Computers in Clinical Development
(Clinical Data Management)

M PHARM II SEM
MPH203T

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Introduction

Clinical Data Management (CDM) is a critical phase in clinical research, which leads to generation of high-quality, reliable, and statistically sound data from clinical trials. Clinical Data Management assures collection, integration and availability of data at appropriate quality and cost.

CDM encompasses the entry, verification, validation, and quality control of data gathered during the conduct of clinical trial

Why do we need clinical data management system

There are no of reason why CDM is needed as most important reason are:

1. Clinical Data Management (CDM) is a critical phase in clinical research, which leads to generation of high-quality, reliable, and statistically sound data from clinical trials. This helps to produce a drastic reduction in time from drug development to marketing.
2. Regulatory Agencies is dependent upon a trust that clinical trials data presented are of sufficient integrity to ensure confidence in results & conclusions presented by Pharma company and it is Important to obtaining that trust is adherence to quality standards & practices hence .

What type of function provided by CDM

1. Case report forms (CRFs) design
2. Database design
3. Database programming
4. 21 CFR part 11 compliant validation process
5. Loading, reconciliation and integration of external data
6. Medical coding
7. Status reporting
8. Forms management
9. Data entry and cleaning
10. Data locking

Key members

The Key members involved in Data Management:

- Clinical Data Manager
- Database Administrator
- Database Programmer
- Clinical Data Coordinator
- Clinical Data Associate

Clinical Data Management System

The clinical trial data gathered at the investigator site in the CRF are stored in the CDMS & this system employ various means to verify the data to reduce possibility of error due to human entry.

Types of CDMS:

1.Paper based system

2.Electronic data capturing system

Key differences b/w paper based and electronic data capturing system

Paper based system

- Data is entered to CDMS from CRF
- Time consuming process
- Inexpensive
- DCF send in paper form to the site

Electronic data capturing system

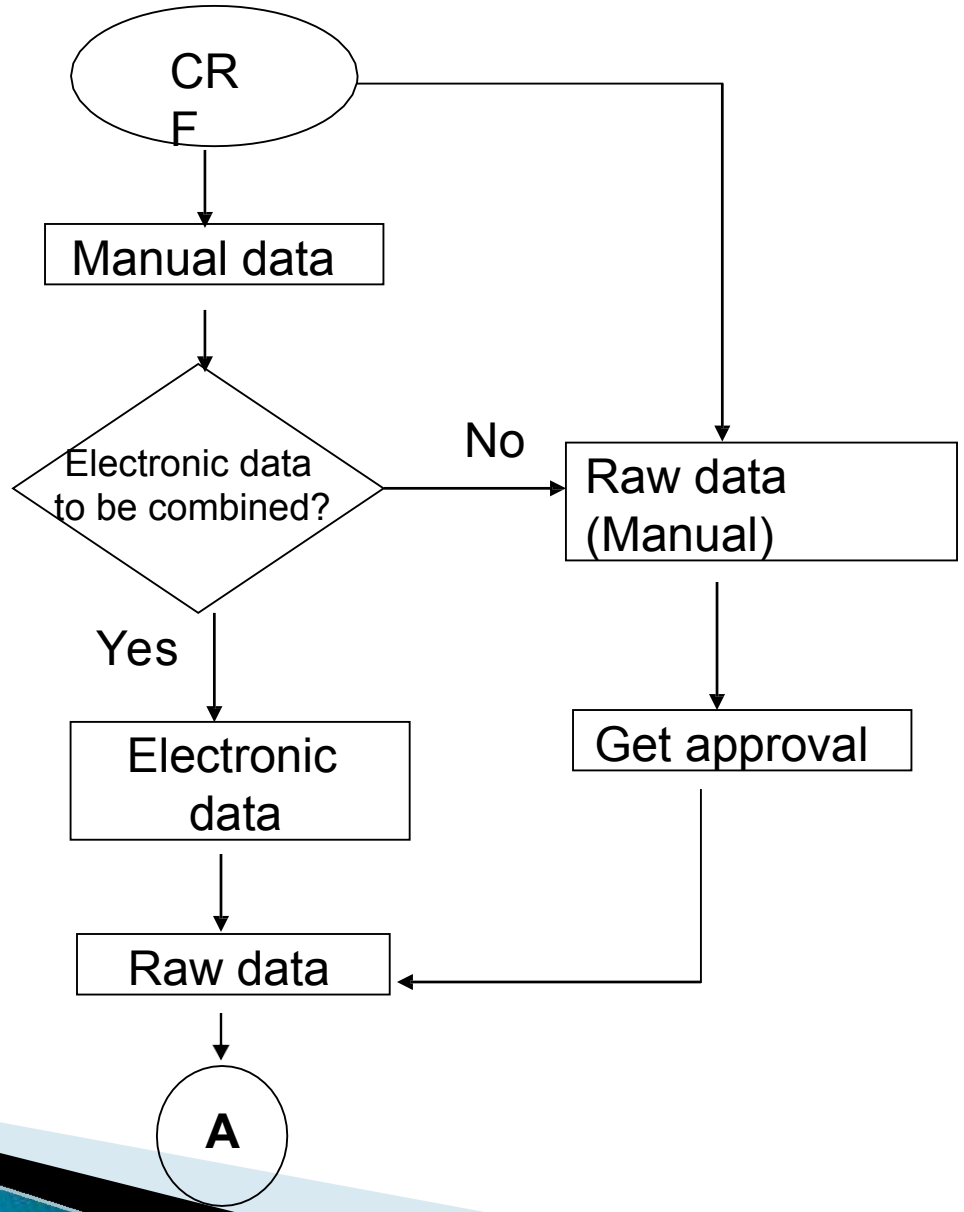
- Data is directly upload to CDMS by investigator
- Time saving process
- expensive
- Electronic alert send to the site if there is any problem

