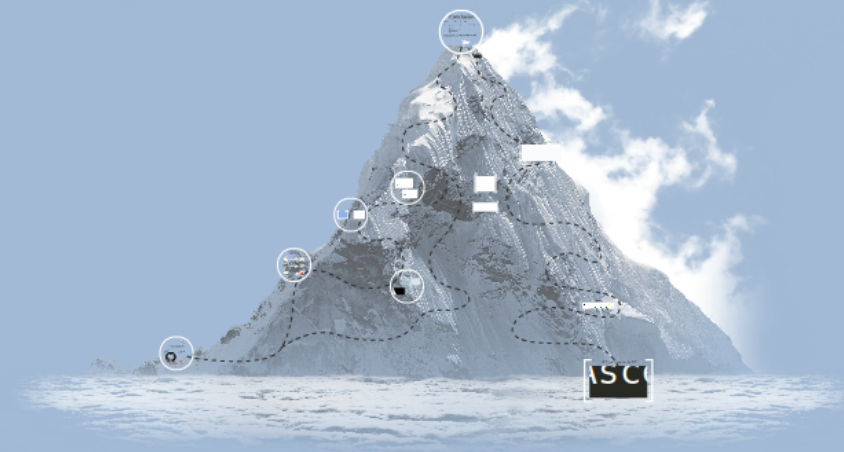


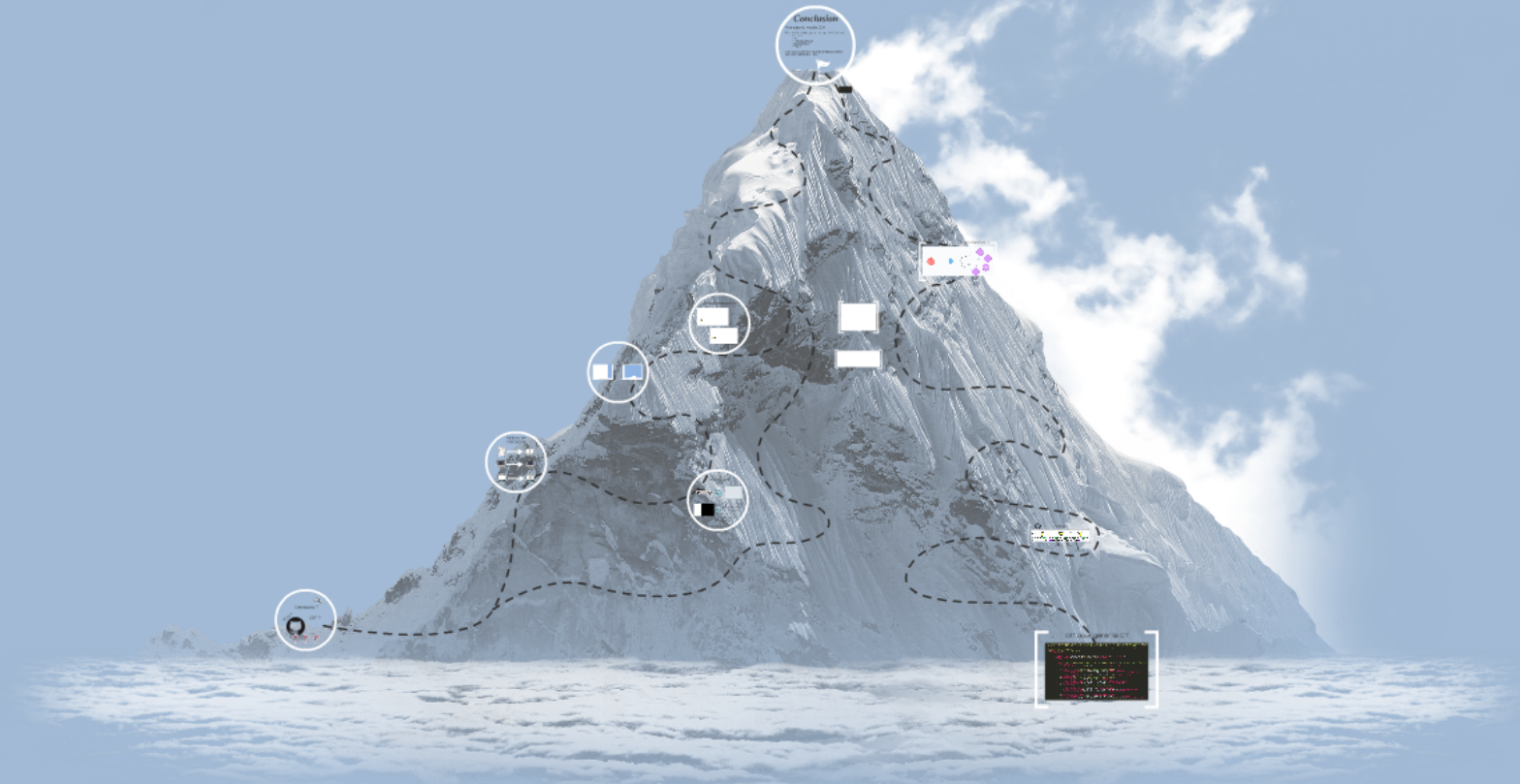
CDISC DANS LA BONNE VERSION...

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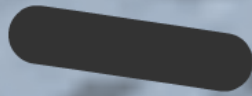


Versions ?

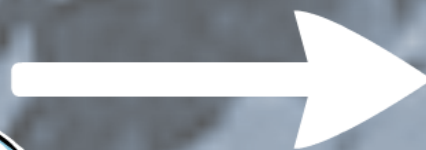
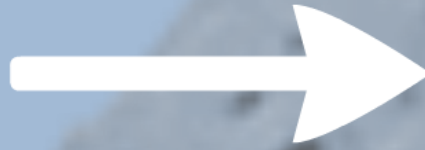
SVN ?



GIT ?



Notion de Versions :



Dernière version!



