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Review Article

ROLE OF CLINICAL DATA MANAGEMENT SYSTEM: CLINICAL RESEARCH MONITORING TOOL IN MULTI-CENTRE CLINICAL TRAIL

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ABSTRACT

Multidisciplinary co-operation in multi trail Centre need an organized data management, configuring to ensure true progress monitoring and high-quality research data. So, that CLINICAL DATA MANAGEMENT (CDM) is an essential tool in the medical study, leads to produce high –quality, reliable and statically significant data from multiple clinical trials and diminish time phase of drug development to marketing. CDM's members are extremely active during all stages of clinical trial or drug development, from inception to completion and maintain the quality standards of CDM process on the other hand, multiple procedure in CDM, including Case Report Form (CRF) designing, CRF annotation, database designing, data entry, data validation, discrepancy management, medical coding, data extraction, and database locking are assessed for quality at regular interval during a multi centric clinical trial. Presently, CDM is becoming compulsory for drug development companies to submit data electronically. This review article spotlight on the process involved and provide the reader on overview of the tool & Elements of CDM, Data management's tools as well as the role and responsibilities in CDM [1].

KEYWORDS: Clinical Data Management, Elements of CDM, Data Management Tools, Data Storage, Scope Responsibility of CDM, Importance of CDM.

INTRODUCTION:

Multi-centre Clinical Trail (MCCT) is group of several disciplines, deliberated to find answer to the research question by mean of generating data for providing a hypothesis and performed at many clinic-centre. Most large clinical Trails, particularly PHASE III Trails, are conducted at different clinical research Centre. MCCT includes a larger number of participates, different geographic locations. The possibility of inclusion of wide range of population group, and the ability to compare results among centre, all of which increase the generalization of the study.

Clinical Data Management is the Technology and process that manage clinical data to produce a high quality, clean and analysable database. [1]

Data including two types like **Information (facts/figures)** & **An Accounting of the study**

Elements of DATA MANAGEMENT: -

Clinical data Management is the handling of information that results from clinical Trails. This data includes developing and maintain software system, database, process, procedure, training, and protocols to support collecting, cleaning, and managing subject or trail data.

This data is important for collecting, organized, and saved to meet compliance requirement, such as Good Laboratory Practices (GLP) and Good Clinical Practices (GCP).

Eight Stages of Clinical Data Management Cycle: -

1) Set Up – Prepare the Overall Plan, Database, and Forms.
2) Collect – To collect over the course of study.
3) Assure – Confirm that the plan, tool and data meet the requirements, including data quality
4) Identify – Monitor for issues or risks.
5) Preserve – Protect the integrity of collected data.
6) Integrate – Map different database and information together in a cohesive, consistent format
7) Analyse – Review data to identify trends and reports outcomes
8) Lock- Secure the database and prevent changes to protect data integrity.[2]

