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CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

The CDISC vision is to inform patient care & safety through higher quality medical research.

Strength *through Collaboration*

A new transport standard for electronic submissions in XML: SDS-XML

Presented by FH-Prof.Dr. Jozef Aerts
University of Applied Sciences FH Joanneum

Graz, Austria

FH | JOANNEUM
University of Applied Sciences

Strength *through Collaboration*

What (the hell) is SDS-XML

- A new transport format for Tabular data, including
  - SDTM
  - SEND
  - ADaM
- SDS = Study Data Set
  - so not "Submission Data Set" as the FDA says
  - but will be used as such

- Based on ODM 1.3.1 and in full alignment with define.xml 2.0

SDS-XML Example

```xml
<?xml version="1.0" encoding="UTF-8"?>
<!-- StudyDataSet-XML: Untyped Data Example (DRAFT version)  -->
<!-- Prepared by Marcelina Hungria / DIcore Group, LLC -->
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3"    xmlns:xlink="http://www.w3.org/1999/xlink"
  xmlns:sds="http://www.cdisc.org/ns/sds/v1.0"    FileType="Snapshot"
  ODMVersion="1.3.2" sds:SDSVersion="1.0" FileOID="www.cdisc.org.Studycdisc01-Define-XML_2.0.0(IG.EX)"
  PriorFileOID="www.cdisc.org.Studycdisc01-Define-XML_2.0.0(IG.CM)"
  Originator="CDISC SDS-XML Team" CreationDateTime="2013-11-13T17:26:14">
  <ClinicalData
    StudyOID="cdisc01"
    MetaDataVersionOID="MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2">
    <!-- Dataset (EX) -->
    <ItemGroupData ItemGroupOID="IG.EX" sds:ItemGroupDataSeq="1">
      <ItemData ItemOID="IT.STUDYID" Value="CDISC01"/>
      <ItemData ItemOID="IT.EX.DOMAIN" Value="EX"/>
      <ItemData ItemOID="IT.USUBJID" Value="CDISC01.100008"/>
      <ItemData ItemOID="IT.EX.EXSEQ" Value="1"/>
      <ItemData ItemOID="IT.EX.EXTRT" Value="Miracle Drug"/>
      <ItemData ItemOID="IT.EX.EXDOSE" Value="10"/>
      <ItemData ItemOID="IT.EX.EXDOSU" Value="mg"/>
      <ItemData ItemOID="IT.EX.EXDOSFRM" Value="TABLET"/>
      <ItemData ItemOID="IT.EX.EXSTDTC" Value="2003-04-29"/>
      <ItemData ItemOID="IT.EX.EXENDTC" Value="2003-05-05"/>
      <ItemData ItemOID="IT.EX.EXSTDY" Value="1"/>
      <ItemData ItemOID="IT.EX.EXENDY" Value="7"/>
    </ItemGroupData>
```

ItemGroupData under ClinicalData

sds:ItemGroupDataSeq

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SDS-XML Advantages

Next 30 slides …

But will limit to the most important ones

- Really vendor neutral
  - Did you ever try to generate Java/C#/C++ software for reading or writing SAS-XPT?

- Modern transport format => huge opportunities

- No more XPT limitations
  - we get rid of 8-, 40-, and 200-character limitations

- SUPPQUALs can stay where they belong: in the parent domain
  - Flagged as such in the define.xml

- Easy validation against define.xml
  - same technology as for ODM

SDS-XML Disadvantages (?)

- File size ? Or is that a Myth?

	XPT	CSV	SDS-XML	SDS-XML (SUPPQUAL included)	SDS-XML With SUPPQUAL & zipped
DM	0.11	0.06	0.4	0.4	0.01
SUPPDM	1.0	0.1	0.6		
AE	1.5	0.3	2.0	1.8	0.05
SUPPAE	1.0	0.1	0.7		
VS	23.5	4.8	34.1	35.7	0.07
LB	33.5	8.3	65.0	79.8	1.6
SUPPLB	55.4	7.1	37.3		
QS	33.1	2.0	122.5	122.5	2.3

Updated Pilot LZZT 2013 - file sizes in MB

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Format and file size - does it matter?

- it does not unless you still are using
  a telephone modem …

- Zipping XML files is extremely efficient

- What matters is:

  MEMORY USAGE IN TOOLS!

