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Review Article

**A REVIEW ON DATA MANAGEMENT IN CLINICAL  
RESEARCH**

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**Article Received:** December 2022    **Accepted:** December 2022    **Published:** January 2023**Abstract:**

*Clinical Data Management (CDM) could be a crucial innovative clinical analysis, that ends up in the generation of high-quality, reliable, and statistically sound information from clinical trials. This helps to provide a forceful reduction in time from drug development to promotion. Team members of CDM square measure actively concerned altogether stages of trial right from origination to completion. they must have adequate method data that helps maintain the standard standards of CDM processes. varied procedures in CDM as well as Case Report From (CRF) coming up with, CRF annotation, info coming up with, data-entry, information validation, discrepancy management, medical committal to writing, information extraction, and info protection square measure assessed for quality at regular intervals throughout an effort. within the gift situation, theirs is an exaggerated demand to enhance the CDM standards to fulfill the regulative necessities and keep them before the competition by suggests that of quicker commercialization of the product. With the implementation of regulative compliant information management tools, the CDM team will meet these demands. Clinical information Management has to draw on a broad variety of skills like technical, scientific, project management, data technology, and systems engineering to offer valued service in managing information at intervals of the anticipated e-clinical age.*

**KEY WORDS:** Clinical data, clinical data management systems, data management, e-CRF, validation, data entry, discrepancy management.

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**INTRODUCTION:**

Clinical Data management (CDM) could be a very important cross-functional vehicle in clinical trials to confirm high-quality knowledge square measure captured by site workers through paper case report form (CRF) or electronic case report form and accessible for early review. The integrity and quality of information being collected and transferred from study subjects to a clinical data management system (CDMS) should be monitored, maintained, and quantified to confirm a reliable and effective base for not solely new drug application (NDA) submission and clinical science reports, however conjointly company clinical designing, decision-making, method improvement, and operational improvement. CDM is the method of assortment, cleaning, and management of subject knowledge in compliance with regulative standards. the first objective of CDM processes is to supply high-quality knowledge by keeping the number of errors and missing knowledge as low as attainable and by gathering the most knowledge for analysis.[1] to fulfill this objective, the best practices square measure is adopted to confirm that the knowledge square measure is complete, reliable, and processed properly. This has been expedited by the employment of package applications that maintain an associate degree audit path and supply straightforward identification and backbone of knowledge discrepancies. subtle innovations have enabled CDM to handle giant trials and make sure the knowledge quality even in advanced trials. [2]

**A. GCP Guidelines:**

- All clinical research data should be recorded, handled, & stored in a way that allows its accurate reporting, interpretation & verification. (ICH GCP 2.10, 4.9, 5.5, 5.14 & ICH E9 3.6 & 5.8)
- Systems with procedures that assure the quality of every aspect of research should be implemented. (GCP 2.13)
- Quality assurance & quality control systems with written standard operating procedures should be implemented & maintained to ensure that research is conducted & data are generated, documented & recorded, & reported in compliance with protocol, GCP & applicable regulatory requirements. (GCP 5.1.1)
- If data are transformed during processing, it should always be possible to compare original data & observations with processed data (ICH GCP 5.5.4)
- Sponsor should use an unambiguous subject identification number or code that allows identification of all data reported for each subject. (ICH GCP 5.5.5)

- Protocol amendments that necessitate a change in the design of CRF, subject diaries, study worksheets, research database & other key aspects of CDM processes need to be controlled. (ICH E9 2.1.2)
- Common standards should be adopted for several features of research such as dictionaries of medical terms, definition & timing of main measurements, and handling of protocol deviations. (ICH E9 2.1.1)

**B. Tools for Clinical Data Management**

Many software system tools are units out there for knowledge management and these area unit are known as Clinical Data Management Systems (CDMS). In multicentric trials, a CDMS has become essential to handle the massive quantity of knowledge. Most of the CDMS employed in pharmaceutical corporation area unit business, however many open supply tools are available further. ordinarily used CDM tools area unit ORACLE CLINICAL, CLINTRIAL, MACRO, RAVE, and eClinical Suite. In terms of practicality, these software system tools are unit additional or less similar and there's no significant advantage of 1 system over the opposite. These software system tools area unit high-ticket and wish refined data Technology infrastructure to perform. in addition, some transnational pharmaceutical giants use custom-made CDMS tools to suit their operational wants and procedures. Among open supply tools, the foremost distinguished one area unit OpenClinica, OpenCDMS, TrialDB, and PhOSCo. These CDM software system area units out there are freed from value and area units are nearly as good as their business counterparts in terms of practicality. These open supply software systems are often downloaded from their several websites.

