

INTRODUCTION TO CLINICAL DATA MANAGEMENT (CDM)

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INTRODUCTION

- Clinical data is a staple resource for most health and medical research.
- Clinical data falls into six major types:
 - Electronic health records
 - Administrative data
 - Claims data
 - Patient/ disease registries
 - Health surveys and
 - Clinical trial data

INTRODUCTION

- Clinical data is either collected during the course of ongoing patient care or as part of a formal clinical trial programme.
- Clinical trial is intended to find answers to the research question by means of generating data for proving or disproving a hypothesis.
- The quality of data generated plays an important role in the outcome of the study.

Abbreviations & meanings:

- **CDM: clinical data management**
- **CRF: case report forms**
- **DMP: data management plan**
- **DVP: data validation plan**
- **CRA: clinical research associate**
- **DCFs: data clarification forms**
- **SEC: Self-evident corrections**
- **SDV: source document verification**

Objectives of the presentation; to:

explain the concept of clinical data management

identify the tools for CDM

discuss the regulations, guidelines and standards in CDM

describe the CDM process

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.
- Members of CDM are actively involved in all stages of clinical trial right from inception to completion.



Clinical data management

- All researchers try their hands on CDM activities during research work knowingly or unknowingly.
- CDM is the process of collection, cleaning and management of data in compliance with regulatory standards.



Clinical data management

- The primary goal of CDM processes is to provide high quality data by keeping the number of errors & missing data as low as possible and gather maximum data for analysis (Gerritsen et al, 1993)
- Best practices are adopted to ensure that data are complete, reliable and processed correctly.



**High
quality
data:**

**should be absolutely
accurate and suitable for
statistical analysis, minimal
or no misses,**

**posses only acceptable level of
variation that would not affect
the conclusion of the study on
statistical analysis.**

Tools for CDM:

There are many software tools available for CDM and they are referred to as CDM systems (CDMS).

CDMS is very important to handle large amount of data especially in multicentric trials.

**Commonly
used
CDM
tool:**

**Commercial: Oracle clinical,
Clintrial, Macro, Rave &
eClinical Suite**

**Open source tools: OpenClinica,
openCDMS, TrialDB, & PhOSCo**

CDM tools:

Ensure audit trail & help in the management of discrepancies.

Multiple user IDs can be created with access limitation to data entry, medical coding,

database designing or quality check. ensures that each user can access only the respective

functionalities allotted to that user ID and cannot make any other changes in the database.

Regulations, guidelines & standards in CDM

Standards in electronic data capture has to be maintained. Electronic records have to comply with a Code of Federal Regulations (CFR), 21 CFR Part 11.

Applicable to records in electronic format that are created, modified, maintained, archived , retrieved or transmitted.

**Society
for
CDM
(SCDM)
:**

**published Good Clinical
Data Management
Practices (GCDMP)
guidelines.**

**Provides guidance on
accepted practices in CDM
that are consistent with
regulatory practices.**

**Clinical
data
interchange
standards
consortium
(CDISC):**

**Study Data Tabulation
Model Implementation
Guide for Human Clinical
Trials (SDTMIG) :standard
terminologies for data**

**Clinical Data Acquisition
Standards Harmonization
(CDASH): defines basic
standard for data collection**

The CMD process:

This begins with the end in mind & is designed to deliver an error free, valid &

statistically sound database. The process include: review & finalization of study

documents, database designing, data collection, CRF tracking, data entry,

data validation, discrepancy management, medical coding, & database locking.

Review & finalization of study documents:

**Review protocol
from database
designing
perspective.**

**Identify data items to be
collected with frequency of
collection.**

**A CRF is designed
with data field
clearly defined &
consistent.**

**concise, self-explanatory,
user friendly. Filling in
instructions provided for
error-free data.**

DCM = DM[S1]		
DEMOGRAPHY		
BRTHTDC [DT] Date of Birth (dd/mm/yyyy):		BRTH [C] DVG = YNNA[S1] ☐ ₁ If Date of Birth unknown
SEX [C] DVG = SEX[S1] Gender: Male ☐ ₁ Female ☐ ₂	HEIGHT [N] Height (cm):	WEIGHT [N] Weight (Kgs):

Annotated sample of a Case Report Form (CRF). Annotations are entered in coloured text in this figure to differentiate from the CRF questions. DCM = Data collection module, DVG = Discrete value group, YNNA [S1] = Yes, No = Not applicable [subset 1], C = Character, N = Numerical, DT = Date format. For example, BRTHTDC [DT] indicates date of birth in the date format

Database designing:

Clinical software applications built to facilitate the CDM task.

system validation is done to ensure data security, system specifications, user requirements & regulatory compliance are evaluated.