Cdisc -> Une version par standard (sans coherence entre 2 standards)



**Study Data Tabulation Model
Implementation Guide:
Human Clinical Trials**

Version 3.2

Prepared by the
CDISC Submission Data Standards Team



CDASH 1.1 SDTM 3.2

CT 2015-03-27

SDTM 3.1.2

CDASH 2.0

CT 2017-09-29

CT 2016-03-25

Updates over time

(JAN 2016)

- Customer Standards
- Technical Standards
- Statistics
- Theoretical Areas

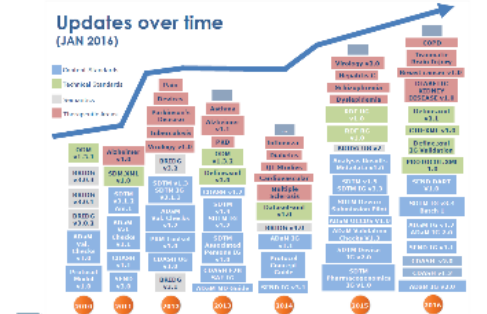


This & next slide with permission from Peter Van Reusel

Updates over time

(JAN 2014)

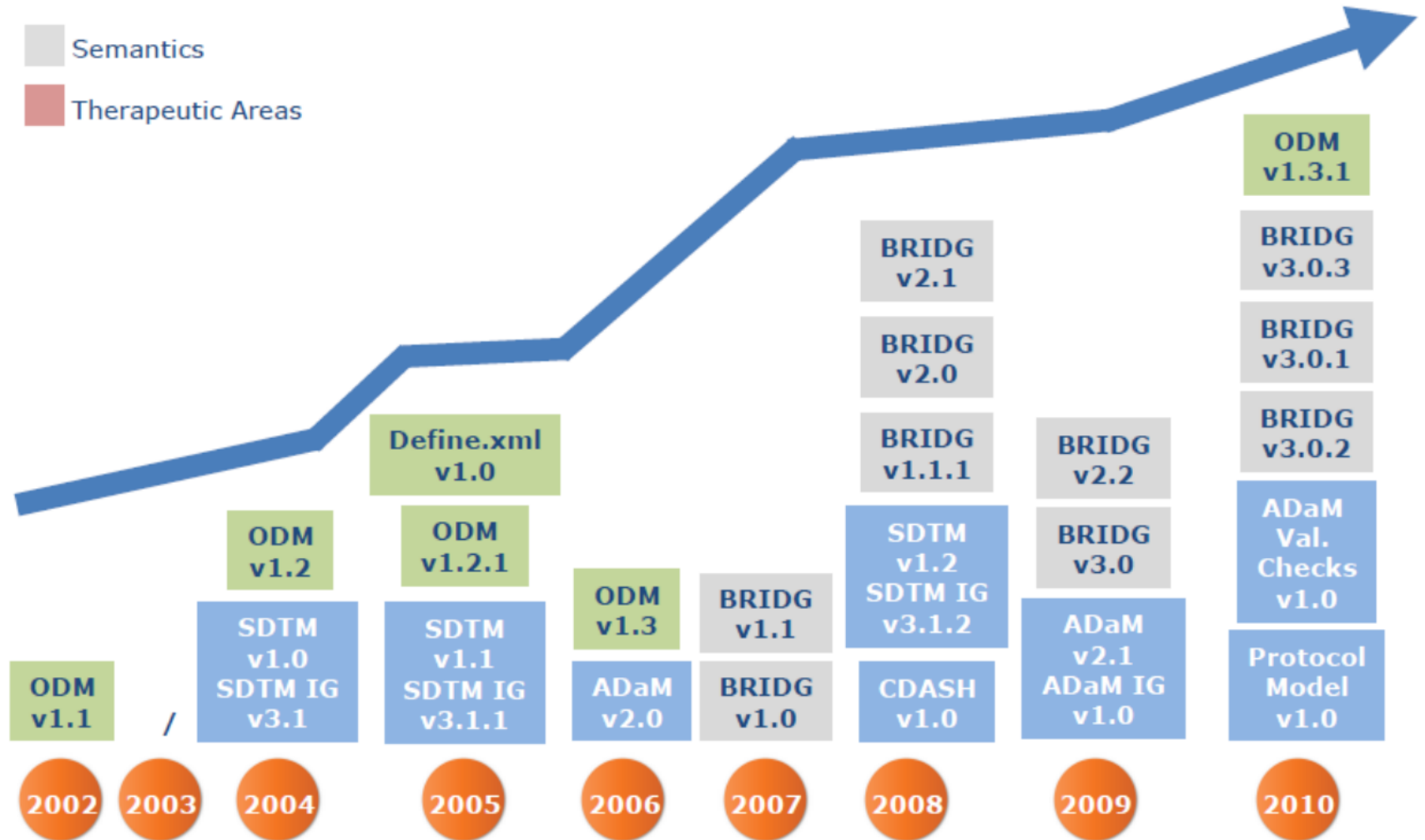
- Customer Standards
- Technical Standards
- Statistics
- Theoretical Areas



Updates over time

(JAN 2016)

