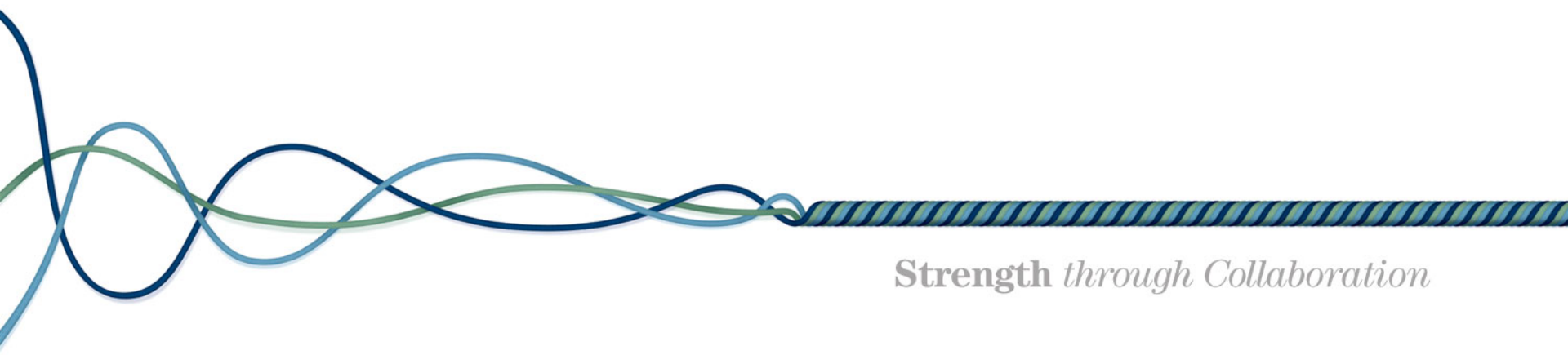
CDISC Public Webinar – Standards Updates and Additions

21 Aug 2014



Agenda

- QT Studies Public Review Period
- CDISC Standards in RDF Reference Guide
- Q&A Session
- *CDISC Education and Events Updates*

Housekeeping

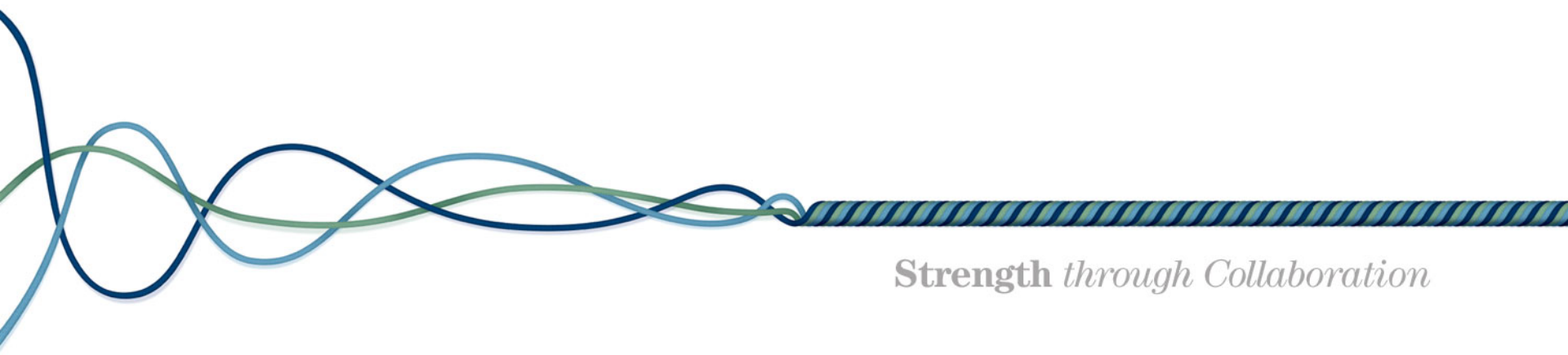
- Attendees will be muted throughout the webinar
- Please submit your questions through the webinar toolbar in the QUESTION box
- Webinar will be recorded and archived in the CDISC Member website
- Scheduled time is 11:00-12:30 ET – but we may finish sooner than 12:30
- All questions will be answered – some offline after the webinar
- Archive will contain the Q&A, recording and PDF of the slides.

Panelists

- QT Studies Public Review Period
  - John Owen, Janssen Pharmaceuticals
- CDISC Standards in RDF Reference Guide
  - Scott Bahlavooni, Biogen Idec
  - Frederik Malfait, Hoffman-La Roche and IMOS Consulting

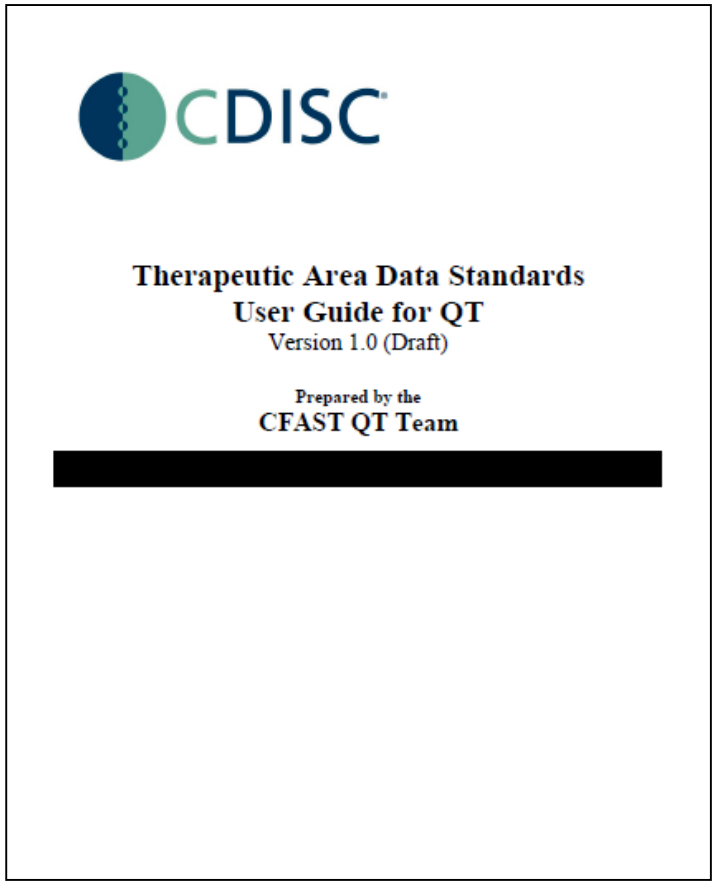
Therapeutic Area User Guide – QT Studies V1.0
Public Review Webinar
July 24, 2014

John Owen, Janssen Pharmaceuticals Research and Development
CFAST QT Studies Project Manager



QT Studies

- CFAST Program
- Development Principles
- QT Studies Background
- QT Studies
- QT Studies TAUG
- Public Review
  - Areas to focus
  - How to submit comments
- Q & A



