Mini Review

Annals of Clinical and Laboratory Research
ISSN 2386-5180

2022
Vol.10 No.8:425

Administration of Data Management in Clinical Research: Mini Review

Divya Dara*

Department of Clinical research, Geethanjali College of Pharmacy, Cheeryal, Keesara, Hyderabad, India

Received: 04-Aug-2022, Manuscript No. IPACLR-22-13082; **Editor assigned:** 08-Aug-2022, PreQC No. IPACLR-22-13082(PQ); **Reviewed:** 22-Aug-2022, QC No. IPACLR-22-13082; **Revised:** 24-Aug-2022, Manuscript No. IPACLR-22-13082(R); **Published:** 31-Aug-2022, DOI: 10.36648/2386-5180.22.10.425

Abstract

A crucial stage in clinical research is clinical data management (CDM), which produces high-quality, trustworthy, and statistically sound data from clinical trials. This results in a significantly shorter period of time between drug development and release. From the beginning to the end of a clinical trial, CDM team members are actively involved. They must have sufficient process knowledge to support upholding the CDM processes high levels of quality. At regular intervals throughout a trial, various CDM processes-including Case Report Form (CRF) designing, CRF annotation, database designing, data entry, data validation, inconsistency management, medical coding, data extraction, and database locking are evaluated for quality. To meet regulatory requirements and stay ahead of the market through quicker product commercialization, there is a greater need to strengthen CDM standards in the current environment. The CDM team can achieve these requirements by implementing regulatory-compliant data management technologies. Additionally, submitting data electronically is becoming required of businesses. Professionals in CDM should have the drive to keep up with the fast evolving technology, satisfy reasonable requirements for data quality, and fulfil reasonable expectations.

Keywords: Validation, e-CRF, Clinical data management systems, Clinical data exchange standards consortium, and Clinical data management

***Corresponding author:**
Divya Dara

divyadara522@gmail.com

Department of Clinical research, Geethanjali College of Pharmacy, Cheeryal, Keesara, Hyderabad, India

Citation: Dara D (2022) Administration of Data Management in Clinical Research: Mini Review. Ann Clin Lab Res. Vol.10 No.8:425

Introduction

A clinical trial aims to answer the research question by producing data that can be used to support or disprove a theory. The outcome of the investigation is significantly influenced by the quality of the generated data. The topic "what is Clinical Data Management (CDM) and what is its significance?" is one that research students frequently ask. A relevant and significant component of a clinical study is clinical data management. In the course of their study, all researchers engage in CDM activities, whether consciously or unconsciously. While doing our research, we engage in some of the CDM processes without specifying the technical steps. The process of gathering, filtering, and managing subject data in accordance with legal requirements is known as CDM. The main goal of CDM procedures is to deliver high-quality data by minimising errors and missing data while collecting as much data as feasible for analysis [1]. In order to achieve this goal, best practises are used to make sure that the data is accurate, trustworthy, and handled properly. The introduction of software programmes that keep an audit trail and make it simple to identify and fix differences has made this possible. Advanced developments have made it possible for CDM to manage massive trials and guarantee the data quality even in challenging trials.

Instruments for CDM

There are numerous software programmes available for managing data, and these are referred to as Clinical Data Management Systems (CDMS). A CDMS is now necessary in multicentric trials to manage the massive volume of data. Several open source tools are also accessible, although commercial CDMS make up the majority of CDMS employed in pharmaceutical businesses. The CDM tools ORACLE CLINICAL, CLINTRIAL, MACRO, RAVE, and eClinical Suite are frequently utilised. There isn't much of a functional difference between two software tools, and neither system has a clear benefit over the other. The most well-known open source tools include OpenClinica, openCDMS, TrialDB, and PhOSCo. These CDM programmes can be downloaded without charge and offer similar functionality to their paid equivalents.

CDM Process

Like a clinical trial, the CDM procedure starts with the goal in mind. This indicates that the deliverable has been kept in mind throughout the entire process. An error-free, valid, and statistically sound database is what the CDM process is meant to give, much as a clinical trial is made to provide an answer to the research question.

Discrepancy Control

Other name for this process is query resolution. Managing differences entails reviewing them, looking into why they exist, and either finding a solution supported by documentation or announcing their irresolution. Distinction operation assists in cleaning up the data and assembles sufficient evidence of the data disagreement seen. Most CDMS contain a database for discrepancies where all differences will be noted and maintained with an audit trail [2]. Differences are either reported to the investigator for clarification based on the kinds discovered, or they are resolved internally *via* Self-Evident Corrections (SEC) without forwarding DCF to the site. Spelling errors are the most frequent SECs. DCFs will be dispatched to the location for discrepancies that call for clarifications from the investigator. DCFs can be created and printed with the aid of CDM tools. The resolution or an explanation of the events that led to the disparity in the data will be written by the investigators. When an investigator provides a resolution, the database will be updated with that information.

