ODM

Vue d'ensemble avec impact pour le Data Management

CDISC®

Setting the
Global Standard
for Clinical Data

CLINICAL DATA INTERCHANGE
STANDARDS CONSORTIUM

Présentation du
04 Décembre 2009

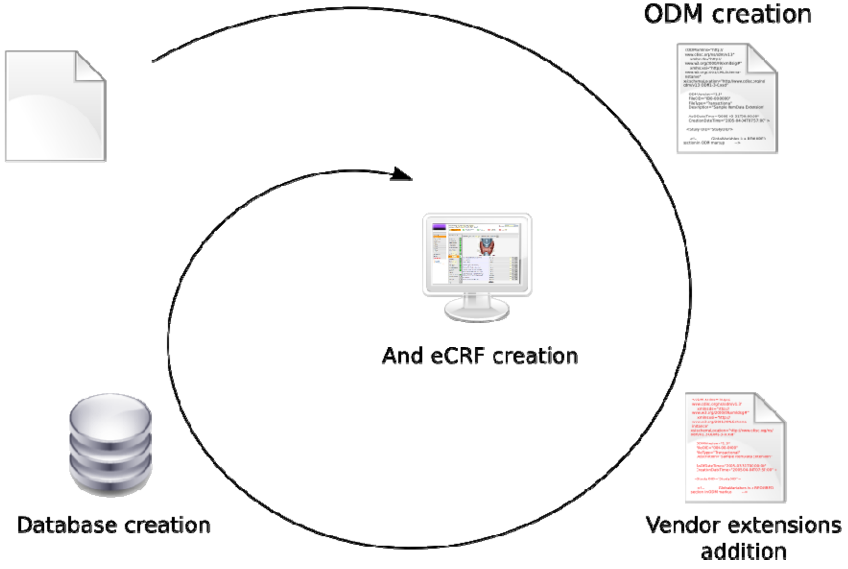
Nicolas de SAINT JORRE

ODM: Operational Data Model

- Standard pour la collecte, l'échange et l'archivage de données dans le cadre d'une étude clinique (3 des 4 missions de CDISC)
- Neutralité architecturale et informatique
- Standard au format XML (via un schéma XSD)
- ->Traduction des objectifs d’un protocole clinique en cahier d’observation (avec une dimension standard électronique)
- Les versions en production :
  - (ODM V1.2.1)
  - (ODM V1.3)

Pourquoi utiliser l'ODM ?

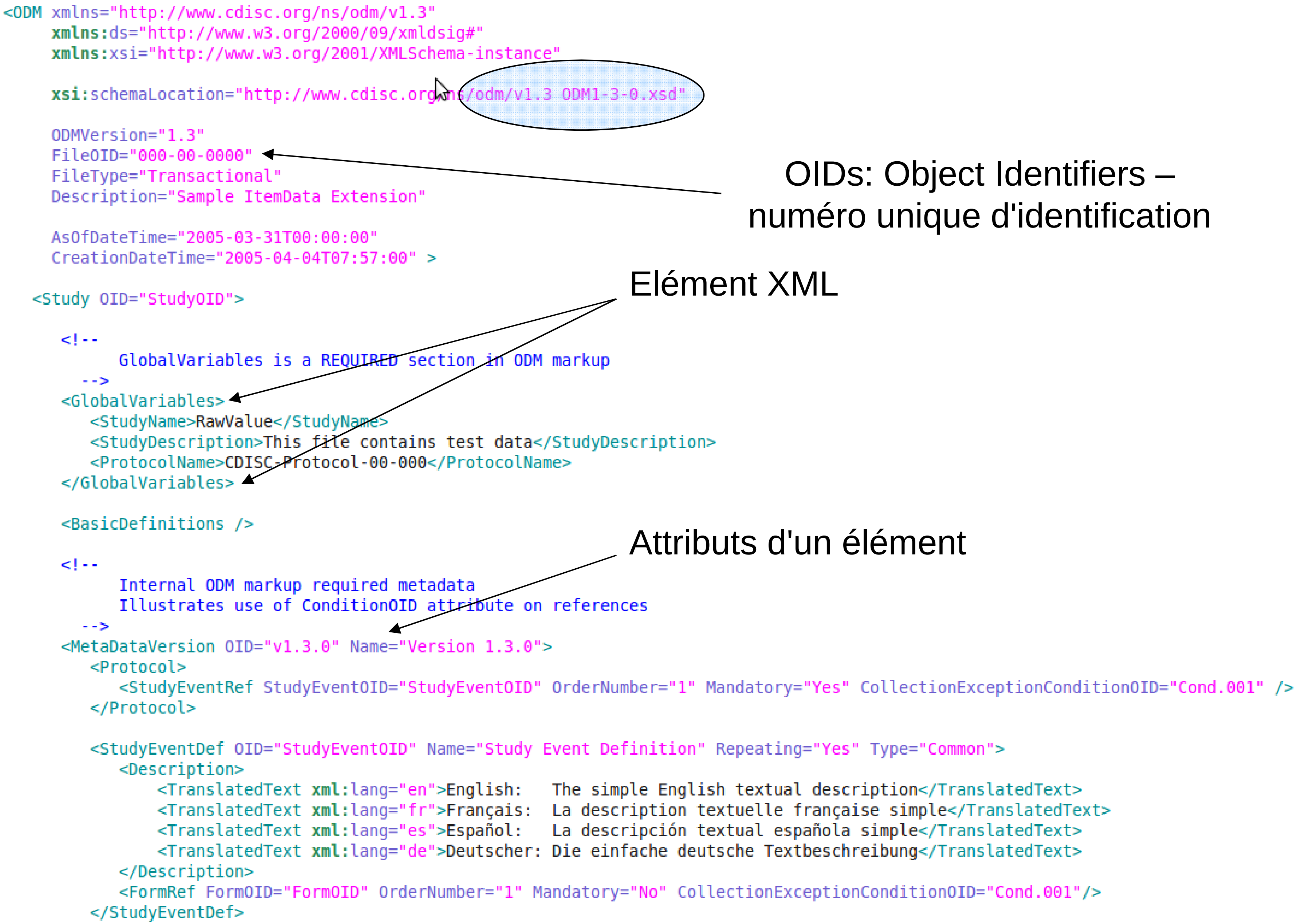
- « The ODM can act as a shared vocabulary between Sponsor and Vendor, helping to eliminate confusion in the specification process. »


ODM creation
Vendor extensions addition
Database creation
And eCRF creation

XML et XSD

•Conformité XML: contraintes de syntaxe et de sémantique

  - L'ODM doit être syntaxiquement correct
  - L'ODM doit être conforme avec le standard 'XML Namespace'
  - L'ODM doit être conforme avec 'odm1-3-0foundation.xsd' et avec 'odm1-3-0.xsd'
  - Et éventuellement, l'ODM peut être conforme avec des 'Extensions vendeurs'



