

Data Entry Methods



Module 10 Topic 6

Understanding Data Entry

- **Understanding data entry:** process of entering data from CRF to response fields in any CDMS, following few guidelines



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Understanding Data Entry (contd)

Work Item



Collection Of
"CRF Images"

Work Flow



Integration Of
Various
"Technical
Components"
to Route Work
items



Understanding Data Entry (contd)

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Understanding Data Entry (contd)

To understand data entry better, one has to follow certain terms like work item, work flow

Work Item



Collection Of
"CRF Images"

Work Flow



Integration Of
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Entering Data

- Accuracy of transcribing data
- Dealing with problem data
- Making edits & changing data
- Quality control



Before Starting with Data Entry Process

- Understanding 21 CFR Part 11, that is, Code of Federal Regulations part 11 chapter 21
- FDA defines that persons handling clinical data have to be sufficiently trained & need to have electronic signatures of their own
- Therefore, each person will have electronic signature as part of 21 CFR Part 11 compliance



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**We are all Trained...
and we have our
Elec. Signatures**



Audit Trail & 21 CFR Part 11

Audit Trail means ...

- “Record of Activities”
- Data entered, deleted, altered, updated etc.
- E-signature help us identify who did what?



CFR Part 11

Food and Drug Administration

Das muss für den
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Data Entry Screen

