Harmonizing Data Processes with the CDISC Family of Standards at a Global CRO

Steve Kirby, Bradford Danner
and Nancy Wang

Data Flow at Celerion Today

- Data processes from collection through analysis and submission built around the CDISC family of standards
  - CDASH mapped to SDTM
  - SDTM mapped to ADaM
  - Data definition documentation integrated with mapping

celerion

How (and why) did we get there?

celerion

Where we started

- Active programming group that mapped data as collected in SAS® to many different structures
- CDISC data standards increasingly relevant
- Formal documentation increasingly important

celerion

Focus on Study Data Tabulations Model

- Mapping focus on CDISC SDTM with release of version 3.1.1.
- Increasing demand indicated optimization of SDTM mapping processes

celerion

Core SDTM Mapping Challenges

- Input data variation
- Output data variation

celerion

SDTM Mapping Key Details

- Metadata helper files used to establish conforming format
- Substantive review checks built into standard SAS mapping code

celerion

Focus on CDASH

CDASH (Clinical Data Acquisition Standards Harmonization)

- Increasing demand indicated further optimization of SDTM mapping processes
- Collection data format updated to CDASH to reduce input variation
- Working group formed to coordinate CDASH and SDTM

celerion

Focus on ADaM

ADaM(CDISC Analysis Data Model)

- Increasing demand for ADaM data indicated optimization of analysis data processes
- SDTM mapping processes leveraged for ADaM with release of v 2.1
- Coordinating data needs with scientists emphasized importance of communication

celerion

Focus on Communication - Define.xml

- Define.xml helps the data say “hello” to scientists and other end-users
  - Navigable data definition document
  - Linked information about data sets, variables, and variable contents

celerion

Integrating Define.xml Production with Data Mapping

- Scope of metadata helper files used in mapping expanded to include all information needed for define.xml creation
- Define content available as a communication tool at each stage of the mapping process

celerion

Lessons Learned

- The CDISC standards can be best applied when used from collection through analysis
- Inputs and outputs are variable – keep processes flexible
- Outreach and communication are critical

celerion

Acknowledgements

- Thanks to Celerion for supporting this presentation and the programming initiatives that made it possible
- Specific thanks to Elizabeth Reinbolt, Matt Wiedel, Luke Reinbolt, Aleksandra Stein, Karl Miller, Deidre Kreifels, Tamara Cuddy and Chun Feng

celerion

Questions?

Please contact info@celerion.com