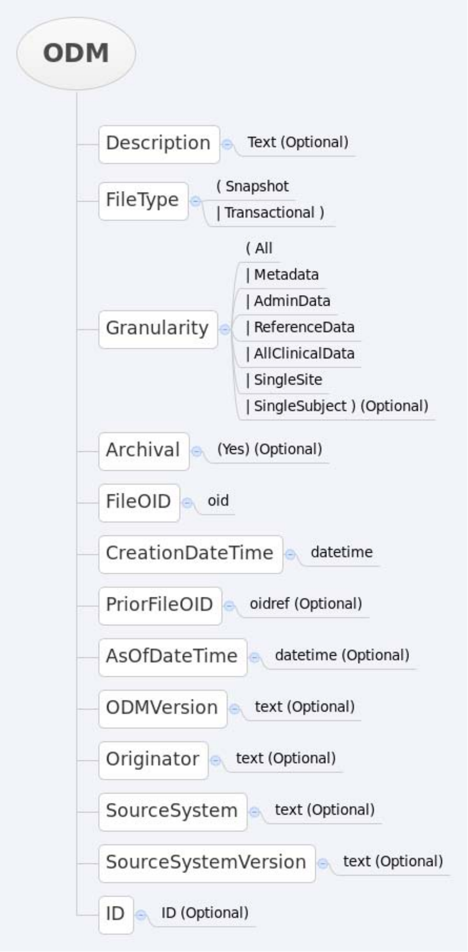
```
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3"
     xmlns:ds="http://www.w3.org/2000/09/xmldsig#"
     xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"

     xsi:schemaLocation="http://www.cdisc.org/ns/odm/v1.3 ODM1-3-0.xsd"

     ODMVersion="1.3"
     FileOID="000-00-0000"
     FileType="Transactional"
     Description="Sample ItemData Extension"

     AsOfDateTime="2005-03-31T00:00:00"
     CreationDateTime="2005-04-04T07:57:00" >

   <Study OID="StudyOID">

      <!--
            GlobalVariables is a REQUIRED section in ODM markup
        -->
      <GlobalVariables>
         <StudyName>RawValue</StudyName>
         <StudyDescription>This file contains test data</StudyDescription>
         <ProtocolName>CDISC-Protocol-00-000</ProtocolName>
      </GlobalVariables>

      <BasicDefinitions />

      <!--
            Internal ODM markup required metadata
            Illustrates use of ConditionOID attribute on references
        -->
      <MetaDataVersion OID="v1.3.0" Name="Version 1.3.0">
         <Protocol>
            <StudyEventRef StudyEventOID="StudyEventOID" OrderNumber="1" Mandatory="Yes" CollectionExceptionConditionOID="Cond.001" />
         </Protocol>

         <StudyEventDef OID="StudyEventOID" Name="Study Event Definition" Repeating="Yes" Type="Common">
            <Description>
                <TranslatedText xml:lang="en">English:   The simple English textual description</TranslatedText>
                <TranslatedText xml:lang="fr">Français:  La description textuelle française simple</TranslatedText>
                <TranslatedText xml:lang="es">Español:   La descripción textual española simple</TranslatedText>
                <TranslatedText xml:lang="de">Deutscher: Die einfache deutsche Textbeschreibung</TranslatedText>
            </Description>
            <FormRef FormOID="FormOID" OrderNumber="1" Mandatory="No" CollectionExceptionConditionOID="Cond.001"/>
         </StudyEventDef>
```

OIDs: Object Identifiers –
numéro unique d'identification

Elément XML

Attributs d'un élément

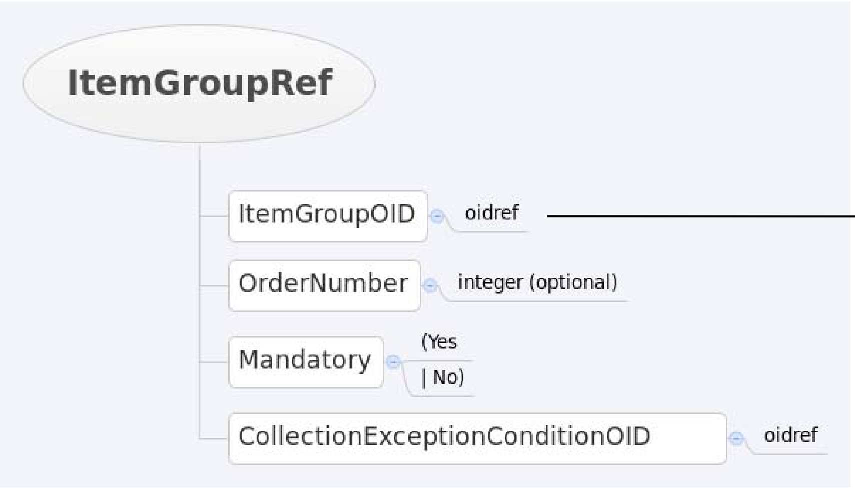
Les attributs d'un ODM



ODM

- Description — Text (Optional)
- FileType — (Snapshot | Transactional)
- Granularity — (All | Metadata | AdminData | ReferenceData | AllClinicalData | SingleSite | SingleSubject) (Optional)
- Archival — (Yes) (Optional)
- FileOID — oid
- CreationDateTime — datetime
- PriorFileOID — oidref (Optional)
- AsOfDateTime — datetime (Optional)
- ODMVersion — text (Optional)
- Originator — text (Optional)
- SourceSystem — text (Optional)
- SourceSystemVersion — text (Optional)
- ID — ID (Optional)

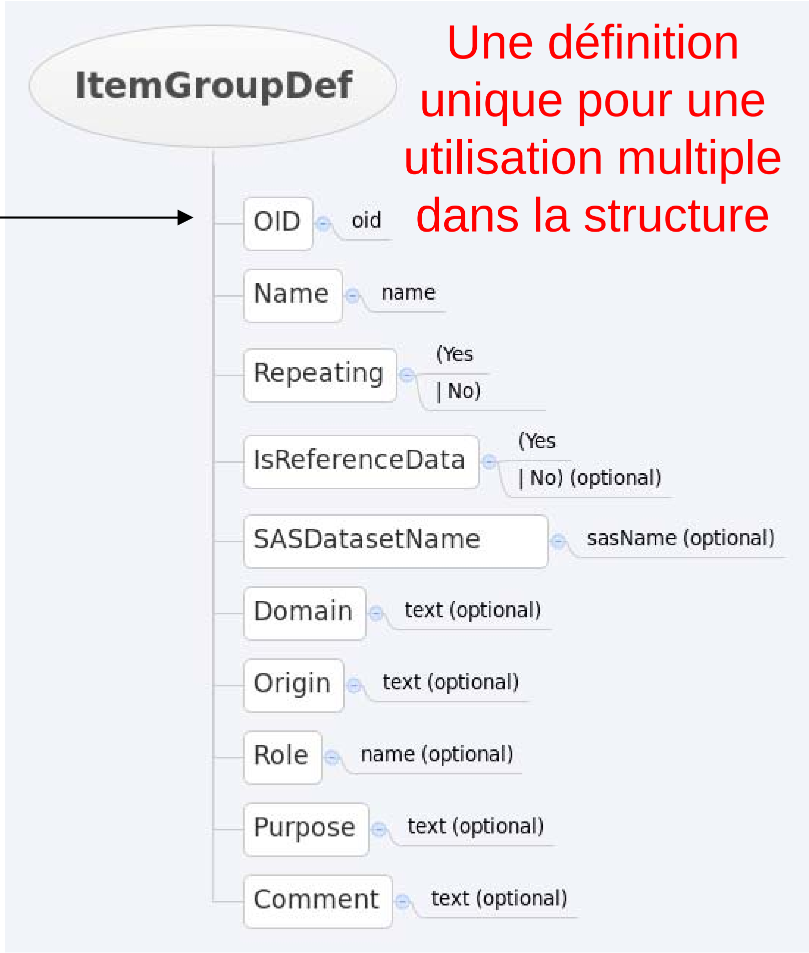
Les attributs d'un ItemGroupRef / Def



ItemGroupRef

ItemGroupOID	oidref
OrderNumber	integer (optional)
Mandatory	(Yes | No)
CollectionExceptionConditionOID	oidref

- CollectionExceptionConditionOID:
  - Nouveauté de la version 1.3
  - Référence vers une condition (ConditionDef) décrivant les conditions d'omissions
- SASDatasetName: référence au nom de la table SAS de votre SI
- Domain, Origin, Purpose et Comment: référence SDTM