- Understanding Data Entry



Left Side
CDMS Screen

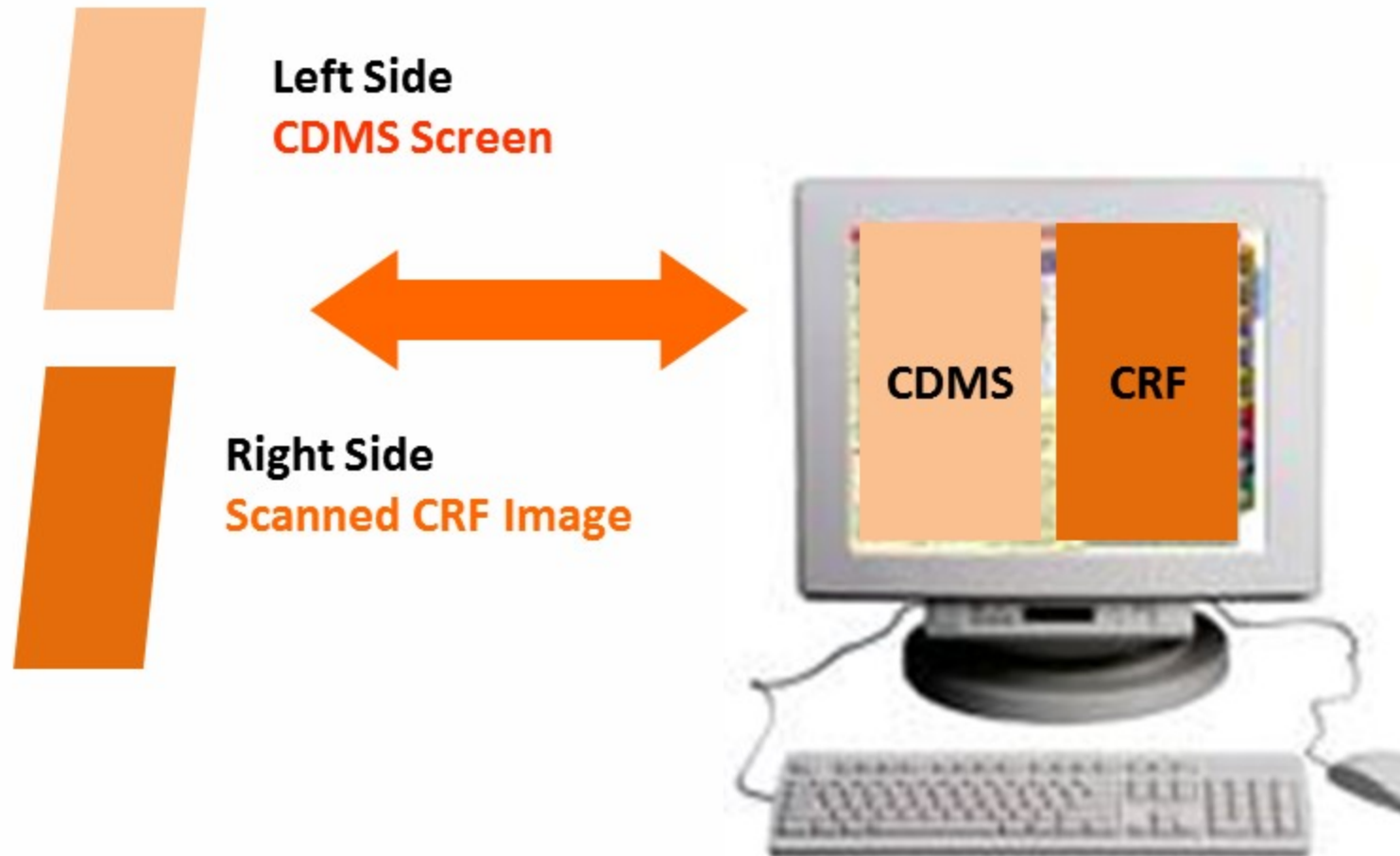


Right Side
Scanned CRF Image



Data Entry Screen

- Understanding Data Entry



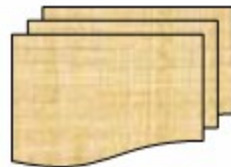
Types of Data Entry

- Double Entry
- Single Entry



Double Data Entry

- DEO selects work items (consisting of CRF pages)



Work Item

- After selecting work item, completes data entry of all CRFs & releases work item for next step



Data Entry

Release Work Item



First Pass Data Entry

- Refers to **data being entered to database for first time**
- DEO enters all data of each document & releases work item



Second Pass Data Entry

- Second pass entry done by another DEO, following first entry
- This becomes **first quality check** in CDM process
- Both DEO & system contribute to this first quality check in CDM process
- **System gives an alert** if second pass enters anything different from first pass
- Correct value is confirmed & entered



