Underpinning the CDISC Operational Data Model (ODM)

Geoff Low

Software Architect

Overview

High-level Overview of ODM

Extension of ODM

Examples of how Medidata has extended ODM

The future…

“Give me my Data in ODM”

What? Can you be a little more specific?

Doesn’t (currently) support Datasets

- CDISC XML Technologies Team are working on a DataSet-XML

Primarily about Study Data (Operational)

- You are most likely to get it as an input from study Archive or from the EDC system
- You will need to turn it into SAS datasets
  - PROC CDISC (only supports ODM v1-2)
  - SAS Clinical Standards Toolkit
  - XML LIBNAME

High level overview of the ODM

What is the Operational Data Model?

- Standard XML model for the transfer of Clinical Data and Metadata
  - Since 1999
- One of the primary 'technologies' of CDISC
  - Operates at ~ 5 year review cycle
- Produced and Maintained by the XML Team
  - Last release is 1-3-1
  - Stable specifications
  - Used:
    - Archive model
    - Transfer model
    - Data model

CDISC ODM Elements

Study
Top level static information about a Study. Includes Study identifiers, Measurement Units

Metadata
The metadata of a study describes the types of study events, forms, item groups, and items that are allowed in the study.

Clinical Data
Clinical data for multiple subjects.

Reference Data
Reference data provides information on how to interpret clinical data.

Administrative Data
Administrative information about users, locations, and electronic signatures

ODM Constituents – Metadata

Metadata (MetaDataVersion)

- Protocol
- StudyEvent
- Form
- ItemGroups
- Item
- CodeList
  - CodeListItem

Referencing

```
<ItemDef OID="DM_11_2011-10-24" Name="Sex" DataType="text" Length="2">
  <Description>
    <TranslatedText xml:lang="en">The assemblage of physical properties or qualities
le; the physical difference between male and female; the distinguishing peculiarity of
n).
e Section 2.2.)</TranslatedText>
  </Description>
  <Question>
    <TranslatedText xml:lang="en">Sex</TranslatedText>
  </Question>
  <CodeListRef CodeListOID="CL.SEX_2011-10-24"/>
  <Alias Context="CDASH" Name="SEX"/>
  <Alias Context="CDASH/SDTM" Name="SEX"/>
</ItemDef>
```

ODM Constituents – Clinical Data

ClinicalData contains data for Number of Subjects
Data can be SnapShot or Transactional

```
<ClinicalData StudyOID="CDASH_Study_2011-10-24" MetaDataVersionOID="CDASH_MetaDataVersion_2011-10-24">
  <SubjectData SubjectKey="0001_0001">
    <StudyEventData StudyEventOID="SE.SCREEN">
      <FormData FormOID="F.VISIT">
        <ItemGroupData ItemGroupOID="IG.VIS">
          <ItemData ItemOID="I.VISDAT">2012-12-12</ItemData>
        </ItemGroupData>
      </FormData>
    </StudyEventData>
  </SubjectData>
  <SubjectData SubjectKey="0001_0002">
    <StudyEventData StudyEventOID="SE.SCREEN">
      <FormData FormOID="F.VISIT">
        <ItemGroupData ItemGroupOID="IG.VIS">
          <ItemDataDate ItemOID="I.VISDAT">2012-12-12</ItemData>
        </ItemGroupData>
      </FormData>
    </StudyEventData>
  </SubjectData>
</ClinicalData>
```

ODM Constituents - Others

Administrative Data

Information about Users, Roles, Locations and Electronic Signatures

Reference Data

Supporting Information for interpretation of the Clinical Data linked to a study/MDV version

