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REVELATORY TRENDS IN CLINICAL RESEARCH

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ABSTRACT

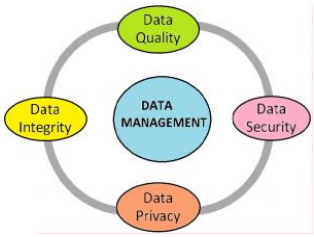
Revelatory Trends in Clinical Research, Clinical data management is a heart and important part of a clinical trials, Due to globalization of clinical trials sponsor needs to meet international standards and strictly comply with regulatory requirements for approvals of new drug application (NDA). Clinical trial operations plays the major role in the drug development process right from the Phase 0 preclinical Studies, Phase I, Phase II, Phase III and Phase IV Post Marketing Surveillance. The clinical trial operations and clinical data management together encompasses three main stages in the drug development phase. Clinical Study Start Up Phase, Clinical Study Conduct Phase, Clinical Study Close Out Phase.

Key words: Clinical trial, Clinical data Management, Preclinical phase.

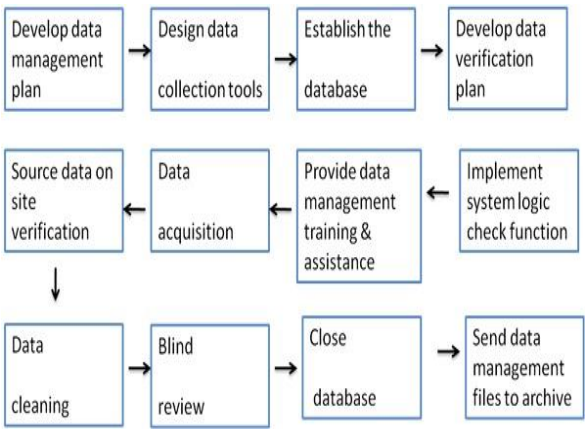
INTRODUCTION

Significance of Data Management in Clinical Research

- Clinical data management is a heart and important part of a clinical trials, the outcome to generate quality data and accounting of records to protect clinical trial participants data leads to highest quality and integrity of clinical trials.
- Due to globalization of clinical trials sponsor needs to meet international standards and strictly comply with regulatory requirements for approvals of new drug application (NDA).
- Clinical Data Management process involves collection, integration and validation of clinical trial data in compliance with regulatory standards
- The quality of data generated during phases of trials play an important role in the outcome of study.



- High quality of data should be absolutely accurate and suitable for statistical analysis which results in sufficient integrity to ensure confidence in result and conclusion depends on data generated, collected and presented during clinical trial for review and approval of new drug by regulatory agencies



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Clinical trial operations plays the major role in the drug development process right from the Phase 0 Pre-Clinical Studies, Phase I, Phase II, Phase III and Phase IV Post Marketing Surveillance.

The clinical trial operations and clinical data management together encompasses three main stages in the drug development phase.

1. Clinical Study Start Up Phase
2. Clinical Study Conduct Phase
3. Clinical Study Close Out Phase

They following phases involves below steps in clinical trials.

Development of Study Protocol / Design of Protocol

1. Clinical Study Start Up Phase

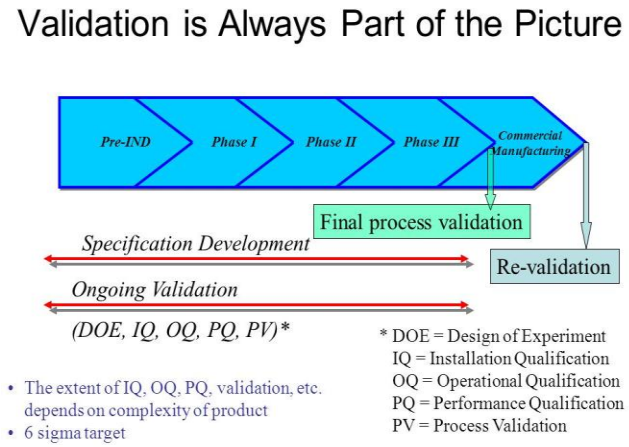
- Case Report Form (CRF) design and development (Paper CRF/ Electronic CRF e-CRF)
- Database Build and Design
- Quality Checks and Edit Checks
- Database Validation
- Database Activation

