

Data Standards for Mobile Devices

Coalition Against Major Diseases 2016 Annual Regulatory
Science Workshop

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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



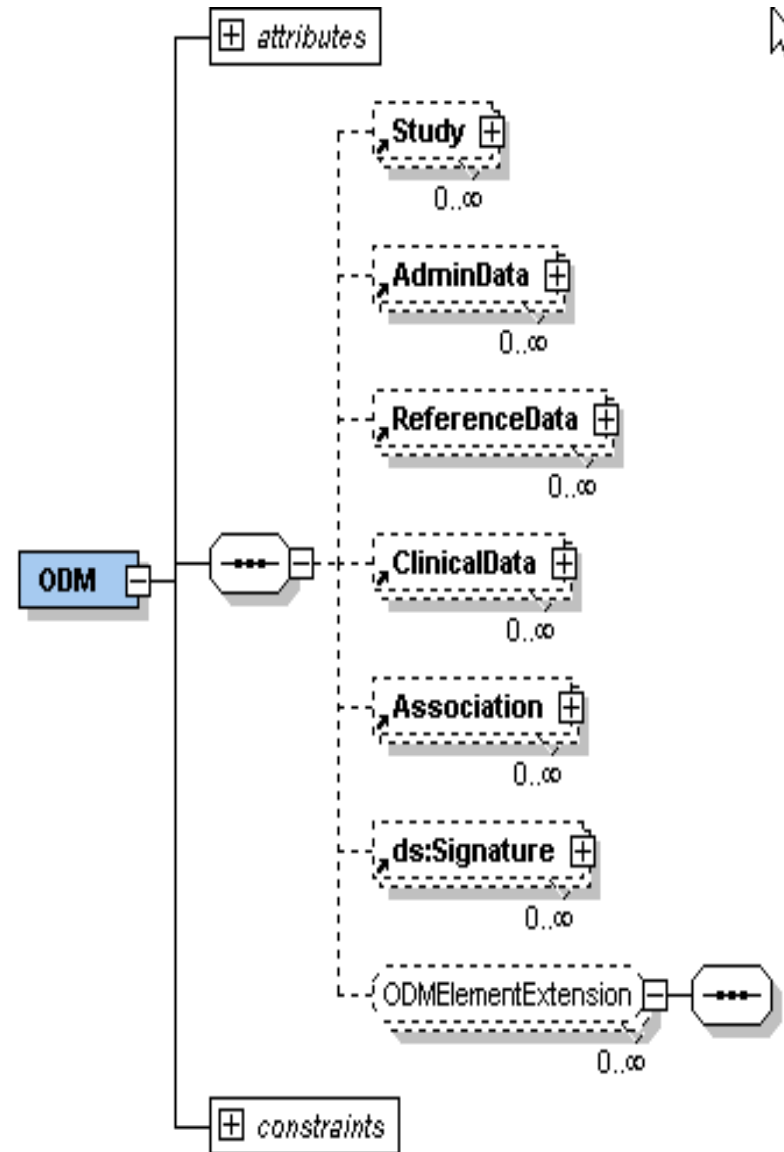
- Regulatory ambiguity
- Bring your own device (e.g. support, training, validation)
- Data collection instrument validation
- Privacy and security (e.g. authentication and access control)
- Population bias