- The Coalition for Accelerating Standards and Therapies (CFAST)
- CFAST sponsors the development of standards for key therapy areas
- A joint initiative of CDISC and the Critical Path Institute (C-Path)
- Launched to accelerate clinical research and medical product development by facilitating the establishment and maintenance of data standards, tools and methods for conducting research in therapeutic areas important to public health.
- CFAST partners include TransCelerate BioPharma Inc. (TCB), the U.S. Food and Drug Administration (FDA), and the National Cancer Institute – Enterprise Vocabulary Service (NCI-EVS), with participation and input from many other organizations
- See http://www.cdisc.org/therapeutic for more information

Program Overview – June 2014

Approved Therapeutic Area Standards Projects

Therapeutic Area	Stage 0	Stage 1	Stage 2	Stage 3a	*Stage 3b	*Stage 3c
	Scoping & Planning	Concept Modeling	Standards Development	Internal Review	Public Review	**Projected Publication
CV Endpoints v1	July	Sep	Nov	Feb	May	*Q314*
Diabetes v1	May	Aug	Dec	Apr	May	*Q314*
QT Studies v1	Oct	Feb	Mar	July	Aug	*Q314*
Traumatic Brain Injury v1	July	Aug				*Q215*
Hepatitis C v1	Feb	Apr	Jul	Aug		*Q414*
Schizophrenia v1	May	Jul	*Aug*			*Q414/Q115*
Breast Cancer v1	May	Aug				*2015*
Influenza v1	May	Jun	Jul			*Q115*
Dyslipidemia v1	May	Aug				*Q115*
COPD v1	*Aug*	Oct				*Q315*

Key: Stage completed | Stage ongoing | All Months reflect when stage is, or is projected to be, completed.

*The Stage3b concludes at the end of the 30-day review period and Stage 3c concludes when all tasks have been completed and the standard is publically available.
** Specific Projected publication dates to be added to the notes section at the conclusion of Stage 3b.

Development Principles

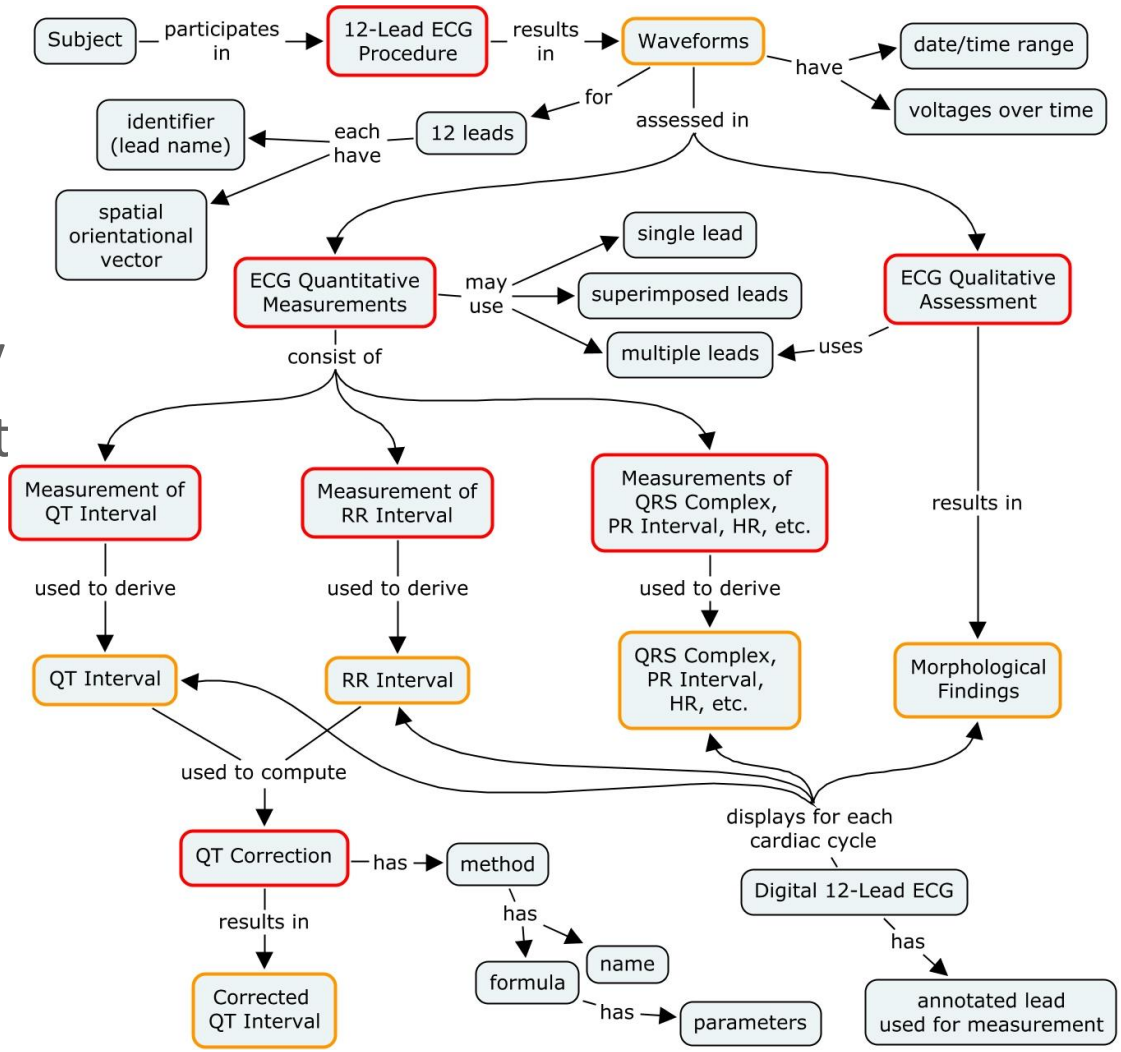
- Scope
  - core, clinically meaningful concepts
  - manage content to meet defined timelines (10-12 months)
- Re-use existing standards (SDTM, CDASH, ADaM)
  - include examples only for situations not covered by existing implementation guide(s)
- Propose new variables for existing domains or new domains
  - only where needed
- Propose new controlled terminology
  - only where needed

What is Different from Previous CDISC TA Standards?

- Disease background & context
- Concept maps
  - To diagram the relationships between concepts and among attributes of a concept
- Regulatory and medical references
  - To help ensure regulatory compliance and medical appropriateness
- SHARE model based metadata development
  - Not just SDTM; but also CDASH and ADaM in later iterations

Concept Maps

- Illustrates relationships among concepts and attributes
- Facilitates understanding (semantic interoperability in standards development



Concept Map 4 - ECG Quantitative Results and Qualitative/Morphological Findings Determination

This concept map displays the process for determining the measurements of the PR, QT, RR intervals and QRS complex as well as determining any abnormal qualitative findings on the ECG.

Regulatory and Medical References

- Regulatory and key medical literature is being reviewed and referenced during the early stages of CFAST projects.

