



CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

The future of ODM

*The CDISC Vision is to Inform Patient Care & Safety
Through Higher Quality Medical Research*

Strength through Collaboration

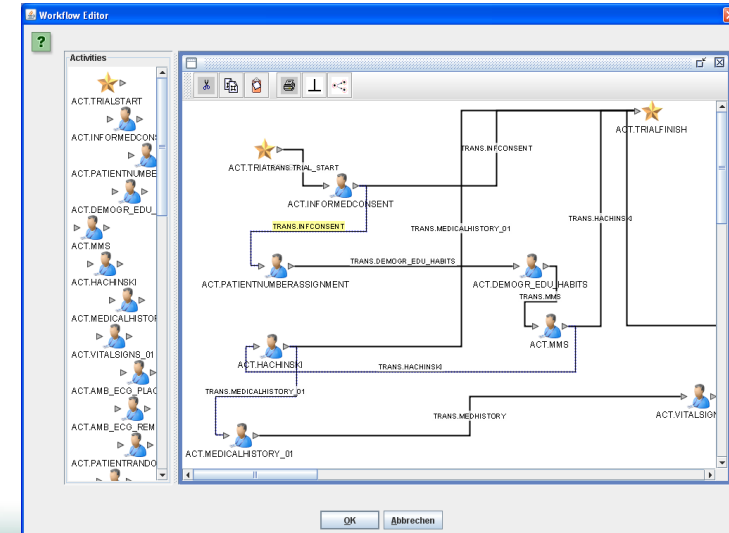
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History of the ODM Standard

- ODM = Operational Data Model
 - XML-based standard for design, exchange, and archival of clinical study information
 - v.1.0: 2000
 - v.1.1: 2002
 - v.1.2: 2004
 - v.1.2.1: 2005
 - v.1.3: 2006
 - v.1.3.1: 2010
- XML-Schema
minor update
i18n, typed ItemData
minor update

Extensions to the ODM Standard

- Define.xml v.1.0 (2005)
 - Metadata for electronic submissions to the FDA (SDTM, SEND, ADaM content)
- Study Design in XML (SDM-XML, 2011)
 - IE criteria, trial parameters, activities, workflows
- Many other extensions by vendors



Some vendors topics on the wishlist for a next version

- Measurement units interconversion
- Multi-select questions /codelists ("select all that apply")
- Recursive ItemGroups ("ItemGroup within ItemGroup")
- Better support for non-visit data (StudyEventData too limited in scope)
- Support for data that is not in forms
- **United language for formal expressions**

Jozef's wishlist for a next version

- Better integration with healthcare
- Integration of SDM-XML into core ODM
- Subactivities and subworkflows in SDM-XML
- Better support for chaining of file (XInclude?)

Better integration with healthcare

- Example: HL7-CDA/CCD (Electronic Health Record)

```
<entry typeCode="DRIV">
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.9.2"/>
    <code code="3137-7" codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LN" displayName="BODY HEIGHT:"/>
    <effectiveTime value="201207190946"/>
    <value xsi:type="PQ" value="193" unit="cm"/>
  </observation>
</entry>
<entry typeCode="DRIV">
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.9.2"/>
    <code code="11378-7" codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LN" displayName="SYSTOLIC BLOOD PRESSURE"/>
    <effectiveTime value="201207190952"/>
    <value xsi:type="PQ" value="131" unit="mm[Hg]"/>
  </observation>
</entry>
```

LOINC
code

Object Identifier (OID)

Better integration with healthcare

- HL7-CDA data points can already be incorporated into ODM documents

```
- <FormData FormOID="F_WEEK_1_2">
- <ItemGroupData ItemGroupOID="IG_COMMON">
  <ItemData ItemOID="I_SITE" Value="23" />
  <ItemData ItemOID="I_SUBJECTID" Value="001" />
  <ItemData ItemOID="I_VISIT" Value="2010-03-13" />
  <ItemData ItemOID="I_VISITTIME" Value="09:12:28" />
</ItemGroupData>
<!-- Demonstration of the capability of ODM to include data points from EHRs -->
- <ItemGroupData ItemGroupOID="IG_PE_WEEK">
- <ItemData ItemOID="I_HEIGHT" Value="193">
  <MeasurementUnitRef MeasurementUnitOID="MU_CM" />
- <cda:observation classCode="OBS" moodCode="EVN">
  <cda:templateId root="2.16.840.1.113883.10.20.1.31" />
  <!-- Result observation template -->
  <cda:id root="d11275e1-67ae-11db-bd13-0800200c9a66" />
  <cda:code code="50373000" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED-CT"
    displayName="Body height" />
  <cda:statusCode code="completed" />
  <cda:effectiveTime value="20100313" />
  <cda:value xsi:type="PQ" value="193" unit="cm" />
</cda:observation>
</ItemData>
```