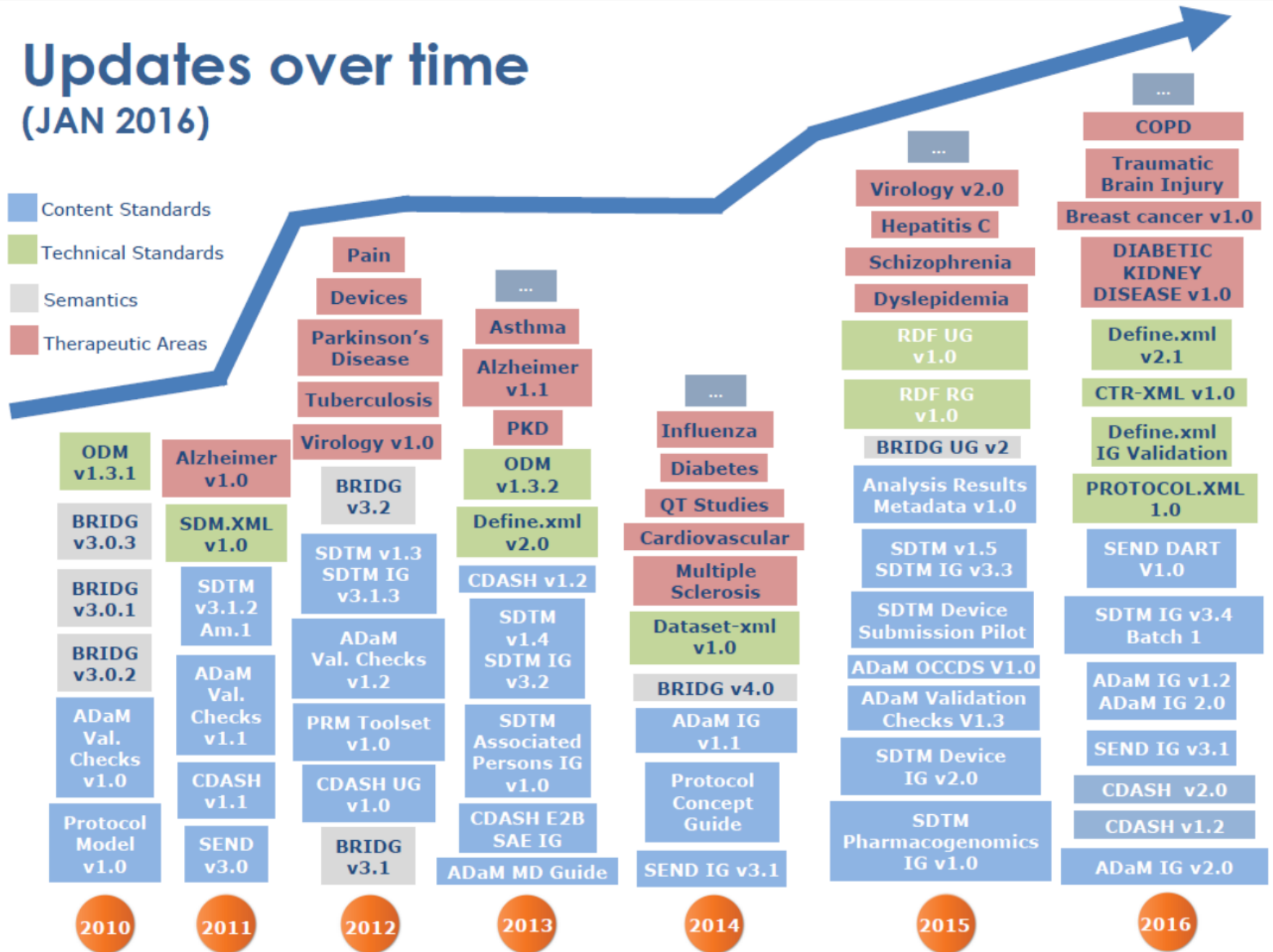
- Content Standards
- Technical Standards
- Semantics
- Therapeutic Areas



This & next slide with permission from Peter Van Reusel

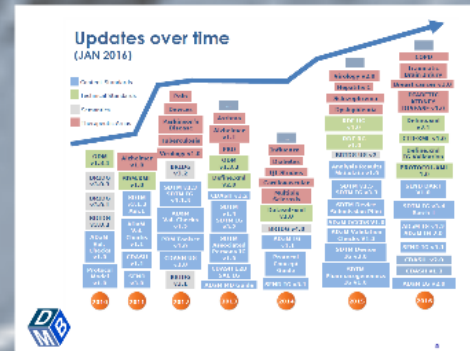
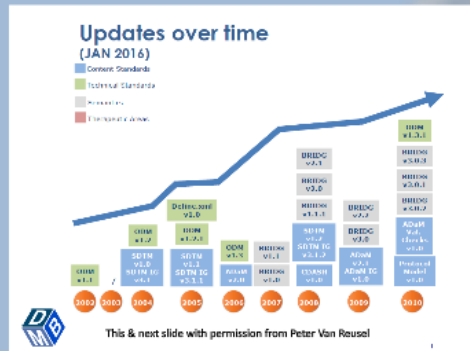
Updates over time (JAN 2016)

- Content Standards
- Technical Standards
- Semantics
- Therapeutic Areas

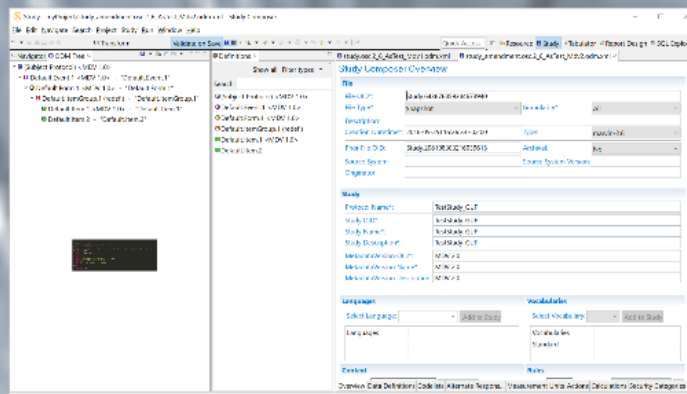
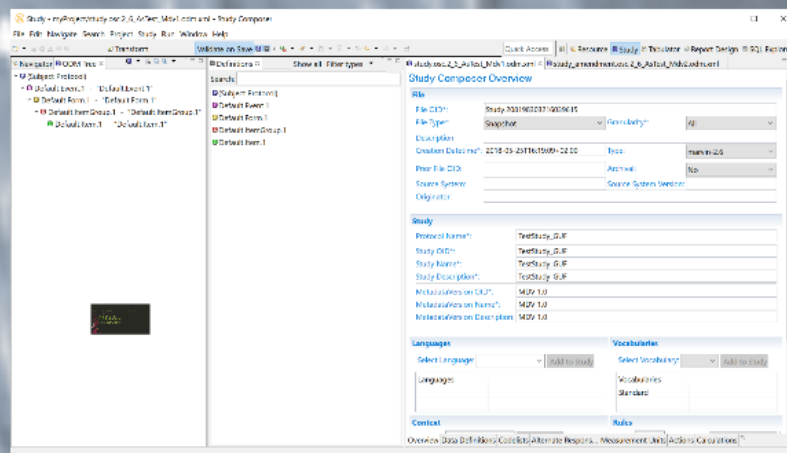


Je vais craquer !





