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Las Vegas, NV
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Practical Implementation of CDISC for Meta and Clinical Data Interchange

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What is CDISC? – A Brief Refresher

- Clinical Data Interchange Standards Consortium
- www.cdisc.org
- The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.

What is CDISC? – A Brief Refresher

- Acknowledge that the data content, structure and quality of the standard data models are of paramount importance, independent of implementation strategy and platform.
- Accomplish the CDISC goals and mission without promoting any individual vendor or organization.

Some Terminology

- **ODM** - Operational Data Model (V1.3)
 - » Transfer
- **SDTM** - Study Data Tabulation Model (V3.1.1)
 - » Submission
- **CDASH** - Clinical Data Acquisition Standards Harmonization
 - » Collection

Why CDISC Certification?

- To allow data (meta and clinical) to be transferred easily between other certified systems using the ODM.
- The certification provides confidence that the system indeed allows this transfer – accurately and consistently.
- Potentially reduce the time and resources for a study setup.

Certification Process

- In order to ensure consistency across toolsets and interoperability between ODM implementations, the ODM Certification Program has been developed.
- Assero Ltd has been selected as the service provider for the ODM Certification Program, as a result of an open RFP process. (www.assero.co.uk).
- Before a site visit from Assero sample extract files were sent for an informal check, with a day's off site preparation.

Certification Process

- Exhaustive on site tests were then conducted over a 2 day period. A number of test files are used, some of which are designed to fail !!
- Certification is completed off site.
- This process is repeated as necessary to obtain certification.

Types of Certification

- **ODM Data Import**
 - Snapshot
 - Meta Data
 - Data
 - Transactional
 - Meta Data
 - Data
- **ODM Data Export**
 - Snapshot
 - Meta Data
 - Data
 - Transactional
 - Meta Data
 - Data

The Difference?

- Basically Transactional includes the audit history, and is probably best suited for conversion to SDTM.
- To date four vendors have achieved certification – none in all areas.

The cost?

- Will depend on the type and size of the organization.
- Initial evaluation \$4,800 plus expenses.
- Additional evaluations are \$2,400 plus expenses.
- CDISC charges for 100-499 employees \$5,000
- CDISC discounts are available for qualifying organizations.
- Resources to modify existing tools to handle ODM requirements.

The reward ?

- Allows the vendor to provide a better quality verified product.
- Provides interoperability assurance.
- Prevent rework or redevelopment of ODM tools to suit different customers.
- Confidence of interoperability with certified partners.
- Get to use the Certification Logo.

How we did it

- **The following slides show examples of the interface to import an ODM file.**
- **While they look simple, a significant programming effort went into the functionality behind the screens.**
- **Do not under estimate the effort required and pay attention to error handling.**

ODM Meta Data Mapping

Microsoft Excel - ODM-EDM-Mapping

File Edit View Insert Format Tools Data Window Live Meeting Help Adobe PDF

Type a question for help

Arial 10

Meet Now User Preferences... Live Meeting Help

	A	B	C	D	E	F
1	XML Element	Tag/Attribute	Required in ODM	Table Name	Column Name	Columns required in EDM, do not exist in ODM and default values
2	Study	Globalvariables				
3	Study	BasicDefinitions				
4	Study	MetadataVersion				
5	Globalvariables	StudyName	Y	PRJ_DEFN	S_DESCR	SCTRY, DRUG, TAREA, PRJDIR
6	Globalvariables	StudyDescription	Y		L_DESCR	
7	Globalvariables	ProtocolName	Y		PNO	
8	BasicDefinitions	MeasurementUnit				
9	MeasurementUnit	Symbol				
10	Symbol	TranslatedText				
11	Study	MetadataVersion				
12	MetaDataVersion	OID	Y			
13		Name	Y			
14		Description				
15						
16						
17						
18	StudyEventRef	StudyEventOID	Y	EVN_DEFN	EVENT_ID	ABS_D.
19		OrderNumber			SEQ_NO	
20		Mandatory (Yes No)	Y			
21		CollectionExceptionConditionOID				
22						
23	StudyEventDef	OID	Y	EVN_PAGE	EVENT_ID	
24		Name = VISIT1	Y	EVN_DEFN	DSCR	
25						