Importance of Data Standards

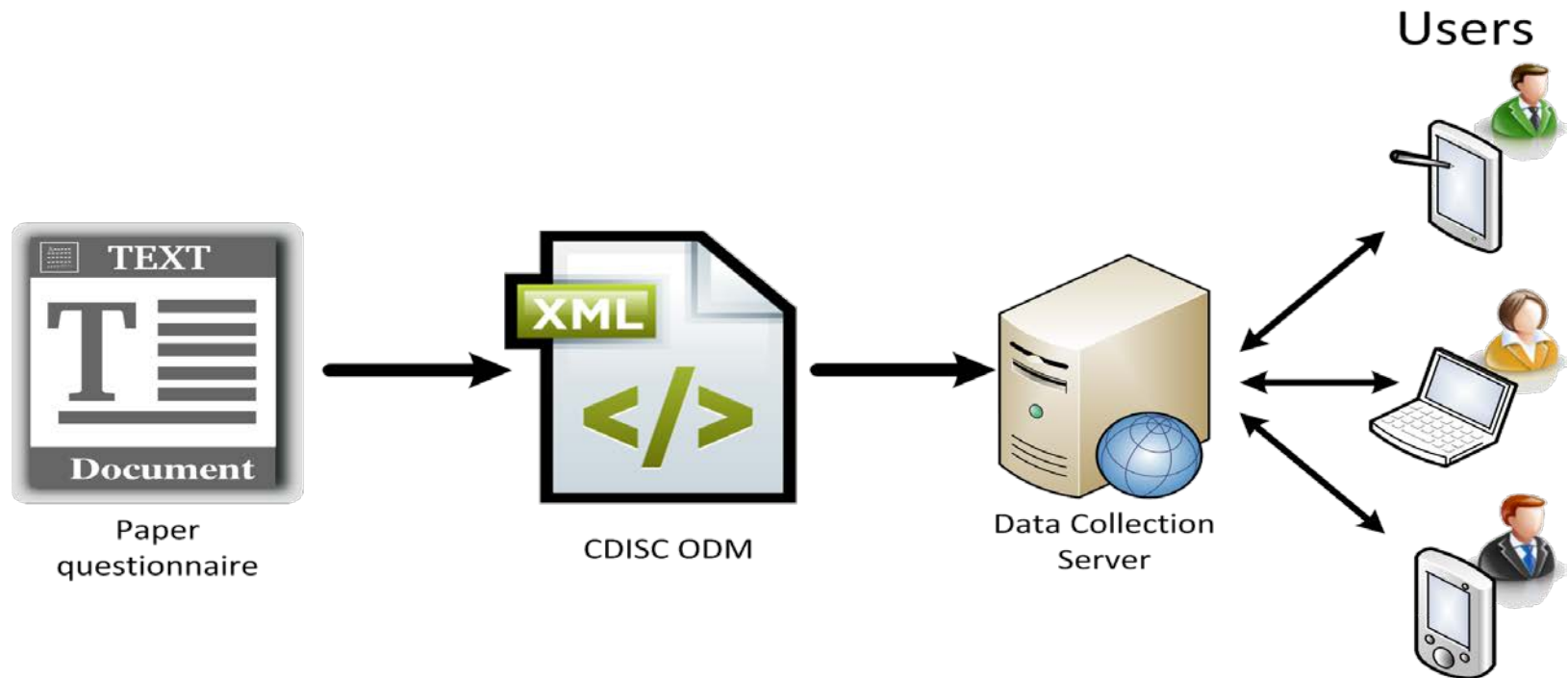
- Support for regulations and provenance
- Enable the development of software tools to exchange, interpret and process data
 - Data sharing
 - Data aggregation / big data
 - EHR / EDC system integration
 - Data / metadata validation
- Reduce barriers to innovation
- Support full clinical research data 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



Contents lists available at [ScienceDirect](#)

Journal of Biomedical Informatics

journal homepage: www.elsevier.com/locate/yjbin

Methodological Review

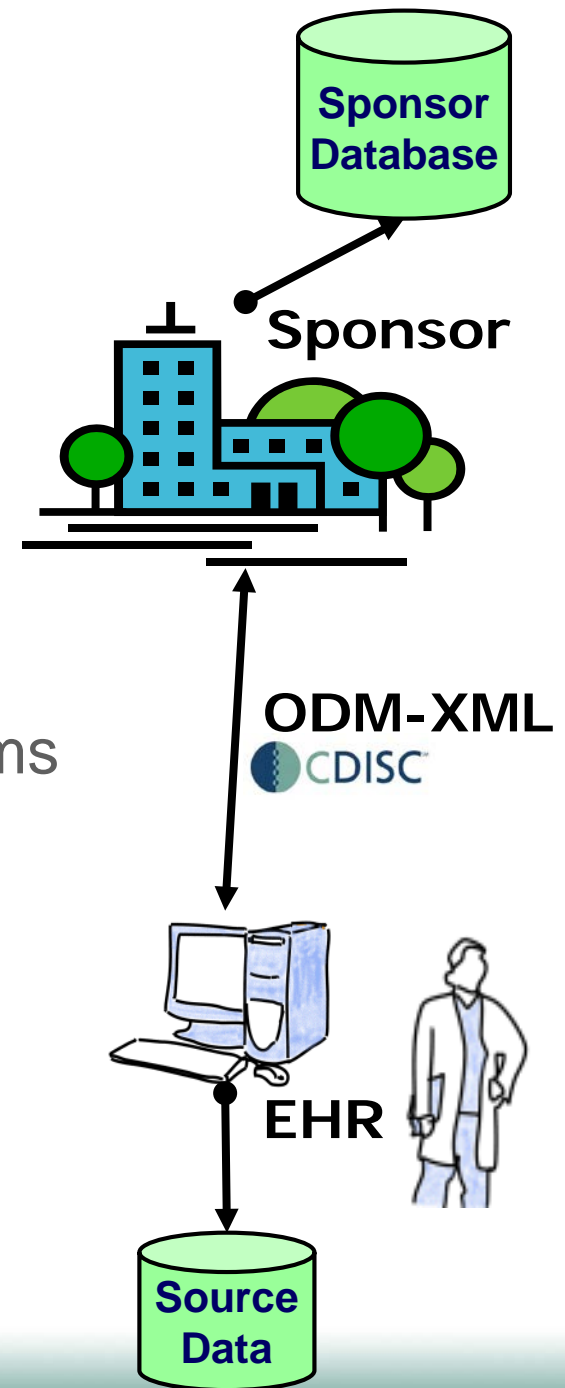
Current applications and future directions for the CDISC Operational Data Model standard: A methodological review