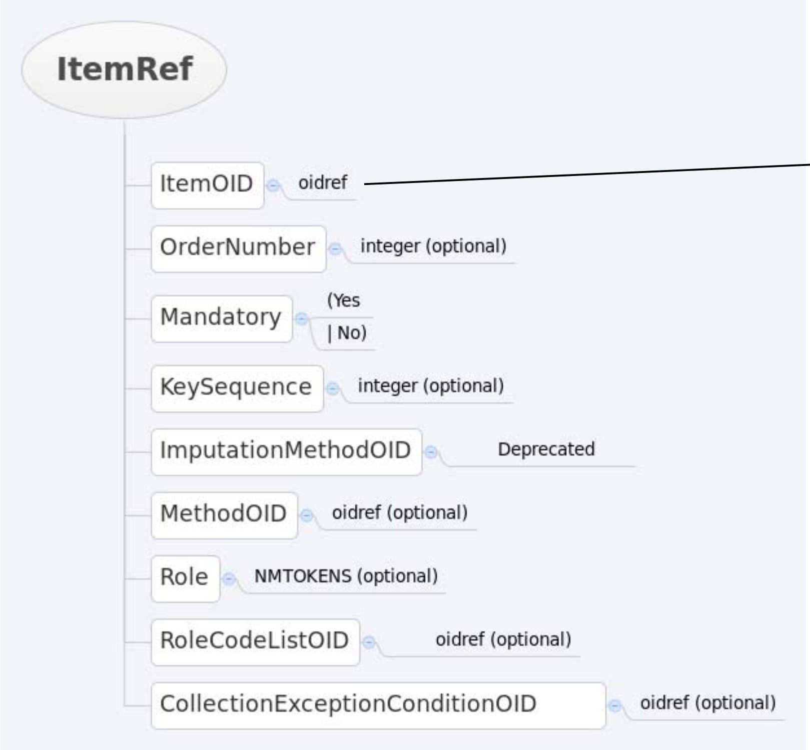


ItemGroupDef

Une définition unique pour une utilisation multiple dans la structure

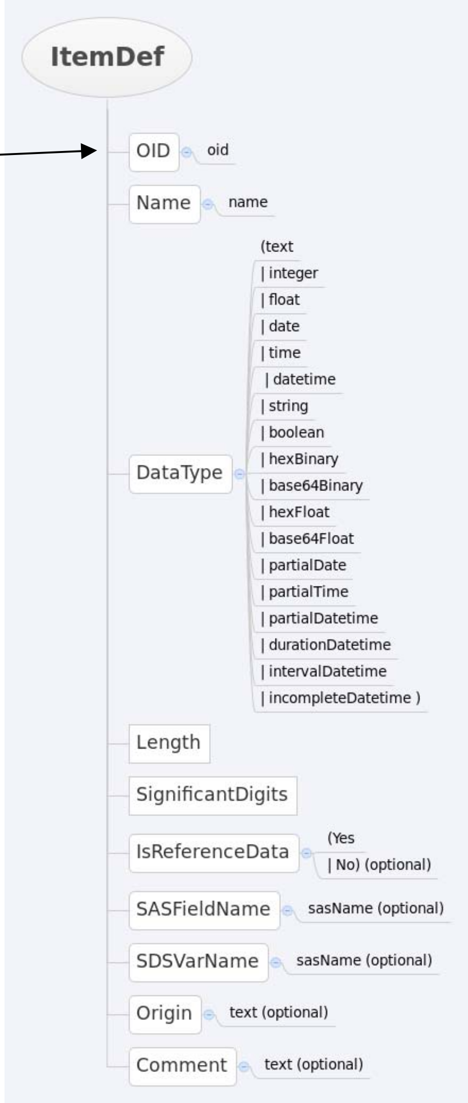
OID	oid
Name	name
Repeating	(Yes | No)
IsReferenceData	(Yes | No) (optional)
SASDatasetName	sasName (optional)
Domain	text (optional)
Origin	text (optional)
Role	name (optional)
Purpose	text (optional)
Comment	text (optional)

Les attributs d'un ItemRef / Def



ItemRef

- ItemOID: oidref
- OrderNumber: integer (optional)
- Mandatory: (Yes | No)
- KeySequence: integer (optional)
- ImputationMethodOID: Deprecated
- MethodOID: oidref (optional)
- Role: NMTOKENS (optional)
- RoleCodeListOID: oidref (optional)
- CollectionExceptionConditionOID: oidref (optional)



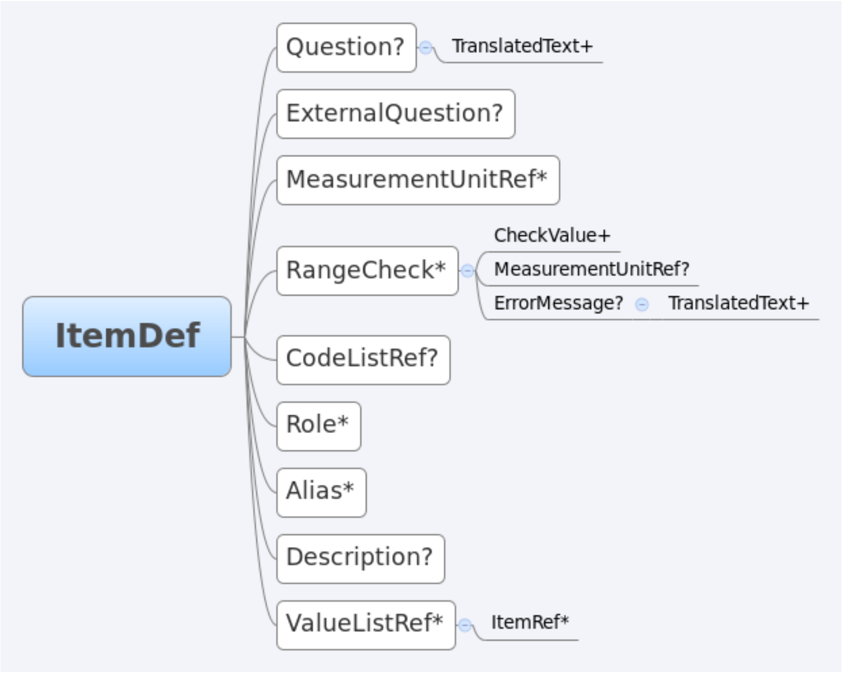
ItemDef

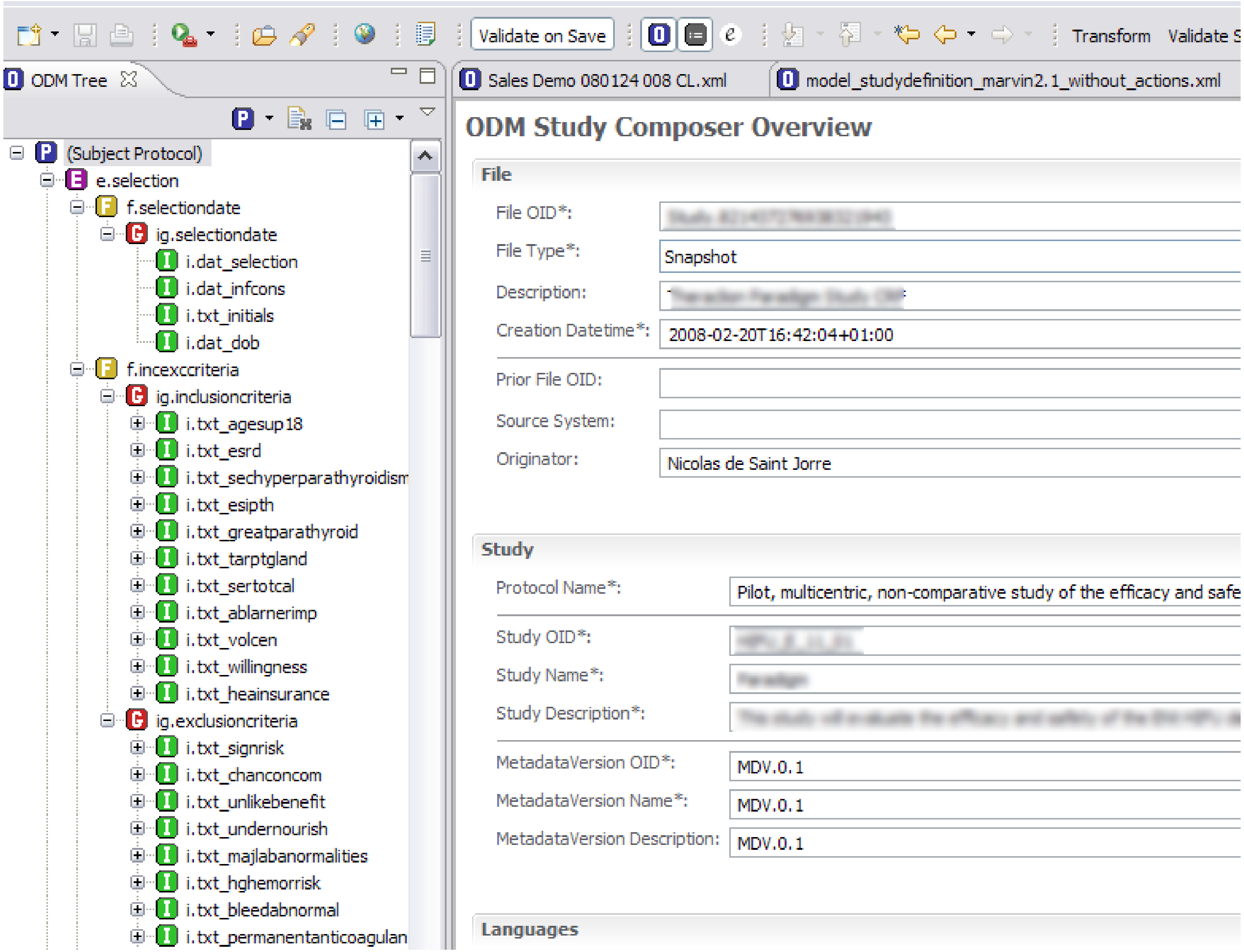
- OID: oid
- Name: name
- DataType: (text | integer | float | date | time | datetime | string | boolean | hexBinary | base64Binary | hexFloat | base64Float | partialDate | partialTime | partialDatetime | durationDatetime | intervalDatetime | incompleteDatetime)
- Length
- SignificantDigits
- IsReferenceData: (Yes | No) (optional)
- SASFieldName: sasName (optional)
- SDSVarName: sasName (optional)
- Origin: text (optional)
- Comment: text (optional)