Occasionally, the CDM team checks all differences to make sure they have been handled. The data discrepancies that have been resolved are marked as "closed." It follows that subsequent data validation efforts on the same data won't result in a discrepancy for the same data point because those validation failures are no longer regarded as active. Closing differences, however, is not always achievable. Sometimes the investigator won't be able to explain why the disparity exists. Such conflicts will be marked in the discrepancy database as "irresolvable" and will be treated. The CDM procedure is most crucial step in discrepancy management. The handling of discrepancies must be done with the utmost care because it is a crucial part of data cleaning [3].

CDM's Roles and Responsibilities

Different duties and responsibilities are given to the team members in a CDM team. Graduation in a life science field and familiarity with computer applications should be the very minimum educational requirements for team members in CDM. Medical graduates are ideal for the position of medical coder. However, paramedical graduates are also hired in the sector as medical coders. All CDM teams need to fill a few crucial jobs. The following roles can be regarded as the bare minimum for a CDM team:

- Medical coder
- Data Entry Associate
- Clinical Data Coordinator
- Quality Control Associate.

The clinical data coordinator creates all additional CDM-related materials, checklists, and guidelines. The quality control associate performs data audits and verifies the accuracy of data entry. A different quality assurance individual may occasionally audit the data entered [4,5]. The quality control associate also checks the paperwork related to the protocols being followed. The team responsible for data entry will keep track of when CRF pages are received and enter the information into the database.

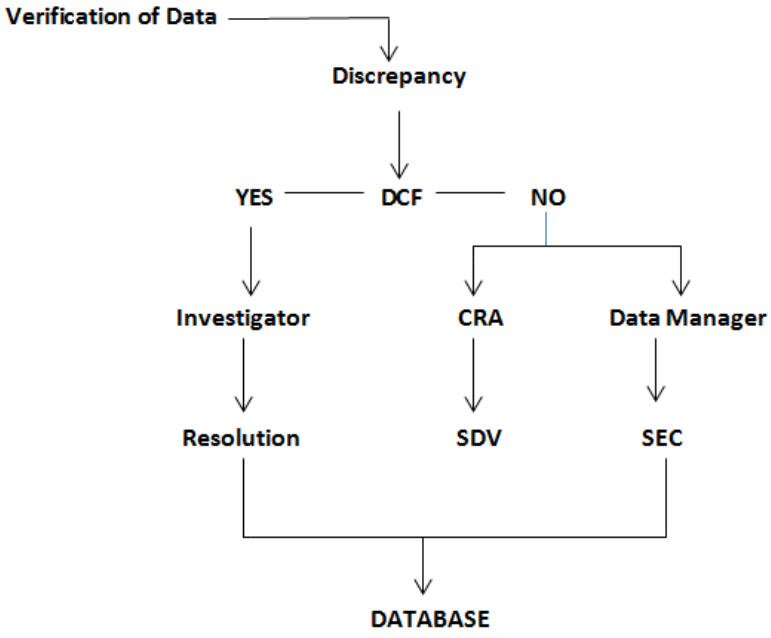

Figure 1 Data Process Management.

Image Represents: CRA: Clinical Research Associate, DCF: Data Collection Associate, SEC: Self Evident Correction, SDV: Source Document Verification.

Conclusion

The need for medication development to be accelerated by pharmaceutical companies and for regulatory agencies to establish quality systems to guarantee the generation of high-quality data for accurate drug evaluation has resulted in the evolution of CDM. The CDM method and systems have benefited from technology advancements, which have produced encouraging results in terms of data generation speed and quality. Professionals in CDM should simultaneously guarantee that the standards for enhancing data quality are followed. The establishment of guidelines to specify the processes to be followed and the data standards, as well as the standardisation of the data management process across businesses, would be the biggest regulatory difficulty. The planning and execution of data management systems in a dynamic operating environment where the quick pace of technological advancement outpaces the current infrastructure would present the biggest challenge from the industry's standpoint. Despite these, CDM is developing into a standard-based clinical research entity by balancing the demands placed on existing systems and their limitations with the demands of commercial and technology advancements.

References

1. Gerritsen MG, Sartorius OE, Veen FM (1993) Data management in multi-center clinical trials and the role of a nation-wide computer network. A 5 year evaluation. Proc Annu Symp Comput Appl Med Care 659-662.
2. Lu Z, Su J (2010) Clinical data management: Current status, challenges, and future directions from industry perspectives. Open Access J Clin Trials 2: 93-105.
3. Fegan GW, Lang TA (2008) Could an Open-Source Clinical Trial Data-Management System Be What We Have All Been Looking For? PLoS Med 5(3): e6.
4. Kuchinke W, Ohmann C, Yang Q, Salas N, Lauristen J, et al (2010) Heterogeneity prevails: The state of clinical trial data management in Europe - results of a survey of ECRIN centres. Trials 11: 79.
5. Cummings J, Masten J (1994) Customized dual data entry for computerized data analysis. Qual Assur 3(3): 300-303.