2. Clinical Study Conduct Phase

- Data Entry
- Discrepancy Management and Query to Investigator
- Data Coding of Medical Terms (using MedDRA [Medical Dictionary for Regulatory Activities] and WHODD [World Health Organization Drug Dictionary])
- Database Updates
- Data Review (Ongoing Quality Checks)
- SAE Reconciliation
- Transfer of Data
- **3. Clinical Study Close Out Phase**
- Data Discrepancy Management
- Query Generation in Data Entered
- Resolution/ Database Update
- Manual Checks/ CRF Tracking
- SAE Reconciliation
- Quality Control of Data
- Database Lock and Freeze
- Data Archival/ Electronic Archival
- Database Transfer

Important process involved in clinical trials

1. Clinical Data Analysis and Reporting Process
2. Release of Database
3. Extraction and Mapping of Clinical Data Entered
4. Statistical Analysis Performed
5. Statistical Analysis Report Generation
6. Electronically Data Publishing
7. Listings, Tables and Figures Publishing
8. CSR (Clinical Study Reports) are Created
9. CSR Submission
10. Overview of clinical trial and different phases in drug development process
11. It involves planning (Creations of protocol as per study requirement)
12. Designing and development of database
13. Database setup
14. Design of forms and CRFs
15. Data edit checks
16. Data validation checks



Responsibilities in clinical research operations

Key Responsibilities Performed

✓ Performing study/protocol procedures in a detailed, accurate manner
✓ Submitting regulatory documents to IRB and Sponsor
✓ Submitting the clinical study agreement
✓ Attending investigator meeting(s)
✓ Recruiting subjects
✓ Getting voluntary subject consent
✓ Screening and scheduling subjects
✓ Dispensing, Dosing
✓ Tracking and maintaining the study budget and payments, including invoicing the sponsor for
✓ completed work
✓ Maintaining communication and correspondence (by telephone, email, fax, etc.) with subjects, sponsor, monitor and other site study personnel, including: IRB
✓ Completing case report forms (CRF) for PI review and approval.
✓ Regulatory communication.
✓ Handling study team
✓ Key role in maintaining corrected data in source and other documents for data management
✓ Patient Handling
✓ Record Keeping.
✓ Systems to ensure quality are implemented in all aspects of the trial.
✓ Maintaining Site Master File, Patient logs, Laboratory data and Patient history data while performing clinical trials
✓ Maintaining all regulatory required documents and IRB approval and other study related documents

Monitoring Activities

✓ Monitor the conduct of clinical trials, especially enrolment and quality of data.
✓ Verify subject safety and site adherence to FDA Regulations and ICH/GCP Guidelines.
✓ Ensure Adverse Events are reported appropriately, accurately and in a timely manner and that follow-up activities are conducted as necessary.
✓ Review CRF, Informed Consent Documents and query language/narratives.
✓ Acquire specific clinical and therapeutic knowledge related to studies monitored.
✓ Conduct Qualification, Initiation, Interim and Closeout Clinical Activity
✓ Manage trial reports, letters, query resolutions and expenses.
✓ Provide support and timely follow-up for all audit and quality assurance activities.
✓ Communicate with study team for all trial related activities and maintain quality work.
✓ Communicate with medical expert team and Coordinating Investigators
✓ Maintain TMF (Trial Master File) as per regulatory requirements.

Terminologies in Clinical Research and Drug Development Process

Clinical Trials

✓ ICH-GCP, Site Selection, Site Initiation, Terminologies, Schedule-Y, ICMR Guidelines, Phase I, II, III & IV trials, Responsibilities of Monitor, CTA, CRA, CRC, Investigator, Sponsor, Protocol, Investigational Brochure, CRF, eCRF, Recruitment and Enrolment, CRF Completion and Submission, Good Understanding of Regulatory guidelines in CR.