Details of the study such as objectives, visits, investigators, sites & patients are defined, CRF layouts are designed for data entry.

**Data
collec-
tion:**

CRF is used to collect data.
May exist in the form of
paper or electronic version.
Paper CRF collect data to be
translated into the database

In e-CRF-based CDM, the
investigator logs into the CDM
system & enter the data directly
on site. Chances of error are less

CRF tracking:

entries made in the CRF will be monitored by CRA for completeness

CRF are handed to CDM team who will track the CRF for missing pages & illegible data

clarification is obtained from the investigator in case of missing or illegible data

Data entry: (paper CRF)

Be done according to guidelines in the DMP. Double data entry is performed.

The second pass helps in verification & reconciliation by identifying transcription

errors & discrepancies caused by illegible data. Ensures better consistency with paper CRF

Data validation:

Process of testing the validity of data in accordance with protocol specification.

Edit check programmes are written to identify the discrepancies in the entered data.

Discrepancy is any data that fails to pass validity check, may be due to inconsistent data, missing

data, range checks & deviations from protocols. DCFs contain queries pertaining to discrepancies.

Also called query resolution. It includes reviewing discrepancies,

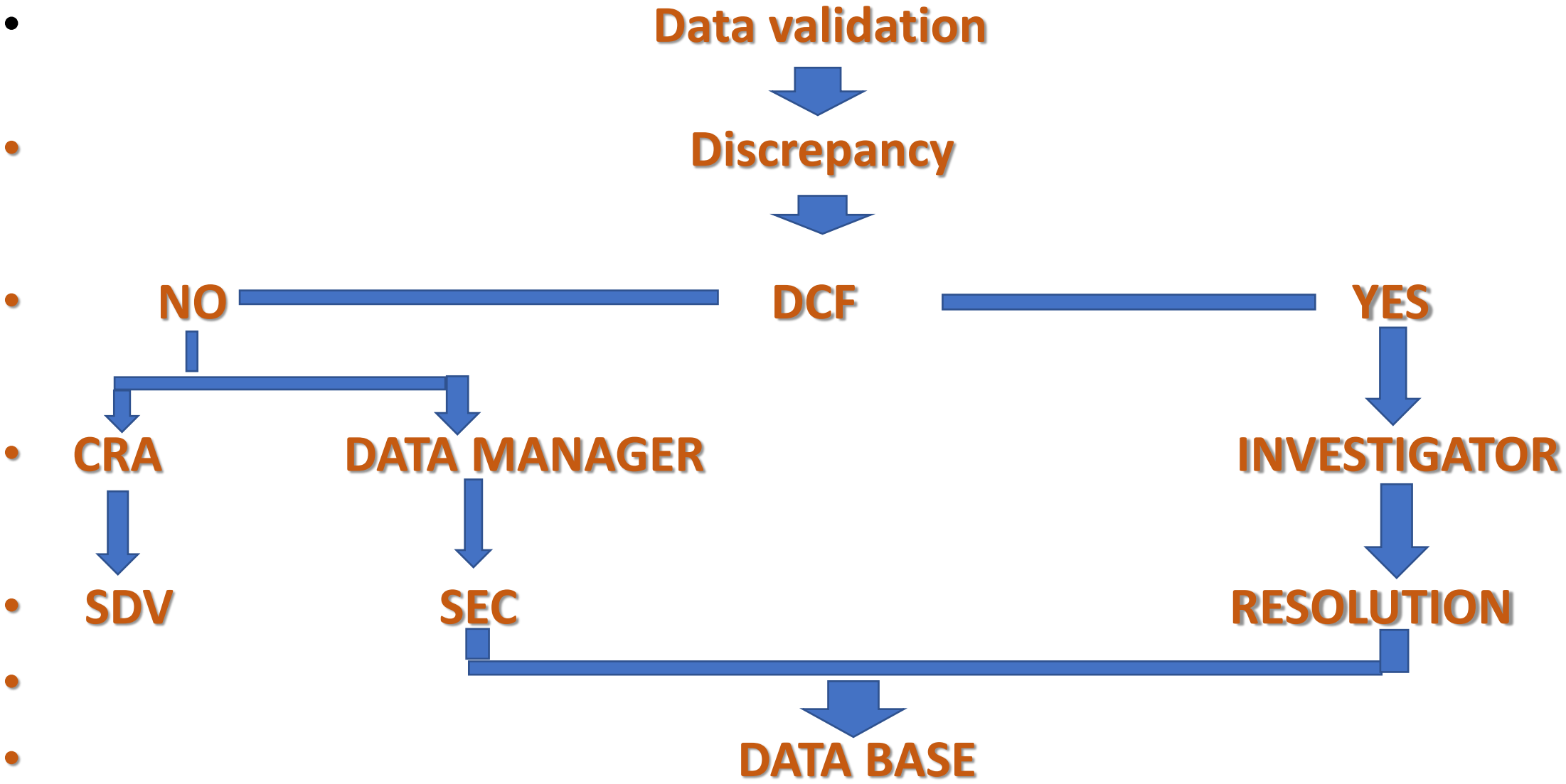
investigating the reason, & resolving them with documentary proof or declaring them as irresolvable