Dealing with Different Kinds of Data

- DEO (Data Entry Operator) should be aware of kind of data to be entered



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DATA

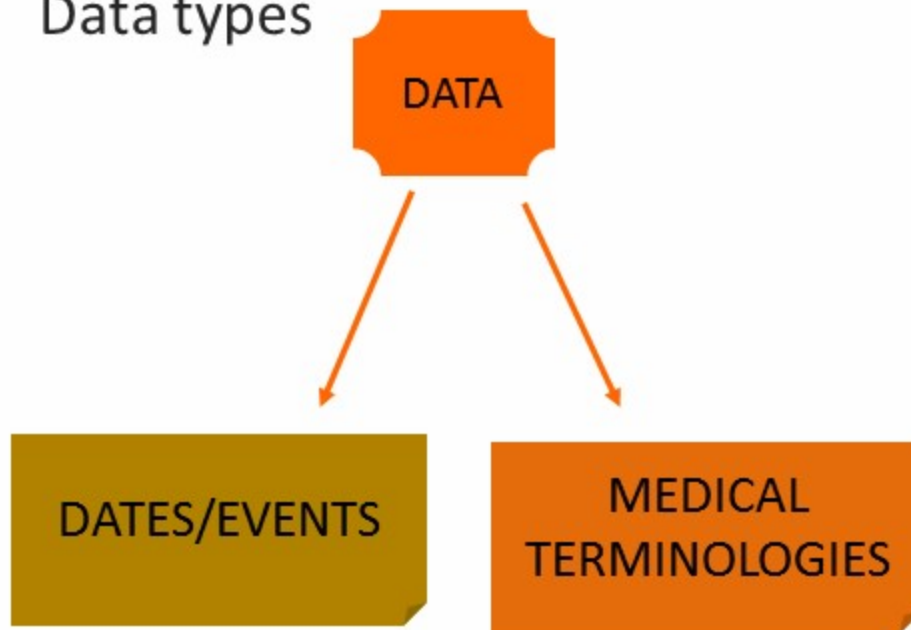