**C. Regulations, Guidelines, and Standards in CDM**

Akin to alternative areas in clinical analysis, CDM has pointers and standards that have got to be followed. Since the pharmaceutical trade depends on electronically captured knowledge for the analysis of medicines, there's a necessity to follow smart practices in CDM and maintain standards in electronic knowledge capture. These electronic records have to be compelled to adjust to a Code of Federal Rules (CFR), twenty-one CFR half eleven. This regulation applies to records in an electronic format that is created, modified, maintained, archived, retrieved, or transmitted. This demands the employment of valid systems to make sure accuracy, reliability, and consistency of knowledge with the employment of secure, computer-generated, time-stamped audit trails to severally record the date and time of operator entries

and actions that make, modify, or delete electronic records.[3]

Society for Clinical Data Management (SCDM) publishes the Great Clinical Data Management Practices (GCDMP) tips, a document providing the standards of excellent application among CDM. GCDMP was at the start printed in Sept 2000 and has undergone many revisions thenceforth. The Gregorian calendar month 2009 version is the presently followed GCDMP document. GCDMP provides steerage on the accepted practices in CDM that area unit per restrictive practices. self-addressed in twenty chapters, it covers the CDM method by highlighting the minimum standards and best practices.

Clinical Data Interchange Standards Consortium (CDISC), a multidisciplinary non-profit organization, has developed standards to support the acquisition, exchange, submission, and repository of clinical analysis knowledge and information. information is the knowledge of the info entered. This includes This knowledge regarding the individual UN agency that created the entry or an amendment within the clinical knowledge, the date and time of entry/change, and details of the changes that are created. Among the standards, necessary one's area units the Study knowledge Tabulation Model Implementation Guide for Human Clinical Trials (SDTMIG) and also the Clinical Data Acquisition Standards Harmonization (CDASH) standards, on the market freed from value from the CDISC website ([www.cdisc.org](http://www.cdisc.org)). [4]

#### **Clinical Data Management Process [5]**

The CDM method, sort of a trial, begins with the tip in mind. this suggests that the full method is meant keeping the deliverable see able. As a trial is meant to answer the analysis question, the CDM method is meant to deliver AN error-free, valid, and statistically sound information. to fulfill this objective, the CDM method starts early, even before the finalisation of the study protocol.

#### **A. Review and finalization of study documents**

During this review, the CDM personnel can determine the information things to be collected and also the frequency of assortment with relation to the visit schedule. A Case Report Form (CRF) is meant by the CDM team, as this is often the primary step in translating the protocol specific activities into knowledge being generated. the information fields ought to be clearly outlined and be consistent throughout. the kind of information to be entered ought to be evident from the CRF. The CRF ought to

be summary, obvious and user friendly (unless you're the one coming into data into the CRF). in conjunction with the CRF, the filling directions (called CRF Completion Guidelines) ought to even be provided to review investigators for error free knowledge acquisition. CRF annotation is completed whereby the variable is called in keeping with the SDTMIG or the conventions followed internally. Annotations are coded terms employed in CDM tools to point the variables within the study.

#### **B. Database designing [6,7]**

Databases are clinical software applications that are engineered to facilitate the CDM tasks to hold out multiple studies. Generally, these tools have constitutional compliance with regulative necessities and are straightforward to use. "System validation" is conducted to confirm data security, throughout that system specifications, user necessities, and regulative compliance are evaluated before implementation. Study details like objectives, intervals, visits, investigators, sites, and patients are outlined within the info and CRF layouts are designed for knowledge entry. These entry screens are tested with dummy knowledge before moving them to the \$64000 knowledge capture.

#### **C. Data collection**

Data collection is completed victimization the CRF which will exist within the kind of a paper or Associate in Nursing electronic version. the standard technique is to use paper CRFs to gather the information responses, that are translated to the information victimization information entry done in-house. These paper CRFs are stuffed up by the investigator in line with the entire tips. within the eCRFbasedCDM, the investigator or a designer are going to be work into the CDM system and getting into the information directly at the positioning. within the eCRF technique, the probabilities of errors are less, and therefore the resolution of discrepancies happens quicker. Since pharmaceutical corporations attempt to cut back the time taken for drug development processes by enhancing the speed of processes concerned, several pharmaceutical corporations are choosing eCRF choices (also known as remote information entry).

#### **D. CRF tracking**

The entries created within the CRF are going to be monitored by the Clinical Research Associate (CRA) for completeness and filled-up CRFs area unit retrieved and bi manual over to the CDM team. The CDM team can track the retrieved CRFs and maintain their record. CRFs area unit caterpillar-tracked for

missing pages and indecipherable information manually to assure that the information doesn't seem to be lost. just in case of missing or indecipherable information, a clarification is obtained from the investigator and therefore the issue is resolved.