Better integration with healthcare

- Usage of Healthcare OIDs

```
+ <CodeList DataType="text" Name="Sex" OID="CL_SEX" SASFormatName="$SEX">  
+ <CodeList DataType="text" Name="Race" OID="CL_RACE" SASFormatName="$RACE">  
+ <CodeList DataType="text" Name="Smoking" OID="CL_SMOKING" SASFormatName="$SMOKE">  
  <ExternalCodeList Dictionary="LOINC" DictionaryOID="2.16.840.1.113883.6.1" href="http://loinc.org/" />
```

- Also integrates very well with FDA's SPL
(Structured Product Labeling)

Better integration with healthcare

- Support for UCUM units

```

- <BasicDefinitions>
- <MeasurementUnit Name="mm Hg" OID="MU_MMHG" UCUM="mm[Hg]">
  - <Symbol>
    <TranslatedText xml:lang="en">mm Hg</TranslatedText>
    <TranslatedText xml:lang="fr">mm Hg</TranslatedText>
    <TranslatedText xml:lang="de">mm Hg</TranslatedText>
    <TranslatedText xml:lang="ko">밀리미터 수은</TranslatedText>
  </Symbol>
</MeasurementUnit>
- <MeasurementUnit Name="Pounds" OID="MU_POUNDS" UCUM="[lb_av]">
+ <Symbol>
</MeasurementUnit>
- <MeasurementUnit Name="Inches" OID="MU_INCHES" UCUM="[in_us]">
+ <Symbol>
</MeasurementUnit>
- <MeasurementUnit Name="Centimeters" OID="MU_CM" UCUM="cm">
+ <Symbol>
</MeasurementUnit>
- <MeasurementUnit Name="Kilograms" OID="MU_KG" UCUM="kg">
+ <Symbol>
</MeasurementUnit>

```



- Also integrates very well with FDA's SPL (Structured Product Labeling)

Better integration with healthcare

More precise definition of tests

```
<ItemDef OID="IT.GLUCOSE" Name="Glucose" DataType="float" Length="8" SignificantDigits="2">
  <!-- Which Glucose Test ? -->
</ItemDef>
<ItemDef OID="IT.BILI" Name="Bilirubin" DataType="float" Length="8" SignificantDigits="2">
  <!-- Which Bilirubin Test ? -->
</ItemDef>
```

- Which glucose test, which bilirubin test?
- RTFP?
- We want to be ODM the protocol!

Better integration with healthcare

Which bilirubin test?

Property measured	Timing aspect	Sample type	Scale	Description	LOINC code
Substance concentration	Spot	Ser/Plas	Quantitative	Bilirubin in Serum /Plasma, Substance Concentration	146316-6
Mass concentration	Spot	Body fluid	Quantitative	Bilirubin in Body Fluid, Mass concentration	1974-5
Mass concentration	Spot	Ser/Plas	Quantitative	Bilirubin in Serum/Plasma, Mass Concentration	1975-2
Arbitrary Concentration	Spot	Urine	Ordinal	Bilirubin in Urine, Arbitrary Concentration, Ordinal	1977-8
Substance concentration	Spot	Body fluid	Quantitative	Bilirubin in Body Fluid Substance Concentration	29767-1

Example Glucose

- CDISC-CT: Plasma Glucose Measurement (NCI C41376)
- There are 5 such, but different tests!

```
- <ItemDef OID="IT.GLU" Name="Glucose" DataType="float" Length="8" SignificantDigits="2"
  code="14749-6" codeSystem="2.16.840.1.113883.6.1">
  <!-- Glucose SerPl-sCnc -->
</ItemDef>
```

- Example Bilirubin - alternative using "Alias"

```
- <ItemDef OID="IT.BILI" Name="Bilirubin" DataType="float" Length="8" SignificantDigits="2">
  <Alias Context="LOINC" Name="14749-6" />
</ItemDef>
```

- Or combined

```
- <ItemDef OID="IT.BILI" Name="Bilirubin" DataType="float" Length="8" SignificantDigits="2">
  <Alias Context="LOINC" ContextCodeSystem="2.16.840.1.113883.6.1" Name="14749-6" />
</ItemDef>
```

SDTM in XML

- ODM is transport format for clinical data
- Is SDTM clinical data?
- Yes => why not use ODM for transport?

