

WHITE PAPER

eCRF Design: Best Practices

The eCRF (electronic Case Report Form) is an Electronic Data Capturing (EDC) tool used in clinical trials to collect protocol required information. A well designed and properly structured eCRF is prerequisite for simplified data collection. eCRF design technique in terms of eCRF layout, organizing eCRF modules with comprehensive eCRF completion instructions are all necessities for its success.

While designing the eCRF, it is the best practices to have interdepartmental inputs such as from Biostatistics-Medical Writing and Clinical Teams, but it should also be reviewed by QC & QA, such that the eCRF should be efficiently capturing all the aspects of the protocol requirements for its success.

Design parameters for eCRF

- Initiate eCRF design along with draft protocol; so as to collect only data that is protocol specific and can be finalized as soon as protocol is finalized and also reduce timelines.
- Design the eCRF to follow the data flow from the study perspective and the person completing it, taking into account the flow of study procedures and typical data in a medical record.
- Design the eCRF with the primary safety and efficacy end points in mind as the main goal of data collection; avoid duplication referential and redundant data points within the eCRF whenever possible, Keep questions, prompts and instructions clear and concise.
- Request minimal free text responses, provide units to ensure comparable values
- Design eCRF with built-in edit checks linked to each data element so that data cleaning will take place during the completion of the eCRF
- Make the eCRF available for review at the clinical site prior to approval.

As a part of standardization, establish and maintain a library of standard eCRF modules/pages according to Global Standards (CDISC-CDASH). A typical eCRF will contain all data as per the protocol specifications and those which adds value during analysis.

Data elements or individual eCRF questions can be classified as Mandatory, Conditional and Optional.

- Mandatory questions are the one which must be collected on the eCRF (e.g., Primary and Secondary Objectives, a regulatory requirement (if applicable).
- Conditional questions are the one which must be collected on the eCRF for specific cases (may be recorded elsewhere in the eCRF or from other data collection sources).
- Optional questions are the one which must be collected on the eCRF and those are available for use if needed (may be recorded elsewhere in the eCRF or from other data collection sources).

eCRF Design Layout:

The eCRF layout should be similar to paper CRF and the design should mimic a typical medical record so as to decrease data collection errors (ease of data entry) and the layout strategy should be such that the design of the eCRF is simple, easily understandable.


Well designed eCRF design layouts are the one which are not overcrowded and have pre coded answer sets.

Organizing eCRF Fields

Well-aligned and structured eCRF fields provide a clear direction for data collection and for annotating eCRF and should always be organized in accordance with Protocol Visit Schedule. For e.g., Demographic data and Informed Consent is always the first data collection modules followed up by physical and laboratory assessments.

Pre defined formats, i.e. Date, Lab Units, It is always better to describe the units in which they need to be captured, For example, height and weight, as shown in Figure1.

Figure 1:

E.g.:	Poorly Designed eCRF Data Fields		Well Designed eCRF Data Fields
1	Height [] [] [] Weight [] [] []		Height [] [] []. [] cm Weight [] [] []. [] kg

eCRF Completion Guidelines:

Data entry personnel are well trained and are familiar with eCRF completion and eCRF completion guidelines are in place to provide the users in regards to eCRF completion, signing and handling protocol related procedures.

eCRF completion guidelines should be written in the layman language, easy to understand, user friendly, should provide clarity and should leave no place for any kind of confusion.

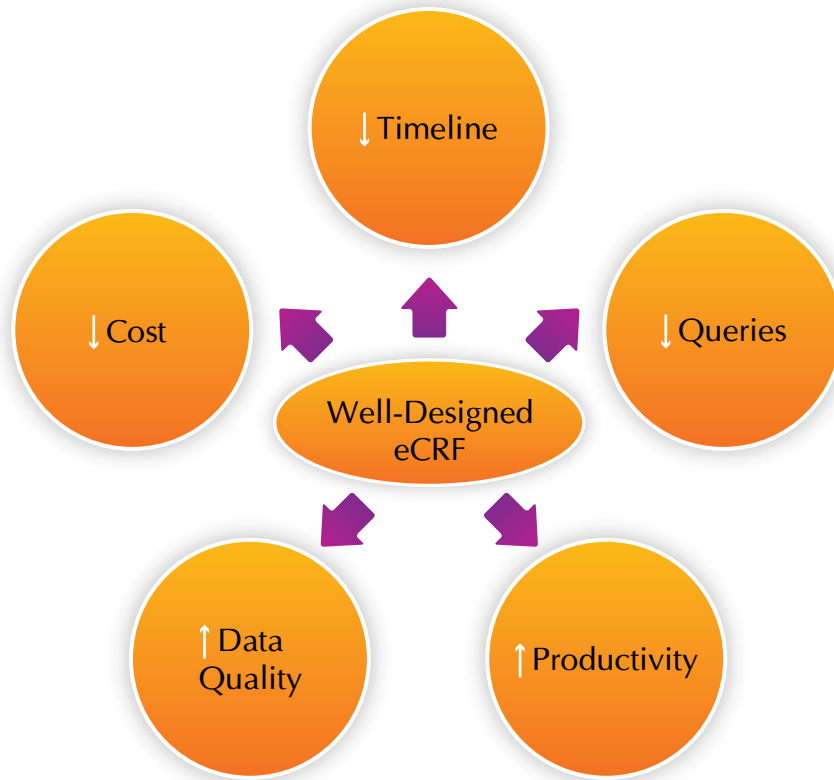
Some of the general eCRF completion guidelines are as follows:

1. All data including comments must be recorded in English. Please make sure all data entered are accurate and consistent. Please avoid using abbreviations and symbols whenever possible
2. Never leave any item blank. If something is 'not done' or 'unknown' or 'not applicable' make a comment (ND/UK/NA). Every effort must be made to complete all data fields in eCRF as much as possible
3. Please complete the corresponding data entry as soon as possible
4. Please make sure to click the [Save] button frequently to avoid losing the data due to "timeouts"
5. Date Formats should in the form of DD/MMM/YYYY. For e.g.: 01/JAN/2011

Above were some of general rule while completing the eCRF. In order to enhance the efficiency of eCRF completion, there should be study-specific eCRF completion guidelines in place.

eCRF Testing:

The eCRFs should be thoroughly tested for protocol specifications, user acceptance, and regulatory compliance, test and document with sample dummy data for edit check specifications and also for database built (Data sets, Listings, Variable Name/ Length etc.).



Conclusion:

Best practices in eCRF designing is a requirement for current challenging clinical research environment. A well designed eCRF which has been reviewed by all the teams who are involved directly with the Study and clear cut CRF filling guidelines such that the sites are able to understand and capture the data accordingly.