ODM Metadata Mapping ODM Clinical Data Mapping Sheet3

Ready

ODM Clinical Data Mapping

Microsoft Excel - ODM-EDM-Mapping

File Edit View Insert Format Tools Data Window Live Meeting Help Adobe PDF

Meet Now User Preferences... Live Meeting Help

	A	B	C	D	E	F
	XML Element	Tag/Attribute	Required in ODM	Table Name	Column Name	Columns required in EDM, do not exist in ODM and default values
1						
2						
3	ClinicalData	StudyOID	Y	All Clinical Data Tables - RCR_D_%	PNO	REC_ID = From Recid sequence F_STATUS = 'V' DRUG, TAREA, SCTRY, CNO, B_STATUS = '00'
4		MetaDataVersionOID	Y			
5						
6						
7	SubjectData	SubjectKey	Y	All Clinical Data Tables - RCR_D_%	PATNO	
8		TransactionType (Insert Update Remove Upsert Context)				
9						
10						
11						
12	StudyEventData	StudyEventOID	Y	All Clinical Data Tables - RCR_D_%	EVENT_ID	
13		StudyEventRepeatKey				
14		TransactionType				
15						
16						
17	FormData	FormOID	Y	All Clinical Data Tables - RCR_D_%	PAG_NAME	
18		FormRepeatKey				

ODM Metadata Mapping ODM Clinical Data Mapping Sheet3

Ready

Sample ODM Test File

```
C:\Documents and Settings\Invivian\Local Settings\Temp\wz453a\eRT\SET23\T_023_030.xml - Microsoft Internet Explorer
File Edit View Favorites Tools Help Links >>

<?xml version="1.0" encoding="UTF-8" ?>
- <!--

ODMTest: CDISC ODM Test Suite, (c) Assero Limited, 2004

Test Set: 009 - Version 1.2 (schema) and V1.2.1, Full Example
Test Item: 020
Description: Contains the Metadata only for the example study.
Result: No errors in file.

($Revision: 2 $)

-->
- <ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" xmlns:ds="http://www.w3.org/2000/09/xmldsig#"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:ert="http://www.ert.com/ns/odm/schema"
  xsi:schemaLocation="http://www.cdisc.org/ns/odm/v1.3 eRT.xsd" FileOID="ODMTest_009_020" FileType="Snapshot"
  Granularity="Metadata" CreationDateTime="2005-05-01T12:00:00+01:00">
- <!--

This file contains a single trial, both the Metadata for that trial and the data.

-->
- <Study OID="ODMTest.Trial.001">
- <!--

Basic information about the trial.

-->
- <GlobalVariables>
  <StudyName>ODMTest Trial 001</StudyName>
  <StudyDescription>A trial to demonstrate the application of the CDISC ODM</StudyDescription>
  <ProtocolName>Protocol for ODMTest Trial 001</ProtocolName>
</GlobalVariables>
- <!--

Measurement definitons.

-->
- <BasicDefinitions>
```