- SASFieldName: référence au nom du champ la table SAS de votre SI
- SDSVarName: référence au nom de la variable SDTM
- Origin et Comment: référence SDTM

La structure d'un Item

- Question: label de la question en suivant CDASH (avec traduction possible)
- Idem pour ExternalQuestion (dans un dictionnaire de codage)
- RangeCheck: solution pour la vérification des données en fonction du type (LT Less than, LE Less than or equal to, GT Greater than, GE Greater than or equal to, EQ Equal to, NE Not equal to)
- CodeListRef: pour les items de type CodeList


ItemDef
Question?
TranslatedText+
ExternalQuestion?
MeasurementUnitRef*
RangeCheck*
CheckValue+
MeasurementUnitRef?
ErrorMessage?
TranslatedText+
CodeListRef?
Role*
Alias*
Description?
ValueListRef*
ItemRef*


Validate on Save
Transform
Validate S
ODM Tree
Sales Demo 080124 008 CL.xml
model_studydefinition_marvin2.1_without_actions.xml

- (Subject Protocol)
  - e.selection
    - f.selectiondate
      - ig.selectiondate
        - i.dat_selection
        - i.dat_infcons
        - i.txt_initials
        - i.dat_dob
    - f.incexccriteria
      - ig.inclusioncriteria
        - i.txt_agesup18
        - i.txt_esrd
        - i.txt_sechyperparathyroidism
        - i.txt_esipth
        - i.txt_greatparathyroid
        - i.txt_tarptgland
        - i.txt_sertotcal
        - i.txt_ablarnerimp
        - i.txt_volcen
        - i.txt_willingness
        - i.txt_heainsurance
      - ig.exclusioncriteria
        - i.txt_signrisk
        - i.txt_chanconcom
        - i.txt_unlikebenefit
        - i.txt_undernourish
        - i.txt_majlabanormalities
        - i.txt_hghemorrisk
        - i.txt_bleedabnormal
        - i.txt_permanentanticoagulan

ODM Study Composer Overview

File

File OID*: [redacted]

File Type*: Snapshot

Description: [redacted]

Creation Datetime*: 2008-02-20T16:42:04+01:00

Prior File OID:

Source System:

Originator: Nicolas de Saint Jorre

Study

Protocol Name*: Pilot, multicentric, non-comparative study of the efficacy and safe

Study OID*: [redacted]

Study Name*: [redacted]

Study Description*: [redacted]

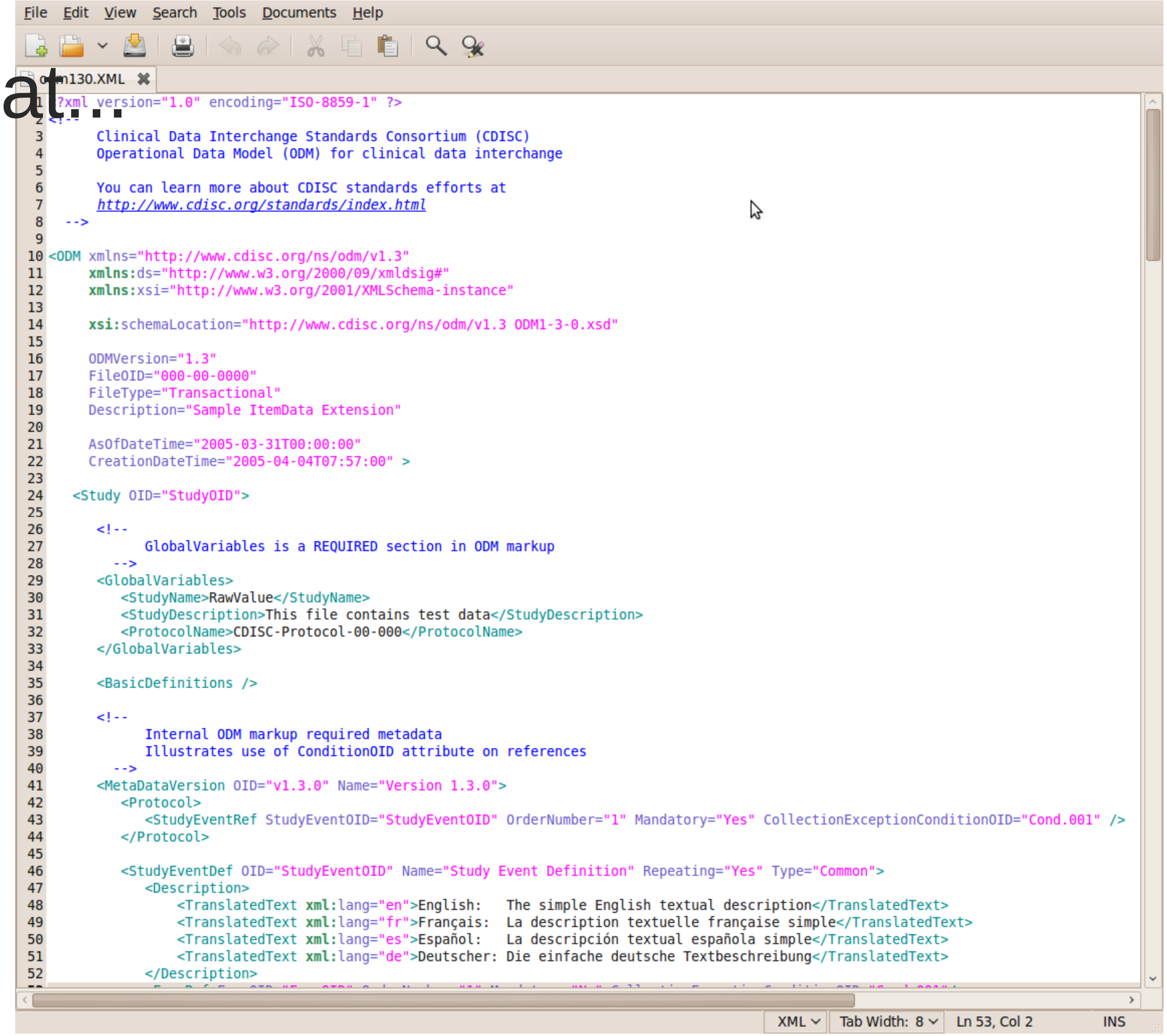
MetadataVersion OID*: MDV.0.1

MetadataVersion Name*: MDV.0.1

MetadataVersion Description: MDV.0.1

Languages

Résultat...