DATES/EVENTS



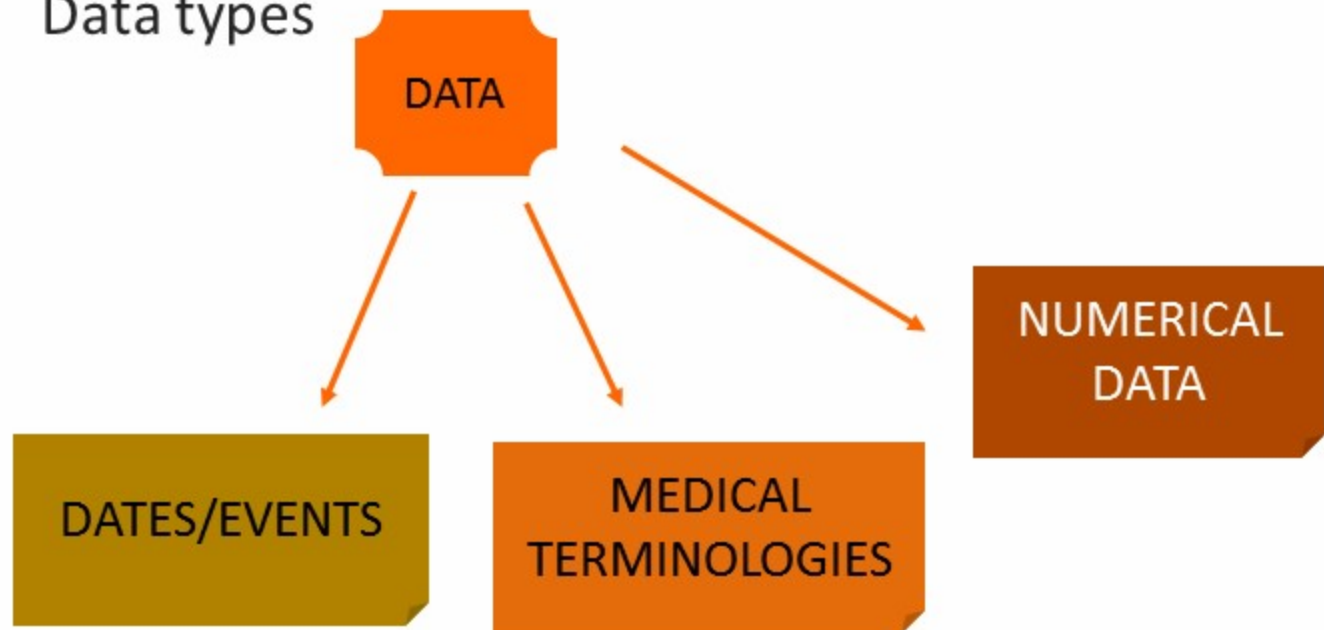
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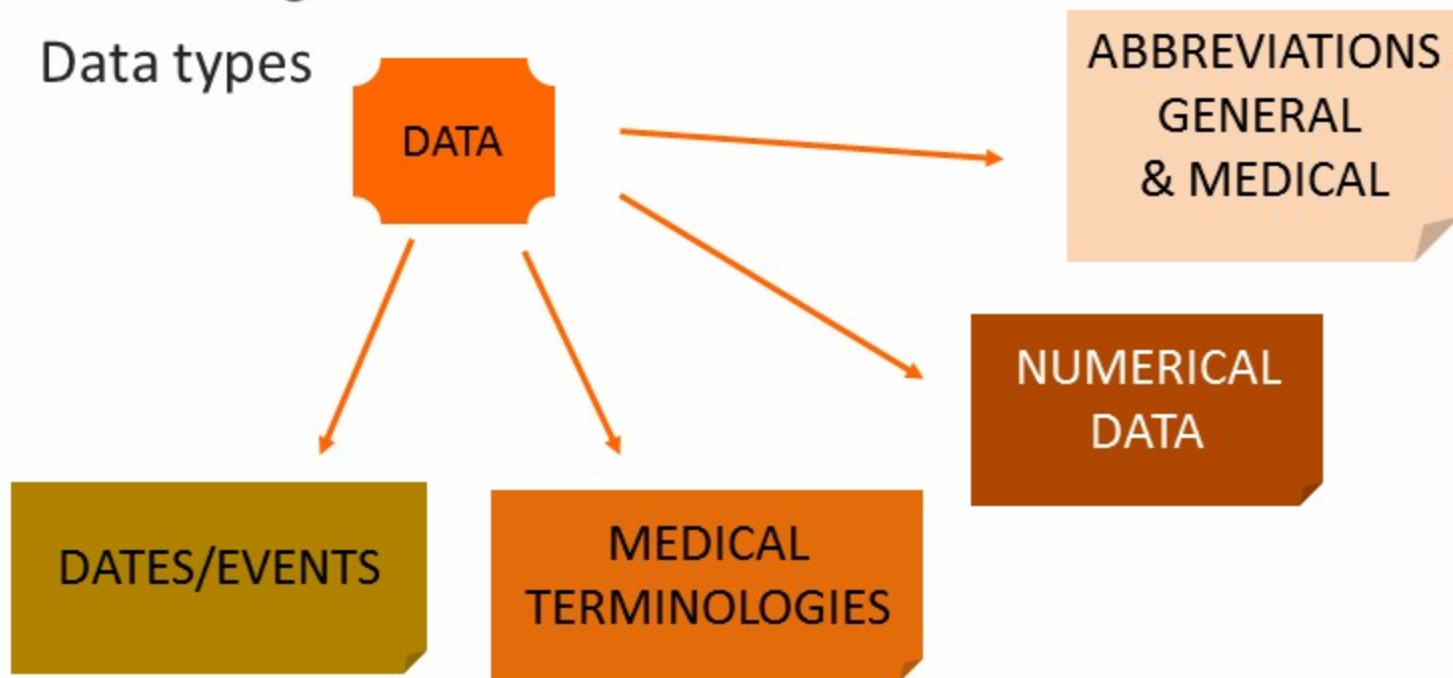
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Handling Dates ??