Sam Hume^{a,*}, Jozef Aerts^b, Surendra Sarnikar^a, Vojtech Huser^c

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

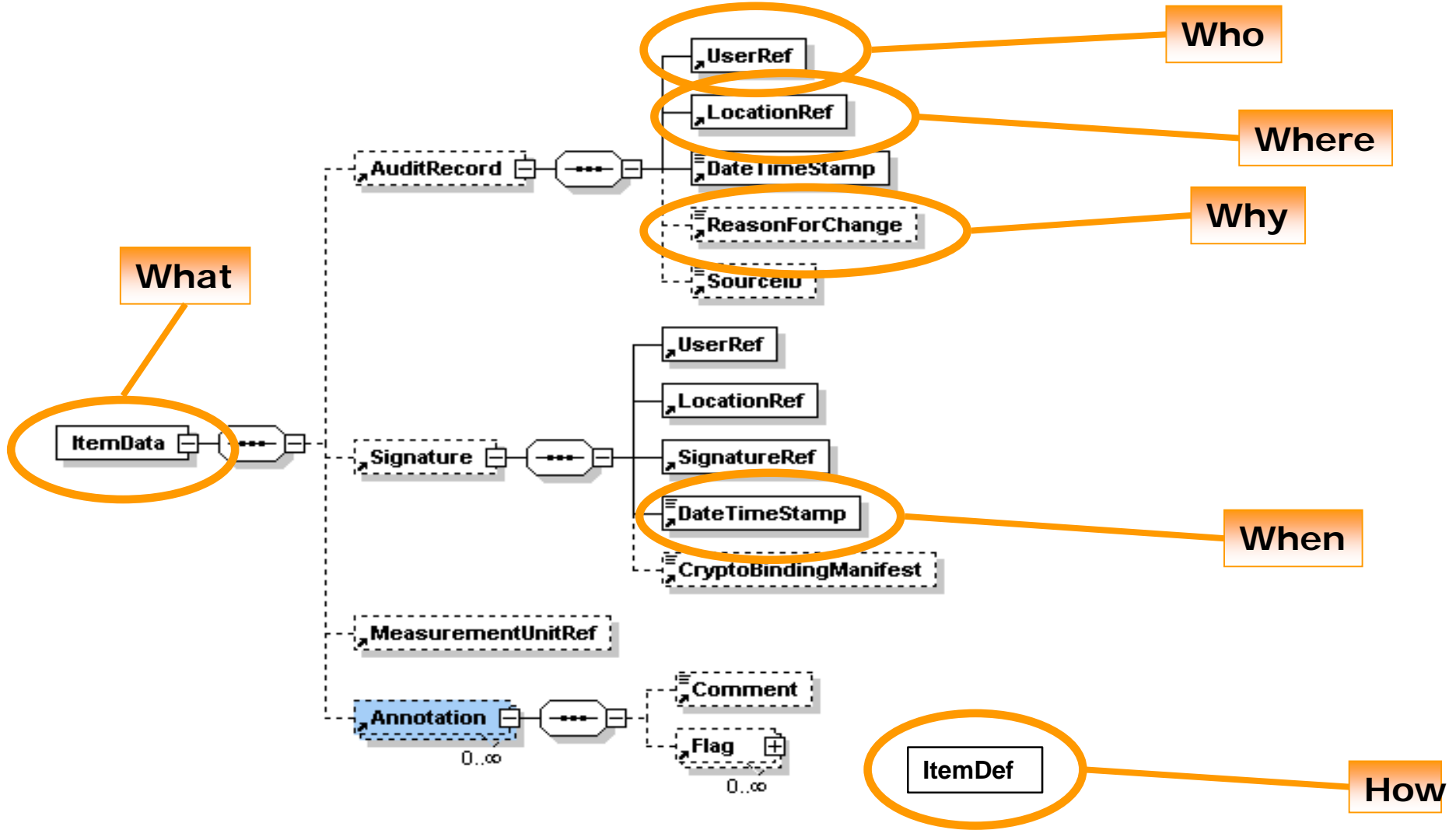
- Retrieve Form for Data capture (RFD)
- EHR to CDASH (E2C)
 - Using HL7 CCD to populate CDASH CRFs
- ODM-XML in learning healthcare systems
 - ODM-XML HL7 CDA/CCD integration
- ODM-on-FHIR
 - Using HL7 FHIR to populate CDASH CRFs



