Data Standards for Mobile Devices

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Mobile Shows Promise in Clinical Research

- Electronic patient reported outcomes
- More timely and higher quality data
- Objective / continuous data collection (better measurements)
- Patient recruiting
- Subject engagement and retention / fewer losses to follow-up
- Supports patient centricity (reducing the burden on patients)
Mobile for Research Examples

• Apple ResearchKit
• ResearchStack for Android
• Verily (Google) is building a wearable for clinical research
• Medidata Patient Cloud App
• TRANSFoRm
• 259,000+ healthcare apps in the major app stores
Mobile Adoption Hurdles for Regulated Clinical Research

- Regulatory ambiguity
- Bring your own device (e.g. support, training, validation)
- Data collection instrument validation
- Privacy and security (e.g. authentication and access control)
- Population bias
Importance of Data Standards

• Support for regulations and provenance

• Enable the development of software tools to exchange, interpret and process data
  ▪ Data sharing
  ▪ Data aggregation / big data
  ▪ EHR / EDC system integration
  ▪ Data / metadata validation

• Reduce barriers to innovation

• Support full clinical research data lifecycle
CDISC Operational Data Model (ODM-XML)

- Standardized XML representation of clinical study data focused on data collection
- Provides a language for defining data collection forms
- Easy to understand and implement
- Defines structure, not content
- History of use in mobile applications
- Supports extensions
- Provides a clinical data archive format compliant with applicable FDA guidance
Example: ODM-XML Supports Multiple Platforms including Mobile Technology

- ODM-XML metadata used to generate data collection forms
- ODM-XML extended with GUI elements
- Platform-agnostic, rendered appropriately for each device
- Captured PRO integrated back into EHR data
ODM-XML is Widely Used in Academic Research

Systematic review of over 69 academic articles using ODM-XML that used ODM-XML as part of a systems solution or critically evaluated ODM-XML against a named solution usage scenario. Several hundred articles mention the use of ODM-XML in their research.
ODM-XML & EHR Integration

- Retrieve Form for Data capture (RFD)
- EHR to CDASH (E2C)
  - Using HL7 CCD to populate CDASH CRFs
- ODM-XML in learning healthcare systems
  - ODM-XML HL7 CDA/CCD integration
- ODM-on-FHIR
  - Using HL7 FHIR to populate CDASH CRFs
Data Provenance: 3 Views

• Data Flow View
  ▪ Traceability, or the flow and transformation or derivation of information

• Responsibility View
  ▪ What people or organizations were involved in generating or manipulating the information in question?

• Process Flow View
  ▪ Capturing the actions and steps taken to generate the information

Provenance describes how a data item in a specific state was derived from a specified source (Moreau, Groth, et al., 2008)
ODM-XML & Audit Trail

Provenance Responsibility View

What

ItemDef

Who

UserRef

Where

LocationRef

Why

DateTimeStamp

When

ReasonForChange

How

UserRef

Signature

SignatureRef

DateTimeStamp

MeasurementUnitRef

Annotation

Comment

Flag

ItemDef
Trace-XML: Generate a Graph Representation using ODM-XML metadata

End-to-end hierarchical view of 2 domains: DM & VS

Provenance Data Flow View

<table>
<thead>
<tr>
<th>Standard</th>
<th>Format Standard</th>
<th>Forms / Datasets</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDASH</td>
<td>ODM-XML</td>
<td>DM, VS</td>
</tr>
<tr>
<td>SDTM</td>
<td>Define-XML</td>
<td>DM, SUPPDM, VS</td>
</tr>
<tr>
<td>ADaM</td>
<td>Define-XML</td>
<td>ADSL, ADVS</td>
</tr>
</tbody>
</table>
Moving forward…

• ODM-XML supports the regulations and good science
  • Risk-based approach
  • ODM-XML has been widely used in non-regulatory environments
  • ODM-XML is used globally

• ODM-XML and the CDISC standards support the full clinical data lifecycle

• Data standards help improve the efficiency and quality of research data collection and processing

• Beginning work on ODM-XML v2.0 in early 2017

• It takes time to become fully proficient in the standards so don’t wait until their use is on the critical path
Thanks!

Q & A

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