OOM avec amendement



Study - myProject/study.osc.2_6_AsTest_Mdv1.odm.xml - Study Composer

File Edit Navigate Search Project Study Run Window Help

Transform Validate on Save Quick Access Resource Study Tabulator Report Design SQL Explorer

Navigator ODM Tree Definitions Show all Filter types

study.osc.2_6_AsTest_Mdv1.odm.xml study_amendment.osc.2_6_AsTest_Mdv2.odm.xml

Study Composer Overview

File

File OID*: Study.208198303216039615
 File Type*: Snapshot Granularity*: All
 Description:
 Creation Datetime*: 2018-05-25T16:19:09+02:00 Type: marvin-2.6
 Prior File OID: Archival: No
 Source System: Source System Version:
 Originator:

Study

Protocol Name*: TestStudy_GUF
 Study OID*: TestStudy_GUF
 Study Name*: TestStudy_GUF
 Study Description*: TestStudy_GUF
 MetadataVersion OID*: MDV 1.0
 MetadataVersion Name*: MDV 1.0
 MetadataVersion Description: MDV 1.0

Languages Select Language: Add to Study

Language	Code

Vocabularies Select Vocabulary: Add to Study

Vocabulary	Code
Standard	

Context **Rules**

Overview Data Definitions Codelists Alternate Respons... Measurement Units Actions Calculations



Study - myProject/study_amendment.osc.2_6_AsTest_Mdv2.odm.xml - Study Composer

File Edit Navigate Search Project Study Run Window Help

Transform Validate on Save Quick Access


```
<?xml version="1.0" encoding="UTF-8"?>
<!--
*****
Written by XClinical Study Composer
Author: Nicolas de Saint Jorre <nicolas.desaintjorre@xclinical.com> xclinical
Info:
*****
-->
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" xmlns:xc="http://www.xclinical.com/xmlns/odm/xc-2-6" FileType="Snapshot" FileOID="Study.208198303216039615" CreationDateTime="
2018-05-25T16:19:09+02:00" AsOfDateTime="2018-05-25T16:23:08+02:00" Granularity="All" ODMVersion="1.3" XClinicalVersion="marvin-2.6">
  <Study OID="TestStudy_GUF">
    <GlobalVariables>
      <StudyName>TestStudy_GUF</StudyName>
      <StudyDescription>TestStudy_GUF</StudyDescription>
      <ProtocolName>TestStudy_GUF</ProtocolName>
    </GlobalVariables>
    <BasicDefinitions/>
    <MetaDataVersion OID="MDV 1.0" Name="MDV 1.0" Description="MDV 1.0">
      <Protocol>
        <StudyEventRef StudyEventOID="Default.Event.1" OrderNumber="1" Mandatory="Yes"/>
      </Protocol>
      <StudyEventDef OID="Default.Event.1" Name="Default.Event.1" Type="Scheduled" Repeating="No">
        <FormRef FormOID="Default.Form.1" OrderNumber="1" Mandatory="Yes"/>
      </StudyEventDef>
      <FormDef OID="Default.Form.1" Name="Default.Form.1" Repeating="No">
        <ItemGroupRef ItemGroupOID="Default.ItemGroup.1" OrderNumber="1" Mandatory="Yes"/>
      </FormDef>
      <ItemGroupDef OID="Default.ItemGroup.1" Name="Default.ItemGroup.1" Repeating="No">
        <ItemRef ItemOID="Default.Item.1" Mandatory="Yes" OrderNumber="1"/>
      </ItemGroupDef>
      <ItemDef OID="Default.Item.1" Name="Default.Item.1" DataType="text">
      </ItemDef>
    </MetaDataVersion>
  </Study>
  <AdminData>
    <SignatureDef OID="Sign 1.0">
      <Meaning/>
      <LegalReason/>
    </SignatureDef>
  </AdminData>
  <xc:EditorSetup xmlns:edit="http://www.xclinical.com/xmlns/editor/xc-1-0">
    <edit:DefineMetaDataFile/>
  </xc:EditorSetup>
</ODM>
```


Study - myProject/study_amendment.osc.2_6_AsTest_Mdv2.odm.xml - Study Composer

File Edit Navigate Search Project Study Run Window Help

Transform Validate on Save Quick Access Resource Study Tabulator Report Design SQL Explorer

Navigator ODM Tree

- (Subject Protocol) <MDV 1.0>
 - Default.Event.1 <MDV 1.0> - "Default.Event.1"
 - Default.Form.1 <MDV 1.0> - "Default.Form.1"
 - Default.ItemGroup.1 (redef.) - "Default.ItemGroup.1"
 - Default.Item.1 <MDV 1.0> - "Default.Item.1"
 - Default.Item.2 - "Default.Item.2"

Definitions

Show all Filter types

Search:

- (Subject Protocol) <MDV 1.0>
- Default.Event.1 <MDV 1.0>
- Default.Form.1 <MDV 1.0>
- Default.ItemGroup.1 (redef.)
- Default.Item.1 <MDV 1.0>
- Default.Item.2

Study Composer Overview

File

File OID*: Study.643676859344673940

File Type*: Snapshot Granularity*: All

Description:

Creation Datetime*: 2018-05-25T16:26:33+02:00 Type: marvin-2.6

Prior File OID: Study.208198303216039615 Archival: No

Source System: Source System Version:

Originator:

Study

Protocol Name*: TestStudy_GUF

Study OID*: TestStudy_GUF

Study Name*: TestStudy_GUF

Study Description*: TestStudy_GUF

MetadataVersion OID*: MDV 2.0

MetadataVersion Name*: MDV 2.0

MetadataVersion Description: MDV 2.0

Languages

Select Language: Add to Study

Language	

Vocabularies

Select Vocabulary: Add to Study

Vocabulary	
Standard	

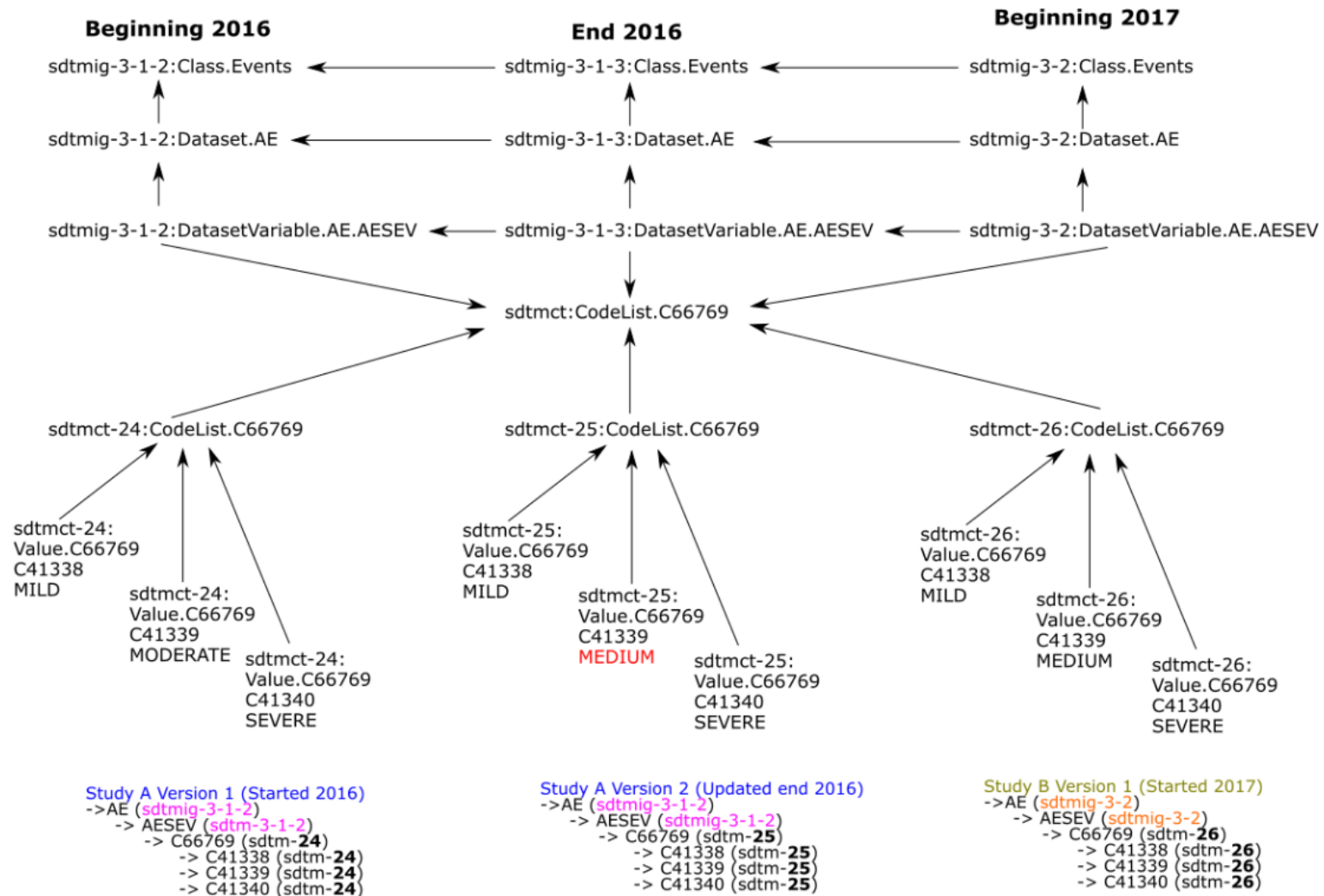
Context

Rules

Overview Data Definitions Codelists Alternate Respons... Measurement Units Actions Calculations Security Categories

```
<?xml version="1.0" encoding="UTF-8"?>
<!--
*****
Written by XClinical Study Composer
Author: Nicolas de Saint Jorre <nicolas.desaintjorre@xclinical.com> xclinical
Info:
*****
-->
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" xmlns:xc="http://www.xclinical.com/xmlns/odm/xc-2-6" FileType="Snapshot" FileOID="Study.643676859344673940" PriorFileOID="
Study.208198303216039615" CreationDateTime="2018-05-25T16:26:33+02:00" AsOfDateTime="2018-05-25T16:28:31+02:00" Granularity="All" ODMVersion="1.3" XClinicalVersion="marvin-2.6">
  <Study OID="TestStudy_GUF">
    <GlobalVariables>
      <StudyName>TestStudy_GUF</StudyName>
      <StudyDescription>TestStudy_GUF</StudyDescription>
      <ProtocolName>TestStudy_GUF</ProtocolName>
    </GlobalVariables>
    <BasicDefinitions/>
    <MetaDataVersion OID="MDV 2.0" Name="MDV 2.0" Description="MDV 2.0">
      <Include StudyOID="TestStudy_GUF" MetaDataVersionOID="MDV 1.0"/>
      <ItemGroupDef OID="Default.ItemGroup.1" Name="Default.ItemGroup.1" Repeating="No">
        <ItemRef ItemOID="Default.Item.1" Mandatory="Yes" OrderNumber="1"/>
        <ItemRef ItemOID="Default.Item.2" Mandatory="Yes" OrderNumber="2"/>
      </ItemGroupDef>
      <ItemDef OID="Default.Item.2" Name="Default.Item.2" DataType="text">
      </ItemDef>
    </MetaDataVersion>
  </Study>
  <xc:EditorSetup xmlns:edit="http://www.xclinical.com/xmlns/editor/xc-1-0">
    <edit:PriorFile edit:ProjectRelativePath="study.osc.2_6_AsTest_Mdv1.odm.xml"></edit:PriorFile>
    <edit:DefineMetaDataFile/>
  </xc:EditorSetup>
</ODM>
```

Adverse Event Severity (AESEV) Severity/Intensity Scale for Adverse Events (C66769) Mild (C41338) / Moderate (C41339) / Severe (C41340)



<u>Metadata Type</u>	Name	OID	Version	Primary Key
Variable	Adverse Event Severity	AESEV	1	AESEV.1
Codelist	Severity/Intensity Scale for Adverse Events	C66769	1	C66769.1
Enumerated Item	Mild	C41338	1	C41338.1
Enumerated Item	Moderate	C41339	1	C41339.1
Enumerated Item	Severe	C41340	1	C41340.1
Variable	Adverse Event Severity	AESEV	2	AESEV.2
Codelist	Severity/Intensity Scale for Adverse Events	C66769	2	C66769.2
Enumerated Item	Medium	C41339	2	C41339.2
Form	Adverse Event Form	FAE	1	FAE.1
Study	Painkiller Blockbuster Study	S12345	1	S12345.1
CDISC Standard	SDTM IG	SDTMIG	32	SDTMIG.32