Sample ODM Test File

```
C:\Documents and Settings\Invivian\Local Settings\Temp\wz453a\RT\SET23\T_023_030.xml - Microsoft Internet Explorer
File Edit View Favorites Tools Help Links
Study MetaData
-->
- <MetaDataVersion OID="ODMTest_Trial_001.Metadata_V001" Name="ODMTest Trial 001 Metadata">
- <!--
Overall protocol

-->
- <Protocol>
  <StudyEventRef StudyEventOID="SE_DM" Mandatory="Yes" OrderNumber="1" />
  <StudyEventRef StudyEventOID="SE_VT_Initial" Mandatory="Yes" OrderNumber="2" />
  <StudyEventRef StudyEventOID="SE_VT_Subsequent" Mandatory="Yes" OrderNumber="3" />
  <StudyEventRef StudyEventOID="SE_PD" Mandatory="Yes" OrderNumber="4" />
</Protocol>
- <!--

Study Event Definitions

-->
- <StudyEventDef OID="SE_DM" Name="Demographics" Repeating="No" Type="Scheduled">
  <FormRef FormOID="F_DM" Mandatory="Yes" OrderNumber="1" />
</StudyEventDef>
- <StudyEventDef OID="SE_VT_Initial" Name="Vitals" Repeating="No" Type="Scheduled">
  <FormRef FormOID="F_VT_1" Mandatory="Yes" OrderNumber="1" />
  <FormRef FormOID="F_VT_2" Mandatory="Yes" OrderNumber="2" />
</StudyEventDef>
- <StudyEventDef OID="SE_VT_Subsequent" Name="Vitals" Repeating="Yes" Type="Scheduled">
  <FormRef FormOID="F_VT_1" Mandatory="Yes" OrderNumber="1" />
</StudyEventDef>
- <StudyEventDef OID="SE_PD" Name="Patient Diary" Repeating="Yes" Type="Scheduled">
  <FormRef FormOID="F_PD" Mandatory="Yes" OrderNumber="1" />
</StudyEventDef>
- <!--

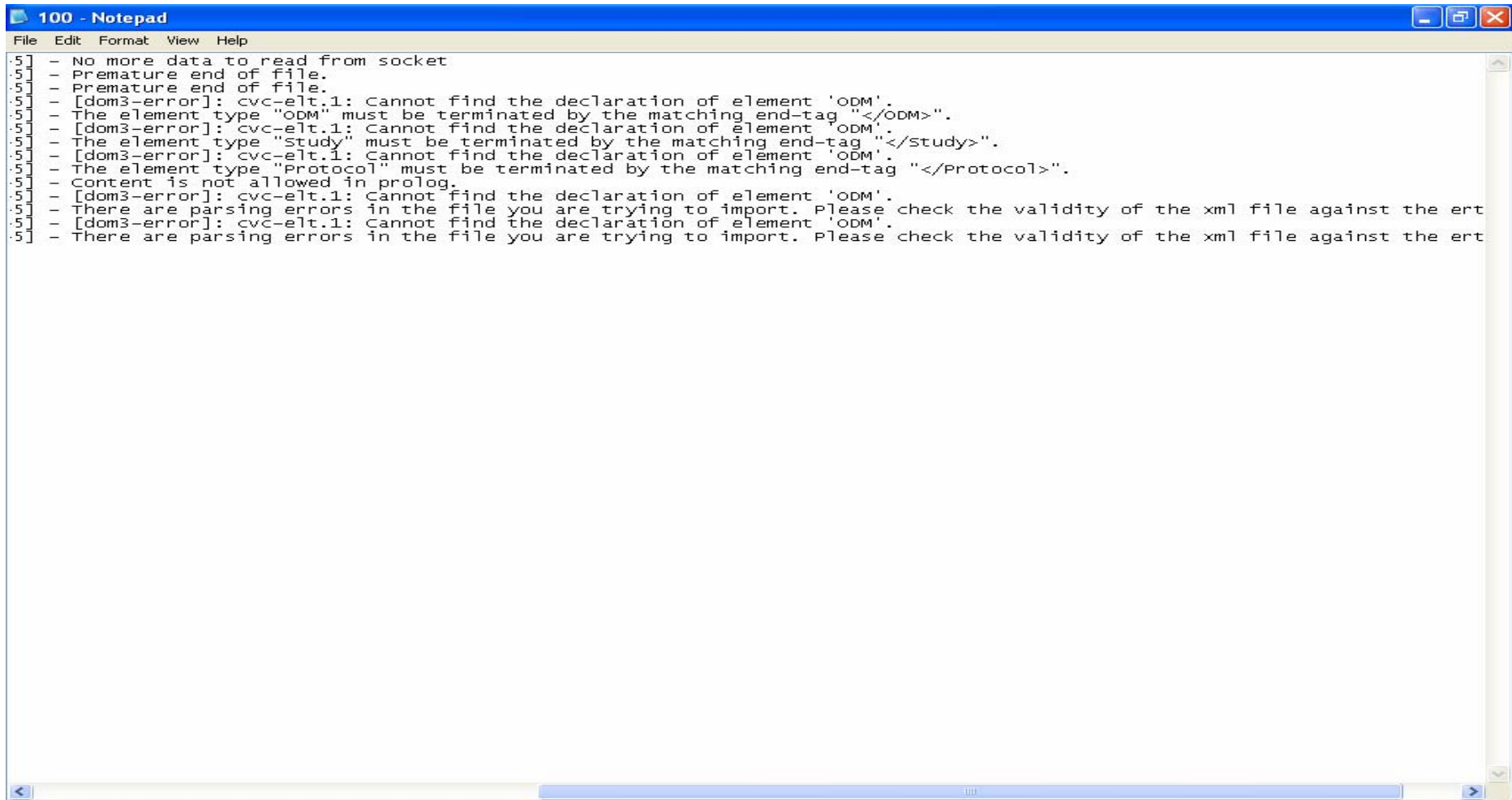
Form Definitions

-->
- <FormDef OID="F_DM" Name="Patient Demographic Information" Repeating="No">
  <ItemGroupRef ItemGroupOID="IG_DM" Mandatory="Yes" OrderNumber="1" />
</FormDef>
- <FormDef OID="F_VT_1" Name="Patient Vital Signs (1)" Repeating="No">
```