- Recording dates on case report forms -plays very integral part
- DEOs must know different schemes of recording dates
- Indians follow **DD-MM-YYYY** pattern
- Americans follow **MM-DD-YYYY** pattern
- Few European countries follow **YY-MM-DD** pattern



Medical Terminologies

- DEOs should encourage themselves from beginning to verify **(use online sources)** & be aware of spellings of various medical terminologies

Refer Online Sources



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- Essential because a slight change or **mis-spelt term can mean totally different**

Refer Online Sources

Check My Spellings
Twice !!



Medical Terminologies

- DEOs should encourage themselves from beginning to verify **(use online sources)** & be aware of spellings of various medical terminologies
- Essential because a slight change or **mis-spelt term can mean totally different**
- Also, many medical terminologies have **more than one way of spelling**

Refer Online Sources

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Stop Entering If Not Sure

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Operator
Comment

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Insert Comment
If not Sure... OK



Operator
Comment



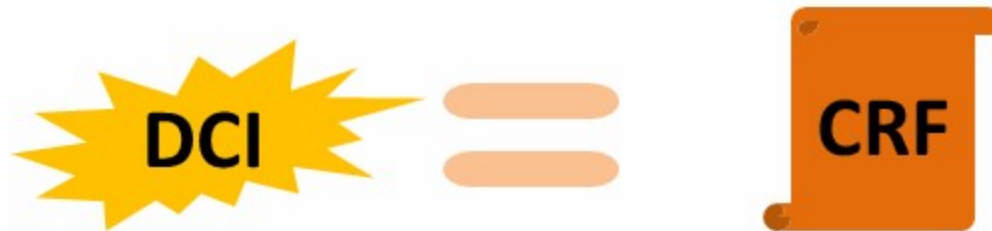
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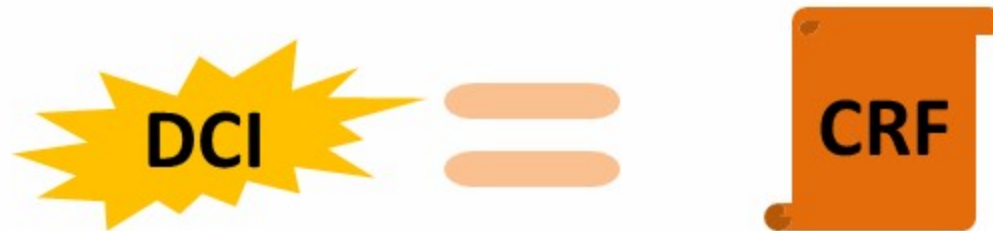
Data Collection Instrument

- DCI is an equivalent of a CRF (Case Report Form)

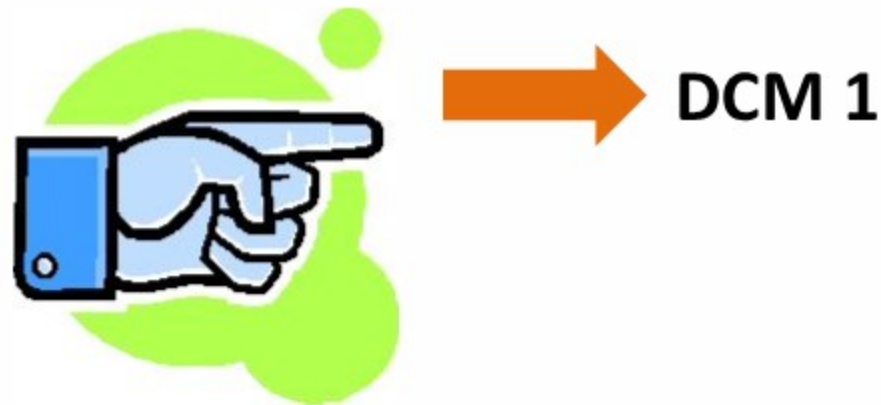


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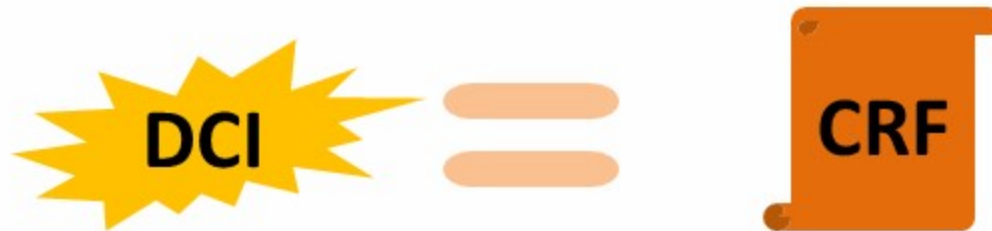


