Perspectives on the FDA Public Meeting

Solutions for Study Data Exchange Standards

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About the Presenter

CDISC ODM Team founding member. Current co-lead with Sam Hume.

Independent consultant with many years experience developing and implementing clinical data software applications.
CDISC ODM for Study Data Exchange

- Platform independent vendor neutral.
- Designed to provide a study data exchange format for clinical trials data
  - Enriched data format
  - Captures data relationships, metadata versions, audit trail and more
  - Uses structures familiar to clinical programmers, pharma IT
- Flexible and extensible
  - Built to support evolving needs of medical science, changing business processes
Industry Case for ODM

• Designed to support CDISC content models
  – SDTM relationships
  – CDISC Controlled Terminology
  – Mapped to BRIDG

• Data structures align well with clinical research applications

• Shallow on-ramp (and lower costs) for sponsors and service providers
  – 150 organizations signed letters of support

• Use of ODM end-to-end makes better SDTM
Alternatives to CDISC ODM proposed at the Public Meeting

Extended SAS V5 format
- Need Base SAS to verify/validate
- Expensive and inconvenient for small software service providers

HL 7 V3 messages
- No message exists yet to support SDTM and ADaM study data exchange
- No message yet to support SDTM and ADaM study metadata transfer

Semantic Web – CDISC2RDF
- Exciting opportunity long term
Next Step Perspective on the Public Meeting

• Industry and the FDA are both eager to have a better exchange standard

• Evidence suggests CDISC ODM would provide the FDA with short term improvements and flexibility to meet evolving review requirements

• A good next step would be to run a submission pilot or POC
Thank You!

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