Cont.

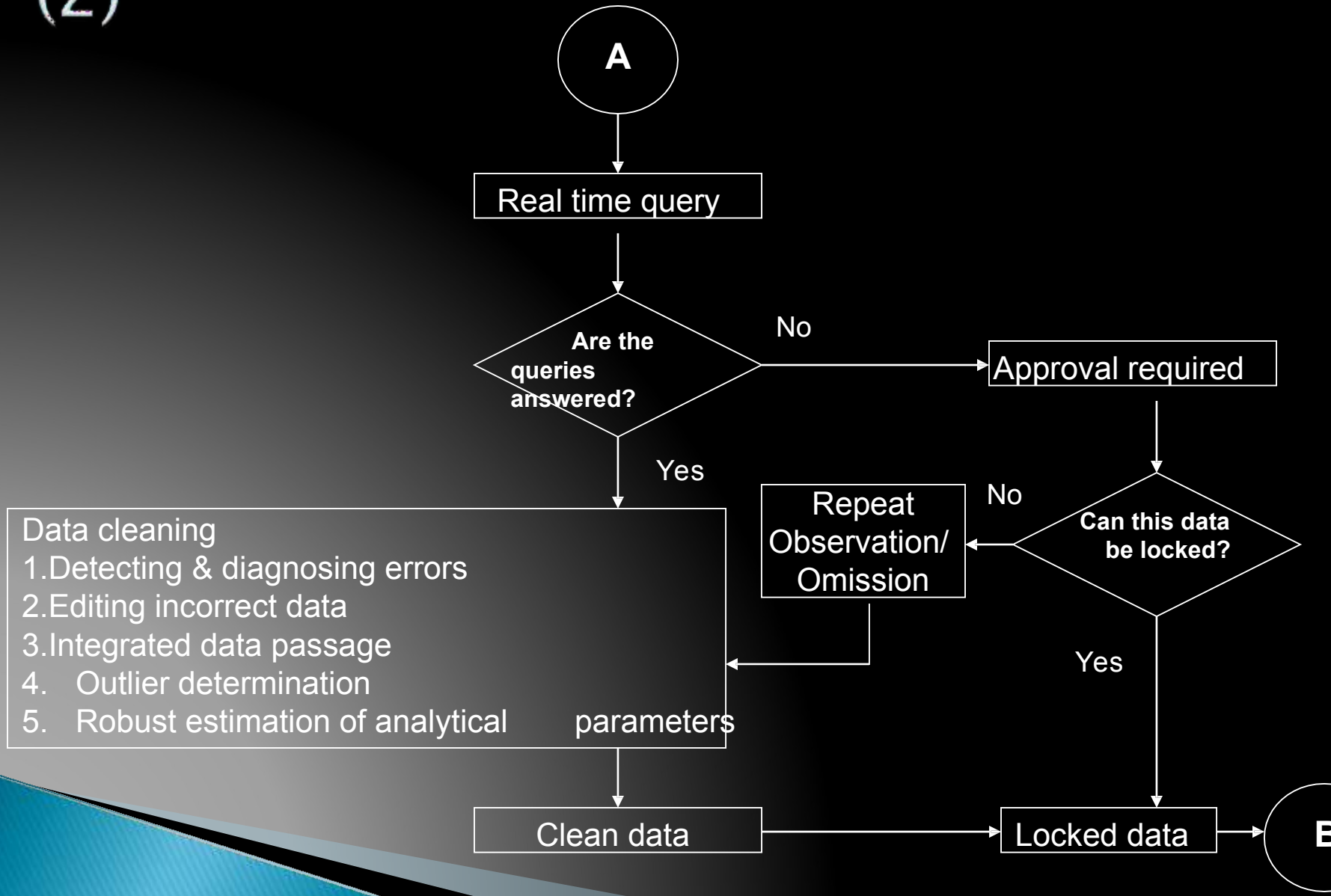
Once the data are uploaded by side then data validation is done by data validation team if there is any discrepancy then alert is send to the site to resolve it.