Data Provenance: 3 Views

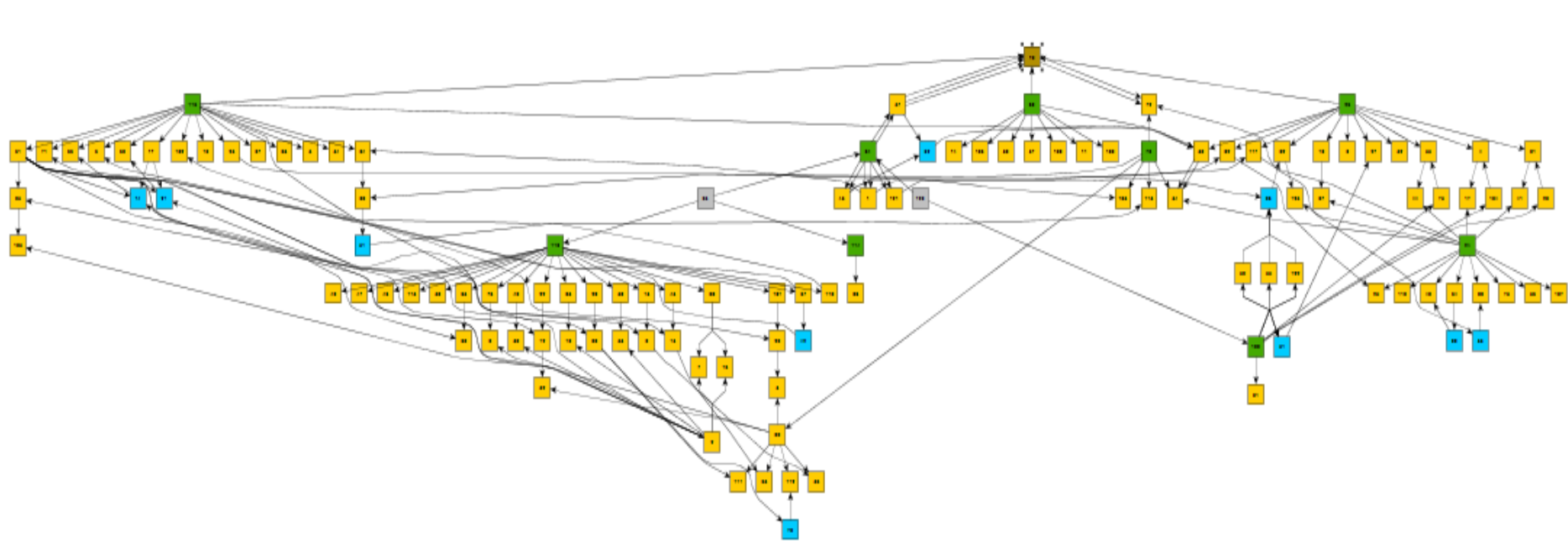
- **Data Flow View**
 - Traceability, or the flow and transformation or derivation of information
- **Responsibility View**
 - What people or organizations were involved in generating or manipulating the information in question?
- **Process Flow View**
 - Capturing the actions and steps taken to generate the information

ODM-XML & Audit Trail



Provenance Responsibility View

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



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

Provenance Data Flow View

Graph Content

Standard	Format Standard	Forms / Datasets
CDASH	ODM-XML	DM, VS
SDTM	Define-XML	DM, SUPPDM, VS
ADaM	Define-XML	ADSL, ADVS

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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