

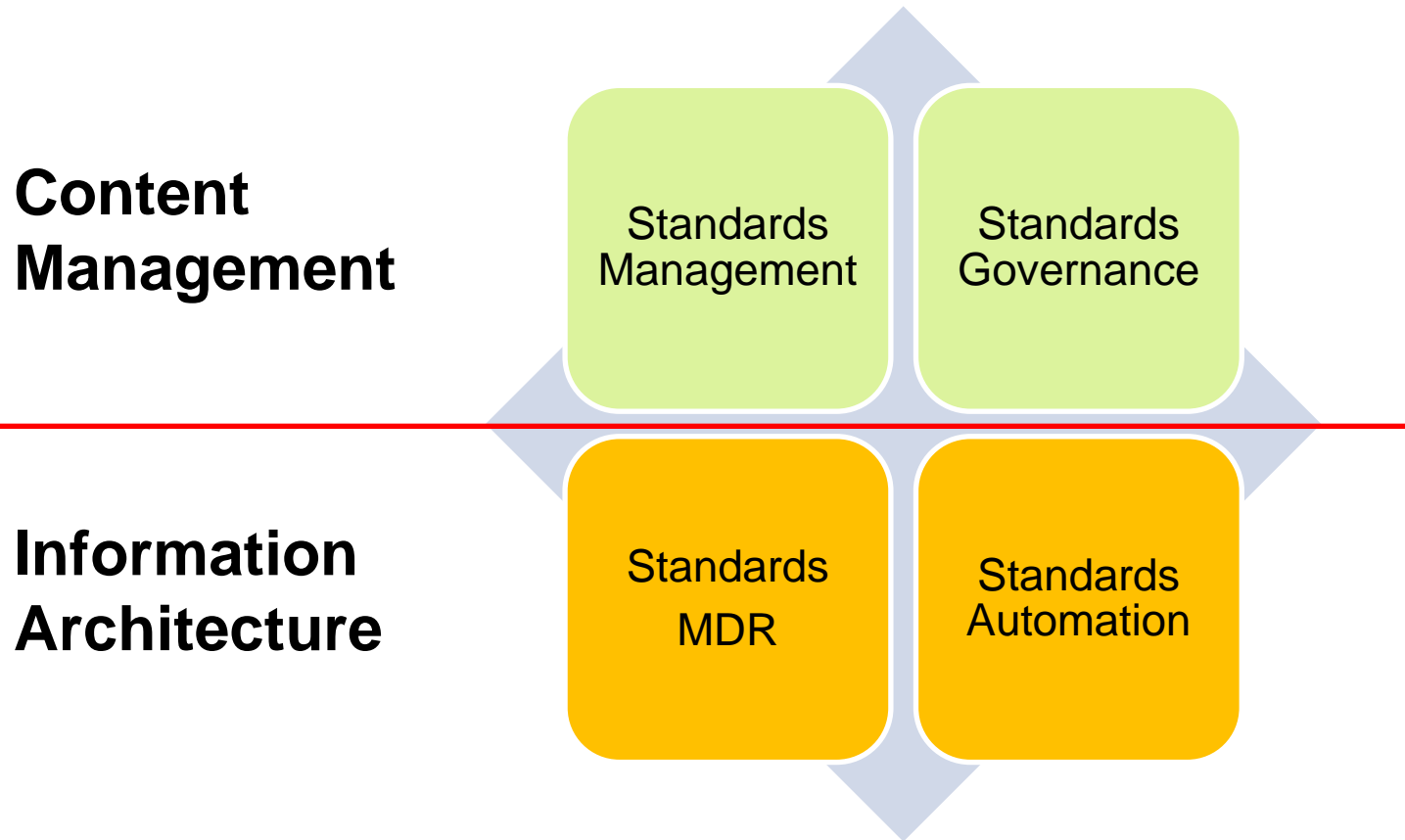
PhUSE Semantic Technology Update

CDISC, US Interchange, PRG Meeting, 11 November 2014

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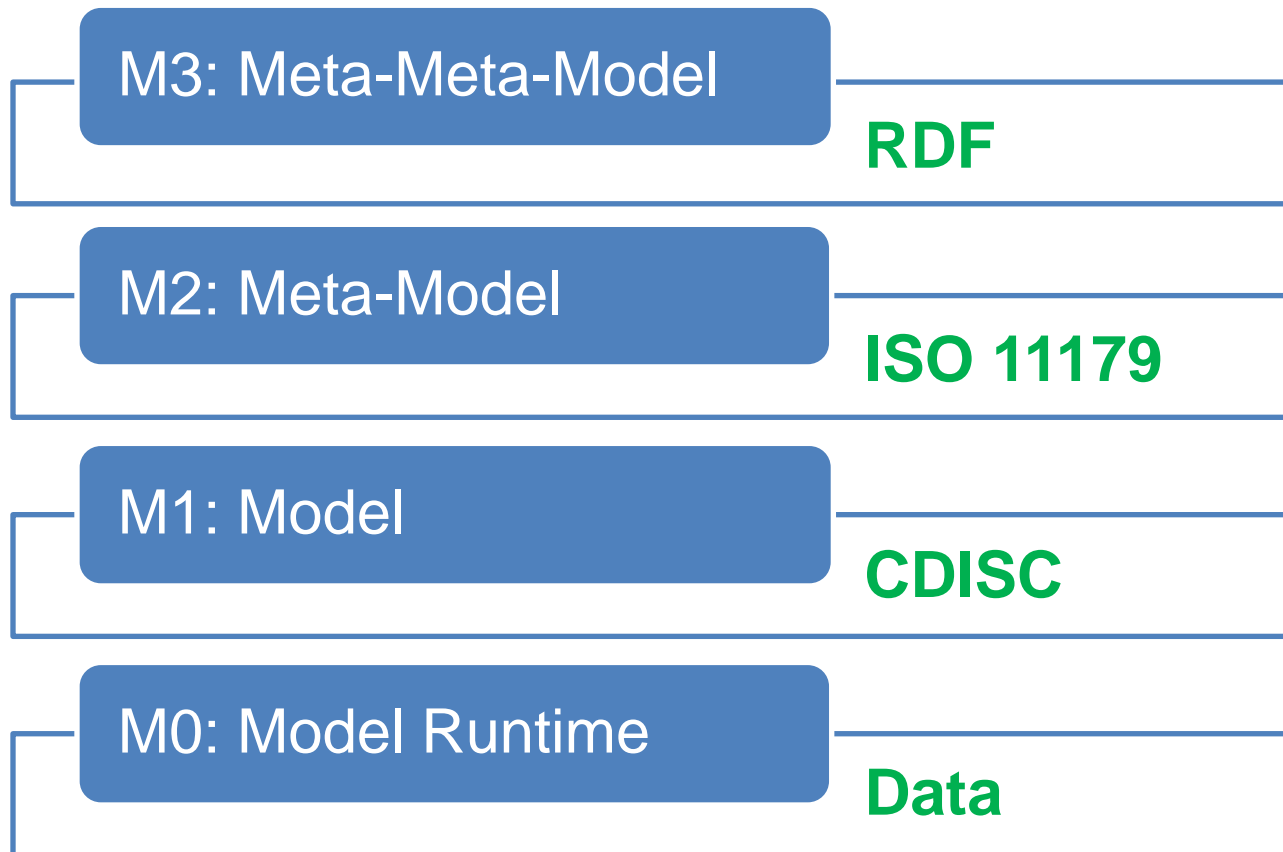
PhUSE Semantic Technology Working Group



- Make data semantically meaningful
 - Precisely define models and content
 - Store semantics with the data, so it can be remembered
 - Supports understanding and transparency of the data
 - Semantically align and integrate data from different sources
- Standards based automation
 - Store data standards in a Metadata Registry (MDR)
 - Workflow automation

