PhUSE Single day event Copenhagen

SDTM Exceptions

H.Lundbeck A/S 28th of May 2013

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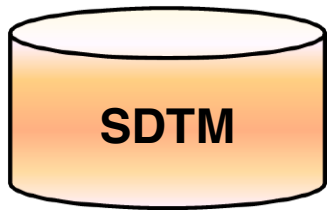
- Background for presentation
- What’s the purpose of SDTM?
- How to fullfill all the purposes?
- Examples of exceptions
- Some best practice recommendation

Some reasons for SDTM to give an FDA reviewer a headache:

- FDA lack the appropriate software to utilize SDTM
- Sponsor SDTM dialects
- Too much noise in SDTM

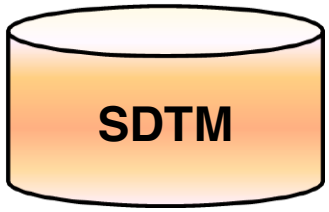

What is the purpose of life?


What is the purpose of
SDTM ?



SDTM IG SAYS:

”SDTM represents an interchange standard…… it is assumed that SDTM will be transformed by software tools to better support viewing and analysis” (IG p 7)



SDTM is used to help me assess the safety of a drug before putting it on the market

An FDA Safety reivewer might say:

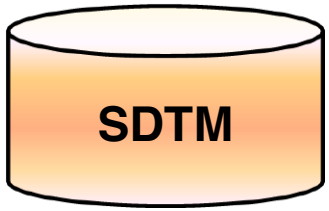
CDER FDA Common Data Standards Issues document

SDTM

- “Please include the variable EPOCH for every clinical subject-level observation ”
- “CDER would like the AE domain to include all adverse events recorded in any way in the patients’ case report forms, regardless of whether the sponsor has determined that particular events were treatment emergent or not.”

FDA Common Data Standards Issues document

An FDA Safety reivewer might say::

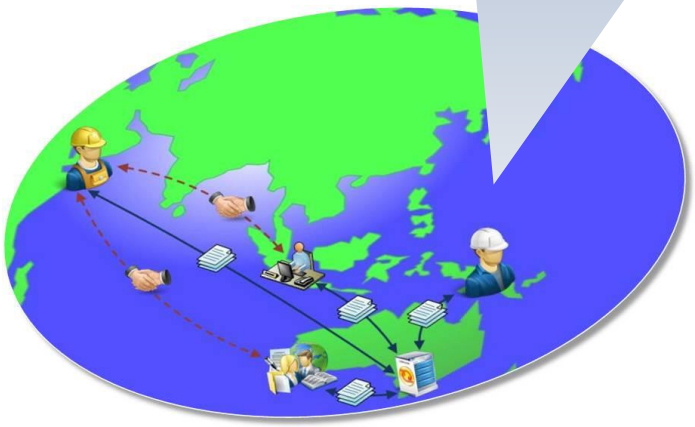


SDTM is the underlying data standard that enables my BI tools to assess the trial data as the trial is ongoing

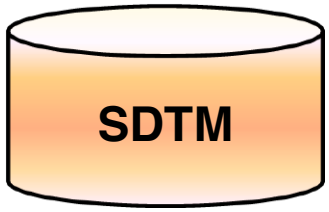
An pharma company safety reviewer might say:

SDTM

SDTM is a format for me to share data with Partners and CRO's



A Data Managers view can be



SDTM must support the statistical analysis and all results can in theory be reproduced from SDTM

A Statistician might think

SDTM

How hard can it be??

When I did the ABC123 study 1994 we did it two days….

The manager WILL say:

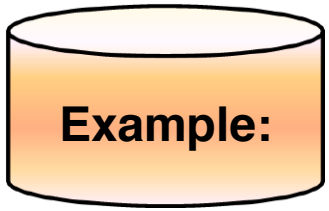
SCUBED

SDTM

How hard can it be??

We have this super tool that migrates 20 legacy studies a day…

The salesman WILL say:



Were any adverse events experienced?

☐ Yes

☐ No

Example:

Were any adverse events experienced?

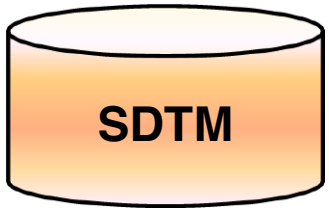
☐ Yes

☐ No

Its important to know if there is ZERO AEs for the subject or if AEs are not yet entered

SCUBED

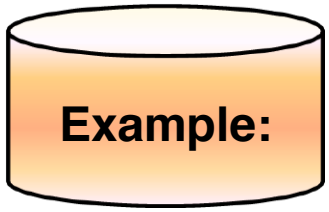
SDTM



At the PhUSE CSS meeting the working group discussed with FDA examples of what is NOT needed in SDTM from their perspective.

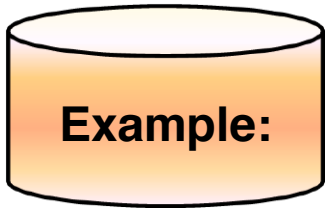
Several of the examples appears obvious for people experienced with SDTM. However – they represent examples that FDA reviewers see in SDTM submissions.

The examples here is nothing but examples of what was discussed….. The work is not finished



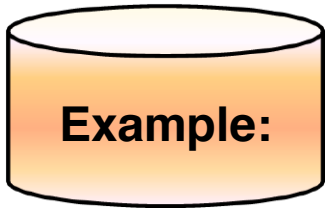
Initials:
Subject initials should never be included

Non-subject initials may be useful for analysis, but they should be anonymized/de-identified before putting them into SDTM.



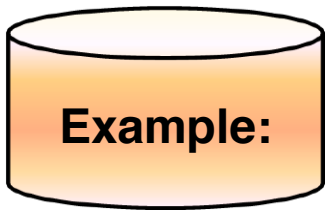
Electronic vendor reconciliation data:

If the dates collected by CRF have been reconciled with the external data file, the CRF dates are effectively included in the data. This information should not be duplicated in SDTM - it should only be in there once.



Edc operational data:

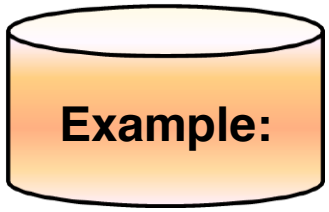
Entry dates.
Audit trail information
Signature dates



Prompts:

Reminders for investigator to follow protocol.

Tickboxes to indicate a form is blank



Blank observations:

Empty artifacts of CDMS systems (e.g., A log form with one record entered and the system generates records for all the rest of the rows in the form.

An AE record that was generated by mistake and only has a system-generated record identifier.

A VS CRF with a "NOT DONE" checkbox that was left empty by mistake, and one blank record is stored in the database)


RECOMMENDED
RECOMMENDED
RECOMMENDED

PURPOSE OF SDTM:

- Acknowledge that SDTM is for diffent purposes. The SDTM you use internally might not be identical to the ones submitted years later.

- FDA is NOT interested in operationalised SDTM. They want you to follow the IG and the common issues document pretty much to the letter. Read the documents and use a validator, to assess the errors in data.

DESIGN WITH THE END IN MIND:

- When designing CRF pages, consider for each data element
  1. submitted to FDA?
  2. used in statistical analysis?
  3. can you store it in SDTM?

- Analyze why a data element is collected -- > Do not collect if it does not serve an important purpose…

COMMUNICATE:

- FDA is eager to improve the way we all work with SDTM and submit. Communicate with them, ask questions and listen.

- Discuss with colleagues, about there experiences.

Thank you for listening

Questions?