File
Edit
View
Search
Tools
Documents
Help
odm130.XML
XML
Tab Width: 8
Ln 53, Col 2
INS

```xml
<?xml version="1.0" encoding="ISO-8859-1" ?>
<!--
      Clinical Data Interchange Standards Consortium (CDISC)
      Operational Data Model (ODM) for clinical data interchange

      You can learn more about CDISC standards efforts at
      http://www.cdisc.org/standards/index.html
  -->

<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"

     xsi:schemaLocation="http://www.cdisc.org/ns/odm/v1.3 ODM1-3-0.xsd"

     ODMVersion="1.3"
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     FileType="Transactional"
     Description="Sample ItemData Extension"

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   <Study OID="StudyOID">

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      <GlobalVariables>
         <StudyName>RawValue</StudyName>
         <StudyDescription>This file contains test data</StudyDescription>
         <ProtocolName>CDISC-Protocol-00-000</ProtocolName>
      </GlobalVariables>

      <BasicDefinitions />

      <!--
            Internal ODM markup required metadata
            Illustrates use of ConditionOID attribute on references
        -->
      <MetaDataVersion OID="v1.3.0" Name="Version 1.3.0">
         <Protocol>
            <StudyEventRef StudyEventOID="StudyEventOID" OrderNumber="1" Mandatory="Yes" CollectionExceptionConditionOID="Cond.001" />
         </Protocol>

         <StudyEventDef OID="StudyEventOID" Name="Study Event Definition" Repeating="Yes" Type="Common">
            <Description>
                <TranslatedText xml:lang="en">English:   The simple English textual description</TranslatedText>
                <TranslatedText xml:lang="fr">Français:  La description textuelle française simple</TranslatedText>
                <TranslatedText xml:lang="es">Español:   La descripción textual española simple</TranslatedText>
                <TranslatedText xml:lang="de">Deutscher: Die einfache deutsche Textbeschreibung</TranslatedText>
            </Description>
```
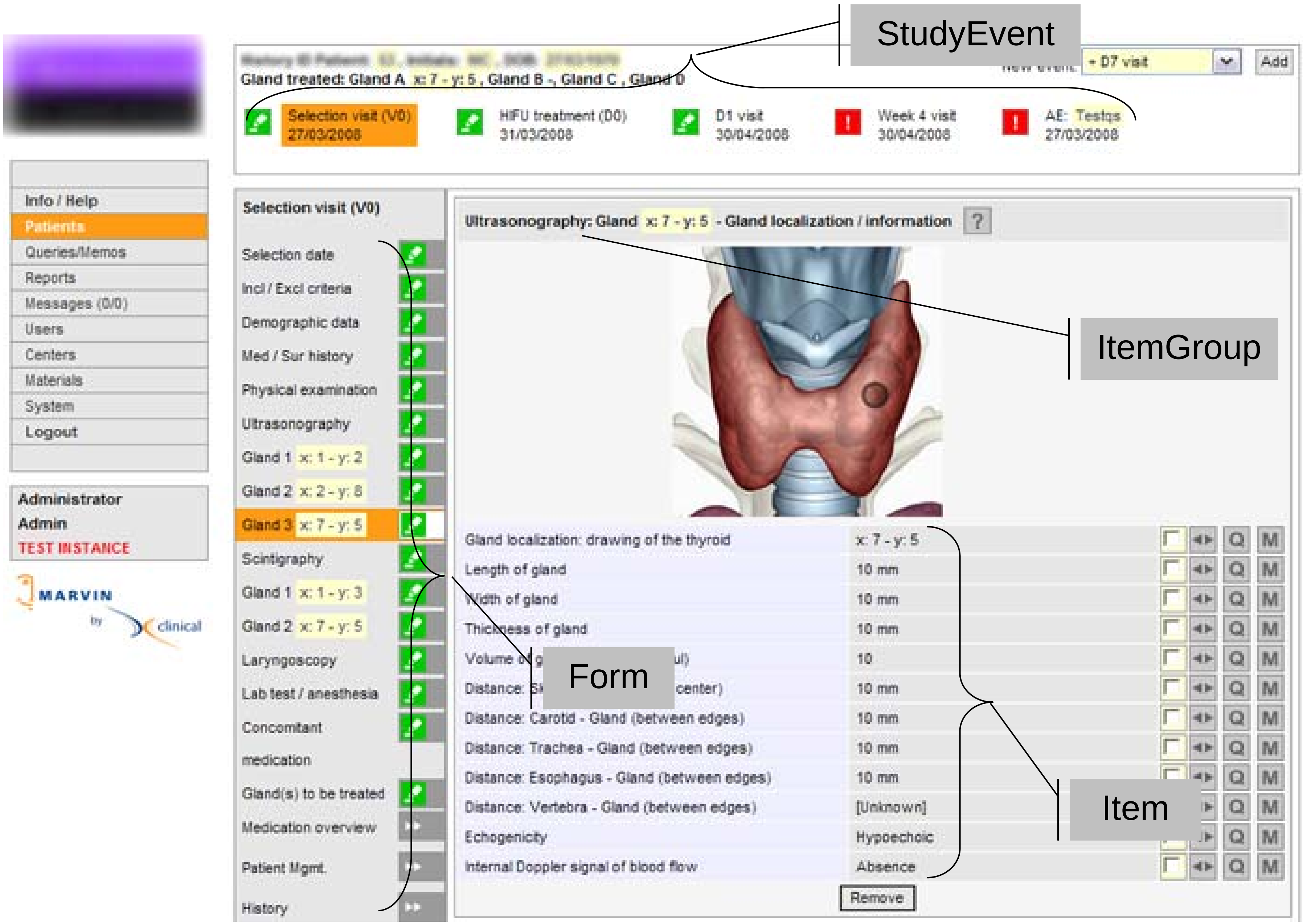



StudyEvent
ItemGroup
Form
Item

[redacted]

Gland treated: Gland A x: 7 - y: 5 , Gland B -, Gland C , Gland D

New event: ▾ D7 visit | Add

✓	Selection visit (V0) 27/03/2008
✓	HIFU treatment (D0) 31/03/2008
✓	D1 visit 30/04/2008
!	Week 4 visit 30/04/2008
!	AE: Testqs 27/03/2008

Info / Help
Patients
Queries/Memos
Reports
Messages (0/0)
Users
Centers
Materials
System
Logout

Administrator
Admin
TEST INSTANCE

MARVIN
by clinical

Selection visit (V0)

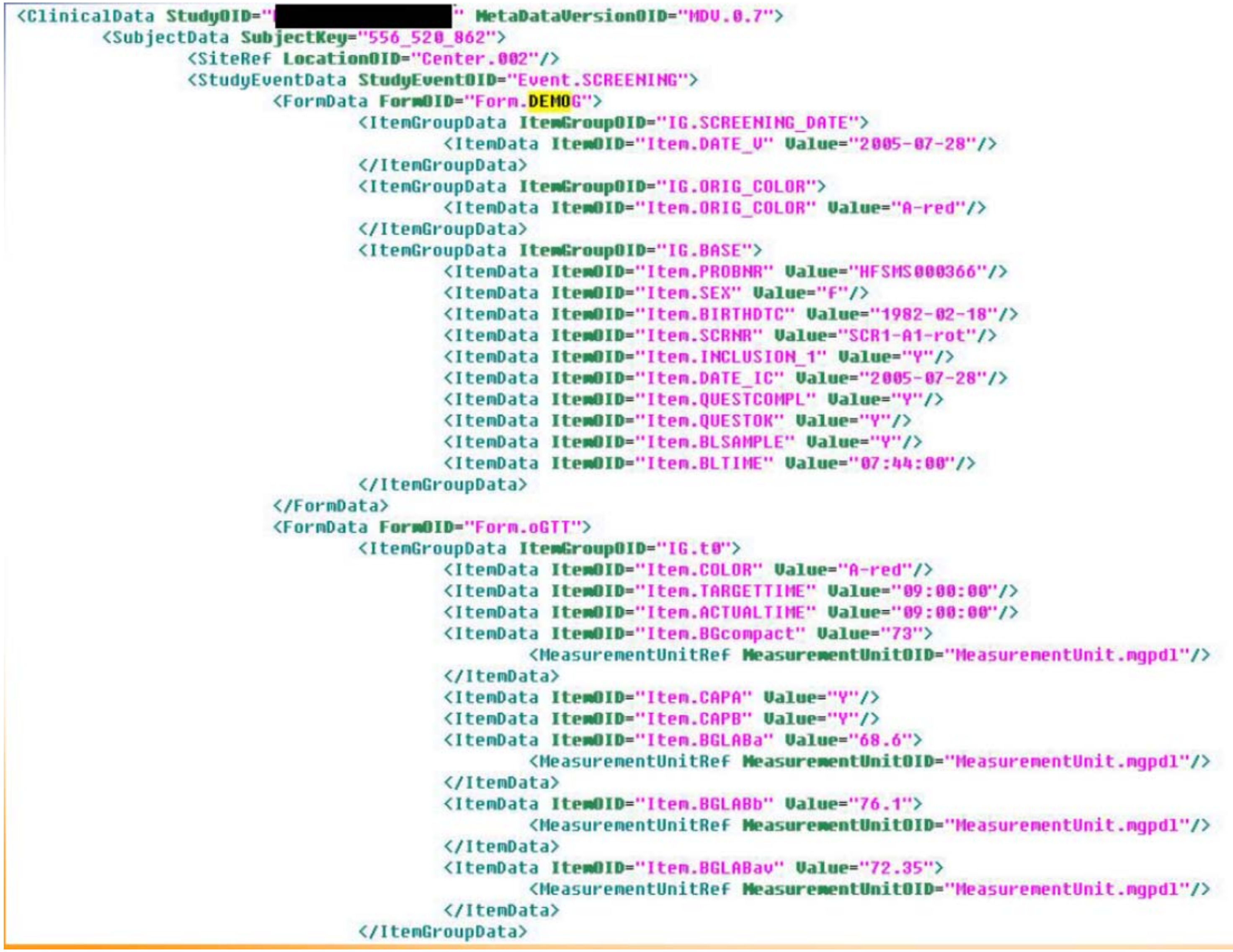
- Selection date
- Incl / Excl criteria
- Demographic data
- Med / Sur history
- Physical examination
- Ultrasonography
- Gland 1 x: 1 - y: 2
- Gland 2 x: 2 - y: 8
- Gland 3 x: 7 - y: 5
- Scintigraphy
- Gland 1 x: 1 - y: 3
- Gland 2 x: 7 - y: 5
- Laryngoscopy
- Lab test / anesthesia
- Concomitant medication
- Gland(s) to be treated
- Medication overview
- Patient Mgmt.
- History

