From eCRF to SDTM

Why is it still hard for many organizations?

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Outline

- SDTM Conversion
- CDASH and Metadata Libraries
- Issues faced
- eCRF Implementation Challenges
- Conclusion

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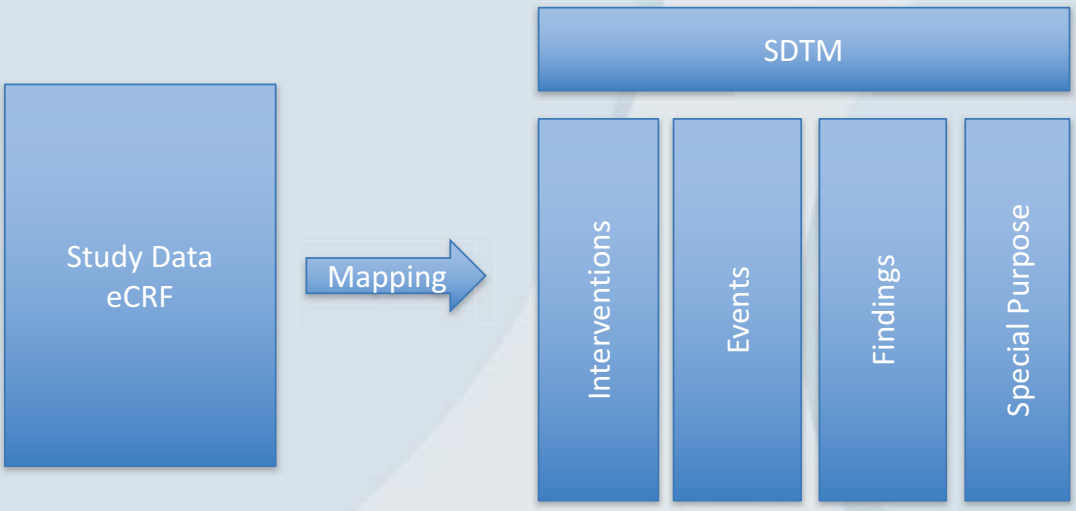
The Challenge: SDTM Conversion



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SDTM Conversion

- Mapping domains and fields
- Mapping of identifiers, timing and qualifier variables
- Relationship (RELREC)
- … and more ...

- ➔ Major effort for each trial!

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Consequences of lack of standardization

- Missing data
- Wrong terminology
- Wrong ‘semantics’
- Missing Timing Information
- Wrong Data Formats

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CDASH to the Rescue

- Standard eCRFs
- Standard Variable Names and Terminology
- Mapping to CDISC SDTM
- Standard Identifiers

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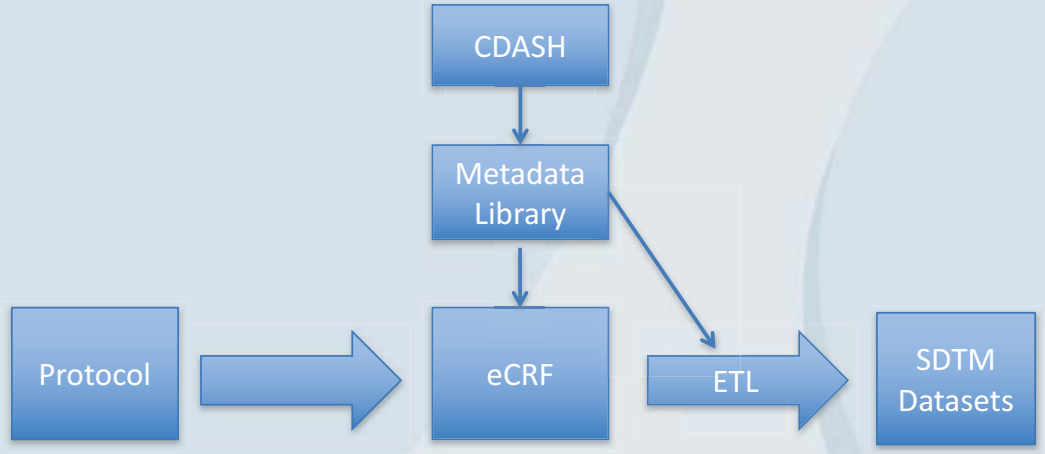
CDASH-based conversion to SDTM



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Additional Benefits of CDASH

- Reduce eCRF Implementation Time
- Reduce Training Efforts at Site
- Standard Format for Data Management
  - Safety Reporting
  - Payments
  - Metrics (i.e Inclusion)

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But… issues in the application of CDASH

- Limited number of standardized domains
- Best practices or Data Standard?
- Many sponsor specific extensions
- Some Gaps between CDASH and STDM

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eCRF Implementation: a complex task

- Compliance with Protocol
- Compliance with CDASH / Metadata standards
- Design for Data Entry Usability
- Meet Sponsor Expectations

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The time pressure issue

- eCRF Implementation usually performed under time pressure
- Additional topics to consider, i.e.:
  - Randomization
  - Drug Shipment
  - SAE

➔ SDTM not on critical timeline for Go-Live

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Required Skills and Trainings

- eCRF Design requires in-depth knowledge of Metadata Standards
- Standards are constantly evolving
- Some Therapeutic Area Specific Standards are complex
- Does the Specification match the standards?
- What level of training is required?

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User Friendliness vs Standardization

- Site staff are “users” of the eCRF
- Flow of fields / forms on eCRF should match the ‘natural order’
- Important questions may need to be placed ‘strategically’

  Example: *Previous Tumor on Demography page for Cancer study*

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CDASH: Race

- CDASH defines RACE as multi-select
- Standard terminology
- FDA ‘recommends’ multi-select
- Many studies implemented as single selection
- Some non-standard terminology
- ‘Implemented as defined in the protocol’

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Ongoing and Continuing

- SDTM defines Reference Date for ‘Ongoing’ and ‘Continuing’
- Some studies do not record the ‘still ongoing after’ date (--ENRTPT)
- Assume date of last visit?

- ➔ Impact on eCRF Design, Data Collection and Monitoring

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Position of Blood Pressure Measurement

- CDASH: Position should only be collected if required
- VSPOS ‘permitted’ (expected?) in SDTM
- Protocol information is required for SDTM Mapping

BP.SYSBP.VSORRES = ?
BP.VSPOS=SITTING

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SAE Reporting

- ICH E2B: XML Standard for electronic transmission of SAE Reports
- Requires Mapping of data from various domains → Standardization
- Requires Non-eCRF Protocol Information
- CDASH E2B project to map from CDASH to E2B

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Standard reports based on metadata library

- Increasing Demand for Reports and Metrics
- Reports should be reusable
  ➔ part of report library
- Data Standards allow for reuse and reduce effort of validation

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The future

- Trials become increasingly complex
- Risk based Monitoring
- Patient Centric Trials
- Use of Mobile Devices
- Measurement Devices / IoT

➔ More Challenges !

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Conclusion

- **Everything is possible** with well managed metadata libraries and validation against standards
- But: many challenges for eCRF Designers and data management
- Standardization includes Protocol, Monitoring and Data Entry

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Final thought (1)

Will SDTM Conversion ever be easy?

Like the push of a button?

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Final thought (2)

We need

SEMANTICS

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THANK YOU

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