#### E. Data entry [8,9]

Data entry takes place per the rules ready at the side of the DMP. this is often applicable solely within the case of paper CRF retrieved from the sites. Usually, double knowledge entry is performed whereby the info is entered by 2 operators severally. The second pass entry (entry created by the second person) helps in verification and reconciliation by distinguishing the transcription errors and discrepancies caused by dirty knowledge. Moreover, double knowledge entry helps in obtaining a cleaner information compared to one knowledge entry. Earlier studies have shown that double knowledge entry ensures higher consistency with paper CRF as denoted by a lesser error rate.

#### F. Data validation

Data validation is that the method of testing the validity of information following the protocol specifications. Edit check programs square measure written to spot the discrepancies within the entered knowledge, that square measure embedded within the information, to make sure knowledge validity. These programs square measure written in keeping with the logical condition mentioned within the DVP. These edit check programs square measure ab initiation tested with dummy knowledge containing discrepancies. The discrepancy is outlined as an information purpose that fails to pass a validation check. The discrepancy is also because of inconsistent knowledge, missing knowledge, vary checks, and deviations from the protocol. In eCRF-based studies, the info validation method is run oftentimes for distinguishing discrepancies. These discrepancies are resolved by investigators when work into the system. in progress internal control of information process is undertaken at regular intervals throughout CDM.

#### G. Discrepancy management

This is conjointly referred to as question resolution. Discrepancy management includes reviewing discrepancies, work the rationale, and resolution them with documentary proof or declaring them as irresolvable. Discrepancy management helps in cleansing knowledge info the information and gathers enough proof for the deviations ascertained in data. most CDMS encompasses a discrepancy info wherever all discrepancies are recorded associate degrees hold on with an audit path. supported the categories known, discrepancies square measure either flagged to the investigator for clarification or closed in-house by Self Evident Corrections (SEC) while not causation DCF to the location. the foremost common

SECs square measure obvious writing system errors. For discrepancies that need clarifications from the investigator, DCFs are sent to the location. The CDM tools facilitate within the creation and printing of DCFs. Investigators can write the resolution or make a case for the circumstances that light-emitting diode to the discrepancy in knowledge. once a resolution is provided by the investigator, identical are updated within the info. within the case of eCRFs, the investigator will access the discrepancies flagged to him and can be able to offer the resolutions on-line. Figure one illustrates the flow of discrepancy management. [10]

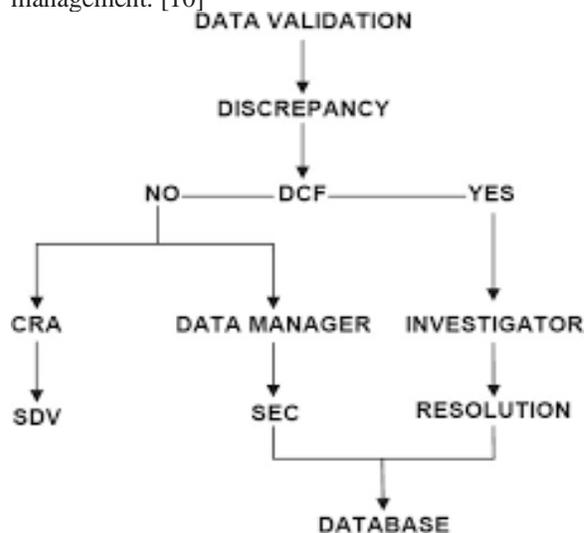


Fig. 1 Discrepancy management.

#### H. Medical coding

Medical secret writing helps in distinctive and properly classifying the medical terminologies related to the clinical test. For the classification of events, medical dictionaries obtainable on-line ar used. Technically, this activity wants the data of medical understanding of sickness entities, drugs used, and basic data of the pathological processes concerned. Functionally, it conjointly needs data concerning the structure of electronic medical dictionaries and also the hierarchy of classifications obtainable in them. Adverse events occurring throughout the study, before and concomitantly administered medications, and previous synchronic diseases are coded mistreatment the obtainable medical dictionaries. Commonly, Medical Dictionary for Regulatory Activities (MedDRA) is employed for the secret writing of adverse events furthermore as different diseases, and World Health Organization–Drug Dictionary Enhanced (WHO DDE) is employed for secret writing the medications. [11]