ds:Signature

The ODM can be digitally signed to ensure integrity

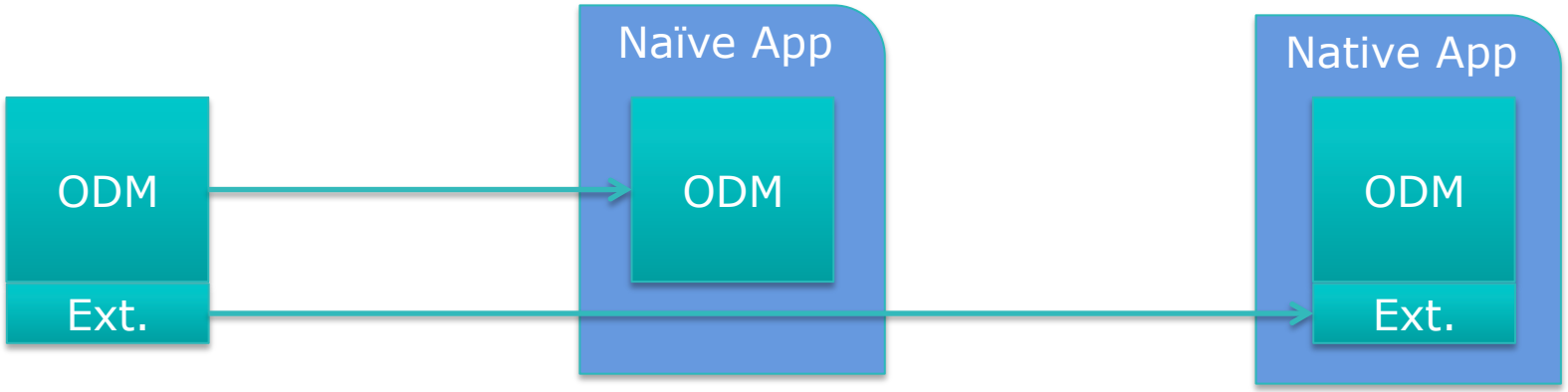
Association

Annotate ordered pair of entities, rather than just one

Extending the ODM

Extensibility

- ODM can be extended to add attributes or elements
  - Called "Vendor extensions"
- Distinguish the extensions from the core
  - Vendor extensions are targeted to a vendor system and may not be meaningful elsewhere
    - *xmlns:mdsol="http://www.mdsol.com/ns/odm/metadata"*
    - *xmlns:fdx=http://www.formedix.com/Schemas/OriginCustomAttributes/1*
  - Develop XML Schema documents (extending ODM schema)



CDISC Extensions for the ODM

Define.XML (CRT-DDS)

- Used with SDTM and ADaM submissions to Regulatory Bodies

Study Design Model – XML (SDM-XML)

- Adds Study Design elements bridging concepts from Protocol Representation Model (PRM) to the Trial Design Model (TDM)
- Extends the existing ODM model to include concepts such as Epochs, Workflow, Timing

Controlled Terminology

- Released as an ODM in concert with the existing versions.

Dataset-XML

- In draft, at the moment.

Using a model

You can build your own standard that you own and maintain
- Dependent on your and your customers' requirements

You can take an industry standard as your own, and then dominate it's progress
- Embrace, extend and extinguish

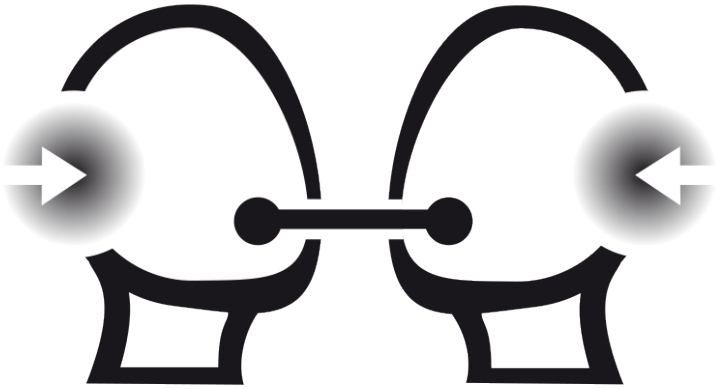
You can use an industry standard as it was intended
- You support the core standard by aligning with it
- You can extend it to add value for you and your customers
- You can contribute to the development of the standard

Why would we want to extend ODM?

The ODM was designed as an archive/transport form for clinical data/metadata

Maps conceptually to a study hierarchy – reuse as a conceptual model for the underlying database structure

- Define mappings from DB -> ODM
- Define mappings from ODM -> DB



Sometimes it could be improved with added business value

- Maintain schema documents to include the Core ODM + extensions

Some Extension Examples

Influencing the representation

Item with a CodeList

- Text Entry
- Radio Button
- Drop Down List

Generally we'll be OK with a Radio Button per field right?

- SEX → yes – 2 CodeListItem
- FRM → not really – 169 CodeListItem

Adding an extension for the ControlType for the ItemDef gives a designer more power

```
<ItemDef OID="I.CMPRIOR" Name="Taken Prior to Study? " DataType="text" Length="8"
         mdsol:ControlType="RadioButton">
        <Question>
            <TranslatedText>Was the medication/ therapy taken prior to the study?</TranslatedText>
        </Question>
        <CodeListRef CodeListOID="CL.NY$NY"/>

      <mdsol:HeaderText>Taken prior to study?</mdsol:HeaderText>
</ItemDef>
```

Influencing the representation – cont.

