CDISC Standards and Digital Health

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CDISC

Strength *through Collaboration*

Mission

To develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare

- Founded in 1997; incorporated in 2000 as a non-profit
- Today > 400 member organizations of all types
- Global Standards Development Organization (SDO) developing global consensus-based standards focusing on Clinical Research
- Collaborate with other SDOs (e.g. ISO, HL7, IHE)
- CDISC Standards required by U.S. FDA and Japan's PMDA
- Goals for standards
  - Enable innovation
  - Support all types of research from protocol through analysis and reporting
  - Streamline research processes and enable data sharing/aggregation
  - Link healthcare delivery and clinical research through EHRs/eSource

Observations from eSource - finding value in digital healthcare data

- Great diversity of stakeholders leads to opportunities and challenges
- In the mobile / wearable space innovation is occurring at several levels
  - Hardware
  - Software
  - Clinical application
  - Consumer / Patient use
  - Regulatory acceptance
- Rarely is a simple translation possible - digitizing processes brings new questions
- Metaphors can be tricky!

Suggestions for the discussion

- “Begin with the end in mind”
  - E.g., Regulatory approval? Clinical usefulness? Biomarker validity?
- Test assumptions
  - E.g., What weight do we put on innovation vs immediate application?
- Take time to return to misunderstandings or to teach across stakeholders
  - E.g., SDTM, ODM, why do they matter?
- Mind your metaphors!
  - E.g., the “eCRF” is not simply an electronic piece of paper

Seeking equilibrium…?