- CDISC Foundational Standards in RDF
 - CDASH
 - SDTM
 - SEND
 - ADaM
 - Controlled Terminology
- Protocol and Schedule of Activities in RDF
- Analysis Results Metadata in RDF
- Link to Electronic Health Records (EHR)
- Regulatory Guidance in RDF

CDISC Foundational Standards in RDF



- CDASH
- SDTM
- SEND
- AdAM
- Controlled Terminology
- IG Assumptions

CDISC Standards in RDF Reference Guide



CDISC Standards in RDF Reference Guide

Version 1.0 Draft

Prepared by

The PhUSE CSS Semantic Technology Team



Notes to Readers

This is the specification of the RDF vocabulary and the RDF data sets that represent the current foundational CDISC standards in a W3C endorsed semantic format.

Revision History

Date	Version	Summary of Changes
2014-06-05	Draft 1.0	Version 1.0 for public comment.

Schedule of Activities

Schedule of Activities

5. SCHEDULE OF ASSESSMENTS AND PROCEDURES

Table 2 Schedule of Assessments and Procedures—Group A (PEG-IFN) and Group C (Advanced Fibrotic PEG-IFN)

Assessment/Procedure	Screen (days)	BL (days)	Treatment Period (weeks)																Initial 24 Weeks of Follow-Up (Weeks Post-End of Treatment)					Extended Long-Term Follow-Up Period (Years Post-End of Treatment Period)				
	-35 to -1	1	1	2	4	8	12	18	24	30	36	42	48*	4*	12*	24*	1*	1.5*	2*	3*	4*	5*						
Informed Consent/Assent ¹	x																											
Complete medical history, including family history of HBV	x																											
Physical examination	x																	x										
Symptom-directed physical examination		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x											
Vital signs	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x											
Weight ²	x	x ¹	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x			x	x	x	x					
Height ^{2,3}	x	x ¹				x ¹	x ¹	x ¹				x		x	x	x				x	x	x	x					
Parental height ⁴	x	x																										
Ultrasound ⁵	x																											
Ophthalmology exam ¹	x												x				x											

* Or upon and following study treatment withdrawal.



- owl:Thing (0 + 509)
 - sdm:StudyDesignElement (0 + 509)
 - sdm:Activity (0 + 455)
 - sdm:DefinedActivity
 - sdm:PlannedActivity (415)
 - sdm:StudyActivity (40)
 - sdm:Arm (2)
 - sdm:Cell (7)
 - sdm:CellReference (10)
 - sdm:Epoch (5)
 - sdm:Protocol
 - sdm:ProtocolVersion
 - sdm:Schedule (1)
 - sdm:Segment (7)
 - sdm:Study
 - sdm:StudyEvent (22)
 - sdm:TimingConstraint
 - sdm:Transition
 - sdm:Trigger
- skos:Collection
- skos:Concept
- skos:ConceptScheme

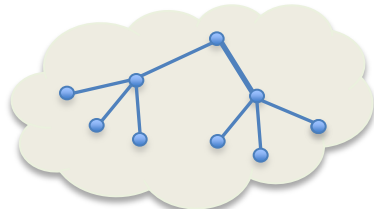
GDSR Browser

Home | Biomedical Concepts | Data Collection | Data Tabulation | Resources | Search

Schedule of Activities YV25718 C

Assessment/Procedure	Screen (days)	BL (days)	Treatment Period (weeks)																Initial 24 Weeks of Follow-Up (Week Post-End of Treatment)					Extended Long-Term Follow-Up Period (Year Post-End of Treatment Period)				
	-35 to -1	1	1	2	4	8	12	18	24	30	36	42	48	4	12	24	1	1.5	2	3	4	5						
Informed Consent/Assent	x																											
Complete medical history, including family history of HBV	x																											
Physical examination	x																	x										
Symptom-directed physical examination		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x											
Vital signs	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x											
Weight	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x			x	x	x	x					
Height	x	x				x	x	x	x				x	x	x	x				x	x	x	x					
Parental height	x	x																										
Ultrasound	x																											
Ophthalmology exam	x												x				x											
Urine or serum HCC pregnancy test (selected subjects)	x												x	x	x	x	x											