Vendor Extensions

```
Z:\CDISC\ODM_PreClinical.xml - Microsoft Internet Explorer
File Edit View Favorites Tools Help
- <ItemGroupDef OID="STENTED_ANALYSIS" Name="Stented Vessel Analysis" Repeating="Yes">
  <ItemRef ItemOID="VESSEL_ANALYSIS" Mandatory="Yes" OrderNumber="1" ert:ScreenControl="Radio Button"
    ert:CodeListPrompt="CD" />
  <ItemRef ItemOID="ANLSLOC1" Mandatory="No" OrderNumber="2" ert:ScreenControl="Radio Button"
    ert:CodeListPrompt="CD" />
  <ItemRef ItemOID="ANLSLOC2" Mandatory="No" OrderNumber="3" ert:ScreenControl="Radio Button"
    ert:CodeListPrompt="CD" />
  <ItemRef ItemOID="ANLSLOC3" Mandatory="No" OrderNumber="4" ert:ScreenControl="Radio Button"
    ert:CodeListPrompt="CD" />
  <ItemRef ItemOID="ANLSLOC4" Mandatory="No" OrderNumber="5" ert:ScreenControl="Radio Button"
    ert:CodeListPrompt="CD" />
  <ItemRef ItemOID="INTERV_COMMENT" Mandatory="No" OrderNumber="6" />
- <ert:CodeSnippets>
- <ert:Derivation ert:Name="INTVCOM1">
  - <ert:TriggerItems>
    <ert:TriggerItem>INTERV_C</ert:TriggerItem>
  </ert:TriggerItems>
  - <ert:TriggerEvents>
    <ert:TriggerEvent>NEW_RECORD</ert:TriggerEvent>
  </ert:TriggerEvents>
  <ert:Text>Sub Main @INTERV_C@ = "N/A" End Sub</ert:Text>
</ert:Derivation>
</ert:CodeSnippets>
</ItemGroupDef>
- <ItemGroupDef OID="STENT_INFO_FOLLOWUP" Name="Stent Information Followup" Repeating="No">
  <ItemRef ItemOID="TIMI_POST" Mandatory="Yes" OrderNumber="1" ert:ScreenControl="Radio Button"
    ert:CodeListPrompt="CD" />
  <ItemRef ItemOID="COMPLICATIONS" Mandatory="Yes" OrderNumber="2" ert:ScreenControl="Radio Button"
    ert:CodeListPrompt="CD" />
  <ItemRef ItemOID="DEVICE_MALFUNCTION" Mandatory="Yes" OrderNumber="3" ert:ScreenControl="Radio Button"
    ert:CodeListPrompt="CD" />
  <ItemRef ItemOID="INTERV_COMMENT" Mandatory="Yes" OrderNumber="4" />
- <ert:CodeSnippets>
- <ert:Derivation ert:Name="INTVCOM2">
  - <ert:TriggerItems>
    <ert:TriggerItem>INTERV_C</ert:TriggerItem>
  </ert:TriggerItems>
  - <ert:TriggerEvents>
    <ert:TriggerEvent>NEW_RECORD</ert:TriggerEvent>
  </ert:TriggerEvents>
  <ert:Text>Sub Main @INTERV_C@ = "N/A" End Sub</ert:Text>
Done Local intranet
```

