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 codelists used in CRF

- Only answers in English

- But life isn't perfect ...

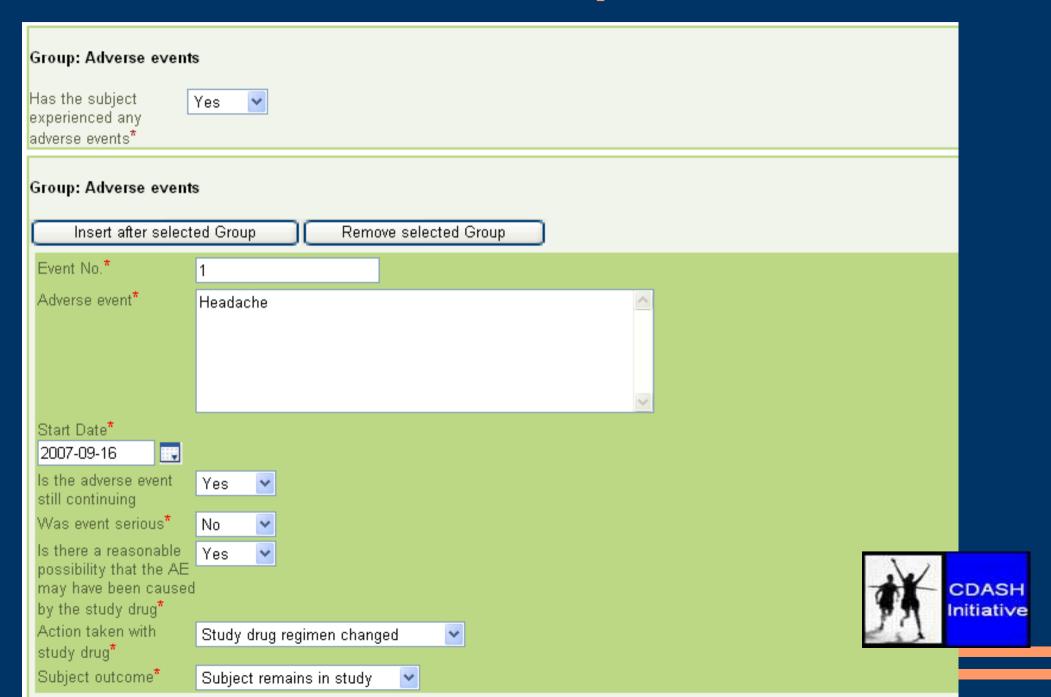# SDTM starts at study design (think SDTM, write ODM)

- 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

[Insert after selected Group]   [Remove selected Group]

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 ▾]

CDASH Initiative

Use CDISC CT as ODM / define.xml Codelists

```xml
<!-- 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>
```