Ultrasonography: Gland x: 7 - y: 5 - Gland localization / information ?

Gland localization: drawing of the thyroid	x: 7 - y: 5	☐	◂▸	Q	M
Length of gland	10 mm	☐	◂▸	Q	M
Width of gland	10 mm	☐	◂▸	Q	M
Thickness of gland	10 mm	☐	◂▸	Q	M
Volume of g… ul)	10	☐	◂▸	Q	M
Distance: S… center)	10 mm	☐	◂▸	Q	M
Distance: Carotid - Gland (between edges)	10 mm	☐	◂▸	Q	M
Distance: Trachea - Gland (between edges)	10 mm	☐	◂▸	Q	M
Distance: Esophagus - Gland (between edges)	10 mm	☐	◂▸	Q	M
Distance: Vertebra - Gland (between edges)	[Unknown]		▸	Q	M
Echogenicity	Hypoechoic		▸	Q	M
Internal Doppler signal of blood flow	Absence	☐	◂▸	Q	M

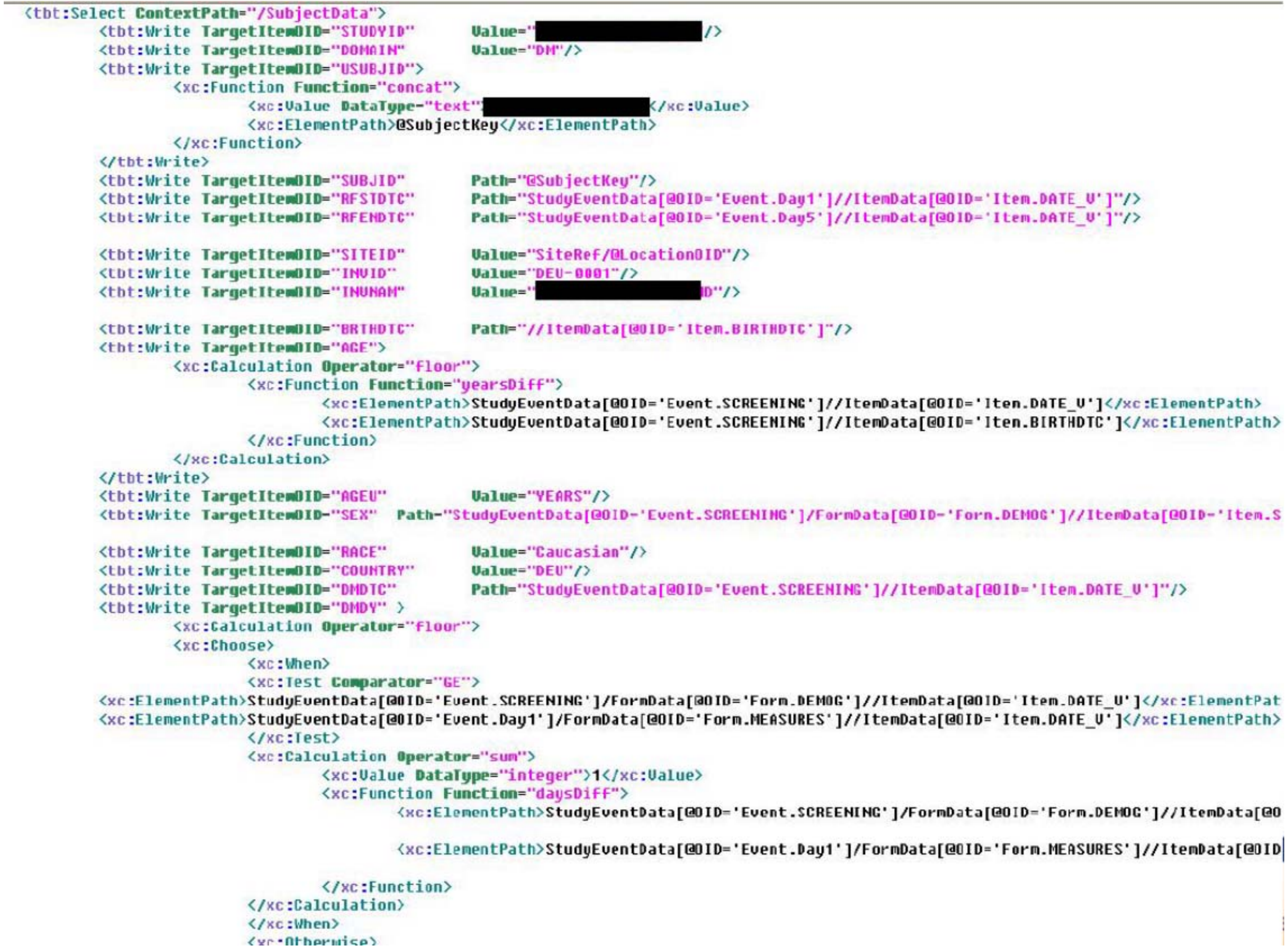
Remove

Exemple d'un export ODM



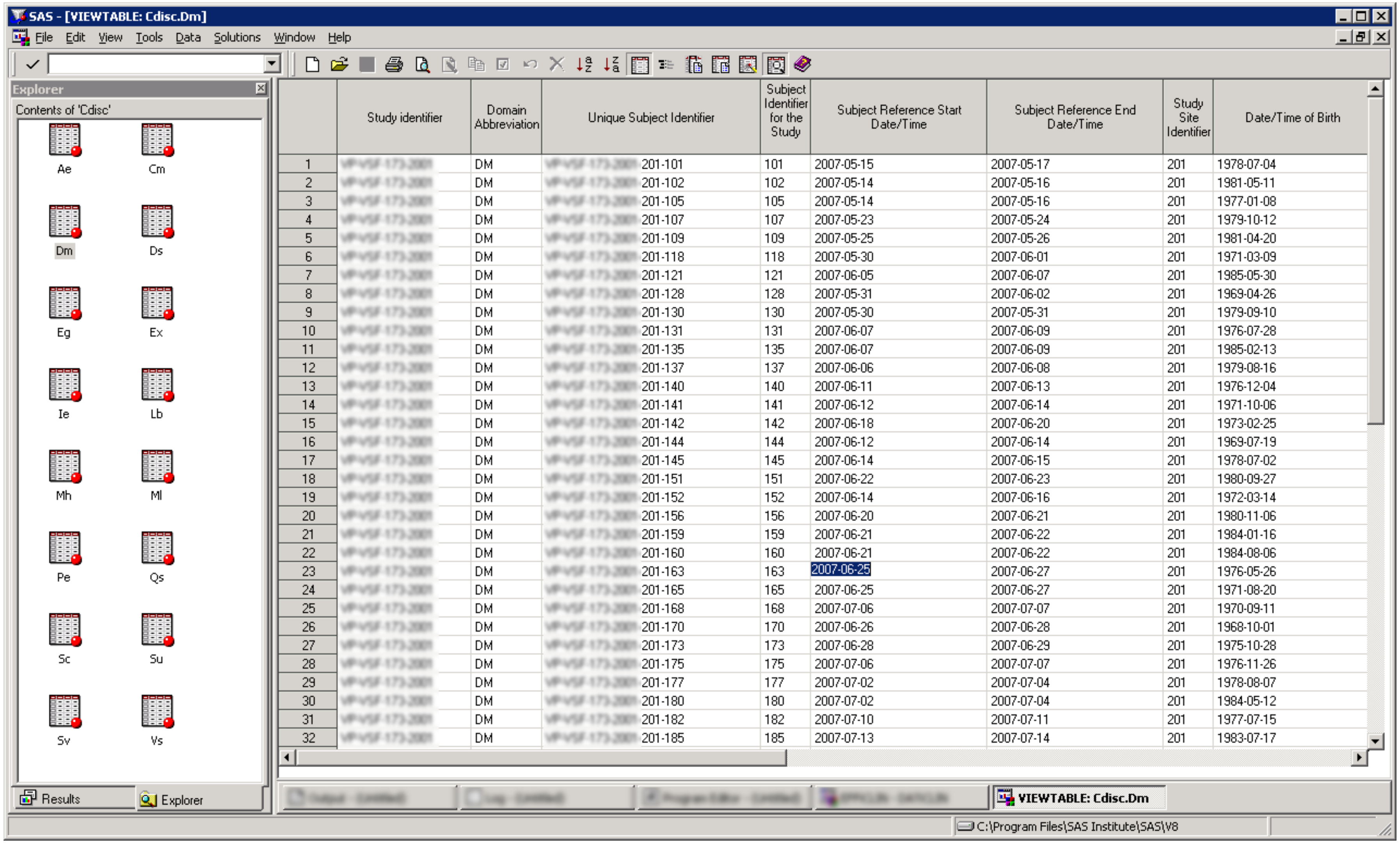
```
<ClinicalData StudyOID="[redacted]" MetaDataVersionOID="MDV.0.7">
        <SubjectData SubjectKey="556_520_862">
                <SiteRef LocationOID="Center.002"/>
                <StudyEventData StudyEventOID="Event.SCREENING">
                        <FormData FormOID="Form.DEMOG">
                                <ItemGroupData ItemGroupOID="IG.SCREENING_DATE">
                                        <ItemData ItemOID="Item.DATE_V" Value="2005-07-28"/>
                                </ItemGroupData>
                                <ItemGroupData ItemGroupOID="IG.ORIG_COLOR">
                                        <ItemData ItemOID="Item.ORIG_COLOR" Value="A-red"/>
                                </ItemGroupData>
                                <ItemGroupData ItemGroupOID="IG.BASE">
                                        <ItemData ItemOID="Item.PROBNR" Value="HFSMS000366"/>
                                        <ItemData ItemOID="Item.SEX" Value="F"/>
                                        <ItemData ItemOID="Item.BIRTHDTC" Value="1982-02-18"/>
                                        <ItemData ItemOID="Item.SCRNR" Value="SCR1-A1-rot"/>
                                        <ItemData ItemOID="Item.INCLUSION_1" Value="Y"/>
                                        <ItemData ItemOID="Item.DATE_IC" Value="2005-07-28"/>
                                        <ItemData ItemOID="Item.QUESTCOMPL" Value="Y"/>
                                        <ItemData ItemOID="Item.QUESTOK" Value="Y"/>
                                        <ItemData ItemOID="Item.BLSAMPLE" Value="Y"/>
                                        <ItemData ItemOID="Item.BLTIME" Value="07:44:00"/>
                                </ItemGroupData>
                        </FormData>
                        <FormData FormOID="Form.oGTT">
                                <ItemGroupData ItemGroupOID="IG.t0">
                                        <ItemData ItemOID="Item.COLOR" Value="A-red"/>
                                        <ItemData ItemOID="Item.TARGETTIME" Value="09:00:00"/>
                                        <ItemData ItemOID="Item.ACTUALTIME" Value="09:00:00"/>
                                        <ItemData ItemOID="Item.BGcompact" Value="73">
                                                <MeasurementUnitRef MeasurementUnitOID="MeasurementUnit.mgpdl"/>
                                        </ItemData>
                                        <ItemData ItemOID="Item.CAPA" Value="Y"/>
                                        <ItemData ItemOID="Item.CAPB" Value="Y"/>
                                        <ItemData ItemOID="Item.BGLABa" Value="68.6">
                                                <MeasurementUnitRef MeasurementUnitOID="MeasurementUnit.mgpdl"/>
                                        </ItemData>
                                        <ItemData ItemOID="Item.BGLABb" Value="76.1">