The Error Log



```
5] - No more data to read from socket
5] - Premature end of file.
5] - Premature end of file.
5] - [dom3-error]: cvc-elt.1: Cannot find the declaration of element 'ODM'.
5] - The element type "ODM" must be terminated by the matching end-tag "</ODM>".
5] - [dom3-error]: cvc-elt.1: Cannot find the declaration of element 'ODM'.
5] - The element type "Study" must be terminated by the matching end-tag "</Study>".
5] - [dom3-error]: cvc-elt.1: Cannot find the declaration of element 'ODM'.
5] - The element type "Protocol" must be terminated by the matching end-tag "</Protocol>".
5] - Content is not allowed in prolog.
5] - [dom3-error]: cvc-elt.1: Cannot find the declaration of element 'ODM'.
5] - There are parsing errors in the file you are trying to import. Please check the validity of the xml file against the ert
5] - [dom3-error]: cvc-elt.1: Cannot find the declaration of element 'ODM'.
5] - There are parsing errors in the file you are trying to import. Please check the validity of the xml file against the ert
```

Using CDISC in an ODM Certified tool

Import CDISC ODM - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites

Address <http://pogo.ert.com/cdiscdemo/LoadODM?TKN=31> Go Links

EXPeRT
Data Management

Import CDISC ODM Exit

Select a study:

Select a file by clicking the browse button.

If metadata exists for this protocol, importing a new file will replace the existing metadata.

Done Internet

Select a language where available

Import CDISC ODM - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites

Address <http://pogo.ert.com/cdiscdemo/LoadODM> Go Links

EXPeRT
Data Management

Import CDISC ODM [Exit](#)

Select a language : =Select a language=

Submit

- =Select a language=
- de
- it
- en
- fr

Done Internet

Exceptions are displayed

Import CDISC ODM - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites

Address http://pogo.ert.com/cdiscdemo/LoadLangODM Go Links

EXPeRT
Data Management Import CDISC ODM [Exit](#)

The study has loaded successfully.

Warnings

The ert:CreateQuery and/or ert:MissingReason attributes have been set to "Yes" for ItemOID : ERTSEQIT which has the "Mandatory" attribute value of "No"
The event : DIARY is of type "scheduled" and "Repeating = Yes". Since this event has no ert:SubEventIDS it will be treated as a single scheduled event
The ert:CreateQuery and/or ert:MissingReason attributes have been set to "Yes" for ItemOID : ERTSEQIT which has the "Mandatory" attribute value of "No"
The event type "Common" is not supported by EDM. StudyEventOID : AE event type has been changed to "Unscheduled".
The ert:CreateQuery and/or ert:MissingReason attributes have been set to "Yes" for ItemOID : IAESTOP which has the "Mandatory" attribute value of "No"
The ert:CreateQuery and/or ert:MissingReason attributes have been set to "Yes" for ItemOID : IAESCONTI which has the "Mandatory" attribute value of "No"
The ert:CreateQuery and/or ert:MissingReason attributes have been set to "Yes" for ItemOID : ERTSEQIT which has the "Mandatory" attribute value of "No"
The ert:CreateQuery and/or ert:MissingReason attributes have been set to "Yes" for ItemOID : ERTSEQIT which has the "Mandatory" attribute value of "No"

Select a study: =Select a study=

Select a file by clicking the browse button.

Done Internet

The English EDC is now ready

eData Entry - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <http://pogo.ert.com:7778/pgprvdemo/servlet/dispatch?rid=93&pno=CDISC&scry=ERT&pagName=FBASELIN> Go Links

Filter Panel

Navigation Panel

- All Protocols

FBASELIN [S] Show... [Exit]

[0/0] **IGCOMMON (Common)** [N] [Q] Utilities [+] [-]

Site #
Subject ID #
Visit Date

[0/0] **IG_DM (Demographics)** [N] [Q] Utilities [+] [-]

Date of Birth
Sex
Race

[0/0] **IG_SH (Smoking History)** [N] [Q] Utilities [+] [-]