- A sponsor may wish to change the order in which CodeListItems occur
  - E.g. In an oncology study looking for location metastases using the CDISC NCI CT codelist LOC

```
<CodeList SASFormatName="$LOC" OID="CL.LOC" Name="Anatomical Location" DataType="text">
  <CodeListItem CodedValue="C12664" mdsol:OrderNumber="3">
    <Decode>
      <TranslatedText>Abdominal Cavity</TranslatedText>
    </Decode>
  </CodeListItem>
  <CodeListItem CodedValue="C52758" mdsol:OrderNumber="1">>
    <Decode>
      <TranslatedText>Abdominal Skin</TranslatedText>
    </Decode>
  </CodeListItem>
  <CodeListItem CodedValue="C32042" mdsol:OrderNumber="2">>
    <Decode>
      <TranslatedText>Acetabulum</TranslatedText>
    </Decode>
  </CodeListItem>
```

Adding validation

EDC systems have a concept of Timing for Study Events, such as when a visit should be available for entry.

ODM doesn't have the workflow elements

- SDM is intended to cover that.

We extend the StudyEvent to include timing elements.

```
<StudyEventDef OID="SE.RUNIN" Name="2 (Five Days Post-Scr)" mdsol:AccessDays="10" mdsol:TargetDays="5"
mdsol:StartWinDays="10" mdsol:TargetDays="5" mdsol:OverDueDays="10" mdsol:CloseDays="20"
Repeating="No" Type="Scheduled" Category="Run-in"/>
  <FormRef FormOID="F.VISIT" OrderNumber="1" Mandatory="Yes"/>
  <FormRef FormOID="F.IE" OrderNumber="2" Mandatory="Yes"/>
</StudyEventDef>
```

Interfacing with other systems

- Using a globally unique subject identifier key to the SubjectData
  - In many downstream this is used to link auxiliary data (eg imaging data) to a Subject
    - Often a combination of Site Code and Subject Code, or Subject Name (Entered Demographic or Contextual Data).
  - For a long-running study using a GUID to refer to a Subject is more consistent; Subject movement is no longer a factor in this case.

```
<SubjectData SubjectKey="85E08788-CBF3-4F31-B7C1-D430B87AAC9A" mdsol:SubjectKeyType="SubjectUUID"/>
  <StudyEventData StudyEventOID="SE.VIS001">
    ..
  </StudyEventData>
</SubjectData>
```

Interfacing with other systems - cont

Opening a Query on a DataPoint

With a flow of messages (ODM) to and from the EDC system there is a use case for an external system to ask the EDC to show a data query, e.g. CTMS system shows a different date of birth for a subject

Raise the data query as a ODM message and send it to the EDC system:

```
<SubjectData SubjectKey="85E08788-CBF3-4F31-B7C1-D430B87AAC9A" mdsol:SubjectKeyType="SubjectUUID"/>
  <StudyEventData StudyEventOID="SE.VIS001">
    <FormData FormOID="F.DEMO.01">
      <ItemGroupData ItemGroupOID="IG.DEMO.01">
        <ItemDataDate ItemOID="I.BIRTHDT" Value="1976-05-01" TransactionType="Context">
          <mdsol:Query Recipient="Site from CRA" Value="Analyse the birth date value" Status="Open"/>
        </ItemDataDate>
      </ItemGroupData>
    </FormData>
  </StudyEventData>
</SubjectData>
```

The future of the ODM - CDISC

If you use the ODM, you might have an opinion on how it can be improved

CDISC are intending to start a call for features towards the end of the year

- see Jozef Aerts's talk from the CDISC EU Interchange

Using a ODM-like language to move Datasets around

- As a possible replacement for SAS XPT v5 for Submissions to the FDA – See Jozef's talk at CDISC EU
- Check out the CDISC XML Technologies Group in LinkedIn

Summary

We believe in supporting standards through ongoing usage, advocacy and involvement

The ODM serves as an excellent mode for transferring and archiving clinical data

Extensions serve as an acceptable way to add business value to the ODM without deprecating the inherent value of the original model

Any Questions?

The nicest thing about standards is that there are so many of them to choose from—Ken Olsen