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Outline of Clinical Data Management

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ABSTRACT

Clinical Data Management (CDM) is a critical phase in clinical research which results in collection of reliable, high-quality and statistically sound data. It consists of three phases i.e. start up, conduct and close out.
Startup phase consists of activities like CRF creation and Designing, Database designing and Testing, Edit checks preparation and User Acceptance Testing (UAT) along with document preparation such as Data Management Plan, CRF Completion Guidelines, Data Entry Guidelines and Data Validation plan.
Conduct phase is the longest and most critical phase were Data capture, Data Cleaning, Data reconciliation, Medical Coding and Data Validation takes place with regular evaluation of data known as Interim Analysis along with documentations such as Query Management Form, Revision Request Form, Post Production Changes.
Close out phase is the success phases for Data Managers were all the clean data are frozen and locked. After the confirmation of locking all the data, it will be in Read only mode. Finally, the Database will be locked, and all the documents are archived.

Keywords: Clinical Data Management, Clinical Trials, User Acceptance Testing, CRF, Query Management, Clinical Research.

TYPES OF STUDIES

Paper Studies and EDC Studies are the two types of studies were the main changes between both occur during Data Collection which is one of the most crucial part in Data Management.

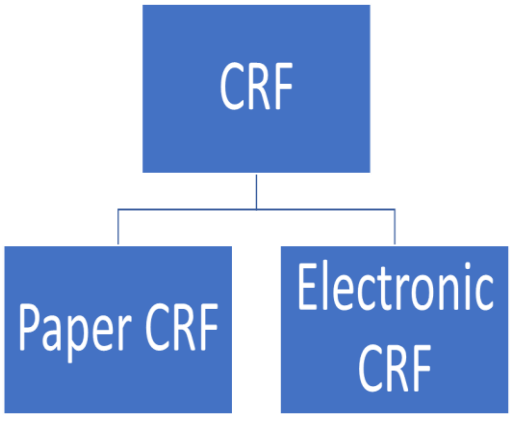
Paper Study:

Paper based study will have Case Report Form (CRF) in paper format were the Clinical Site manually write the data in wet ink in the Paper CRF.

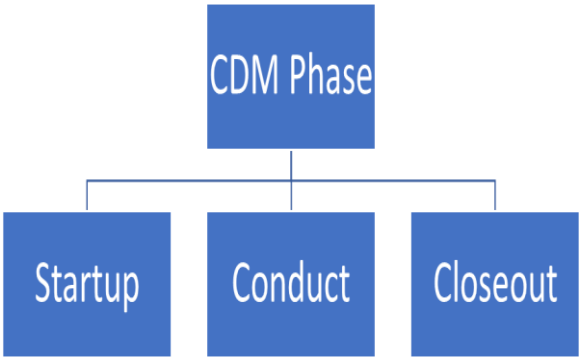
Once all the data in Paper CRF is filled, Site scan the CRF and sent to Data Management Team to capture the data in EDC along with Tracking Sheet.
Tracking Sheet or Transmittal Sheet is a document were the Site mention How many Pages of Paper CRF are scanned for each patient and sent to Data management team to avoid missing pages.
Once the Data Management Team receive the Scanned CRFs and Transmittal Sheet, Data Management Team verifies does Data Management Team received all the CRF pages as per mentioned in Tracking sheet.
Once Tracking sheet matches, Data Management Team sign it and send back to Clinical Site. After this process, Data Entry Team captures the data present in scanned paper CRF to EDC (Electronic Data Capture) with the help of Data Entry Guidelines (DEG).

EDC Study:

In EDC studies, Clinical Site will have access to the EDC and capture the Clinical Data directly in EDC which is called as electronic CRF (e-CRF). Once Site completes capturing the data, Data Managers start cleaning activity.



PHASES IN CLINICAL DATA MANAGEMENT



STARTUP PHASE

Startup phase consists of activities like CRF creation and Designing, Database designing and Testing, Edit checks preparation and User Acceptance Testing (UAT) along with document preparation such as Data Management Plan, CRF Completion Guidelines, Data Entry Guidelines and Data Validation plan.

CRF Designing:

CRF designing has two types, Paper CRF and eCRF. Paper CRF will be prepared by CRF Designer and send to site for review. Upon site confirmation, Paper CRF will be designed in EDC for DM Team for Data capture. In EDC Studies, eCRF will be designed directly in the EDC by EDC Tech Lead and CRF Designer and site will have EDC access to review it.

Database Designing:

Database designing is done by Database Programmer and EDC Designer. Key points like Field length, dynamic forms, acceptable range, access level management will be designed as per the study requirement. CRF annotation plays a vital role in assigning the variables for each field. After Database designing is successful, DB Programmer will implement the conditions as per Data Validation Specification (DVS) for queries to fire for out of range conditions.