The Myth of filesize

- Relative <u>**memory usage**</u> for different transport formats
- Assuming that software is correctly designed and implemented …

File format	Relative memory usage
CSV	1.0
XPT	1.0
XML	1.0
Zipped-XML	1.0

Opportunities

- Next 40 slides …

- But I will limit myself to the most important ones …

Audit Trails & Signatures

```xml
<ItemData ItemOID="AE.AESEV" Value="MILD">
    <AuditRecord EditPoint="Monitoring" UsedImputationMethod="Yes">
        <UserRef UserOID="ZBIuser000"/>
        <LocationRef LocationOID="XML4PharmaLocation"/>
        <DateTimeStamp>2013-12-21T11:59:59.9+01:00</DateTimeStamp>
        <ReasonForChange>Originally classified as moderate, then
        corrected to mild as subject had worked the whole day in the
        forest</ReasonForChange>
    </AuditRecord>
    <Signature>
        <UserRef UserOID="XML4Pharmauser000"/>
        <LocationRef LocationOID="XML4PharmaLocation"/>
        <SignatureRef SignatureOID="XML4PharmaSignature000"/>
        <DateTimeStamp>2013-12-31T11:59:59.9+01:00</DateTimeStamp>
    </Signature>
</ItemData>
<ItemData ItemOID="AE.AESER" Value="N"/>
```

Integration with electronic health records (EHRs)

```xml
<ItemGroupData ItemGroupOID="VS">
    <ItemData ItemOID="VS.STUDYID" Value="CDISCPILOT01"/>
    <ItemData ItemOID="VS.DOMAIN" Value="VS"/>
    <ItemData ItemOID="VS.USUBJID" Value="01-701-1015"/>
    <ItemData ItemOID="VS.VSSEQ" Value="2"/>
    <ItemData ItemOID="VS.VSTESTCD" Value="DIABP"/>
    <ItemData ItemOID="VS.VSTEST" Value="Diastolic Blood Pressure"/>
    <ItemData ItemOID="VS.VSPOS" Value="STANDING"/>
    <ItemData ItemOID="VS.VSORRES" Value="83"/>
    <ItemData ItemOID="VS.VSORRESU" Value="mmHg"/>
    <ItemData ItemOID="VS.VSSTRESC" Value="83"/>
    <ItemData ItemOID="VS.VSSTRESN" Value="83"/>
    <ItemData ItemOID="VS.VSSTRESU" Value="mmHg"/>
    <ItemData ItemOID="VS.VISITNUM" Value="1"/>
    <ItemData ItemOID="VS.VISIT" Value="SCREENING 1"/>
    <ItemData ItemOID="VS.VISITDY" Value="-7"/>
    <ItemData ItemOID="VS.VSDTC" Value="2013-12-26"/>
    <ItemData ItemOID="VS.VSDY" Value="-7"/>
    <ItemData ItemOID="VS.VSTPT" Value="AFTER STANDING FOR 1 MINUTE"/>
    <ItemData ItemOID="VS.VSTPTNUM" Value="816"/>
    <ItemData ItemOID="VS.VSELTM" Value="PT1M"/>
    <ItemData ItemOID="VS.VSTPTREF" Value="PATIENT STANDING"/>
    <cda:observation classCode="OBS" moodCode="EVN">
        <cda:id root="E6F45742-BA20-7224-15A0-6D8836E96789"/>
        <cda:code code="8462-4" displayName="Intravascular Diastolic" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC">
            <cda:originalText>
                <cda:reference value="#vitsigtype3"/>
            </cda:originalText>
        </cda:code>
        <cda:text>
            <cda:reference value="#vitsig3"/>
        </cda:text>
        <cda:statusCode code="completed"/>
        <cda:value xsi:type="PQ" value="83" unit="mm[Hg]"/>
    </cda:observation>
</ItemGroupData>
```

