management team. After extensive discussions with the PI, study project manager, statisticians, and other key study personnel, the eCRFs are approved and edit checks are built. Edit checks are used to fire a query when discrepant data is entered in any of the eCRF fields. A User Acceptance Testing (UAT) is performed by the data management team to ensure that edit checks fire when needed (and not inadvertently fire when irrelevant). The data management team also creates a data management plan which is specific to each study. This plan details how the data is handled for that particular study.

After UAT and validation of the system, and after changes/adjustments are made if needed, the eCRFs are released into production. This means they are ready to be used by sites when a subject is enrolled.

Below are several examples of paper CRFs and electronic CRFs from different vendors.

**Examples of paper CRFs:**
Examples of eCRFs from EDC vendors:

Concomitant Medication Example 1

Concomitant Medication Example 2

Concomitant Medication Example 3

Subject Identification / Demographic Data Example 1

Subject Identification / Demographic Data Example 2
### Subject Identification / Demographic Data Example 3

![Subject Identification / Demographic Data Example 3](image1)

### Laboratory Form Example 1

![Laboratory Form Example 1](image2)

### Laboratory Form Example 2

![Laboratory Form Example 2](image3)

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