- DCI can have several groups of DCM - Data Collection Modules

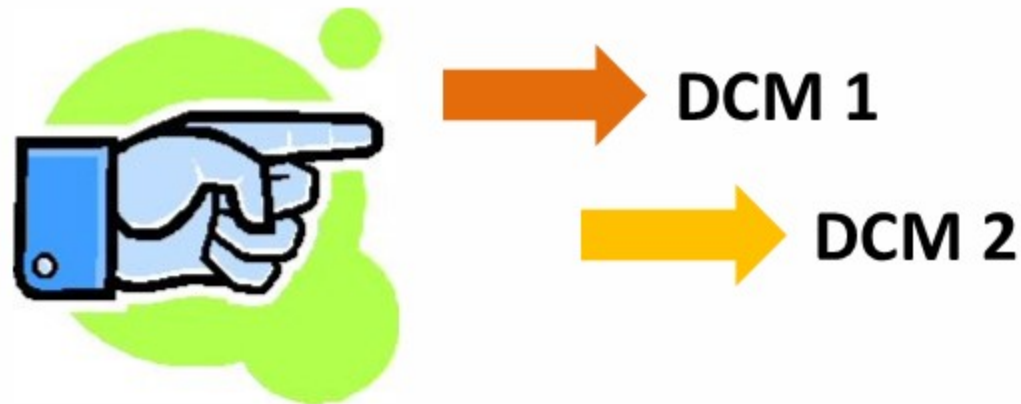


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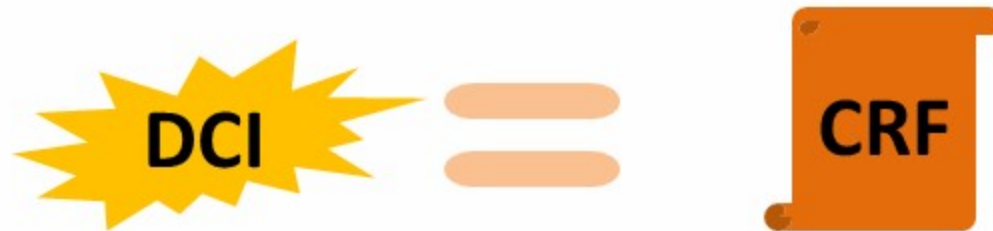


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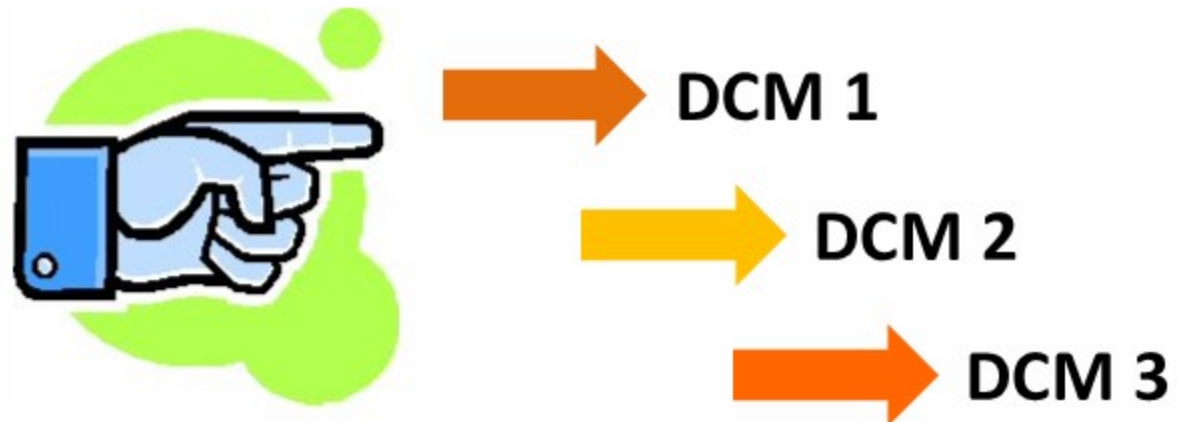


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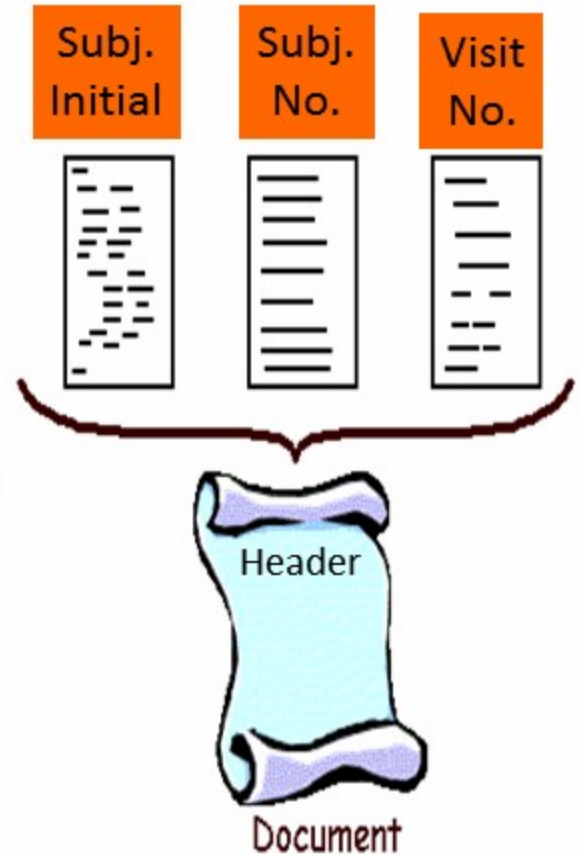
Data Collection Module- DCM