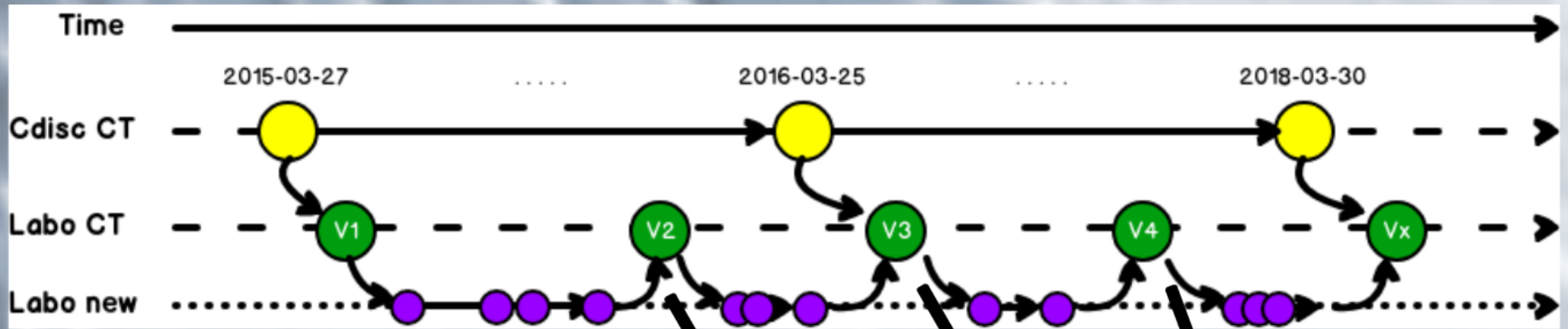


GIT pour gerer la CT

```
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" xmlns:xs="http://www.w3.org/2001/XMLSchema-instance" xmlns:nciodm="http://n
http://www.nci.nih.gov/EVS/CDISC ../schema/controlledterminology1-0-0.xsd" FileType="Snapshot" FileOID="CDISC_CT.SDTM.201
2018-03-29T16:46:06" AsOfDateTime="2018-03-30T00:00:00" ODMVersion="1.3.2" Originator="CDISC XML Technologies Team (Termi
SourceSystemVersion="2018-03-30">
  <Study OID="CDISC_CT.SDTM.2018-03-30">
    <GlobalVariables>
      <StudyName>CDISC SDTM Controlled Terminology</StudyName>
      <StudyDescription>CDISC SDTM Controlled Terminology, 2018-03-30</StudyDescription>
      <ProtocolName>CDISC SDTM Controlled Terminology</ProtocolName>
    </GlobalVariables>
    <MetaDataVersion OID="CDISC_CT_MetaDataVersion.SDTM.2018-03-30" Name="CDISC SDTM Controlled Terminology" Descript
    <CodeList OID="CL.C141663.A4STR1TC" Name="4 Stair Ascend Functional Test Test Code" DataType="text" nciodm:Ex
      <Description>
        <TranslatedText xml:lang="en">4 Stair Ascend test code.</TranslatedText>
      </Description>
      <EnumeratedItem CodedValue="A4STR101" nciodm:ExtCodeID="C141706">
        <nciodm:CDISCSynonym>A4STR1-Time to Ascend 4 Stairs</nciodm:CDISCSynonym>
        <nciodm:CDISCDefinition>4 Stair Ascend - Time taken to ascend 4 stairs.</nciodm:CDISCDefinition>
        <nciodm:PreferredTerm>4 Stair Ascend - Time to Ascend 4 Stairs</nciodm:PreferredTerm>
      </EnumeratedItem>
      <EnumeratedItem CodedValue="A4STR102" nciodm:ExtCodeID="C141707">
        <nciodm:CDISCSynonym>A4STR1-Test Grade</nciodm:CDISCSynonym>
        <nciodm:CDISCDefinition>4 Stair Ascend - Test grade.</nciodm:CDISCDefinition>
        <nciodm:PreferredTerm>4 Stair Ascend - Test Grade</nciodm:PreferredTerm>
      </EnumeratedItem>
      <EnumeratedItem CodedValue="A4STR103" nciodm:ExtCodeID="C147590">
        <nciodm:CDISCSynonym>A4STR1-Wear Orthoses</nciodm:CDISCSynonym>
        <nciodm:CDISCDefinition>4 Stair Ascend - Did subject wear orthoses?</nciodm:CDISCDefinition>
        <nciodm:PreferredTerm>4 Stair Ascend - Wear Orthoses</nciodm:PreferredTerm>
      </EnumeratedItem>
      <nciodm:CDISCSubmissionValue>A4STR1TC</nciodm:CDISCSubmissionValue>
      <nciodm:CDISCSynonym>4 Stair Ascend Functional Test Test Code</nciodm:CDISCSynonym>
      <nciodm:PreferredTerm>CDISC Functional Test 4 Stair Ascend Test Code Terminology</nciodm:PreferredTerm>
    </CodeList>
```




GitHub...