User Acceptance Testing (UAT):

User Acceptance Testing (UAT) is the process were edit checks with specific conditions as per protocol is created by the Clinical Data Analyst (CDA) and Clinical Database Programmer (CDP) creates those condition in the Database to fire query for the conditions.

Data Validation Specification (DVS) is the document were CDA writes all the edit checks and CDP modifies the EDC as per DVS.

E.g.: As per protocol, Age Inclusion is 18 to 55 years.

When the data is captured as below 18 or above 55, Query fires with Query Text as "As per protocol, Age Inclusion is 18 to 55 years, please confirm"

CONDUCT PHASE

Conduct phase is the longest and most critical phase were Data capture, Data Cleaning, Data reconciliation, Medical Coding and Data Validation takes place with regular evaluation of data known as Interim Analysis along with documentations such as Query Management Form, Revision Request Form, Post Production Changes.

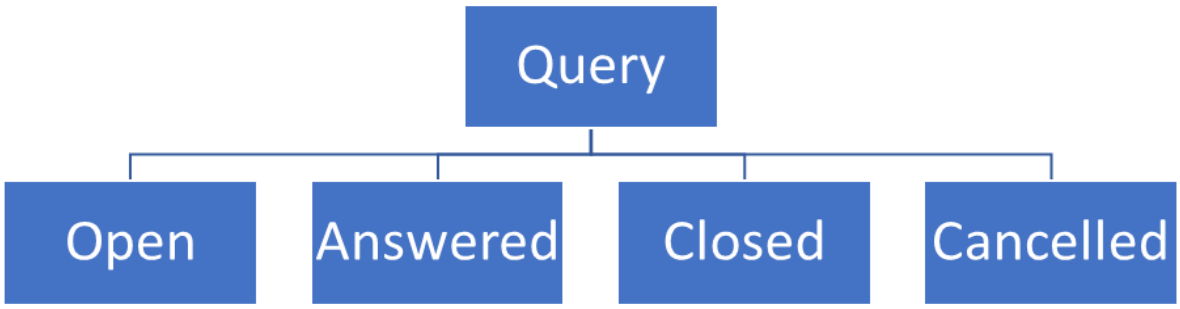
Data Collection:

In Paper CRF, Data Collection is captured by Clinical Site in paper CRF and later Data Management Team captures the data in EDC. This process is an old process which is more prone to Data Entry Errors.

In e-CRF studies, Clinical Site will directly capture the data in EDC and confirm Source Data Verification which is the latest most welcoming method by sponsors to avoid discrepancies.

Discrepancy Management:

Query Management is the major process in Discrepancy Management which helps to clean the data by system generated queries or manual queries. The four types of queries are,



Open Query:
Open query are queries which is open to DM or Site which is not answered yet.

Logic	Sodium should be between 135-145 mEq/L
Data	150 mEq/L
Query	Sodium is out of range. Please clarify.
Action	No action taken by DM/Site

Answered Query:
Answered query are queries which is either answered by DM or Site but not closed yet.

Logic	Sodium should be between 135-145 mEq/L
Data	150 mEq/L
Query	Sodium is out of range. Please clarify.
Action	Site responded as "NCS"

Closed Query:
Closed query are queries which are closed as per the confirmation from either DM Team or Clinical Site.

Logic	Sodium should be between 135-145 mEq/L
Data	150 mEq/L
Query	Sodium is out of range. Please clarify.
Action	Site responded as "NCS". So, DM closed the Query.

Cancelled Query:
Cancelled query are queries which is cancelled by the DM Team which has many reasons such as misfiring query, query not required, or query raised manually by mistake.

Logic	Sodium should be between 135-145 mEq/L
Data	140 mEq/L
Query	DM raised Manual Query by mistake.
Action	Query closed by DM since created by mistake.

CLOSE OUT PHASE

Close out phase is the success phases for Data Managers were all the clean data are frozen and locked. After the confirmation of locking all the data, it will be in Read only mode. Finally, the Database will be locked, and all the documents are archived.

Database Lock:

Database lock is the final process in Clinical Data Management. After all the queries are actioned and all outstanding issues are resolved, The Final Clean Data is frozen either manually or by script to ensure the data is not edited further which means, post Freezing, data will be in Read-only mode. Once all the data are frozen, The Database lock approval is sent to stakeholder and sponsors. Post- approval, The Database will be successfully locked and is always considered as a milestone achieved by the Data Management Team. Post Database lock, the data will be extracted by Statistical programmers for analysis and Data management team completes all further documentation and proceed for Archival.

CONCLUSION

Clinical Data Management helps the pharmaceutical companies to speed up the drug development process by providing clean, high quality and reliable data which helps to submit relevant documents with strong support for the drug to regulatory authorities.

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