Discrepancy management: most critical activity in CDM process

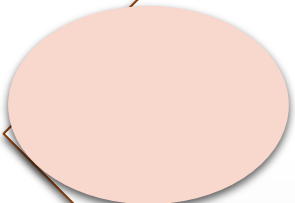
Discrepancies are either sent to investigator for clarification or closed-in-house by SEC without DCF.

Resolved discrepancies are recorded as 'closed'. Closure may not be possible in some cases ('irresolvable').

Discrepancy management:



Medical coding:



helps in identifying & properly classifying the medical terminologies associated with the clinical research. Online medical dictionaries are used for classification of events eg WHO drug dictionary enhanced (WHO-DDE).

Technically, this requires the knowledge of medical terminology, understanding of disease entities & pathological process among others.

Database locking:

- **After a proper quality check and assurance, the final data validation is run.**
- **If there are no discrepancies, the datasets are finalized in consultation with the statistician.**
- **All data management should have been completed prior to database lock.**

Database locking:

- A pre-lock check list is used to confirm completion of all activities.
- Once approval is obtained from all stakeholders, the database is locked & clean data is extracted for statistical analysis.
- Generally, no modification in database is possible.

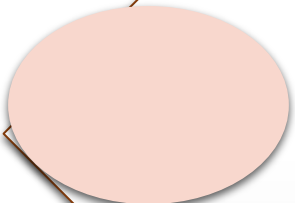
Roles & responsibilities in CDM:

- **The minimum educational requirement for a team member in CDM is graduation in life science & knowledge of computer applications.**
- **The minimum requirements for a CDM team include:**
- **Data manager, database programmer/ designer, clinical data coordinator, quality control associate & data entry associate.**

Data manager:

- **Responsible for supervising the entire CDM process.**
- **Prepares the DMP, approves the CDM procedures & all internal documents related to CDM activities.**
- **Control & allocate the database access to team members.**

The database programmer/ designer:



Performs the CRF annotations, creates the study database & programmes the edit checks for data validation.

Also responsible for designing the data entry screens in the database. Validates the edit checks with dummy data.

Medical coder:

- **Codes medical terminology such as adverse events, medical history, co-illnesses, medication administered during the study and other medical terms.**

Clinical data coordinator:

Designs the CRF, prepares the CRF completion instructions.

Responsible for developing the DVP & discrepancy management.

All other CDM-related documents, checklists & guideline documents.

Quality control associate:

Checks the accuracy of data entry & conducts data audits.

Sometimes, there is a separate quality assurance person to conduct audit on the data entered.

Verifies documentation pertaining to the procedure being followed.

Data entry personnel:

- **Tracks the receipt of CRF pages and performs data entry into the database.**

Conclusion:

- **CDM should be evaluated by means of the systems and processes being implemented and the standards being followed.**
- **The biggest challenge from the regulatory perspective would be the standardization of data management processes across organizations & development of regulations to define the procedures to be followed and data standards.**

Acknowledgement:

- **Krishnankutty, B., Bellary, S. & Moodahadu, L.S. (2012). Data management in clinical research: An overview. Indian Journal of Pharmacology, Wolters Kluwer Medknown Publications.**