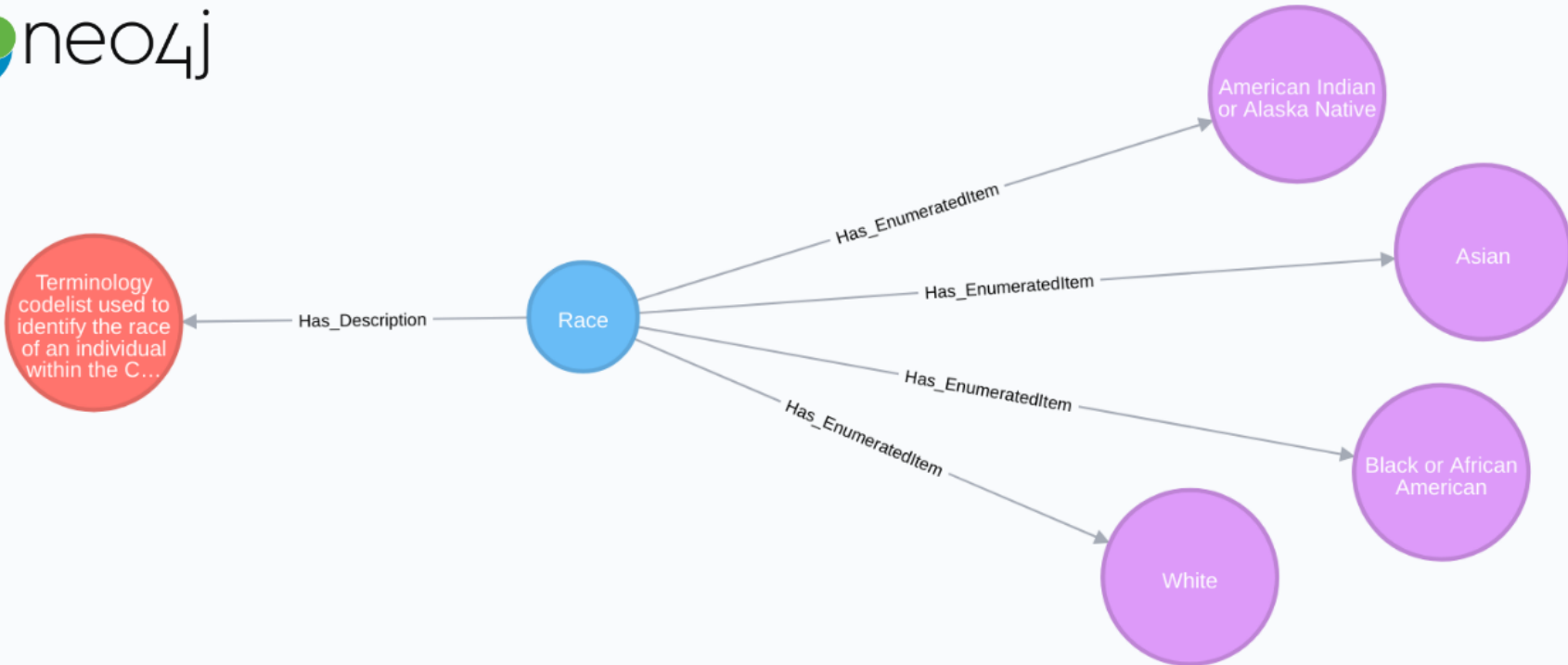


Etude XY
MOV 1.0

Etude XY
MOV 1.1

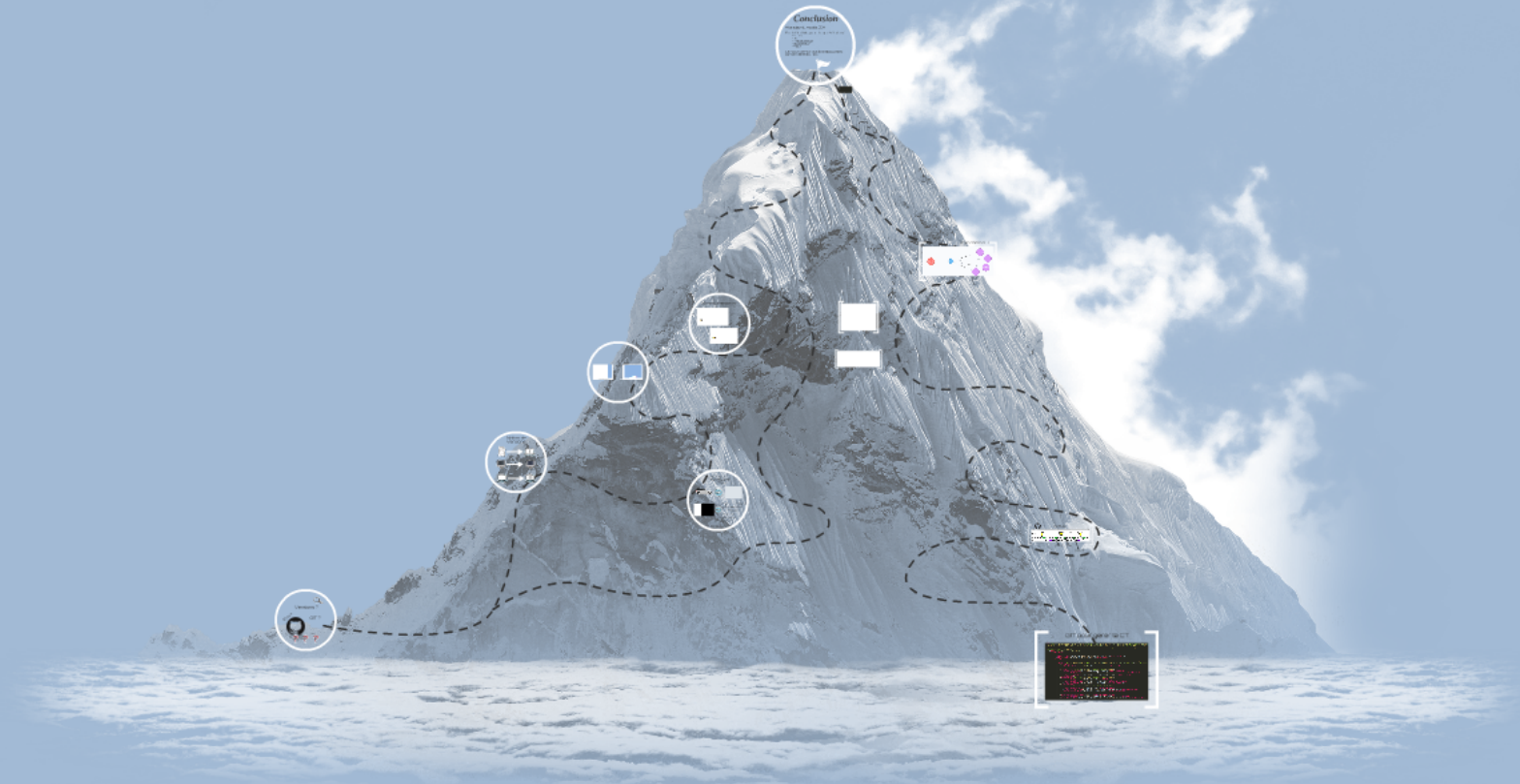
Etude YZ
MOV 1.0

Graph Database !!!



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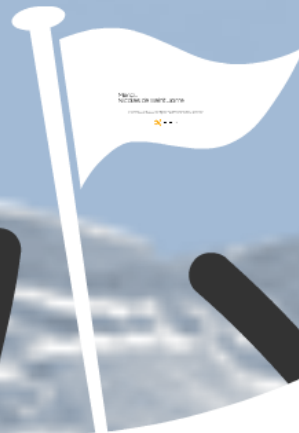
Conclusion

Mise à jour du modèle ODM!