Web Service

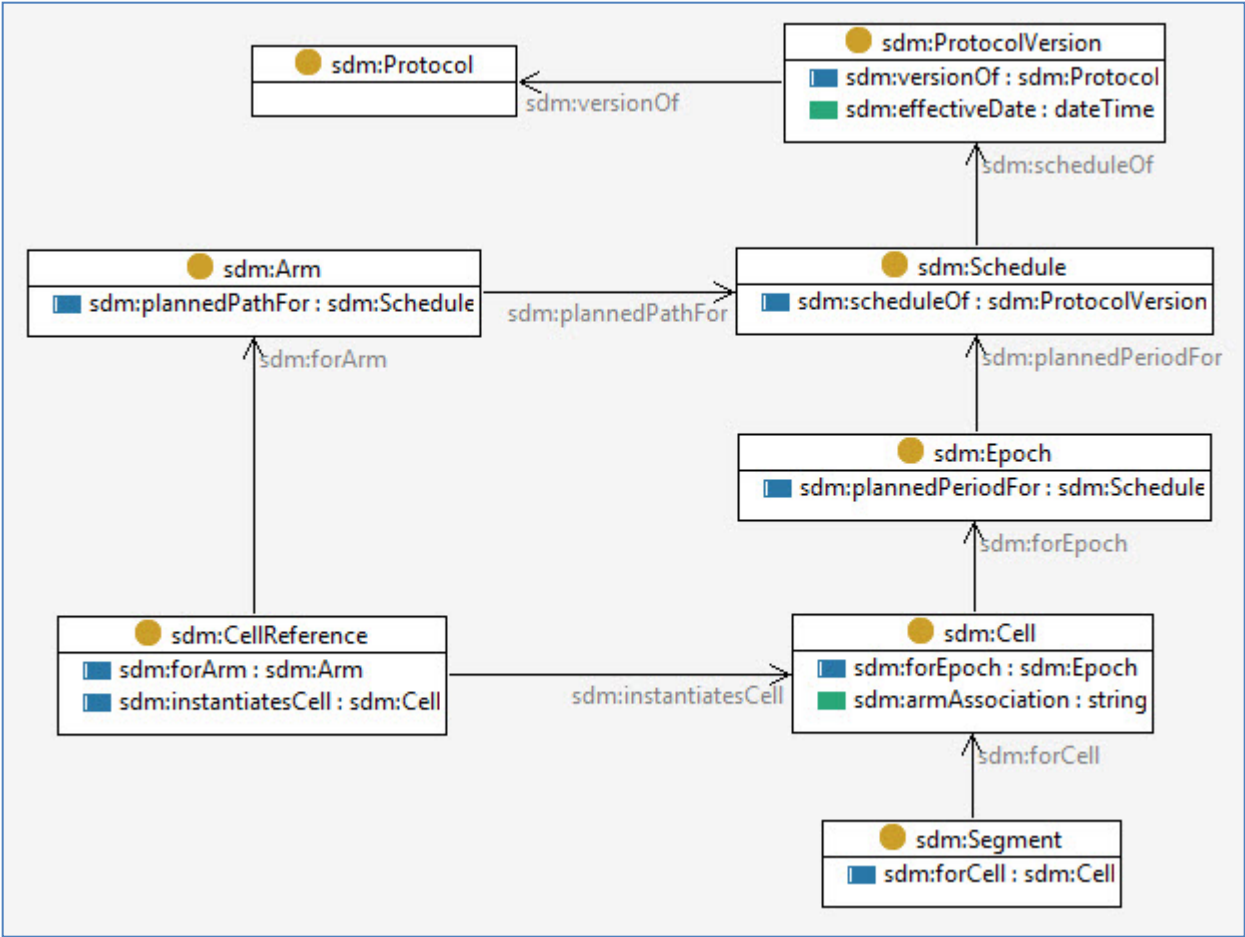


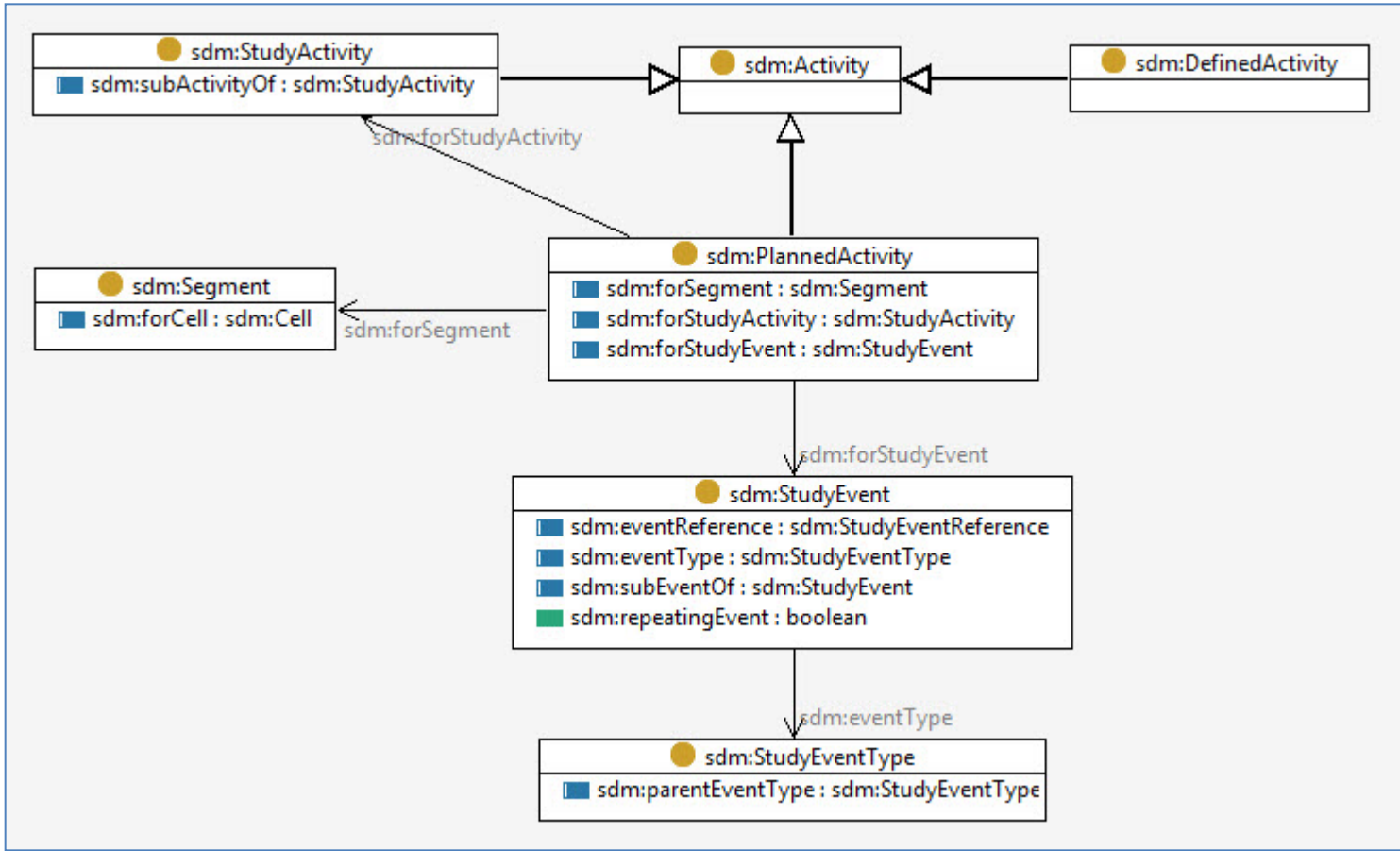