A diastolic blood pressure…

Data point from EHR

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The same in detail …

```xml
<ItemData ItemOID="VS.VSTPTREF" Value="PATIENT STANDING"/>
<cda:observation classCode="OBS" moodCode="EVN">
    <cda:id root="E6F45742-BA20-7224-15A0-6D8836E96789"/>
    <cda:code code="8462-4" displayName="Intravascular Diastolic"
    codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC">
        <cda:originalText>
            <cda:reference value="#vitsigtype3"/>
        </cda:originalText>
    </cda:code>
    <cda:text>
        <cda:reference value="#vitsig3"/>
    </cda:text>
    <cda:statusCode code="completed"/>
    <cda:value xsi:type="PQ" value="83" unit="mm[Hg]"/>
</cda:observation>
</ItemGroupData>
```
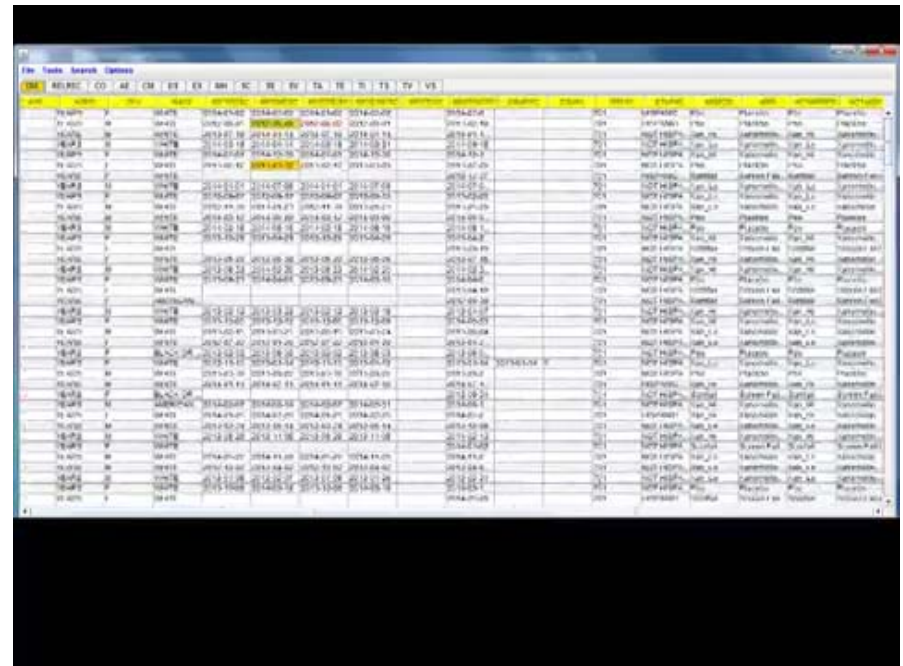
Tools for working with SDS-XML

- XPT2SDSXML
  - transforms XPT datasets into SDS-XML datasets
  - does not take advantage of advantages SDS-XML
  - so <u>don't use if</u> you do not really need to …
- Smart SDS-XML Viewer
  - like the SAS Viewer
  - but much much smarter
- SAS Clinical Standards Toolkit - extension
  - coming …
  - Special thanks to Lex Jansen
- EZ Convert (Sally Cassells)
  - converts SDS-XML files into SAS Datasteps
  - Allows easy import into SAS

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The Smart SDS-XML Viewer

- Open Source (similar to OpenCDISC license)
- For working with define.xml + SDS-XML files
  - also reads zipped SDS-XML
- Understands SDTM, SEND and ADaM

- Freely available at:
  http://sourceforge.net/projects/smart-sds-xml-viewer/
  - Includes a full tutorial

The Smart SDS-XML Viewer

- An introductory movie at:
  - http://www.youtube.com/watch?v=wRBktVtB47s
- And a demo after this meeting if you want…
  (my plane is at 22:00 …)

EZ Convert (Sally Cassells)

- Converts SDS-XML into SAS Datasteps

- Movie available at:
  http://www.youtube.com/watch?v=Xlky6ePfo1I

SDTM-ETL 3.0 now also generates SDS-XML

- My own mapping tool for generation of SDTM datasets from ODM

- v.3.0 supports define.xml 2.0 and SDTM 1.4 (SDTM-IG 3.2)

- Choice between output in SAS-XPT and SDS-XML
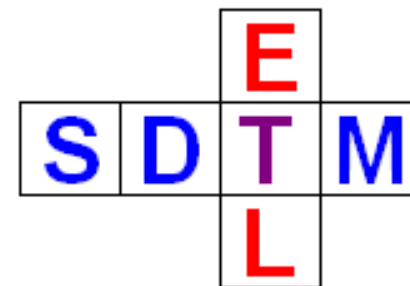
To do …

- Publish final specification

- Convince FDA
  - Get the announced pilot running
  - Make tools available
  - Education and training

  - Integration with FDA data warehouse

- Update OpenCDISC validation tool

Thank you for your attention