Over all view of CDMS

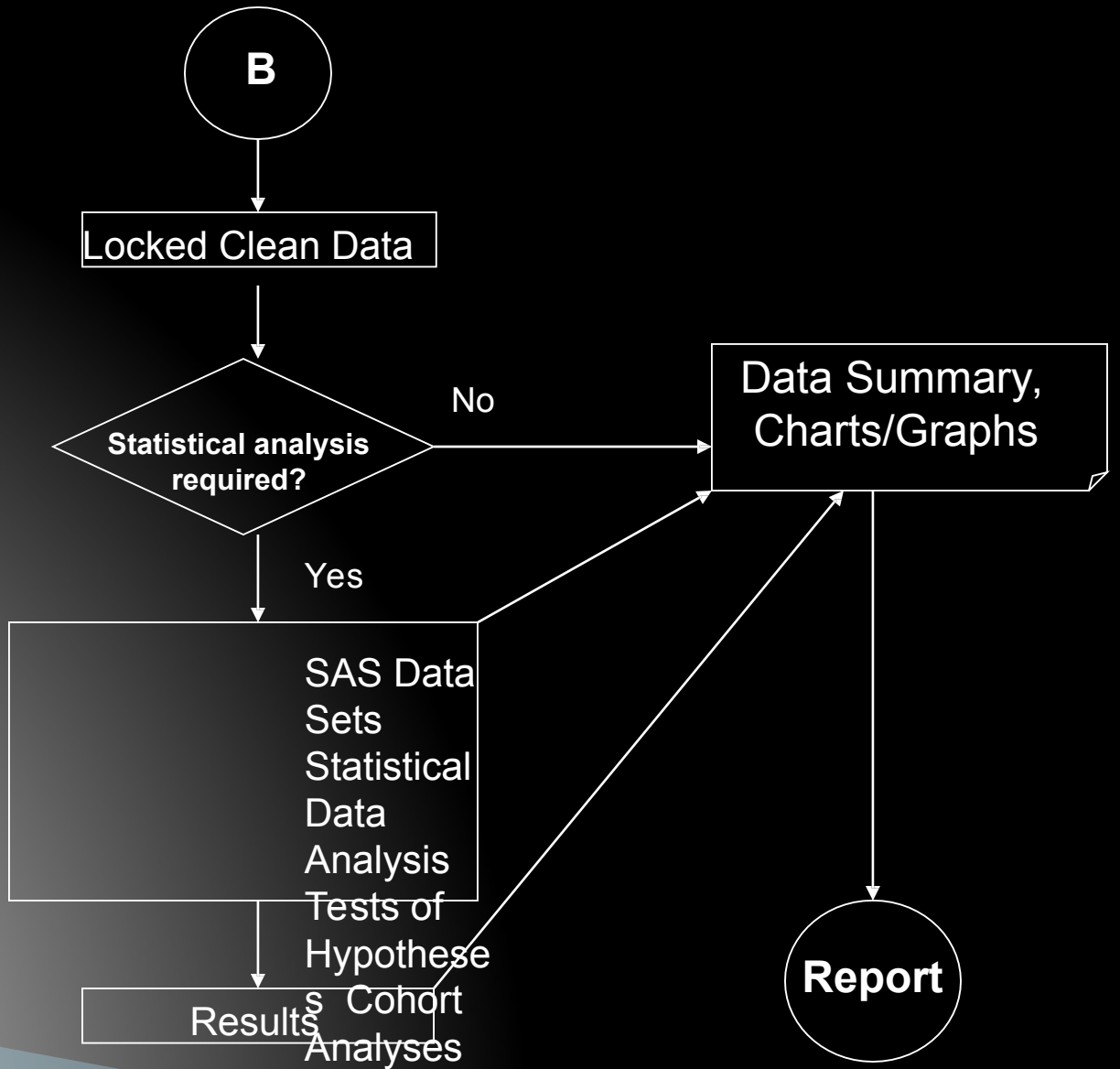
Data capturing



Data Extraction, Cleaning & Locking (2)



Data Processing & Reporting (3)

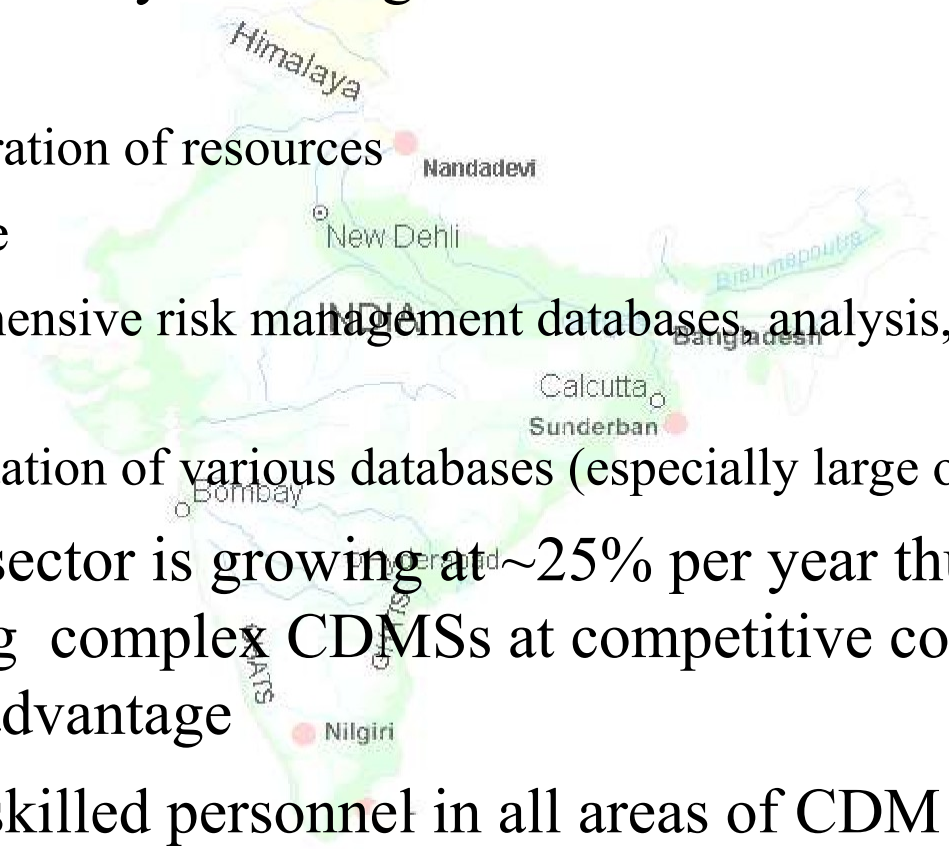


Objective of CDMS

- The Integrity & quality of data being transferred from trial subjects to a database system
- That the collected data is complete and accurate so that results are correct
- That trial database is complete and accurate, and a true representation of what took place in trial
- That trial database is sufficiently clean to support statistical analysis, and its subsequent presentation and interpretation

India as a Hub

- India offers many advantages as a CDMS hub
  - Cost
  - Concentration of resources
  - Expertise
  - Comprehensive risk management databases, analysis, mitigation and PV centers
  - Consolidation of various databases (especially large ones)
- India's IT sector is growing at ~25% per year thus maintaining complex CDMSs at competitive costs in India is an added advantage
- Abundant skilled personnel in all areas of CDM available
- Hub of almost all clinical trial activities in coming years



Conclusion

The ultimate goal of CDM is to assure that data support conclusions drawn from research. Achieving this goal

protects public health and confidence in marketed therapeutics.

references

- http://www.ncbi.nlm.nih.gov/
- clinical-data-management-training-gratisol- labs


Thank you!