Clinical Data Management

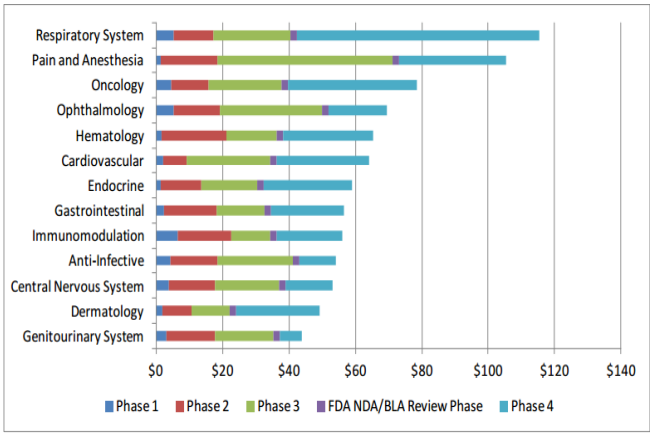
✓ Electronic Data Capture , CRF designing, Validation, Clinical Data Management (Process Flow), Data Collection, Data Load/Transfer, Data Storage, Data Validation, Data Archiving, SOPs and Audits, Query resolution.
✓ Oracle Clinical® overview, Metadata Rave, EDC, 21 CFR part11 and Data entry and data collection including Data transfer

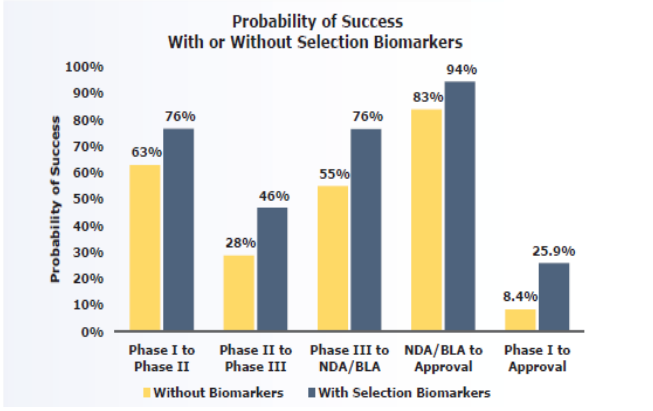
Key Responsibilities in Document and Data Managements

✓ Identification of clinical documents, including but not restricted to study, site, country & project level.
✓ Mapping of CREDI document types to Subway artifacts
✓ Capture the attributes as per migration requirement based on content of document
✓ Ensure 100% quality
✓ Maintaining daily production reports
✓ Performing QC of documents processed by the Document specialist as per defined guidelines.
✓ Maintaining Quality logs.
✓ Making required corrections/ Updating users to correct data as per feedback provided
✓ Update and maintain the data with accuracy and integrity within all relevant Clinical study systems.
✓ Supporting Client Clinical Study team to meet urgent deliverables ensuring inspection readiness
✓ Manage and Archive essential documents as per Sponsor TMF SOP.
✓ Organize and participating in all appropriate meetings with Study team
✓ Compile the NDA , and ANDA document to be submitted to regulatory Agency
✓ Follow regulatory requirement as per e-CTD, CTD, & ACTD formats

Different Tools and Databases Used in Clinical Trials and Data Management

- MS-office tools
- Med DRA,
- Metadata Rave, Oracle Clinical, Openclinica.
- Master Scope
- ERT(e-Research Technology)
- MS-Access
- Square- Adverse Event Report
- Credi
- Synflow
- e-TMF Tool





CONCLUSION

The revelatory trends in clinical trials provide the evidence that trials conducted currently are standardized due to which the generated data is more accurate for regulatory submissions. Thus it can be concluded that approved drugs are highly beneficial for community and revelatory trends in clinical trial shows higher success rate.

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