- Bibliography and footnotes included

Appendix E: References

1. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. E14: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-antiarrhythmic Drugs. *ICH*. May 12, 2005. Available at: http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E14/E14_Guideline.pdf. Accessed April 11, 2014.
2. Committee for Medicinal Products for Human Use. ICH topic E14: the clinical evaluation of QT/QTc interval prolongation and proarrhythmic potential for non-antiarrhythmic drugs questions and answers (EMA/CHMP/ICH/310133/2008). *EMA*. May 2012. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002878.pdf. Accessed March 18, 2014.
3. Garnett CE, Zhu H, Malik M, et al. Methodologies to characterize the QT/corrected QT interval in the presence of drug-induced heart rate changes or other autonomic effects. *Am Heart J*. 2012;163(6):912-930. doi: 10.1016/j.ahj.2012.02.023.
4. Darpo B. The thorough QT/QTc study 4 years after the implementation of the ICH E14 guidance. *Br J Pharmacol*. 2010;159(1):49-57. doi: 10.1111/j.1476-5381.2009.00487.x.
5. Couderc JP, McNitt S, Hyrien O, et al. Improving the detection of subtle I(Kr)-inhibition: assessing electrocardiographic abnormalities of repolarization induced by moxifloxacin. *Drug Saf*. 2008;31(3):249-260.
6. Shah RR, Hondeghem LM. Refining detection of drug-induced proarrhythmia: QT interval and TRIaD. *Heart Rhythm*. 2005;2(7):758-772. doi: 10.1016/j.hrthm.2005.03.023.
7. Morganroth J. Design and conduct of the thorough phase I ECG trial for new bioactive drugs. In: Morganroth J, Gussak I, eds. *Cardiac Safety of Noncardiac Drugs*. Totowa, NJ: Humana Press; 2005.
8. Couderc JP, Xiaojuan X, Zareba W, Moss AJ. Assessment of the stability of the individual-based correction of QT interval for heart rate. *Ann Noninvasive Electrocardiol*. 2005;10(1):25-34. doi: 10.1111/j.1542-474X.2005.00593.x.
9. Dmitrienko A, Beasely C, Mitchell M. Design and Analysis of Thorough QT Studies. *BioPharmaceutical Network*. April 29, 2008. Available at: http://www.biopharmnet.com/doc/2008_04_29_report.pdf. Accessed July 6, 2014.
10. United States Food and Drug Administration. Guidance for Industry: E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs. Questions and Answers (R1). *U.S. Food and Drug Administration*. October 2012. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073161.pdf. Accessed March 15, 2014.

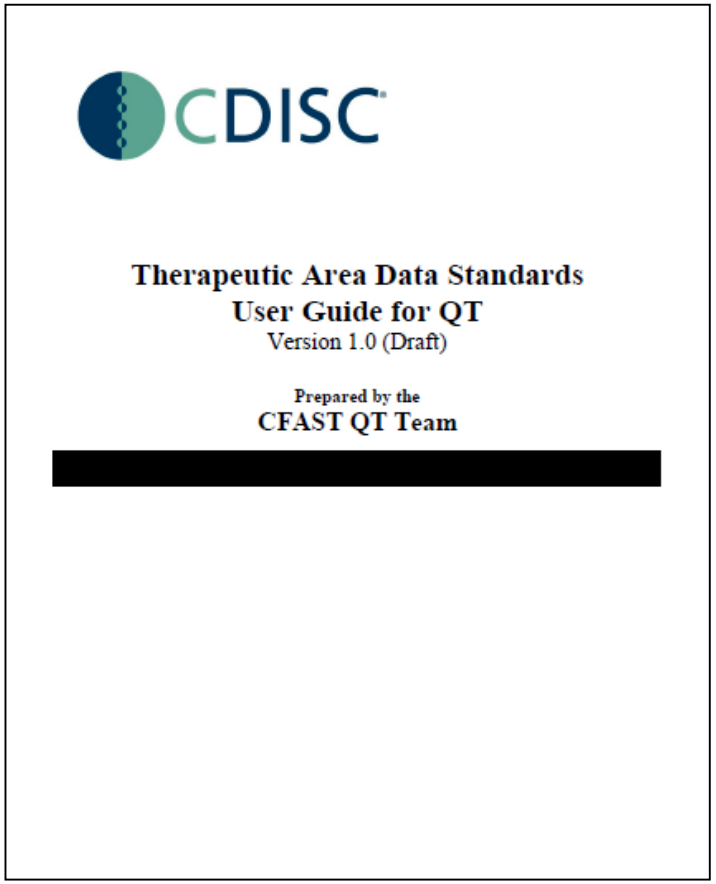
SHARE Model-Based Metadata Package

- Future plans to develop all CDISC SHARE metadata:
  - BRIDG
  - SDTM
  - CDASH
  - ADaM
  - Controlled Terminology
  - Data types
  - Definitions
  - Trial Summary Parameters/Protocol

CDISC SHARE

- Will be a global electronic repository for developing, integrating and accessing CDISC metadata standards in electronic format.
- SHARE is envisioned to help users find, understand and use rich metadata and controlled terminologies relevant to clinical studies more efficiently and consistently, and to improve integration and traceability of clinical data from protocol through analysis.

QT Studies TAUG



QT Studies

- This draft version 1.0 (v1.0) of the TAUG-QT highlights the data endpoints for clinical studies characterizing the QT effects of drugs in healthy volunteers or in patients.

- The primary focus of the TAUG-QT is on a specific type of QT study, the “thorough QT (TQT) study.”

  operationally defined by an ICH E14 guidance document[1] and the associated Question & Answer document[2]

- [1] http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E14/E14_Guideline.pdf
- [2] http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002878.pdf

QT Studies

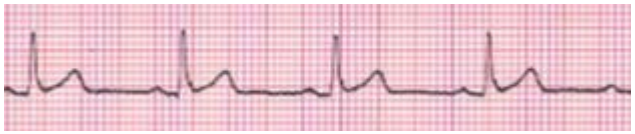
- Routine clinical practices focus on the individual patient and substantial changes in QT and/or absolute QT values, TQT studies can find relatively small differences between groups of patients treated with an experimental drug compared to a control treatment to be of interest

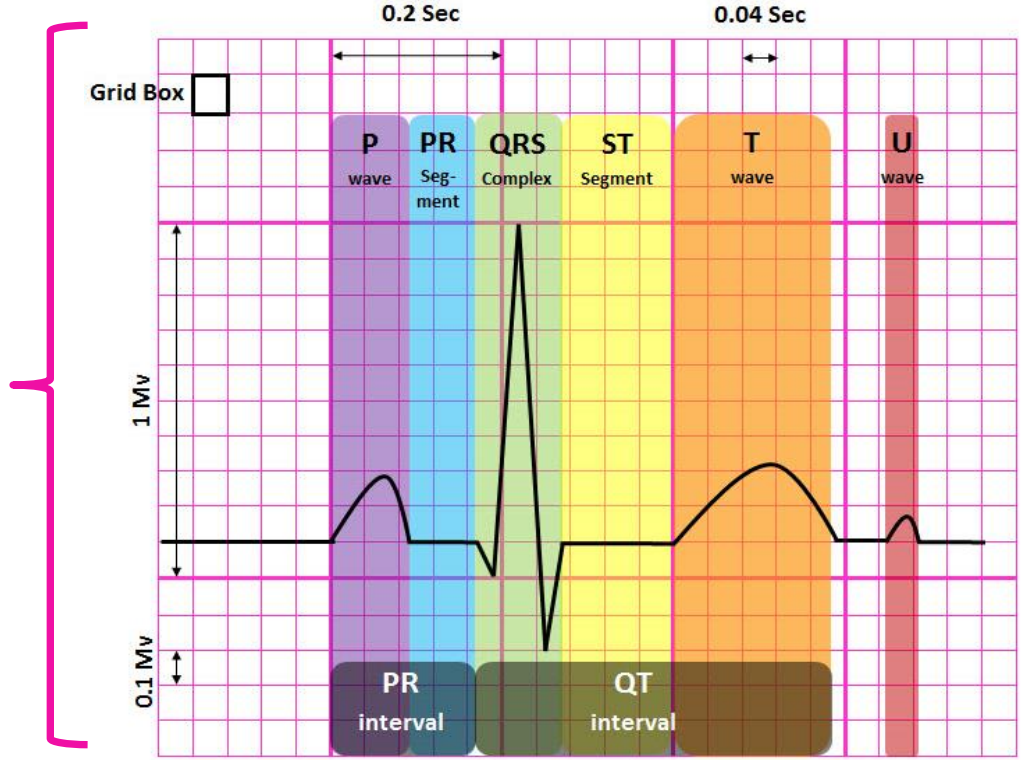
- When ventricular repolarization (i.e. the relaxing of the bottom chambers of the heart, which perform the majority of its pumping action) is delayed, it can lead to cardiac arrhythmias which may be fatal.