- Format developed 5 years ago by the ODM team but rejected by the FDA
 - "we want an HL7-v3 message" - integrates better with healthcare

If we use the same truck for cows
and for oranges, we can breed
cows that produce orange juice

SDTM in XML - 5 year later

- The HL7-v3 message still isn't there
- Nov 5th 2012: FDA Public Meeting on Transport Standards => most stakeholders for ODM-based format
- Start of 2013: resurrection of CDISC team
- April 2013: first prototype consensus format

SDTM in XML - Advantages

- 8-, 40- and 200-character limitations disappear (and all other limitations of SAS-Transport 5)
- Supplemental qualifiers can stay where they belong (in the parent domain)
- Easy validation against define.xml (just use the ODM validation)
- Toolmakers know ODM => Rapid development of new software tools

Smart SDTM-XML Viewer

- Reads SDTM-XML data + define.xml
- Allows fast visualization of SDTM-IG violations and inconsistencies with respect to define.xml
- Shows SUPPQUALS in parent domain
- Rapid navigation between RELREC / CO records and parent records
- Easy filtering and sorting

- Will become open source
- Demo available

Smart SDTM-XML Viewer

Smart SDTM-XML Viewer

Standard: **SDTM**

Define.xml: D:\CDISC\SDTM_in_XMLFiles_from_LZZT_Pil...

AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM
56	YEARS	M	WHITE	HISPANIC ...	Xan_Hi	Xanomelin...
57	YEARS	F	BLACK OR ...	NOT HISPA...	Scrnfail	Screen Fail...
61	YEARS	M	AMERICAN...	NOT HISPA...	Xan_Hi	Xanomelin...
56	YEARS		WHITE	HISPANIC	Xan_Hi	Xanomelin...

STUDYID	CDISCPIL...	AE	CDISCPIL...	AESEQ	CDISCPIL...	CDISCPIL...	CDISCPIL...	CDISCPIL...
	CDISCPIL...	AE	01-701-1302	AESEQ	8			01-701-1302-E16
	CDISCPIL...	AE	01-701-1302	AESEQ	18			01-701-1302-E16
	CDISCPIL...	AE	01-701-1341	AESEQ	5			01-701-1341-E13
	CDISCPIL...	AE	01-701-1444	AESEQ	7			01-701-1444-E16
	CDISCPIL...	AE	01-703-1076	AESEQ	4			01-703-1076-E08
	CDISCPIL...	AE	01-703-1076	AESEQ	7			01-703-1076-E08

Tools

DM AE CM

STUDYID	CDISCPIL...	AE	CDISCPIL...	AESEQ	CDISCPIL...	CDISCPIL...	CDISCPIL...	CDISCPIL...
	CDISCPIL...	AE	01-702-1082	7	E06	RECTAL HAEMORRHAGE	RECTAL BLEEDING	
	CDISCPIL...	AE	01-702-1082	8	E06	RECTAL HAEMORRHAGE	RECTAL BLEEDING	
	CDISCPIL...	AE	01-702-1082	10	E08	SKIN IRRITATION	SKIN IRRITATION	
	CDISCPIL...	AE	01-702-1082	3	E04	URINE ANALYSIS ABNORMAL	URINE ANALYSIS ABNORMAL	
	CDISCPIL...	AE	01-702-1082	4	E04	URINE ANALYSIS ABNORMAL	URINE ANALYSIS ABNORMAL	
	CDISCPIL...	AE	01-702-1082	1	E02	WHITE BLOOD CELL COUNT INC...	WBC INCREASED	
	CDISCPIL...	AE	01-702-1082	5	E02	WHITE BLOOD CELL COUNT INC...	WBC INCREASED	
	CDISCPIL...	AE	01-703-1042	1	E04	DIARRHOEA	DIARRHEA	
	CDISCPIL...	AE	01-703-1042	2	E05	INSOMNIA	INSOMNIA	
	CDISCPIL...	AE	01-703-1076	5	E09	APPLICATION SITE DERMATITIS	APPLICATION SITE RASH	
	CDISCPIL...	AE	01-703-1076	4	E08	APPLICATION SITE PRURITUS	APPLICATION SITE ITCHING	
	CDISCPIL...	AE	01-703-1076	7	E08	APPLICATION SITE PRURITUS	APPLICATION SITE ITCHING	
	CDISCPIL...	AE	01-703-1076	2	E01	BENIGN PROSTATIC HYPERPLA...	BENIGN PROSTATIC HYPERTROPHY	
	CDISCPIL...	AE	01-703-1076	1	E02	BIOPSY PROSTATE	BIOPSY OF PROSTATE	
	CDISCPIL...	AE	01-703-1076	3	E05	HYPERCHOLESTEROLAEMIA	HYPERCHOLESTEROLEMIA	
	CDISCPIL...	AE	01-703-1076	6	E07	HYPERHIDROSIS	SWEATING	

Nachricht

There are 3 related records with RELID '01-703-1076-E08':
Domain = AE - USUBJID = 01-703-1076 - AESEQ = 4

Our projects at the university

- Work on SDTM-XML and "Smart SDTM Viewer"
- Write a few whitepapers ...
- Develop Schematron for ODM 1.3.1
- Encourage / work on integration with healthcare (semantics!)
- Start working on future ODM 1.4
 - User requirements (CDISC community)
 - Some work needed for healthcare integration

Thank you for your
attention!