                                                <MeasurementUnitRef MeasurementUnitOID="MeasurementUnit.mgpdl"/>
                                        </ItemData>
                                        <ItemData ItemOID="Item.BGLABav" Value="72.35">
                                                <MeasurementUnitRef MeasurementUnitOID="MeasurementUnit.mgpdl"/>
                                        </ItemData>
                                </ItemGroupData>
```

Exemple: ODM – SDTM mapping



```
<tbt:Select ContextPath="/SubjectData">
        <tbt:Write TargetItemOID="STUDYID"      Value="[redacted]/>
        <tbt:Write TargetItemOID="DOMAIN"       Value="DM"/>
        <tbt:Write TargetItemOID="USUBJID">
                <xc:Function Function="concat">
                        <xc:Value DataType="text"[redacted]</xc:Value>
                        <xc:ElementPath>@SubjectKey</xc:ElementPath>
                </xc:Function>
        </tbt:Write>
        <tbt:Write TargetItemOID="SUBJID"       Path="@SubjectKey"/>
        <tbt:Write TargetItemOID="RFSTDTC"      Path="StudyEventData[@OID='Event.Day1']//ItemData[@OID='Item.DATE_V']"/>
        <tbt:Write TargetItemOID="RFENDTC"      Path="StudyEventData[@OID='Event.Day5']//ItemData[@OID='Item.DATE_V']"/>

        <tbt:Write TargetItemOID="SITEID"       Value="SiteRef/@LocationOID"/>
        <tbt:Write TargetItemOID="INVID"        Value="DEU-0001"/>
        <tbt:Write TargetItemOID="INVNAM"       Value="[redacted]D"/>

        <tbt:Write TargetItemOID="BRTHDTC"      Path="//ItemData[@OID='Item.BIRTHDTC']"/>
        <tbt:Write TargetItemOID="AGE">
                <xc:Calculation Operator="floor">
                        <xc:Function Function="yearsDiff">
                                <xc:ElementPath>StudyEventData[@OID='Event.SCREENING']//ItemData[@OID='Item.DATE_V']</xc:ElementPath>
                                <xc:ElementPath>StudyEventData[@OID='Event.SCREENING']//ItemData[@OID='Item.BIRTHDTC']</xc:ElementPath>
                        </xc:Function>
                </xc:Calculation>
        </tbt:Write>
        <tbt:Write TargetItemOID="AGEU"         Value="YEARS"/>
        <tbt:Write TargetItemOID="SEX"  Path="StudyEventData[@OID='Event.SCREENING']/FormData[@OID='Form.DEMOG']//ItemData[@OID='Item.S

        <tbt:Write TargetItemOID="RACE"         Value="Caucasian"/>
        <tbt:Write TargetItemOID="COUNTRY"      Value="DEU"/>
        <tbt:Write TargetItemOID="DMDTC"        Path="StudyEventData[@OID='Event.SCREENING']//ItemData[@OID='Item.DATE_V']"/>
        <tbt:Write TargetItemOID="DMDY" >
                <xc:Calculation Operator="floor">
                <xc:Choose>
                        <xc:When>
                        <xc:Test Comparator="GE">
        <xc:ElementPath>StudyEventData[@OID='Event.SCREENING']/FormData[@OID='Form.DEMOG']//ItemData[@OID='Item.DATE_V']</xc:ElementPat
        <xc:ElementPath>StudyEventData[@OID='Event.Day1']/FormData[@OID='Form.MEASURES']//ItemData[@OID='Item.DATE_V']</xc:ElementPath>
                        </xc:Test>
                        <xc:Calculation Operator="sum">
                                <xc:Value DataType="integer">1</xc:Value>
                                <xc:Function Function="daysDiff">
                                        <xc:ElementPath>StudyEventData[@OID='Event.SCREENING']/FormData[@OID='Form.DEMOG']//ItemData[@O

                                        <xc:ElementPath>StudyEventData[@OID='Event.Day1']/FormData[@OID='Form.MEASURES']//ItemData[@OID

                                </xc:Function>
                        </xc:Calculation>
                        </xc:When>
                        <xc:Otherwise>
```