- DCM is a collection of
 - Similar questions
 - Group of related questions
- E.g., in a subject demography form
 - Date of birth
 - Sex
 - Race
 - Height/weight




Data Seen in Header Section

- Header information includes
 - Subject number
 - Initials of subjects
 - Visit number
- Confidentiality of subjects in clinical trial



Header Information

- Subject number
- Each of subjects in clinical trial will be assigned a particular subject number
- Facilitates accessing information of particular subject during verification of data



Subject
Number

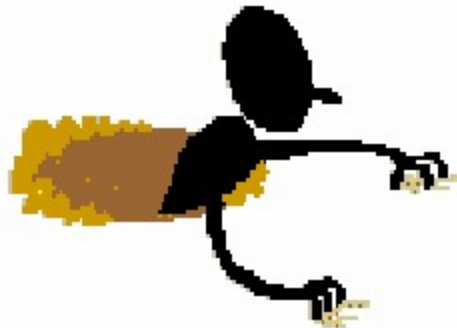
Initials of Subject

- Further to subject number
- Subject's name usually reduced to a combination of "three-letter" e.g.,
 - Name- naveen prasad sharma
 - Initial recorded as - "n p s"
- **Confidentiality of subject** throughout clinical trial should be secured & not disclosed; hence only initials recorded



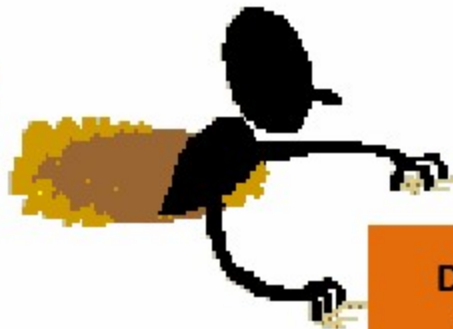
DVG or Discrete Value Groups

- Refers to a question where in there is a fixed set of answers
- DEOs have to just select one of response as answer to a question instead of keying in text
- e.g., **Subject Diagnosis**
 - Mild Asthma
 - Moderate Asthma
 - Severe Asthma



