International Journal of Leading Research Publication
IJLRP

© IJLRP | ISSN (O) - 2582-8010
December 2020 | Vol. 1 Issue. 4
www.ijlrp.com

Basics of Case Report Form Designing And Benefits of implementing CDASH in Clinical Research

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ABSTRACT

The case report form Case Report form (CRF) is a specialised clinical research document, to gather the research relevant data. A Case Report Form (CRF) should be study protocol oriented & robust in content. Electronic Case Report Form (E-CRF)'s are preferred over Paper Case Report Form (CRF)'s, as they provide, improved data quality, management of online differences and faster locking of databases, etc. Preserving data quality and integrity are the key goals behind Case Report Form (CRF) growth. To meet the needs of all users, such as investigator, site planner, research monitor, data entry workers, and statistician, the Case Report Form (CRF) architecture should be standardised. Data should be structured in a way that promotes data processing and simplifies it. The collection of vast volumes of data results in the collection of wasted resources. Standard guidelines should be followed while designing the Case Report Form (CRF). The site workers should be supplied with the Case Report Form (CRF) completion manual to facilitate correct data entry by them. These steps would result in decreased generation of queries and improve the integrity of data. In the below article we have performed an observational study to find about two major concepts of Electronic Case Report form (E-CRF) designing.

1. ***Importance of an Electronic Case Report Form (E-CRF) standard template library.***
2. ***Preferred Electronic Data Capture (EDC) Software.***

Keyword: *case report form (CRF), electronic case report form (ECRF), database, case report form designing, standard template, software*

1. INTRODUCATION

A case report form (CRF) is a specifically used paper or electronic questionnaire for clinical trial research. The case report form is the method used by the clinical trial sponsor to gather data from each patient participating. All data, including adverse effects, on each patient involved in a clinical trial shall be kept and/or recorded in the Case Report Form (CRF). In order to test their theories or answer their research questions, the sponsor of the clinical trial develops the Case Report Form (CRF) to gather the particular data they need. A Case Report Form (CRF)'s size can vary from a one-time handwritten 'snapshot' of the physical state of a patient to hundreds of pages of electronically recorded data collected over a period of weeks or months.

The creation of case report forms involves immense scheduling and attention to minute detail. In a clinical trial, developing a Case Report Form (CRF) is important as it will help to reliably determine the safety and effectiveness of the medicinal product. The Case Report Form (CRF) should be configured for optimal data collection in accordance with compliance with the study procedure, regulatory requirements and allow the hypothesis to be tested by the researcher or answer questions relevant to the experiment.

The design of the Case Report Form (CRF) (paper form / electronic form) is recognized as a key quality step in ensuring the protocol-required data, regulatory compliance and/or safety requirements / comments, study specific hypothesis attributes, site work flow, and cross-checking of data items are addressed within a form or across different forms. The CRF (Case Report Form) used in clinical research reduces messy analysis. In this article we would talk about implementation of standard templates in designing of Electronic Case Report Form & Commonly used software's.

2. GIGANTIC REFORM IN DATA BASE STORAGE

In clinical science, there are two types of CRF (Case Report Forms), i.e., standard paper CRF and improvised electronic CRF (E-CRF). The conventional method of data

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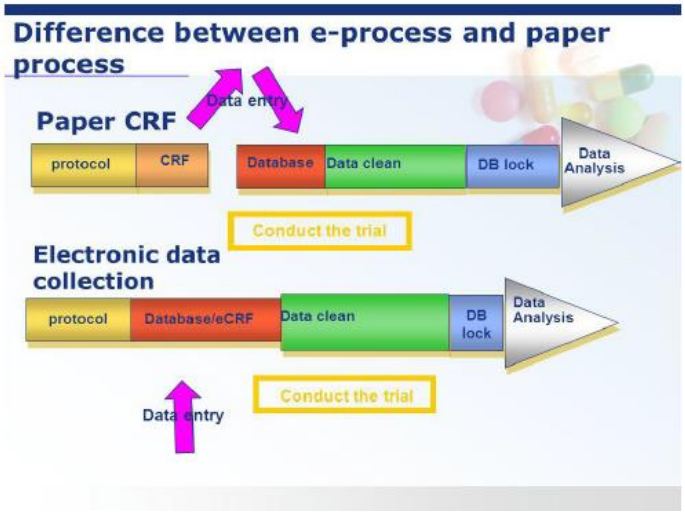
December 2020 | Vol. 1 Issue. 4
www.ijlrp.com

capture is paper CRF and a better choice if studies are small or differ in design, while eCRFs are taken into account if studies with similar designs are large. Information technology (IT) offers a fast and reliable way for science and clinical data to be obtained and has become the most efficient way to exchange data collaboratively.