- Historically, a number of drugs have been found to cause such a delay, thus, determining whether a drug delays ventricular repolarization is important in assessing its safety

QT Studies

- One measure of the time required for ventricular repolarization is the QT interval on an ECG, corrected for heart rate; or QTc

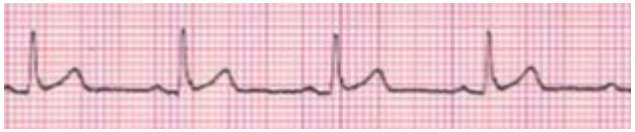


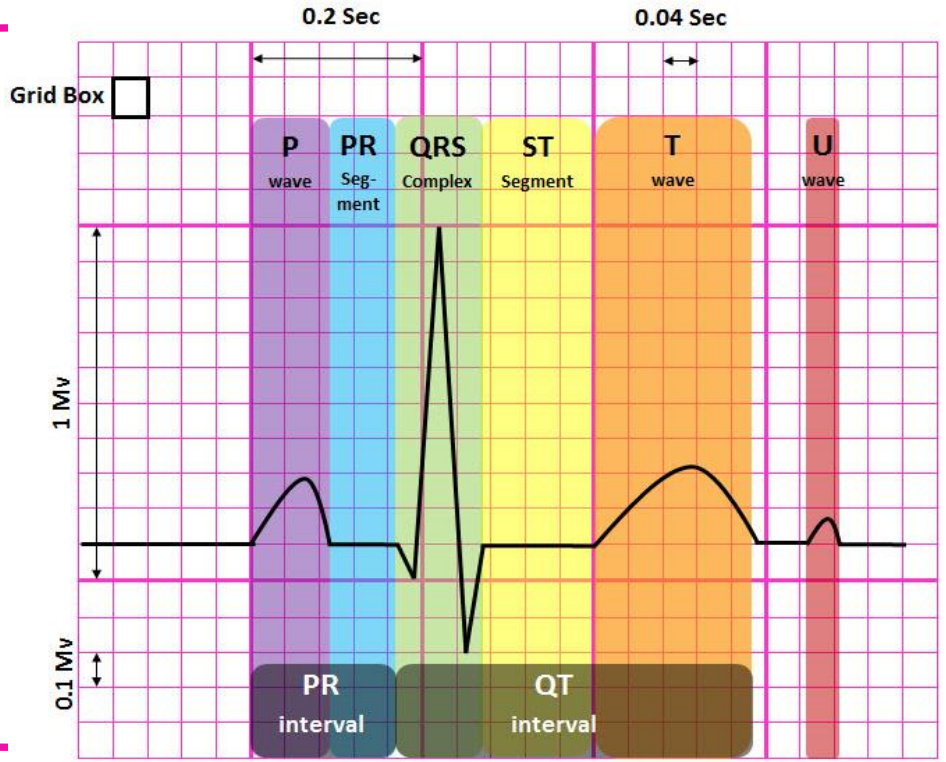


Electrocardiogram Waveform Illustration
Electrocardiogram recorded on grid paper with lines 1mm apart. X-axis is the time axis. Y-axis is the voltage axis. Figure assumes a paper speed of 25mm/sec and a calibration of 10mm/mV.

QT Studies

- Why correct QT?





QT	QT interval. The portion of an ECG between the onset of the QRS complex and the end of the T-wave, representing the total time for ventricular depolarization and repolarization.
QTc	HR-corrected QT interval. The QT interval is inversely related to HR. When the QT interval is corrected for HR by use of various formulas, it is expressed as QTc and allows an assessment of the QT interval that is intended to be independent of HR.
RR Interval	The time between 2 consecutive heart beats/cycles (P-QRS-T complexes), measured as the time between the peaks of 2 consecutive R waves. The RR interval is the time between individual heart beats and is related to HR in that HR is essentially the number of R waves in 1 minute. In most QT correction formulas the RR interval is used for correction.

QT Studies

- QT Correction Methods
  - Population-based formula derived from a historical population
  - Population-based formula derived from the population under study
  - Individual-based formula derived for each individual in the population under study

The most well-known and clinically used is **Bazett's formula** (QTcB), which was derived/developed in 1920 from ECGs recorded in a small group of healthy subjects:

$$\mathrm{QTc} = \frac{\mathrm{QT}}{\sqrt{\mathrm{RR}}}$$

Fridericia's formula (QTcF) was also developed in 1920 from ECGs recorded in a small group of healthy subjects:

$$\mathrm{QTc} = \frac{\mathrm{QT}}{\sqrt[3]{\mathrm{RR}}}$$

QT Studies TAUG

- QT Studies are cross-TA
- Sections of the document will differ to other Disease Area TAUG's
  - Section 2 – ECG Overview
    - ECG Fundamentals
    - ECG Machinery
  - Section 3 – The TQT Study
  - Section 4 – Trial Design
  - Section 5 – Subject Characteristics/Eligibility
  - Section 6 – Study Assessments
    - ECG
    - QT Correction
    - PK/Vital signs Assessments
  - Section 7 – Data Analysis

QT Studies TAUG

- SDTM Domains referenced

Domains from SDTMIG	Section
Findings	
EG – ECG Test Results	6.1.3
QT – ECG QT Correction Model Data*	6.1.3
VS – Vital Signs	6.4.1
Trial Design	
TA – Trial Arms	4.1.1, 4.1.2
TE – Trial Elements	4.1.3
TS – Trial Summary	4.1.4

** Domain is not final.*

Domains from SDTMIG-MD	Section
DI – Device Identifier	2.3.3.1
DO – Device Properties	2.3.3.1

QT Studies TAUG

- **EG** - ECG Test Results
  - Already well documented in SDTM IG
  - It includes two newly approved variables

    - **EGREPNUM** - Used to indicate the chronological order of repeated tests
      - Used in 10-second ECG replicates extracted from a continuous recording
    - **EGBEATNO** - Variable describing ECG measurements of individual beat data
      - Used in ECG results where beat-to-beat measurements are recorded

QT Studies TAUG

- SDTM Domains referenced

Domains from SDTMIG	Section
Findings	
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QT – ECG QT Correction Model Data*	6.1.3
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Trial Design	
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** Domain is not final.*

Domains from SDTMIG-MD	Section
DI – Device Identifier	2.3.3.1
DO – Device Properties	2.3.3.1

QT Studies TAUG

- Proposed new domain – Why was this developed
  - **QT – ECG QT Correction Model Data**

  - Data describing the description, correction formula and the coefficients of the correction formula used in correction of QT values.
  - CDISC controlled terminology handles standard correction factors such as Bazett's and Fredericia's, however, due to the large and growing number of correction methods used, controlled terminology will not be developed for those alternative correction factors
  - This new findings domain was proposed to store the correction formula information.