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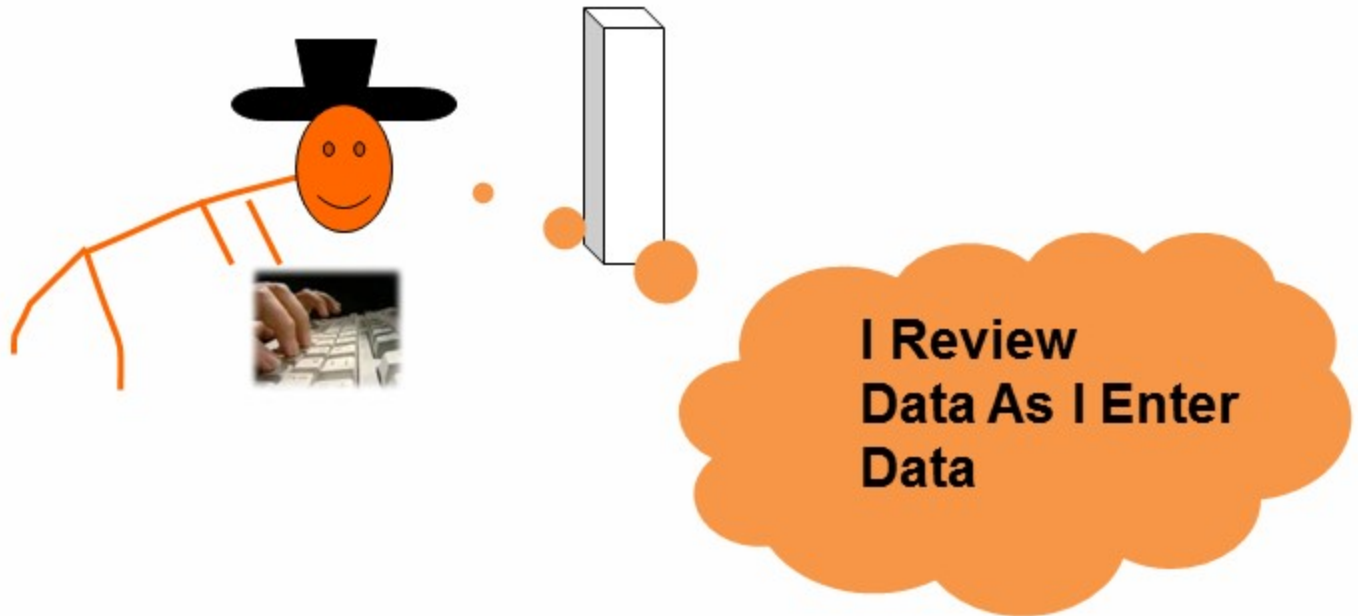


Data Entry Person
Will Just Select
One Answer From
Drop Down Menu



Heads-Up Data Entry

- Also called thinking data entry persons
- They raise a flag when data is illegible for data reviewers or data managers



Heads-Down Data Entry

- Simply put, these entry personnel enter what they see on CRF
- Entry faster as they follow natural flow of CRF
- Skill emphasis on number of keystrokes made and specific training on database to be utilized
- Second pass entry provided after heads down data entry
- Only few checks provided while entry is made



DE Guidelines

Best Practices of Data Entry

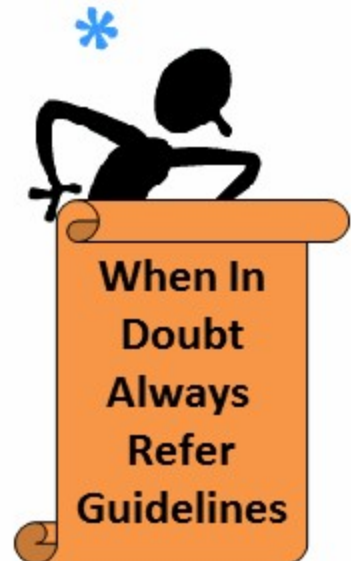
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DE Guidelines

Best Practices of Data Entry

- DEOs should develop habit of referring data entry guidelines when in doubt
- If still unclear, they can raise a comment or flag for further review of data



Standard & Project Specific Guidelines: Which One to Follow ?

- DEOs are required to follow numerous guidelines
- They should be aware that always **“project specific guidelines supercedes standard guidelines”**

Which
Guidelines To
Follow..??



Single Entry

- Used in EDC systems
- Extensive checking routines should be built into data entry application
- DEO to be trained in protocol, data capture system, study specific issues and key data, & to review entry process
- Possibility of higher error rate, hence more extensive audit needed



Single Entry versus Double Entry

- FDA & ICH regulations do not require double entry or any other specific data entry process
- Skill level of resource, time availability and cost contribute to choice of entry process
- Double entry helpful where data are subject to frequent random keystroke errors or where a random error would be likely to impact the analysis
- Single entry with good manual review can be better than a sloppy double entry one



QA/QC

- Quality Assurance is a process
- Quality Control is a check of process
- Accuracy of data entry checked by auditing data stored in database against CRF
- Ongoing internal and external audits
- Error Rate: “number of errors / number of fields on CRF or Database”
- Acceptable error rates – client specific