IT and electronic data capture (EDC)-based clinical research also relies on interfacing with Healthcare IT systems, which typically involves a variety of different software systems and storage formats for patient data storage.

Designing a paper CRF (Case Report Form) is a repetitive process that could lead to data errors and incorrect assumptions, requiring diligent consideration to avoid CRF (Case Report Form) page duplication. It is normal to have a chance of error during data transfer from the source document to paper CRF. In addition, if the conventional method of data collection by paper CRFs is chosen for studies with large sample size, then manual data cleaning may be a major concern. However, user training and system validation may not be needed for this process, as in the case of Electronic Data Capture (EDC) systems, where such things are necessary before implementation. In spite of their many benefits, E-CRFs (Electronic Case Report Forms) have not been generally recognize.



3. STANDARD OPERATING PROCEDURE FOR CASE REPORT FORM DESIGN

Designing a CRF (Case Report Form) is a skill that should be focused on science practices, and keeping the end user (the one who enters the CRF data) in mind, the design should be implemented.

The primary purpose of the design of the CRF is to collect full and precise data by avoiding duplication and facilitating the transcription into the CRF of data from source documents. As the main objective of data collection, CRF should be built with the primary endpoints of protection and efficacy. A descriptive header and footer that can be modified is a vital part of the CRF. In general, the header contains protocol ID, site code, and topic ID, and patient initials. In comparison, the footer contains the signature of the investigator, date of signature, version number, and page number. Major points to be kept in mind during CRF (Case Report Form) Designing:

1. The use in the CRF (Case Report Form) booklet of consistent formats, text type and font sizes.
2. Portrait versus landscape range versus combination templates
3. Usage of simple and succinct queries, directions and prompts
4. The person recording the data as often as possible should be provided with visual signs, such as boxes that clearly show the location and format of the data to be registered.
5. Specific instructions on skip patterns such as what to skip and what not to skip should be given at appropriate locations.
6. Skips (the instructions given on the CRF page to maintain inter page connectivity) should be held to a minimum by asking questions to prevent misunderstanding.
7. Provide boxes to carry the comments, or separate lines. This tells the data recorder implicitly where to write / enter the answer and helps to distinguish it visually from the entry fields for other queries.
8. Separate dense lines from the columns, Provide instructions that are bold and italicized
9. Minimize free text responses to ease and pace up the process of data entry in e-CRF.
10. Date should be entered in (dd/mm/yyyy) format throughout the e-CRF.
11. Pre-coded answer sets such as Yes/No, male/female, methods of administration should be used.

4. METHODS

An observational study was conducted by reading various literature, from various websites such as – PubMed, PMCin, Myoclonic etc. The objective was to know about:

1. Importance of Standard Templates in CRF designing.

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December 2020 | Vol. 1 Issue. 4
www.ijlrp.com

2. Preferred Electronic Data Capture (EDC) Software's.

5. DISCUSSION

After scrapping data from various articles, reports the data was collected and observed.

Importance of Standard Template – When the data was analyzed it was found that all the companies involved in installing of Electronic Data Capture (EDC) systems contain a standard library of ECRF (Electronic Case Report Forms) templates. These templates are used for production of New E-CRF's (Electronic Case Report Forms) as these are in accordance to all the regulatory guidelines & are certified by the higher authorities, and preparing of E-CRF is a daunting task by referring to the templates one can easily complete the process in an ethical manner in less time.

For various types of data, such as adverse events or demographics, CDASH (The Harmonization of Clinical Data Acquisition Practices) describes sets of standard data collection fields. These definitions include the text of the query, variable name, field description, instructions for completion of the E-CRF, and additional detail. CDASH is a standard for data collection from clinical trials. The Clinical Data Interchange Standards Consortium (CDISC) maintains it as part of a suite of standards designed to work together from protocol preparation through submission to the clinical trial process.

The norm for CDASH includes 18 domains that are prevalent in several clinical trials.

After formation of sample E-CRF (Electronic Case Report Forms), it can be compared with the standard E-CRF present in CDASH database, Gap analysis is performed to check whether any important fields are missing and then the Sample is discussed among the team members.

Preferred Software - After observing various articles it can be said that , the software for Electronic Data Capture (EDC) should be user – friendly , it should directly perceived as a Good system in terms of – Utility , Ease of use & Efficiency. With timely submission, analysis, and strict criteria for data acceptability in clinical research, user experience becomes more crucial.

In the world of clinical trial the word spreads fast , as the Electronic Data Capture (EDC) systems which are user – friendly make an appealing impression on the clinical trial industry workers . Until deciding for their best option, any prospective buyer (clinical research agency or a trial sponsor) is likely to receive input from different resources.