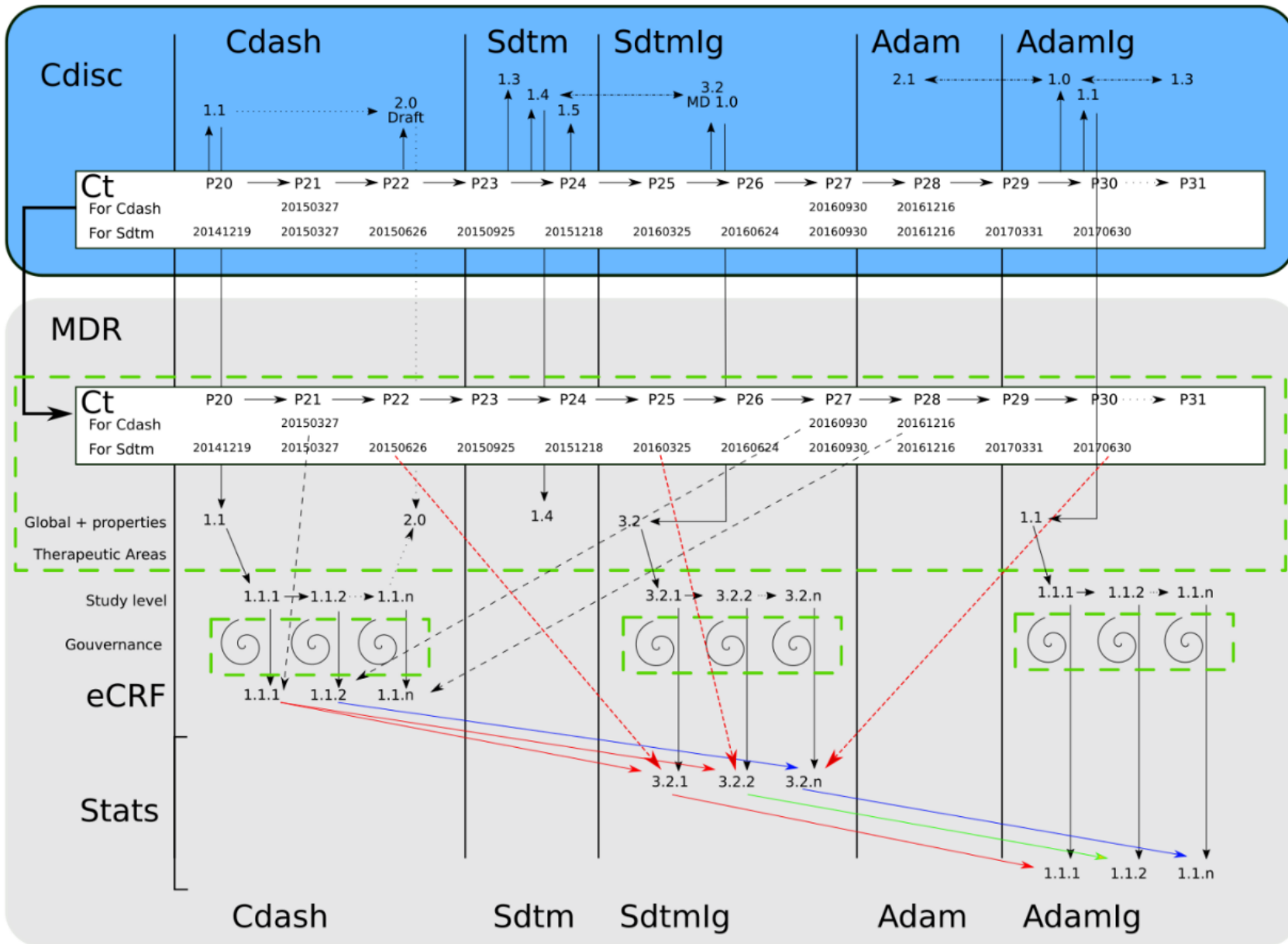
Ajout d'attributs pour chaque Métadonnée

- From
- To
- Predecessor
- Successor
- MDV

La notion de MDV doit être absolument conservée avec l' OIO



Time →




```
<?xml version="1.0" encoding="UTF-8"?>
<!--
*****
Written by XClinical Study Composer
Author: Nicolas de Saint Jorre <nicolas.desaintjorre@xclinical.com> xclinical
Info:
*****
-->
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3" xmlns:xc="http://www.xclinical.com/xmlns/odm/xc-2-6" FileType="Snapshot" FileOID="Study.208198303216039615" CreationDateTime="
2018-05-25T16:19:09+02:00" AsOfDateTime="2018-05-25T16:23:08+02:00" Granularity="All" ODMVersion="1.3" XClinicalVersion="marvin-2.6">
  <Study OID="TestStudy_GUF">
    <GlobalVariables>
      <StudyName>TestStudy_GUF</StudyName>
      <StudyDescription>TestStudy_GUF</StudyDescription>
      <ProtocolName>TestStudy_GUF</ProtocolName>
    </GlobalVariables>
    <BasicDefinitions/>
    <MetaDataVersion OID="MDV 1.0" Name="MDV 1.0" Description="MDV 1.0">
      <Protocol>
        <StudyEventRef StudyEventOID="Default.Event.1" OrderNumber="1" Mandatory="Yes"/>
      </Protocol>
      <StudyEventDef OID="Default.Event.1" Name="Default.Event.1" Type="Scheduled" Repeating="No" From="2017-05-25" To="Now" MDV="1.0" Predecessor="None" Successor="None">
        <FormRef FormOID="Default.Form.1" OrderNumber="1" Mandatory="Yes"/>
      </StudyEventDef>
      <FormDef OID="Default.Form.1" Name="Default.Form.1" Repeating="No" From="2017-05-25" To="Now" MDV="1.0" Predecessor="None" Successor="None">
        <ItemGroupRef ItemGroupOID="Default.ItemGroup.1" OrderNumber="1" Mandatory="Yes"/>
      </FormDef>
      <ItemGroupDef OID="Default.ItemGroup.1" Name="Default.ItemGroup.1" Repeating="No" From="2017-05-25" To="Now" MDV="1.0" Predecessor="None" Successor="None">
        <ItemRef ItemOID="Default.Item.1" Mandatory="Yes" OrderNumber="1"/>
      </ItemGroupDef>
      <ItemDef OID="Default.Item.1" Name="Default.Item.1" DataType="text" From="2017-05-25" To="Now" MDV="1.0" Predecessor="None" Successor="None">
      </ItemDef>
    </MetaDataVersion>
  </Study>
  <AdminData>
    <SignatureDef OID="Sign 1.0">
      <Meaning/>
      <LegalReason/>
    </SignatureDef>
  </AdminData>
  <xc:EditorSetup xmlns:edit="http://www.xclinical.com/xmlns/editor/xc-1-0">
    <edit:DefineMetaDataFile/>
  </xc:EditorSetup>
</ODM>
```

Merci...
Nicolas de Saint Jorre

nicolas.desaintjorre@xclinical.com



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NICOLAS DE SAINT JORRE - GUF 20180530