Invest in translations of CT in multi-language studies

```xml
- <CodeList OID="CL.AEREL" Name="AE Relationship to Study Drug" DataType="text" SASFormatName="AEREL">
  - <CodeListItem CodedValue="0">
    - <Decode>
        <TranslatedText xml:lang="en">None</TranslatedText>
        <TranslatedText xml:lang="de">Keine</TranslatedText>
        <TranslatedText xml:lang="fr">Aucun</TranslatedText>
      </Decode>
    </CodeListItem>
  - <CodeListItem CodedValue="1">
    - <Decode>
        <TranslatedText xml:lang="en">Unlikely</TranslatedText>
        <TranslatedText xml:lang="de">Unwahrscheinlich</TranslatedText>
        <TranslatedText xml:lang="fr">Peu probable</TranslatedText>
      </Decode>
    </CodeListItem>
  - <CodeListItem CodedValue="2">
    - <Decode>
        <TranslatedText xml:lang="en">Possible</TranslatedText>
        <TranslatedText xml:lang="de">Möglich</TranslatedText>
        <TranslatedText xml:lang="fr">Possible</TranslatedText>
      </Decode>
    </CodeListItem>
  - <CodeListItem CodedValue="3">
    - <Decode>
        <TranslatedText xml:lang="en">Probable</TranslatedText>
        <TranslatedText xml:lang="de">Wahrscheinlich</TranslatedText>
        <TranslatedText xml:lang="fr">Probable</TranslatedText>
      </Decode>
    </CodeListItem>
</CodeList>
```
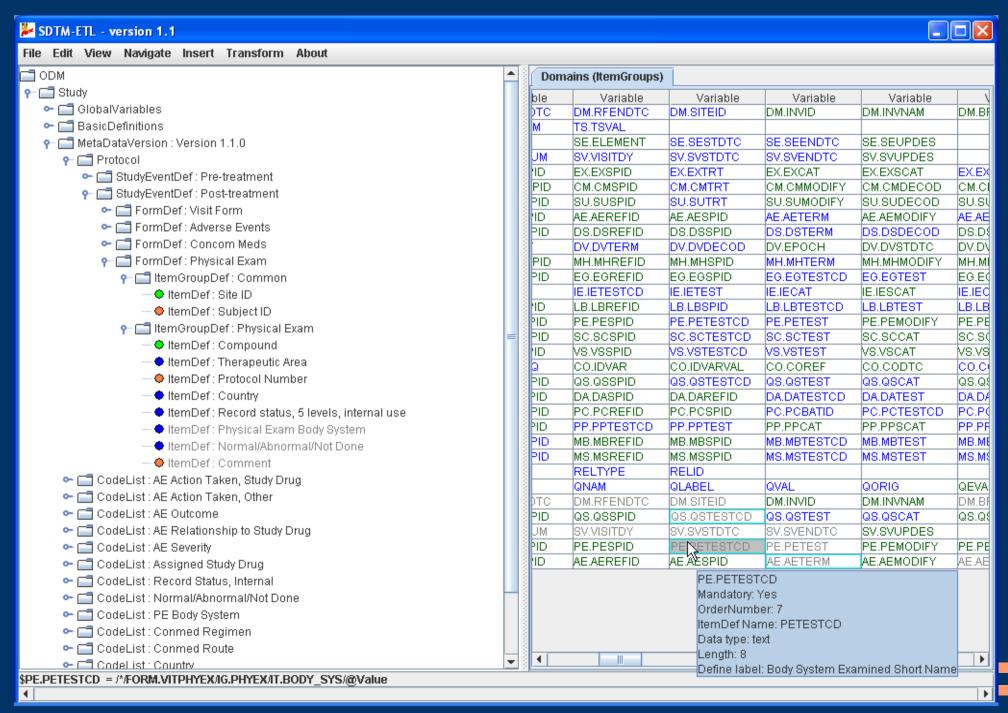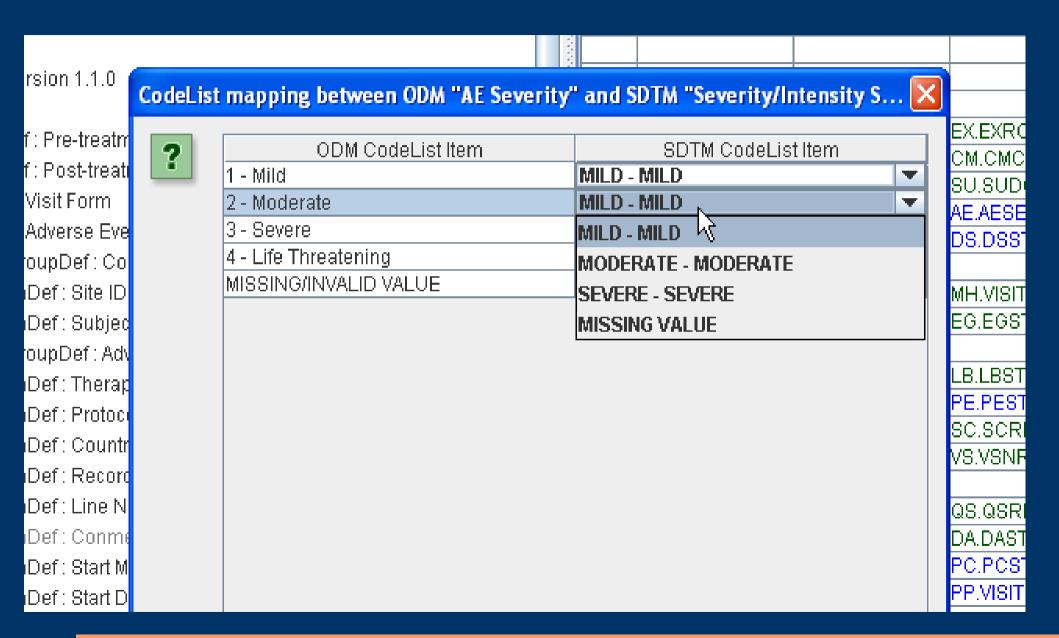
From operational data (ODM) to SDTM records