QT Studies TAUG

- Proposed new domain
  - **QT – ECG QT Correction Model Data**

qt.xpt

Row	DOMAIN	USUBJID	QTSEQ	QTGRPID	QTTESTCD	QTTEST	QTORRES	…
1	QT	P384QT204_001	1	QTCIAG1	QTCDESC	QT Correction Method Description	PARABOLIC LOG/LOG	…
2	QT	P384QT204_001	2	QTCIAG1	QTCFORM	QT Correction Formula	QTC=QT/(RR^A)	…
3	QT	P384QT204_001	3	QTCIAG1	QTCCOEFA	QT Correction Coefficient A	0.432	…
4	QT	P384QT204_001	4	QTCIAG2	QTCDESC	QT Correction Method Description	LINEAR	…
5	QT	P384QT204_001	5	QTCIAG2	QTCFORM	QT Correction Formula	QTC=QT+(A*(1-RR))	…
6	QT	P384QT204_001	6	QTCIAG2	QTCCOEFA	QT Correction Coefficient A	0.154	…
7	QT	P384QT204_001	7	QTCNAG	QTCDESC	QT Correction Method Description	RAUTAHARJU COR	…
8	QT	P384QT204_001	8	QTCNAG	QTCFORM	QT Correction Formula	QTC=QT+A-(B*(e^(C^HR))	…
9	QT	P384QT204_001	9	QTCNAG	QTCCOEFA	QT Correction Coefficient A	0.2425	…
10	QT	P384QT204_001	10	QTCNAG	QTCCOEFB	QT Correction Coefficient B	0.434	…
11	QT	P384QT204_001	11	QTCNAG	QTCCOEFC	QT Correction Coefficient C	-0.0097	…

eg.xpt

Row	DOMAIN	USUBJID	EGSEQ	EGCAT	EGTESTCD	EGTEST	EGORRES	EGORRESU	…
1	EG	P384QT204_001	1	INTERVAL	QTCIAG1	QTCI Interval, Aggregate 1	345	msec	…
2	EG	P384QT204_001	2	INTERVAL	QTCIAG2	QTCI Interval, Aggregate 2	350	msec	…
3	EG	P384QT204_001	3	INTERVAL	QTCNAG	QTCN Interval, Aggregate	353	msec	…

QT Studies – Public Review

- 30-day public review upcoming
- Download the document using Adobe Reader (http://get.adobe.com/reader/)
- Submit comments using the CDISC public commenting tool located on the CDISC website located here:
- http://cdiscportal.digitalinfuzion.com/CT/Review%20Documents/Forms/AllItems.aspx
- Instructions on using the comment tracker tool
- http://cdiscportal.digitalinfuzion.com/CT/Documents/How%20to%20Use%20the%20CDISC%20Public%20Comment%20Tracker.docx

Future QT Studies Training

- Future QT Studies implementation training will include:
  - Implementation examples
  - Exercises
  - Tests to check knowledge level
  - And additional detail
- Training will be delivered online soon after publication of the standard
  - so you can train at your convenience

CFAST QT Core Team

John Owen	Janssen Research & Development
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Natalie Boone	Astellas Pharma Global Development, Inc.
Marty Cisneroz	C-Path
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Rene DahlHeimer	CDISC
Nate Freimark	Theorem Clinical
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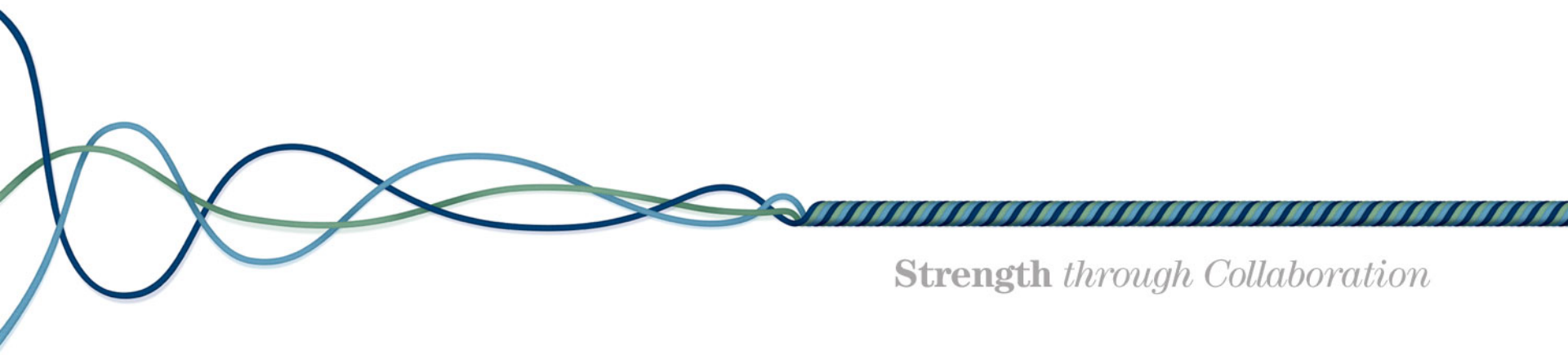
Bernice Yost	CDISC

CDISC Standards
RDF Reference Guide

Presented by Frederik Malfait and Scott Bahlavooni

Acknowledgements to Geoff Low and Mitra Rocca



Agenda

- PhUSE Computational Science Symposium
  - Semantic Technology Working Group
- Introduction and Rationale
- W3C Resource Description Framework (RDF)
- CDISC Foundational Standards
  - RDF Schemas
  - RDF Datasets
- RDF SDTM IG Walk-through
- Accessing GitHub

PhUSE Computational Science Symposium

Semantic Technology Working Group

PhUSE CSS Collaboration

- Mission:
  - *"…bring together academia, industry, technology providers and the FDA to collaborate on projects to address unmet computational science needs."*
- Working Groups:
  - Optimizing the Use of Data Standards
  - Development of Standard Scripts for Analysis and Programming
  - Non-Clinical Roadmap and Impact on Implementation
  - Emerging Technologies
  - Semantic Technology

Semantic Technology Working Group

Investigate the application of W3C semantic standards to support the clinical and non-clinical data life-cycle from protocol development to submission to regulatory agencies.