Screenshot of the SDTM Demographics table


SAS - [VIEWTABLE: Cdisc.Dm]
File Edit View Tools Data Solutions Window Help
Explorer
Contents of 'Cdisc'
Ae
Cm
Dm
Ds
Eg
Ex
Ie
Lb
Mh
Ml
Pe
Qs
Sc
Su
Sv
Vs
Results
Explorer
VIEWTABLE: Cdisc.Dm
C:\Program Files\SAS Institute\SAS\V8

	Study identifier	Domain Abbreviation	Unique Subject Identifier	Subject Identifier for the Study	Subject Reference Start Date/Time	Subject Reference End Date/Time	Study Site Identifier	Date/Time of Birth
1	[redacted]	DM	[redacted]201-101	101	2007-05-15	2007-05-17	201	1978-07-04
2	[redacted]	DM	[redacted]201-102	102	2007-05-14	2007-05-16	201	1981-05-11
3	[redacted]	DM	[redacted]201-105	105	2007-05-14	2007-05-16	201	1977-01-08
4	[redacted]	DM	[redacted]201-107	107	2007-05-23	2007-05-24	201	1979-10-12
5	[redacted]	DM	[redacted]201-109	109	2007-05-25	2007-05-26	201	1981-04-20
6	[redacted]	DM	[redacted]201-118	118	2007-05-30	2007-06-01	201	1971-03-09
7	[redacted]	DM	[redacted]201-121	121	2007-06-05	2007-06-07	201	1985-05-30
8	[redacted]	DM	[redacted]201-128	128	2007-05-31	2007-06-02	201	1969-04-26
9	[redacted]	DM	[redacted]201-130	130	2007-05-30	2007-05-31	201	1979-09-10
10	[redacted]	DM	[redacted]201-131	131	2007-06-07	2007-06-09	201	1976-07-28
11	[redacted]	DM	[redacted]201-135	135	2007-06-07	2007-06-09	201	1985-02-13
12	[redacted]	DM	[redacted]201-137	137	2007-06-06	2007-06-08	201	1979-08-16
13	[redacted]	DM	[redacted]201-140	140	2007-06-11	2007-06-13	201	1976-12-04
14	[redacted]	DM	[redacted]201-141	141	2007-06-12	2007-06-14	201	1971-10-06
15	[redacted]	DM	[redacted]201-142	142	2007-06-18	2007-06-20	201	1973-02-25
16	[redacted]	DM	[redacted]201-144	144	2007-06-12	2007-06-14	201	1969-07-19
17	[redacted]	DM	[redacted]201-145	145	2007-06-14	2007-06-15	201	1978-07-02
18	[redacted]	DM	[redacted]201-151	151	2007-06-22	2007-06-23	201	1980-09-27
19	[redacted]	DM	[redacted]201-152	152	2007-06-14	2007-06-16	201	1972-03-14
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28	[redacted]	DM	[redacted]201-175	175	2007-07-06	2007-07-07	201	1976-11-26
29	[redacted]	DM	[redacted]201-177	177	2007-07-02	2007-07-04	201	1978-08-07
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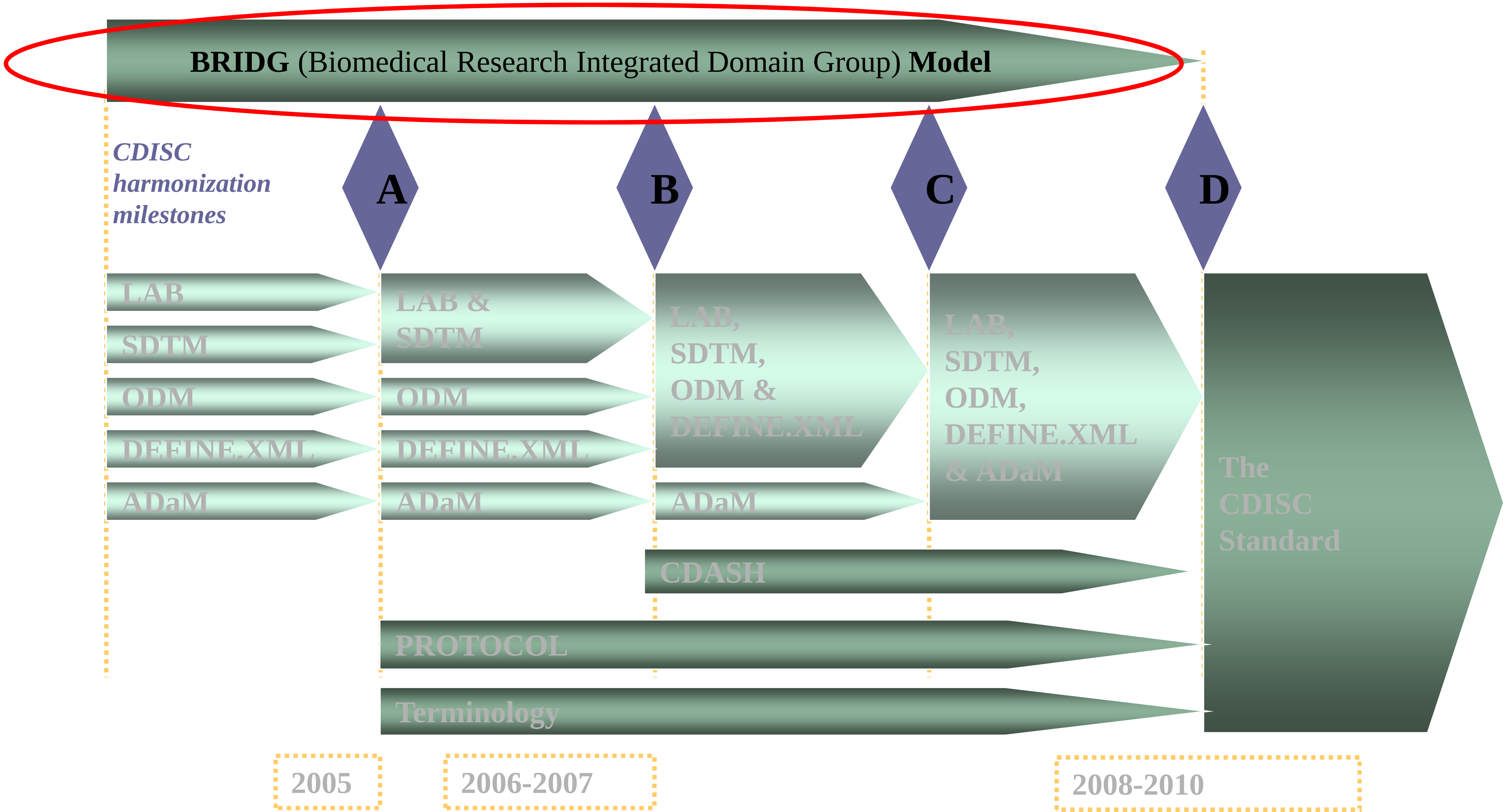
31	[redacted]	DM	[redacted]201-182	182	2007-07-10	2007-07-11	201	1977-07-15
32	[redacted]	DM	[redacted]201-185	185	2007-07-13	2007-07-14	201	1983-07-17

CDISC Technical Roadmap



BRIDG (Biomedical Research Integrated Domain Group) **Model**

CDISC harmonization milestones

A

B

C

D

LAB
SDTM
ODM
DEFINE.XML
ADaM

LAB & SDTM
ODM
DEFINE.XML
ADaM

LAB, SDTM, ODM & DEFINE.XML
ADaM

LAB, SDTM, ODM, DEFINE.XML & ADaM

The CDISC Standard

CDASH

PROTOCOL

Terminology

2005

2006-2007

2008-2010

Strength *through collaboration.*

Merci…
Questions - Réponses

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