#### I. Database locking

After a correct quality check and assurance, the ultimate knowledge validation is run. If there aren't any discrepancies, the SAS datasets square measure finalized in consultation with the statistician. All knowledge management activities ought to be completed before info lock. to make sure this, a pre lock listing is employed and completion of all activities is confirmed. this can be done because the info cannot be modified in any manner when protection. Once the approval for protection is obtained from all stakeholders, the info is latched and clean knowledge is extracted for applied math analysis. Generally, no modification within the info is feasible. however just in case of a vital issue or for alternative vital operational reasons, privileged users will modify the information even when the info is latched. [06]

### **ROLES AND RESPONSIBILITY IN CLINICAL DATA MANAGEMENT**

In a CDM team, different roles and responsibilities are attributed to the team members. The minimum educational requirement for a team member in CDM should be graduation in life science and knowledge of computer applications. Ideally, medical coders should be medical graduates. However, in the industry, paramedical graduates are also recruited as medical coders. Some key roles are essential to all CDM teams. The list of roles given below can be considered as minimum requirements for a CDM team:

- Data Manager
- Database Programmer
- Designer
- Medical Coder
- Clinical Data Coordinator
- Quality Control Associate
- Data Entry Associate

The data manager is liable for oversight the whole CDM method. the info manager prepares the DMP, approves the CDM procedures and every one internal document associated with CDM activities. dominant and allocating information the base access to team members is additionally the responsibility of the data manager. The info programmer/designer performs the CRF annotation, creates the study info, and programs the edit checks for knowledge validation. He/she is additionally liable for coming up with {of knowledge| information} entry screens within the info and substantiating the edit checks with dummy data. The medical technologist can do the writing for adverse events, amnesics, co-illnesses, and concomitant medication administered throughout the study. The clinical knowledge arranger styles the CRF, prepares the CRF filling directions, and is liable for developing

the DVP and discrepancy management. All different CD related documents, checklists, and guideline documents area unit ready by the clinical knowledge arranger.

### **ELECTRONIC SOLUTION IN CLINICAL DATA MANAGEMENT**

Technology-driven ways and initiatives have the potential to alleviate the many pressure to promote a medicine as early within the patent life as doable to maximize the amount while not competition, each to extend total revenue and to shorten the time to promote sales. the rise in regulative necessities and competition seen in recent years, not to mention reforms in health care services, has given extreme challenges for the biopharmaceutical trade, suggesting the requirement for sponsor firms to speculate considerably in technological solutions and add a stress on business method re-engineering and improvement to engender semi-permanent clinical efficiencies and value advantages. during this atmosphere, the effectiveness of the clinical knowledge management perform is crucial to substantiate early approval for a brand new product launch and resultant eminent selling. Delay, deficiency, or quality problems within the CDM method may be pricey.

#### **A. Clinical data management from industry perspectives**

Through participation with the team throughout the look of the study, knowledge the information manager or study designer gains the required understanding of the specified knowledge from the protocol and also the standards expected with relevancy data quality. it's vital for knowledge managers or study designers to know the numerous sources of the information and also the type during which the information is retrieved, i.e., hospital records, laboratory take a look at results, insurance and government records, non-public MD records, or e-diaries/patient-reported outcomes. it's more and more recognized that the look of the CRF oreCRF could be a key quality step in guaranteeing the information needed by the protocol, regulative compliance and/or safety needs/comments, study scientific-specific hypothesis attributes, website advancement, and cross-checking of information things among a type or across totally different forms square measure self-addressed.

#### **CONCLUSION:**

CDM has evolved in response to the ever-increasing demand from pharmaceutical companies to fast-track the drug development process and from the regulatory authorities to put quality systems in place to ensure the generation of high-quality data for accurate drug evaluation. To meet the expectations, there is a gradual

shift from paper-based to electronic systems of data management. Developments on the technological front have positively impacted the CDM process and systems, thereby leading to encouraging results in speed and quality of data being generated. At the same time, CDM professionals should ensure the standards for improving data quality.[12]

The competitive pressure in today's marketplace is forcing the biopharmaceutical industry to seek better ways of reducing drug development times and increasing productivity. The market acceptance of EDC technology has fueled new demands for improvement, configurability, and intelligent features. The need to improve clinical efficiencies and accelerate study times continues to grow, driving industry sponsors to seek an e-clinical environment that provides and promotes flexible eCRF trial design, build, and speedy deployment, robust data management, real-time data visibility, reporting and analysis, and global trial management and study scalability. To meet the expectations, there is a gradual shift from paper-based to electronic systems of data management. Developments on the technological front have positively impacted the CDM process and systems, thereby leading to encouraging results in the speed and quality of data being generated. at the same time, CDM professionals should ensure the standards for improving data quality.[07]

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