Number of cigarettes per day

Done Internet

Other languages are easily imported

Import CDISC ODM - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Refresh Print Mail Stop Send To

Address <http://pogo.ert.com/cdiscdemo/LoadODM> Go Links

EXPeRT Import CDISC ODM
Data Management [Exit](#)

Select a language : =Select a language=

Submit

- =Select a language=
- de
- it
- en
- fr

Done Internet

The French EDC is now ready

eData Entry - Microsoft Internet Explorer

Address <http://pogo.ert.com:7778/pgprvdemo/servlet/dispatch?rid=93&pno=CDISC&sctry=ERT&pagName=FBASELIN>

FBASELIN [S] Show... [Exit]

[0/0] **IGCOMMON (Common)** [N] [Q] Utilities [+] [-]

Emplacement #
Sujet Identification #
Date de Visite

[0/0] **IG_DM (Demographics)** [N] [Q] Utilities [+] [-]

Date de Naissance
Genre
Appartenance ethnique

[0/0] **IG_SH (Smoking History)** [N] [Q] Utilities [+] [-]

Nombre de cigarettes par jour

Data is entered

File30_CRF_Report.pdf - Adobe Acrobat Standard

File Edit View Document Comments Forms Tools Advanced Window Help

Create PDF Combine Files Export Start Meeting Secure Sign Review & Comment

2 / 11 102% Find

06-Dec-2007 20:53:34 GMT Page 2

Program:	NC_PROG/ERT	Protocol :	CDISC1/US
Center :	2	Patient ID :	2
Event ID :	SE_DM	Page ID :	Patient Demographic Information
Page Entry Status:	√		

-- Module IG_DM (IG_DM) --

Date of Birth	06-Dec-1965
Sex	M
Race	BLACK

Then exported as Meta Data

```
Z:\CDISC\File30_Export.xml - Microsoft Internet Explorer
File Edit View Favorites Tools Help

<?xml version="1.0" encoding="ISO-8859-1" ?>
<!-- ODMTest: CDISC ODM Test Suite, (c) Assero Limited, 2004 Test Set: 009 - Version 1.2 (schema) and V1.2.1,
Full Example Test Item: 020 Description: Contains the Metadata only for the example study. Result: -->
- <ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" CreationDateTime="2005-05-01T12:00:00+01:00" FileOID="ODMTest_009_020"
  FileType="Snapshot" Granularity="Metadata" xmlns:ds="http://www.w3.org/2000/09/xmldsig#"
  xmlns:ert="http://www.ert.com/ns/odm/schema" xmlns:xs="http://www.cdisc.org/ns/odm/v1.3"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="http://www.cdisc.org/ns/odm/v1.3 eRT.xsd">
  <!-- This file contains a single trial, both the Metadata for that trial and the data. -->
- <Study OID="ODMTest.Trial.001">
  <!-- Basic information about the trial. -->
- <GlobalVariables>
  <StudyName>ODMTest Trial 001</StudyName>
  <StudyDescription>A trial to demonstrate the application of the CDISC ODM</StudyDescription>
  <ProtocolName>Protocol for ODMTest Trial 001</ProtocolName>
</GlobalVariables>
  <!-- Measurement definitons. -->
+ <BasicDefinitions>
  <!-- Study MetaData -->
- <MetaDataVersion Name="ODMTest Trial 001 Metadata" OID="ODMTest_Trial_001.Metadata_V001">
  <!-- Overall protocol -->
- <Protocol>
  <StudyEventRef Mandatory="Yes" OrderNumber="1" StudyEventOID="SE_DM" />
  <StudyEventRef Mandatory="Yes" OrderNumber="2" StudyEventOID="SE_VT_In" />
  <StudyEventRef Mandatory="Yes" OrderNumber="3" StudyEventOID="SE_VT_Su" />
  <StudyEventRef Mandatory="Yes" OrderNumber="4" StudyEventOID="SE_PD" />
</Protocol>
  <!-- Study Event Definitions -->
- <StudyEventDef Name="Demographics" OID="SE_DM" Repeating="No" Type="Scheduled">
  <FormRef FormOID="F_DM" Mandatory="Yes" OrderNumber="1" />
</StudyEventDef>
- <StudyEventDef Name="Vitals" OID="SE_VT_In" Repeating="No" Type="Scheduled">
  <FormRef FormOID="F_VT_1" Mandatory="Yes" OrderNumber="1" />
  <FormRef FormOID="F_VT_2" Mandatory="Yes" OrderNumber="2" />
</StudyEventDef>
- <StudyEventDef Name="Vitals" OID="SE_VT_Su" Repeating="Yes" Type="Scheduled">
  <FormRef FormOID="F_VT_1" Mandatory="Yes" OrderNumber="1" />
</StudyEventDef>
- <StudyEventDef Name="Patient Diary" OID="SE_PD" Repeating="Yes" Type="Scheduled">
  <FormRef FormOID="F_PD" Mandatory="Yes" OrderNumber="1" />
</StudyEventDef>
</Study>
</ODM>
```