Semantic Technology Teams

- Semantic Technology Primer *
- Representation of CDISC Foundational Standards in RDF *
- Protocol and Study Design Representation in RDF
- Representation of Analysis Metadata to Support Clinical and Non-Clinical Applications
- Representation of Regulations and Guidance in RDF
- Representation of CDISC Conformance Checks in RDF *
- keyCRF: Reusing Medical Summaries for Enabling Clinical Research

* Completed project

Acknowledgements

CDISC Foundational Standards in RDF

Phil Ashworth, Scott Bahlavooni, Daniel Boisvert, Susan DeHaven, Nathan Freimark, Josephine-Anne Gough, Laura Hollink, Dave Jordan, Ron Katriel, Kirsten Langendorf, Geoff Low, Frederik Malfait, Mitra Rocca, Gary Walker.

Introduction and Rationale

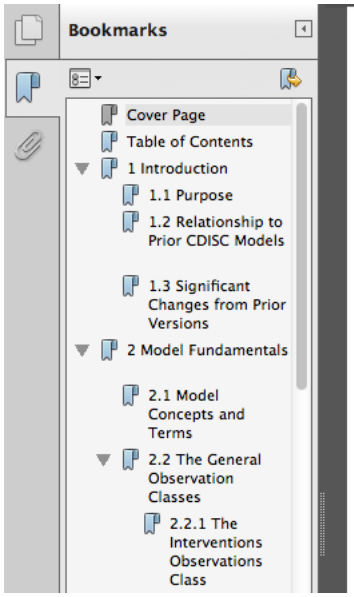
Recall CDISC Mission

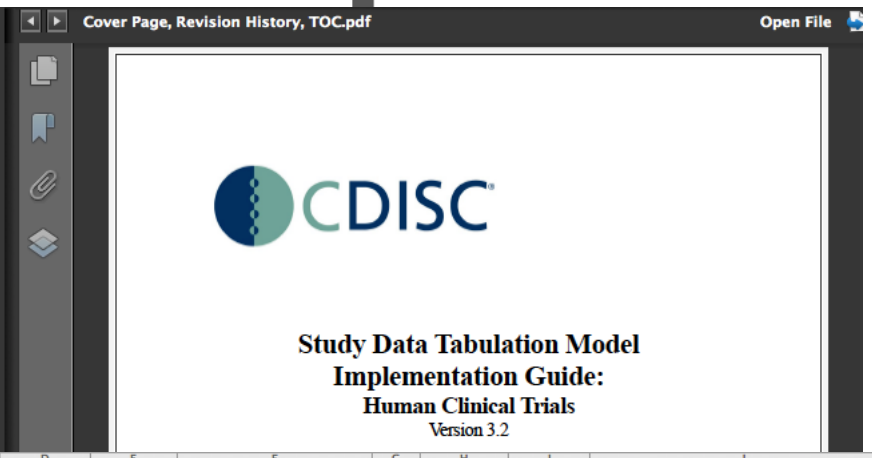
The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.

Recall CDISC Principles

- Recognize the ultimate goal of creating regulatory submissions that allow for flexibility in scientific content and are easily interpreted, understood, and navigated by regulatory reviewers.
- Acknowledge that the data content, structure and quality of the standard data models are of paramount importance, independent of implementation strategy and platform.
- Work with other professional groups to encourage that there is maximum sharing of information and minimum duplication of efforts.

Current State





	A	B	C	D	E	F	G	H	I	J	K	L
1	Seq. For Orde	Observation Class	Domain Pr	Variable Name (minus domain prefix)	Variable Name	Variable Label	Ty	Controlled Ter... Codelist or For	Role	CDISC Notes (for domains) Description (for General Classes)	Cor	References
2	1	Interventions-General		TRT	--TRT	Name of Treatment	Char		Topic	The topic for the intervention observation, usually the verbatim name of the treatment, drug, medicine, or therapy given during the dosing interval for the observation.		
3	2	Interventions-General		MODIFY	--MODIFY	Modified Treatment Name	Char		Synonym Qualifier of --TRT	If the value for --TRT is modified for coding purposes, then the modified text is placed here.		
4	3	Interventions-General		DECOD	--DECOD	Standardized Treatment Name	Char		Synonym Qualifier of --TRT	Standardized or dictionary-derived name of the topic variable, --TRT, or the modified topic variable (--MODIFY), if applicable. Equivalent to the generic drug name in WHO Drug, or a term in SNOMED, ICD9, or other published or sponsor-defined dictionaries.		
5	4	Interventions-General		CAT	--CAT	Category	Char		Grouping Qualifier	Used to define a category of topic-variable values.		
6	5	Interventions-General		SCAT	--SCAT	Subcategory	Char		Grouping Qualifier	Used to define a further categorization of --CAT values.		
7	6	Interventions-General		PRESP	--PRESP	Pre-specified	Char		Variable Qualifier of --TRT	Used when a specific intervention is pre-specified on a CRF. Values should be "Y" or null.		
8	7	Interventions-General		OCCUR	--OCCUR	Occurrence	Char		Record Qualifier	Used to record whether a pre-specified intervention occurred when information about the occurrence of a specific intervention is solicited.		
9	8	Interventions-General		STAT	--STAT	Completion Status	Char		Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE.		
10	9	Interventions-General		REASND	--REASND	Reason Not Done	Char		Record Qualifier	Reason not done. Used in conjunction with --STAT when value is NOT DONE.		

W3C Semantic Standards

- Can express a wide range of information
  - Meta-models, models, data
- Consistent language and modeling framework
- Formal, computable, executable
- Identical at design and run-time
- Designed for
  - Platform independence
  - Semantic interoperability
  - Sharing and linking information
- Proven backbone of the semantic web
- Acronyms: RDF, RDFS, OWL, SKOS, SPARQL

W3C Resource Description Framework (RDF)