Examples of source document: -

1) Original Lab Reports

2) Surgical reports

3) Physician's progress report

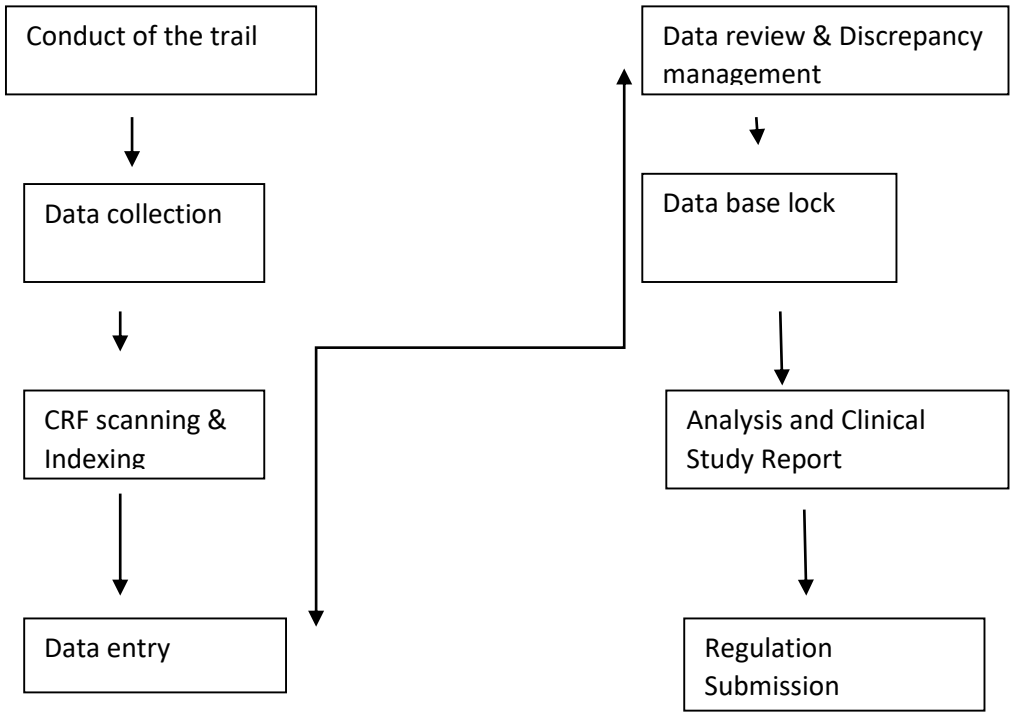
4) Nurse report

5) Medical Record

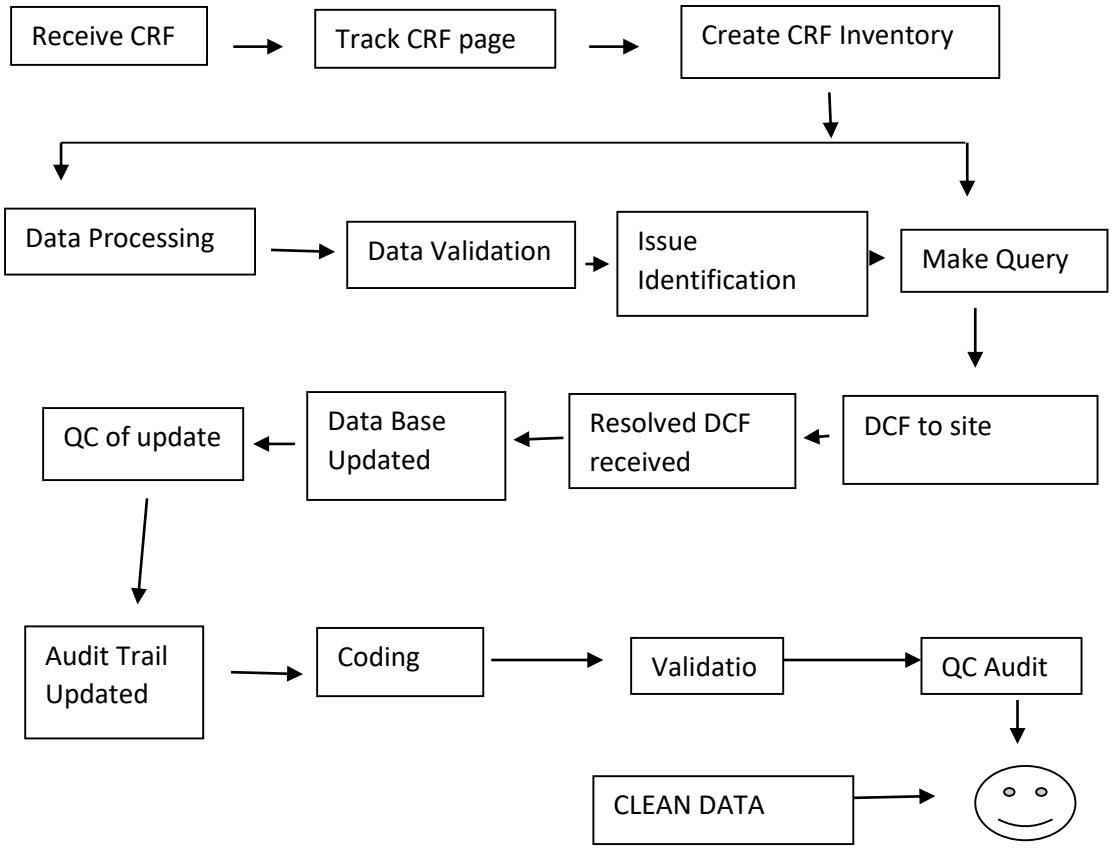
6) Letters from refereeing physician

7) Original radiological film [8]