1. Employees' previous experience
2. Feedback from relatives, former colleagues and staff associates
3. Products ratings online
4. Products live demonstration
5. Requirements from sponsor
6. It is enough to say that a good product is supposed to get a favourable word going around, much quicker than having an unfavourable one for a not-so-good product.

There is sometimes a false belief that that CDASH defines the layout of the CRF and eCRF. The function of CDASH is to define the naming conventions for the clinical database, and outline how variables are mapped to SDTM.

It defines how questions should be formulated for data collection within the CRF and eCRF making use of standard CDISC controlled terminology. The key benefit of implementing CDASH standards is improvements to quality of outputs. With the development of more structured information, during study set up, design of eCRFs can become easier with ability to reuse and retrieve information. There can be a beneficial effect on timelines with time for tasks being considerably reduced.

Beyond the immediate benefits during study set up, data review is improved through use of standards, and data transfers are eased. A standard approach across studies serves to support subsequent data analysis. Importantly, from a regulatory submission point of view, CDASH is a starting point for ensuring we begin thinking about standards at the outset of the clinical data collection and analysis data flow, and supports traceability.

There are so many benefits of implementing a standard data collection methodology. The standardizing the definition for the data that is collected over multiple sites is a unique feature.

CDASH defines data that can be used in the cleaning of data and for the conformation of missing data. CDASH is valuable for reducing the production time for CRF design, reducing the training time for sites.

The close alignment between Cytel's data management, statistical programming and bio statistics teams helps to ensure appropriate data lineage between CDASH , SDTM and onward to ADaM standards. Cytel has a track record

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December 2020 | Vol. 1 Issue. 4
www.ijlrp.com

of successful CDISC delivery and is a CDISC registered solutions provider.

Some of the known Electronic Data Capture (EDC) systems in the market:

Software	Company
Rave	Medidata
Inform	Oracle
Oracle RDC	Oracle
Data Labs EDC	Perceptive
Data Trek EDC	Data Trek
Encapsia	Cmed
IBM EDC	IBM
e Case link	DSG
Medrio EDC	Medrio
Red Cap EDC	Red Cap Cloud
iMed net EDC	Mednet
Bioclinica EDC	Bioclinica

After analysis of these graphs it can be stated that Rave from Medidata & Inform from Oracle are the most preferred EDC.

6. CONCLUSION

From the above literature review we can conclude that:

CRF (Case Report Form) is a clinical trial document, which is used for collection of data such as – Past Medical History, Adverse event recording, Demo graphical studies etc.

CRF are of two types – Paper CRF (conventional) & E-CRF (Electronic Case Report Form)

E-CRF's are preferred over Paper CRF's as they provide real-time access, are robust, reduce time, help in pharma covigilance etc.

CRF designing is a tedious task as these CRF's should be in accordance to all the regulatory guidelines, should be user – friendly & should be protocol – oriented.

For E-CRF development, most of the companies have standard templates as E-CRF designing is a daunting process standard templates can be refereed .CDASH – (The Harmonization of Clinical Data Acquisition Practices) is a standard for data collection from clinical trials. It is maintained by The Clinical Data Interchange Standards Consortium (CDISC). CDASH has 18 domains of clinical trial. After designing a sample E-CRF it can be compared with the E-CRF's present in CDASH database to confer any missing information boxes.

There are various Electronic Data Capture (EDC) software's in the market in the above literature paper i have listed the software's whose names have been popularized through word of mouth including Rave, Inform, Bioclinica, IBM EDC, Data Trek EDC etc. Finding represented Rave & Inform as the most preferred EDC software's as they are user – friendly, efficient & usage.

REFERENCES

1. E-CRF (Electronic Case Report Form Introduction from
2. https://www.sofpromed.com/what-is-anecrf/#:~:text=An%20eCRF%20(electronic%20case%20report,clinical%20trials%20or%20observational%20studies.
3. Standard Operating Procedure for E-CRF (Electronic Case Report Form)
4. https://forteresearch.com/news/study-and-standard-ecrf-creationpros-of-ecrf-mock-up/
5. ICH-GCP guidelines
6. Standard Templates for E-CRF https://blog.xclinical.com/reducingthe-effort-of-building-an-ecrf
7. https://www.google.com/search?q=standard+templates+library+in+e-crf&oq=standard+templates+library+in+ecrf+&aqs=chrome..69i57j33i10i160l3.14855j0j4&sourceid=chrome&ie=UTF-8#
8. http://www.cdisc.org/
9. Electronic Data Capture (EDC) system Comaprison
10. https://credevo.com/articles/2019/02/28/what-is-the-best-Electronic DataCapture-system-ecrf-youve-ever-used-review-of-online-user-initiatedsurveys-on-social-media/
11. A Practical Introduction to Clinical Data Acquisition Standards Harmonization (CDASH) Jennifer Price, Phoenix Data Systems, Inc, King of Prussia, PA.