New software tool available:

SDTM-ETL™

SDTM-ETL : drag-and-drop

With many wizards

And an easy-to-learn scripting language

The Transformation Script

```
$BIRTHDATE = xpath(/StudyEventData[@StudyEventOID='SE.VISIT0']/FormData[@FormOID='FORM.DEMOG']/ItemGrou
# Date of first visit (reference date)
$VISITDATE = xpath(/StudyEventData[@StudyEventOID='SE.VISIT0']/FormData[@FormOID='FORM.VISIT']/ItemGrou
# 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

+	-	*	/		
xpath	usubjid	investigator	site		
substring	substring-before	substring-after	concat	string-length	replace
if	elsif	else	trim	upper-case	lower-case
<	>	<=	>=	==	!=

Test - Transform to XSLT

Features of the SDTM-ETL software

- All scripts stored in the define.xml structure / file

- Define.xml in sync with the mapping <u>and</u> 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

SDTM Tables

(i)

| | MyStudy:DM | MyStudy:QS | MyStudy:SV | MyStudy:PE | MyStudy:AE | MyStudy:SUPPPE |

STUDYID	DOMAIN	USUBJID	SUBJID	DM.RFSTDTC	DM.RFENDTC	DM.S
MyStudy	DM	001		2006-04-01	2006-05-12	LOC.site0
MyStudy	DM	002		2006-04-02	2006-05-02	LOC.site0
MyStudy	DM	003		2006-04-03	2006-05-03	LOC.site0
MyStudy	DM	004		2006-04-04	2006-05-04	LOC.site0
MyStudy	DM	005		2006-04-04	2006-05-05	LOC.site0
MyStudy	DM	006		2006-04-06	2006-05-06	LOC.site0
MyStudy	DM					
MyStudy	DM					
MyStudy	DM					
MyStudy	DM					
MyStudy	DM					
MyStudy	DM					
MyStudy	DM					

SAS System Viewer - [PE.xpt]

File **Edit** **View** **Window** **Help**

	STUDYID	DOMAIN	USUBJID	PESEQ	PETESTCD	PETEST	PEORRES	PESTAT	PE
1	MyStudy	PE	001	1	1	Head, Ne	Normal	.	.
2	MyStudy	PE	001	2	2	Eyes, Ea	Normal	.	.
3	MyStudy	PE	001	3	3	Chest	Normal	.	.
4	MyStudy	PE	001	4	4	Lungs	Abnormal	.	.
5	MyStudy	PE	001	5	5	Heart	Abnormal	.	.
6	MyStudy	PE	001	6	6	Lymph No	Abnormal	.	.
7	MyStudy	PE	001	7	7	Abdomen	Normal	.	.
8	MyStudy	PE	001	8	8	Anorecta	Not Done	NOT DONE	The
9	MyStudy	PE	001	9	9	Genitali	Normal	.	.
10	MyStudy	PE	001	10	10	Skin	Abnormal	.	.
11	MyStudy	PE	001	11	11	Musculos	Normal	.	.
12	MyStudy	PE	001	12	12	Neurolog	Normal	.	.
13	MyStudy	PE	001	13	13	Other	Normal	.	.

Ready   Hdn cols:0   Obs 1-273 of 273   NUM

OK

OK

$DM.AGE = $A

OK

USUBJID	CM.CMSEQ	CM.CMGRPID	CM.CMSPID
USUBJID	SU.SUSEQ	SU.SUGRPID	SU.SUSPID
USUBJID	AE.AESEQ	AE.AEGRPID	AE.AEREFID
USUBJID	DS.DSSEQ	DS.DSGRPID	DS.DSREFID
USUBJID	DV.DVSEQ	DV.DVCAT	DV.DVTERM
USUBJID	MH.MHSEQ	MH.MHGRPID	MH.MHREFID
USUBJID	EG.EGSEQ	EG.EGGRPID	EG.EGREFID
USUBJID	IE.IESEQ	IE.IESPID	IE.IETESTCD

SDTM Standard

<ODM>
metadata

Study
<define.xml>

SDTM-ETL™

<ODM>
clinical data

EDC / CDM
System

<SDTM>
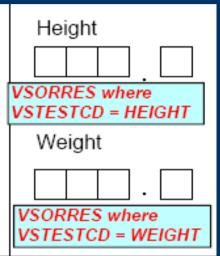datasets

SDTM
Database

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