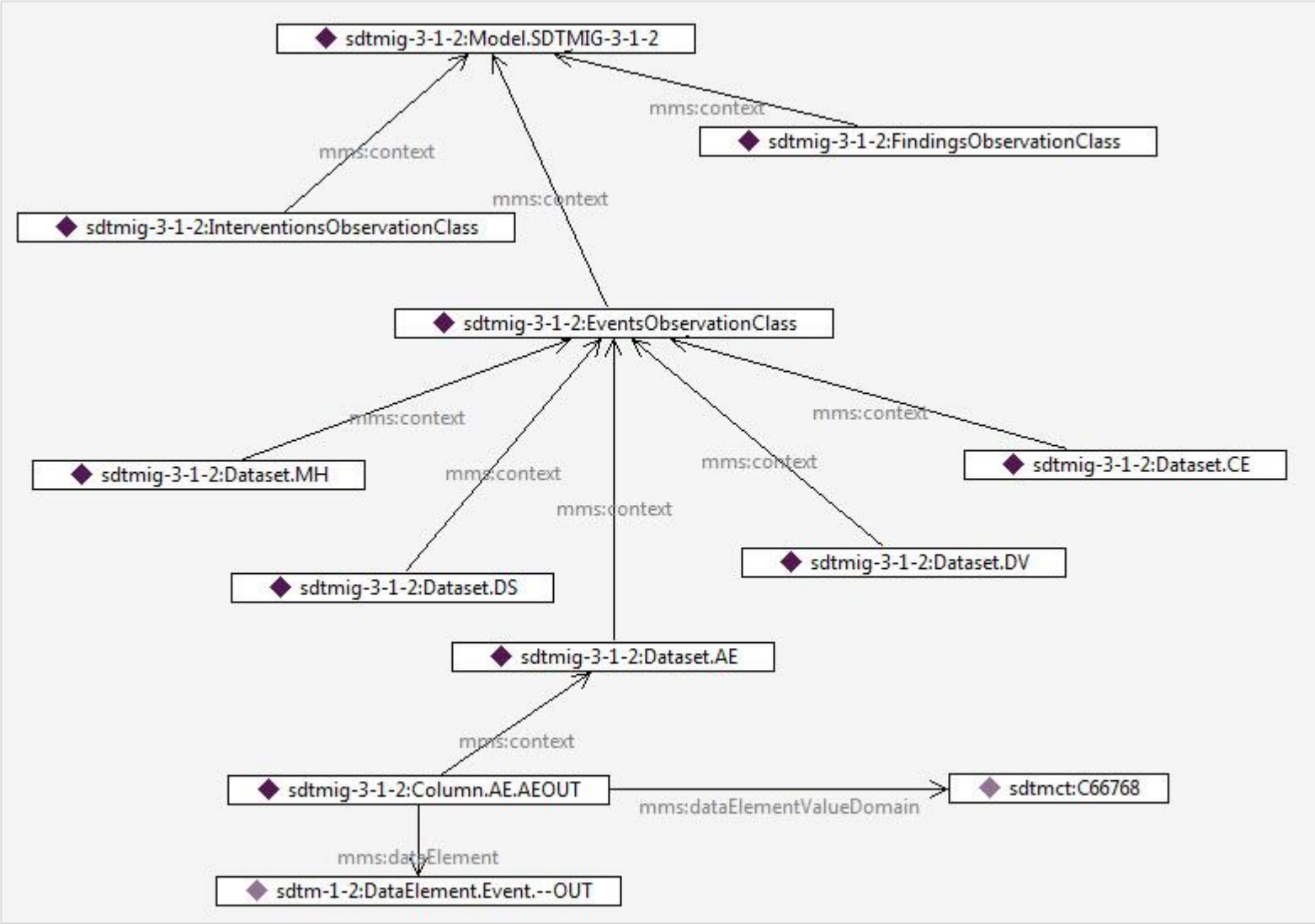
Resources

- A resource is anything we like to talk about
- Uniform Resource Identifier
  - http://rdf.cdisc.org/std/sdtmig-3-1-2#Column.AE.AEOUT
- Namespaces
  - sdtmig-3-1-2: "http://rdf.cdisc.org/std/sdtmig-3-1-2#"
- Qualified Names
  - sdtmig-3-1-2:Column.AE.AEOUT
- Creates globally unique identifiers
- A representation of a resource can be made available over a network or the web

Triples

- Statements about resources, e.g. attributes
  - Subject: sdtmig-3-1-2:Column.AE.AEOUT
  - Predicate: mms:dataElementName
  - Object: "AEOUT"
- Statements about resources, e.g. relationships
  - Subject: sdtmig-3-1-2:Column.AE.AEOUT
  - Predicate: mms:dataElementValueDomain
  - Object: sdtmct:C66768

Graphs



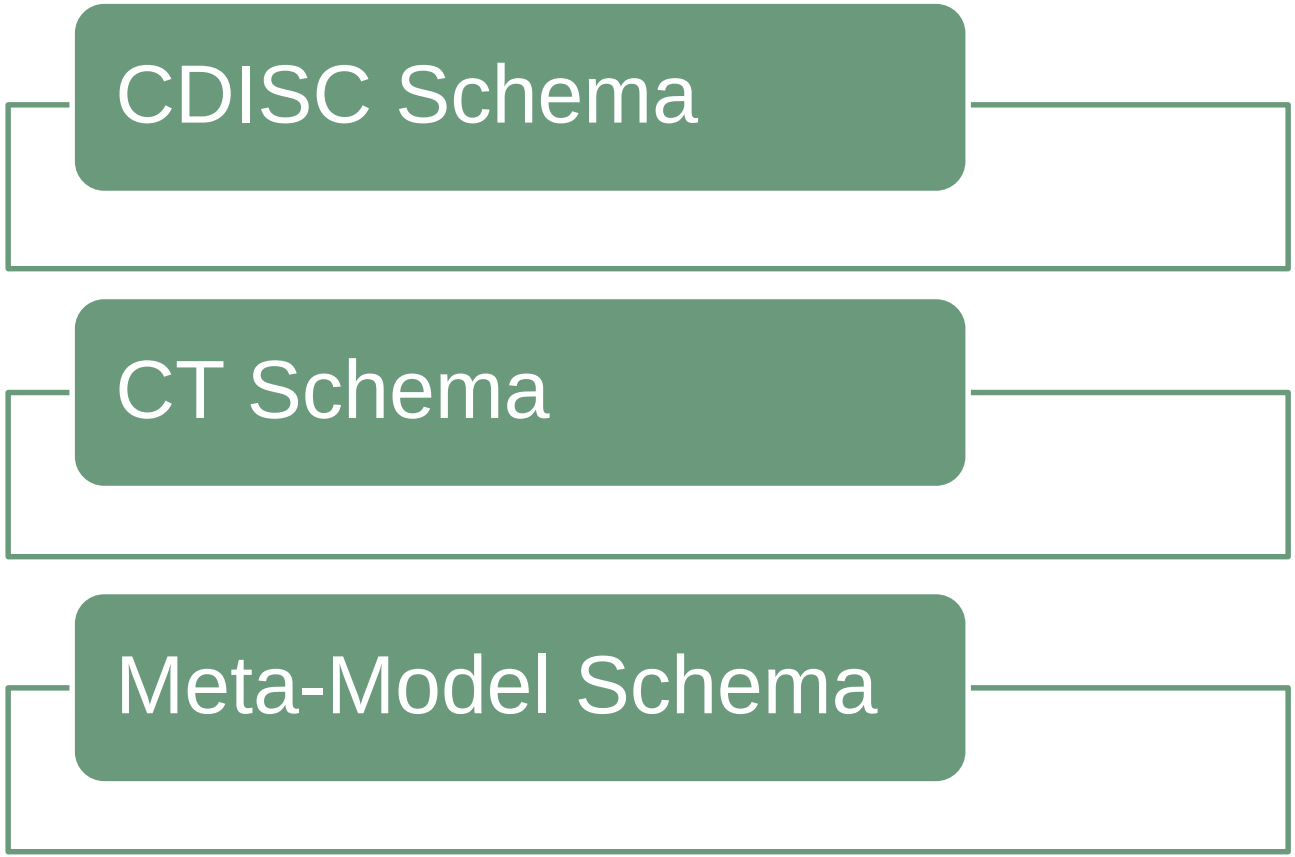
Schemas and Ontologies

- A set of resources and predicates that defines a vocabulary or ontology
- Resources can be organized in classes
- Predicates and classes are also resources
- W3C defined schemas
  - Resource Description Framework (RDF)
  - RDF Schema (RDFS)
  - Web Ontology Language (OWL)
  - Simple Knowledge Organization (SKOS)