Schedule of Activities

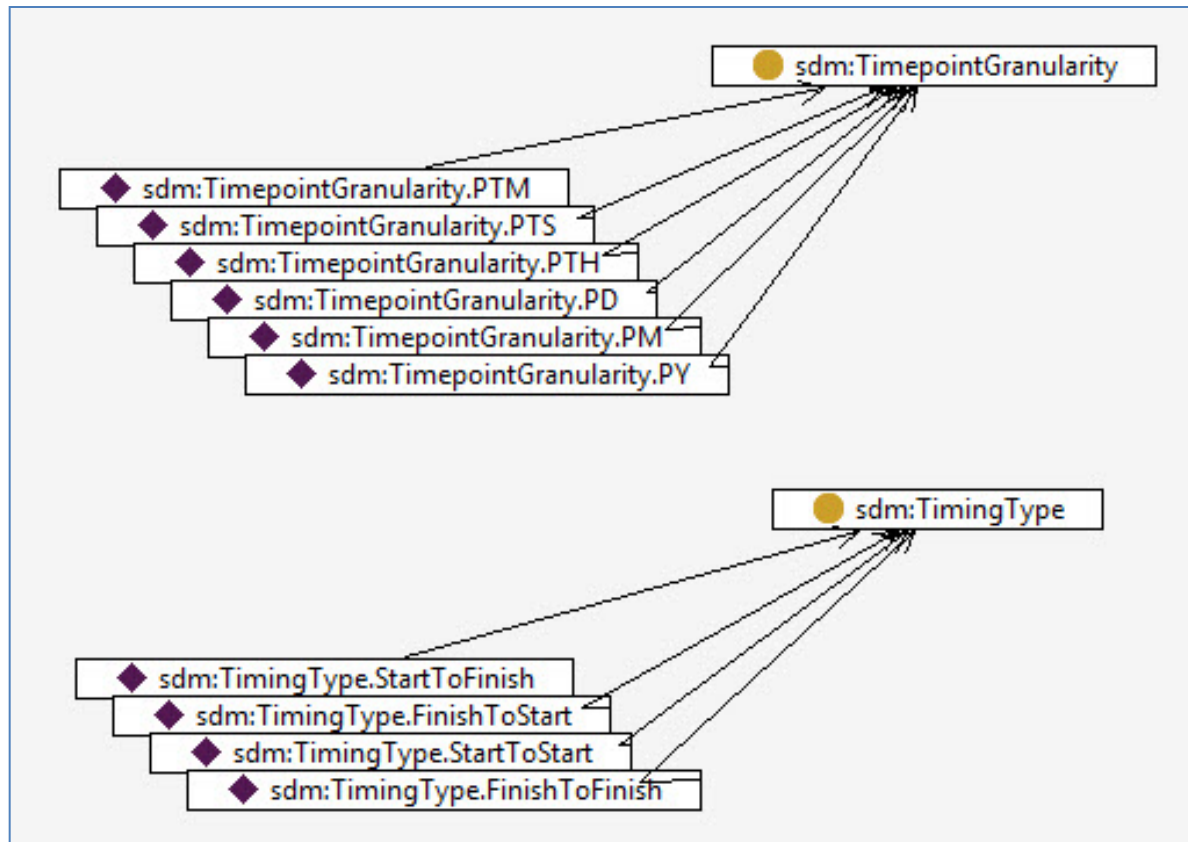
