ODM seeks SDTM - The missing link revisited

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ODM seeks SDM
For quality long-term interchange.
The missing link

- ODM Study Design -> EDC system (oper.database)
- Data collection -> Operational Database
- Operational database -> ODM export
- Generation of submission data (SDTM)
If life were perfect ...

- One question on CRF: one SDTM field
- SDTM codelist used in CRF
- Only answers in English

- But life isn't perfect ...
SDTM starts at study design (think SDTM, write ODM)

• Use ODM for study design (tools available)

• Annotate questions with SDTM information (SDSVarName attr. on ItemDef)

• Set up operational database / EDC system from ODM

• Annotate (sub)forms with Domain information (Domain attribute on ItemGroupDef)

```xml
<ItemDef OID="IT.AECONTRT" Name="Actions taken, other" DataType="text"
  SDSVarName="AEACNOTH">
  <CodeListRef CodeListOID="CL.AECONTR" />
</ItemDef>
```
**Think SDTM, write ODM**

- Use CDASH forms if possible
- Use CDISC Controlled Terminology if possible
- Invest in Localization (translations) of CDISC Controlled Terminology
- Think about future mapping problems when designing the study
  - Data types
  - Codelists
  - ...
Use CDASH forms if possible

**Group: Adverse events**

Has the subject experienced any adverse events* 

- Yes

**Group: Adverse events**

Event No. * 

- 1

Adverse event* 

- Headache

Start Date* 

- 2007-09-16

Is the adverse event still continuing 

- Yes

Was event serious* 

- No

Is there a reasonable possibility that the AE may have been caused by the study drug* 

- Yes

Action taken with study drug* 

- Study drug regimen changed

Subject outcome* 

- Subject remains in study
Use CDISC CT as ODM / define.xml Codelists

<!--[-- Vital Signs Test Codes, Source: CDISC Controlled Terminology SDTM Package-1 and Lab Test Terms Final, June 2007 -->

- <CodeList OID="CL.VSTESTCD" Name="Vital Signs Test Code" DataType="text">
  - <CodeListItem CodedValue="BMI">
    - <Decode>
      <TranslatedText xml:lang="en">Body Mass Index</TranslatedText>
    </Decode>
  </CodeListItem>
  - <CodeListItem CodedValue="BODYFAT">
    - <Decode>
      <TranslatedText xml:lang="en">Adipose Tissue</TranslatedText>
    </Decode>
  </CodeListItem>
  - <CodeListItem CodedValue="BSA">
    - <Decode>
      <TranslatedText xml:lang="en">Body Surface Area</TranslatedText>
    </Decode>
  </CodeListItem>
  - <CodeListItem CodedValue="DIABP">
    - <Decode>
      <TranslatedText xml:lang="en">Diastolic Blood Pressure</TranslatedText>
    </Decode>
  </CodeListItem>
  - <CodeListItem CodedValue="FRMSIZE">
    - <Decode>
      <TranslatedText xml:lang="en">Body Frame Size</TranslatedText>
    </Decode>
  </CodeListItem>
</CodeList>
Invest in translations of CT in multi-language studies
From operational data (ODM) to SDTM records

New software tool available:

SDTM-ETL™
SDTM-ETL: drag-and-drop
With many wizards

<table>
<thead>
<tr>
<th>ODM CodeList Item</th>
<th>SDTM CodeList Item</th>
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<tbody>
<tr>
<td>1 - Mild</td>
<td>MILD - MILD</td>
</tr>
<tr>
<td>2 - Moderate</td>
<td>MILD - MILD</td>
</tr>
<tr>
<td>3 - Severe</td>
<td>MILD - MILD</td>
</tr>
<tr>
<td>4 - Life Threatening</td>
<td>MODERATE - MODERATE</td>
</tr>
<tr>
<td>MISSING/INVALID VALUE</td>
<td>SEVERE - SEVERE</td>
</tr>
<tr>
<td></td>
<td>MISSING VALUE</td>
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And an easy-to-learn scripting language

The Transformation Script

```plaintext
$BIRTHDATE = xpath(/StudyEventData[@StudyEventOID='SE.VISITO']/FormData[@FormOID='FORM.DEMOG']/ItemGroup
# Date of first visit (reference date)
$VISITDATE = xpath(/StudyEventData[@StudyEventOID='SE.VISITO']/FormData[@FormOID='FORM.VISIT']/ItemGroup
# Get the difference between the dates as a number of days
# datediff gives the date difference as number of days
$AGEDAYS = datediff($VISITDATE,$BIRTHDATE) ;
# the floor function transforms to an integer
$AGE = floor($AGEDAYS / 365.2);
```

Scripting Language Functions

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<thead>
<tr>
<th>+</th>
<th>-</th>
<th>*</th>
<th>/</th>
<th>xpath</th>
<th>usubjid</th>
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Features of the SDTM-ETL software

- All scripts stored in the define.xml structure / file
- Define.xml in sync with the mapping and SDTM records
- Contains latest CDISC SDTM Controlled Terminology
- SDTM “CDISC Notes” implemented ("Help")
- Mapping can be tested during development
SDTM-ETL: output

- SDTM records in XML format
- SDTM records in SAS Transport format
  - Automatic creation of SUPPQUAL when necessary
- define.xml in sync with SDTM records
- SQL “Create Table” statements
  - For generation of SDTM database / datawarehouse
- SQL “Insert” statements
  - For population of SDTM database / datawarehouse
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**SAS System Viewer - [PE.xpt]**

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Ready

Hdn cols:0  Obs 1-273 of 273  NUM
Best practices

- Use a study design tool that is based on, or at least exports in ODM

- Annotate your ODM Forms with SDTM
  - ItemGroupDef : **Domain**
  - ItemDef : **SDSVarName**
    - **Alias**

- Keep a repository of forms, subforms, questions, codelists in ODM format

- Select only EDC vendors that import/export ODM
  - Is your EDC Vendor ODM Certified?
Best practices

- Try to use CDISC Controlled Terminology as much as possible / reasonable
  - Also in your (e)CRFs

- Train your people in SDTM

- Start your mapping before database closing
The future

- SDTM *and* ADaM in XML
- define.xml 1.1
- No more SAS Transport ...
- SDTM, ADaM and define.xml all speak the same language
- Submit CRFs to FDA as ODM
ODM seeks SDTM?
Update to:

Think SDTM – Write ODM