And Clinical Data in the same ODM file

```
Z:\CDISC\File30_Export.xml - Microsoft Internet Explorer
File Edit View Favorites Tools Help

<?xml version="1.0" encoding="ISO-8859-1" ?>
<!-- ODMTest: CDISC ODM Test Suite, (c) Assero Limited, 2004 Test Set: 009 - Version 1.2 (schema) and V1.2.1,
Full Example Test Item: 020 Description: Contains the Metadata only for the example study. Result:
- <ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" CreationDateTime="2005-05-01T12:00:00+01:00" FileOID="ODMTest_009_020"
  FileType="Snapshot" Granularity="Metadata" xmlns:ds="http://www.w3.org/2000/09/xmldsig#"
  xmlns:ert="http://www.ert.com/ns/odm/schema" xmlns:xs="http://www.cdisc.org/ns/odm/v1.3"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="http://www.cdisc.org/ns/odm/v1.3 eRT.xsd">
  <!-- This file contains a single trial, both the Metadata for that trial and the data. -->
- <Study OID="ODMTest.Trial.001">
  <!-- Basic information about the trial. -->
  - <GlobalVariables>
    <StudyName>ODMTest Trial 001</StudyName>
    <StudyDescription>A trial to demonstrate the application of the CDISC ODM</StudyDescription>
    <ProtocolName>Protocol for ODMTest Trial 001</ProtocolName>
  </GlobalVariables>
  <!-- Measurement definitons. -->
+ <BasicDefinitions>
  <!-- Study MetaData -->
+ <MetaDataVersion Name="ODMTest Trial 001 Metadata" OID="ODMTest_Trial_001.Metadata_V001">
</Study>
- <AdminData xs:StudyOID="ODMTest.Trial.001">
- <Location xs:LocationType="Site" xs:Name="Center2" xs:OID="2">
  <MetaDataVersionRef xs:EffectiveDate="06-DEC-2007" xs:MetaDataVersionOID="ODMTest_Trial_001.Metadata_V001"
  xs:StudyOID="ODMTest.Trial.001" />
  <DisplayName>Center2</DisplayName>
</Location>
</AdminData>
- <ClinicalData xs:MetaDataVersionOID="ODMTest_Trial_001.Metadata_V001" xs:StudyOID="ODMTest.Trial.001">
- <SubjectData xs:SubjectKey="2">
  <SiteRef xs:LocationOID="2" />
  - <StudyEventData xs:StudyEventOID="SE_DM">
    - <FormData xs:FormOID="F_DM">
      - <ItemGroupData xs:ItemGroupOID="IG_DM">
        <ItemData xs:ItemOID="I_DM_BRT">06-DEC-1965</ItemData>
        <ItemData xs:ItemOID="I_DM_SEX">M</ItemData>
        <ItemData xs:ItemOID="I_DM_RAC">BLACK</ItemData>
      </ItemGroupData>
    </FormData>
  </StudyEventData>
</ClinicalData>
</Study>
</ODM>
Local intranet
```

Observations

- **The CDISC ODM works !**
- **It allows interoperability between certified systems.**
- **Allows external applications to be used to design studies.**
- **May reduce study setup time.**
- **In 2007 the FDA proposed that all submissions will use SDTM.**
- **CDISC is looking for global adoption by 2010**
- **CDISC is a significant/essential requirement for vendor selection**

Thank you.

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