Schedule of Activities - SDM XML ToC

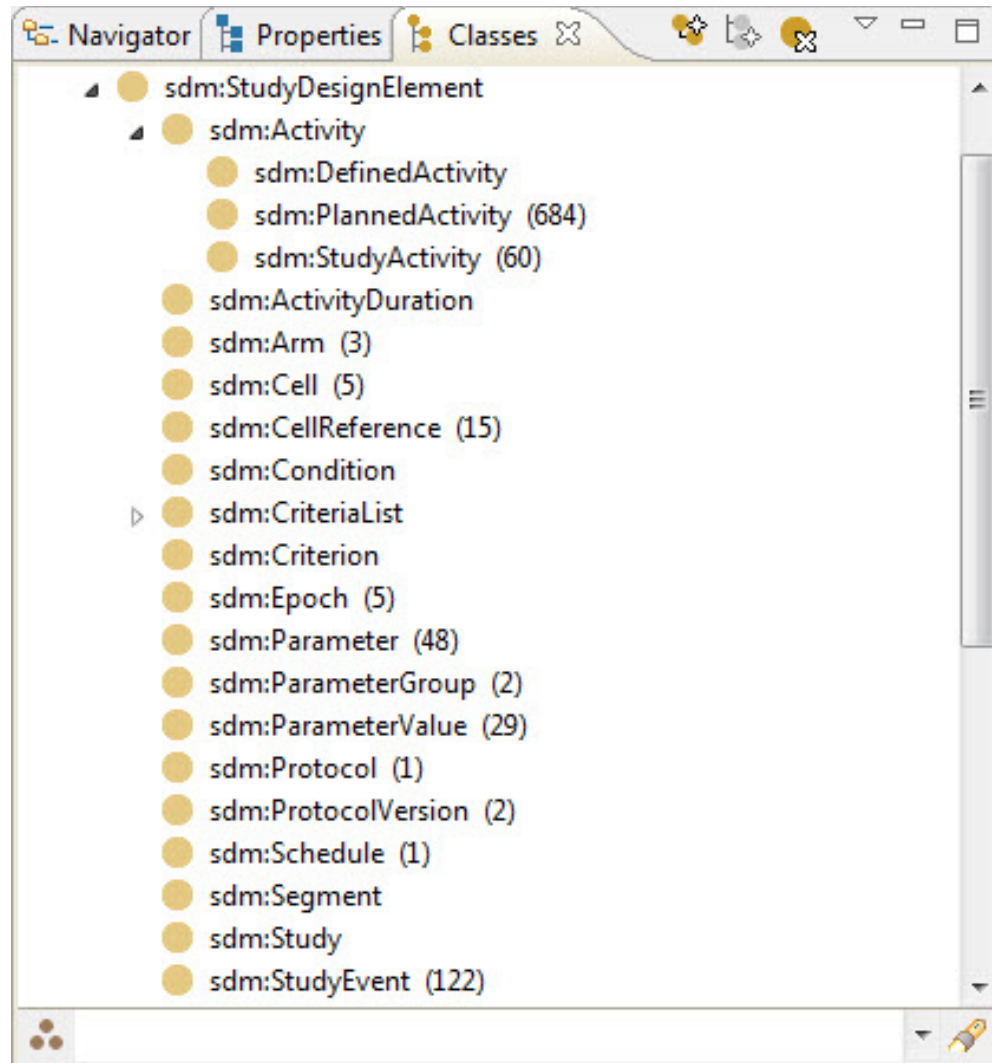
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Arms and Epochs