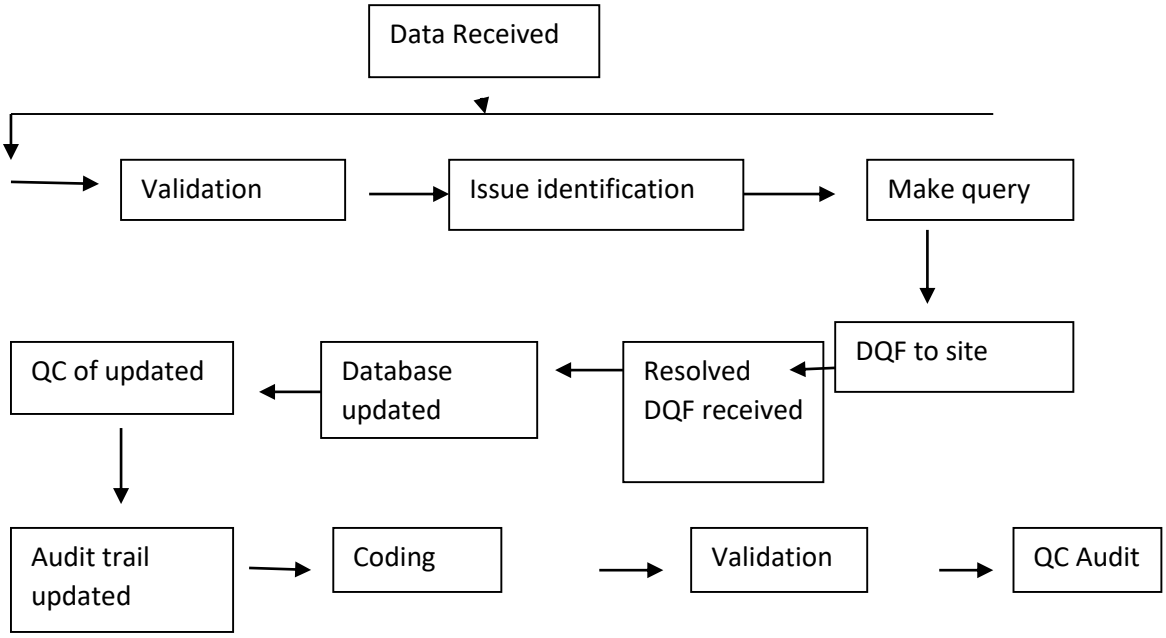
Flow Of activities in Clinical Trials: -



CRF work Flow: -



Electronic data capture process Flow: -



Manage the data collection:-

Set up plan

Plan CRF to capture the need data

Collect data as it happens

Standardize data entry procedure

Data Management plans: -

Data management plan is the plan for study specific Data Management Process. It serves as the backbone of overall quality system of Data Management [7].

Consideration in data management plan: -

1) What is the work to be performed?
2) Who is responsible for the work?
3) Which SOP or guideline will apply?
4) Which documentation or output to collect or produce?
5) What level of quality should be achieved?

Responsibility in CDM: -

In CDM Team, Different roles and responsibilities are attributed to the team members.

The list of roles as below can be considered as minimum requirements for the CDM team.

a) Data Manager
b) Database Programmer/ Designer
c) Medical coder
d) Clinical data Coordinator
e) Quality Control Associate
f) Data Entry associate.
g) Data manager is responsible for supervising the entire CDM process.
h) The data manager prepare the data management plan and approve the CDM procedures[4]

Data Review and Validation: -

- Data cleaning or validation refers to a collection of activates by data management, used to assure **Validity** and **accuracy** of the clinical data.

- It comprises of both logical and statically checks to detect impossible values due to data entry errors, coding and inconsistent data.
- Point-by-point check
- Missing data/black filed checks
- Data consistency checks
- Lab data ranges checks
- Header inconsistency checks
- Protocol violation checks
- External data checks
- Textual data checks
- SAE reconciliation.
- Med DRA: Medical Dictionary for Regulatory activities
- WHO –ART: World Health Organization Averse Reaction Terms
- CTCAE v 3.0: Common Terminology Criteria for Adverse Events[9]

Data Storage and Archival: -

All trials related paper documents including CRFs and /or Electronics Files must be stored in a secure and controlled place. [10]

Advantage of CLINICAL DATA MANAGEMENT: -

- More automation reduces manual inputs
- Allows process to be linked
- Increase processing speed
- Store large volumes of data
- Enables aggregate database to get answer that may eliminate need for a new study
- Enables global studies
- Web-based technologies allow site involvement earlier
- Automates tracking of process
- Eliminates or simplifies steps in process
- More updated information available in real time
- Reduce chance of human error
- Electronic data more accurate/eliminated guessing
- Automated quires will have consistent terminology across sites

Roles and Importance of CDM: -

CDM is vital vehicle in Clinical Trials to ensure integrity and quality of data being transferred from trail subjects to a database system.

It helps: To provide consistency, accurate & valid clinical data & to support accuracy of final conclusion & report. [3]

Scope of CDM: -

1) Main scope of CDM is to collect, valid and analyse the clinical data
2) Design and development of data collection instrument such as paper CRF, Electronic CRF, Clinical database etc.
3) Design and development of tools for Validation such as Checks, User Acceptance Testing etc.
4) Design and Development of tools for analysing data such as DDR/DDS (Derived database requirement/specification) etc. [11]

CONCLUSION:

CDM has involved in response to the increasing demand from pharmaceutical companies to fast track the drug development process and from regulatory authority to put the quality system in place to ensure generation of high-quality data for accurate drug evaluation.

Development of technology in front of positive impact of CDM. And that's why it's encouraging the result of speed and quality of data being generated.

At the same time, CDM professionally should ensure the standards for improving data quality [6].

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