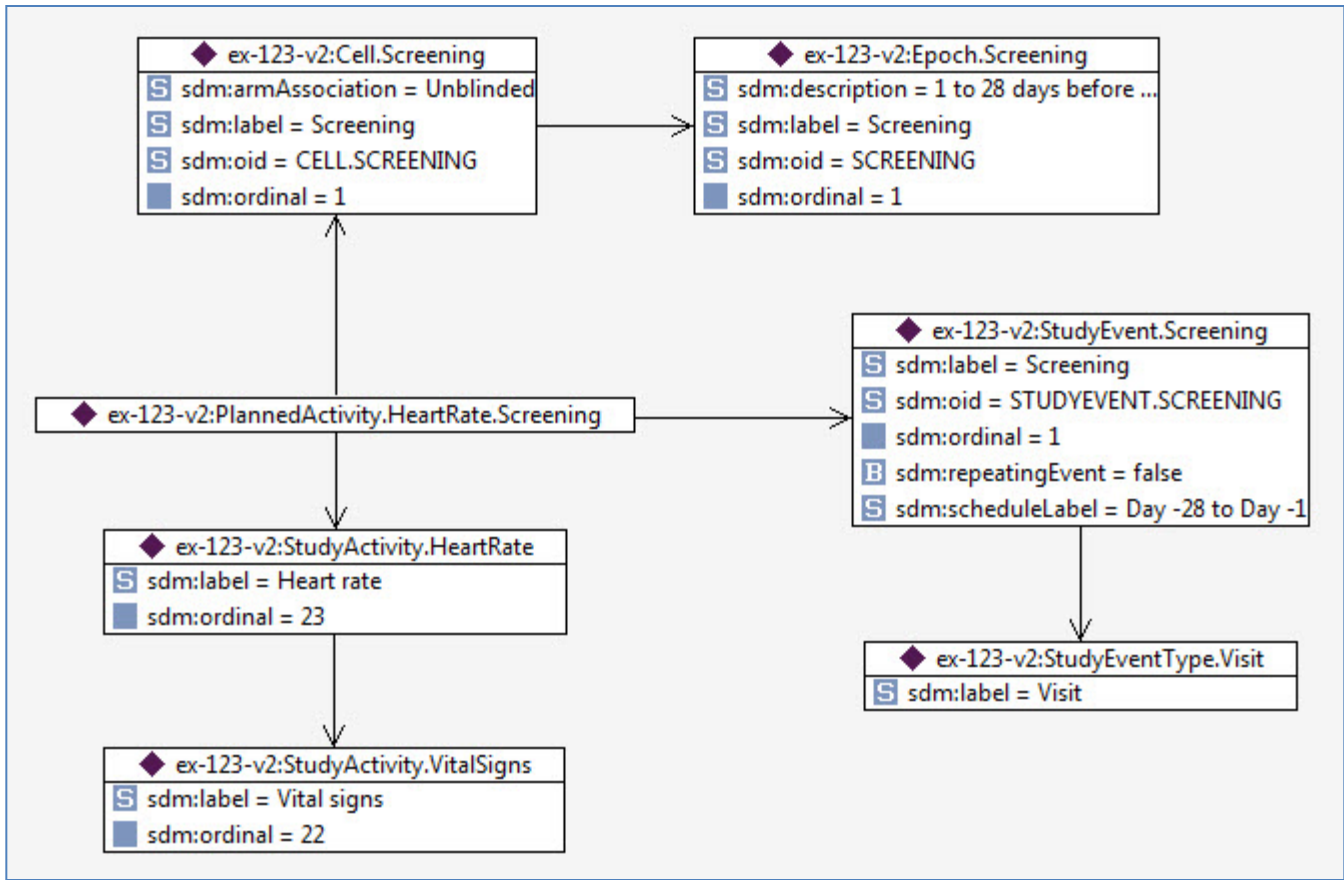








SoA Instance Snapshot



Protocol and SoA Concepts

- TransCelerate Common Protocol Template
 - Human readable protocol
 - Endpoints
 - Technology sub-team
- CDISC Protocol Concept List
- PhUSE
 - 2014: RDF model for Schedule of Activities
 - 2015: Protocol and Authoring
- All these activities complement each other
- Concept Management is a key component to be successful
- End to end standards
 - Create CDISC standards for TA endpoints and activities
 - Link activities to data collection standards and metadata
 - Link endpoints to data analysis standards and metadata