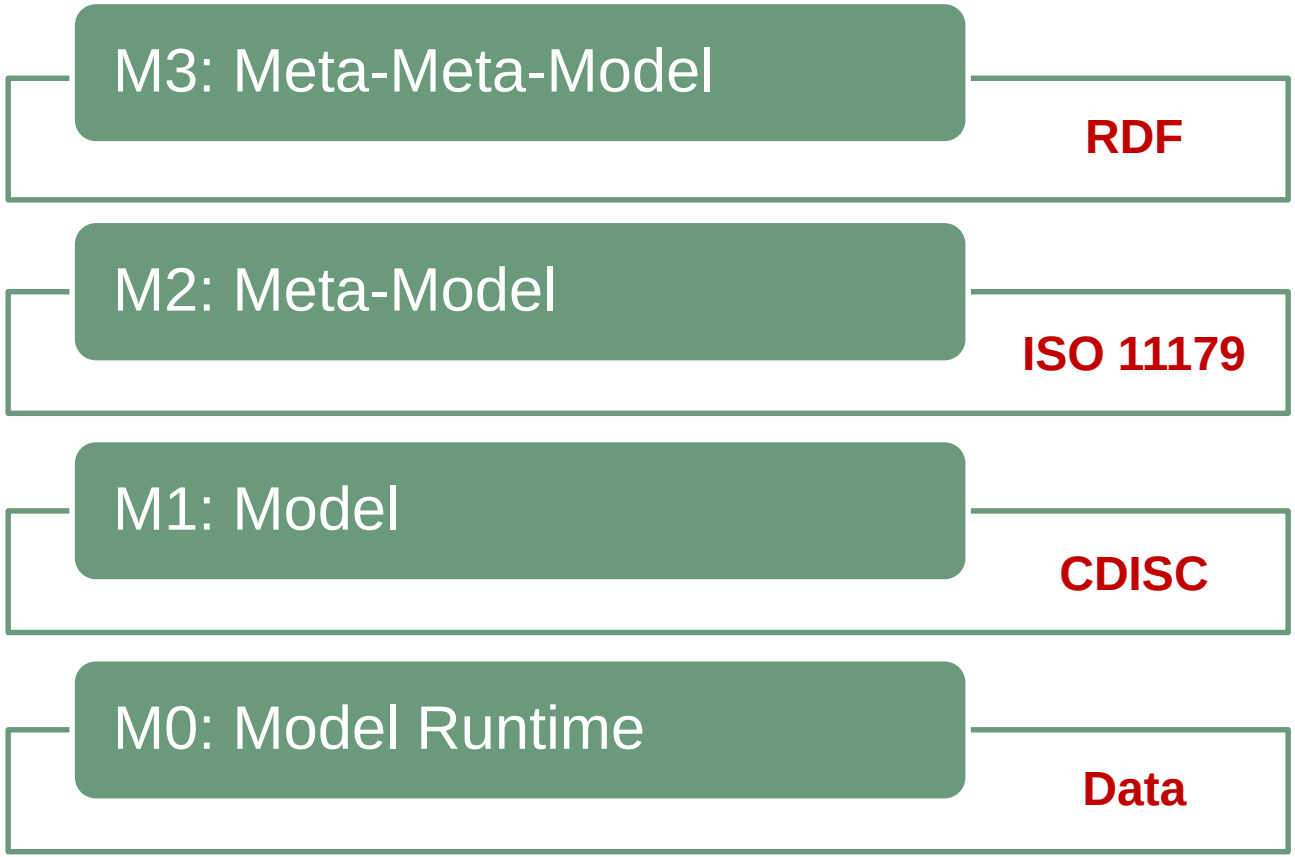
CDISC Foundational Standards

RDF Schemas

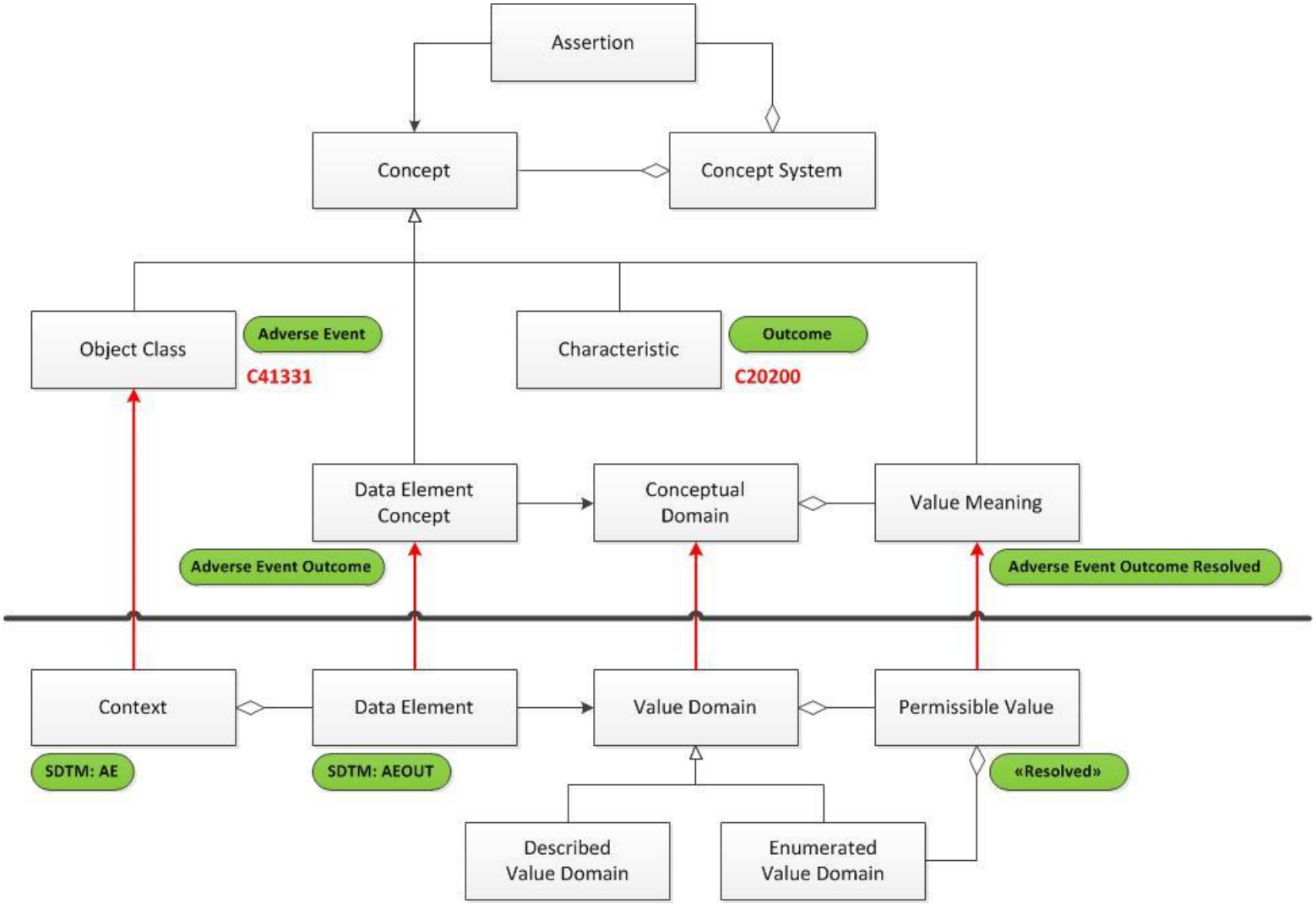
Layered Schemas



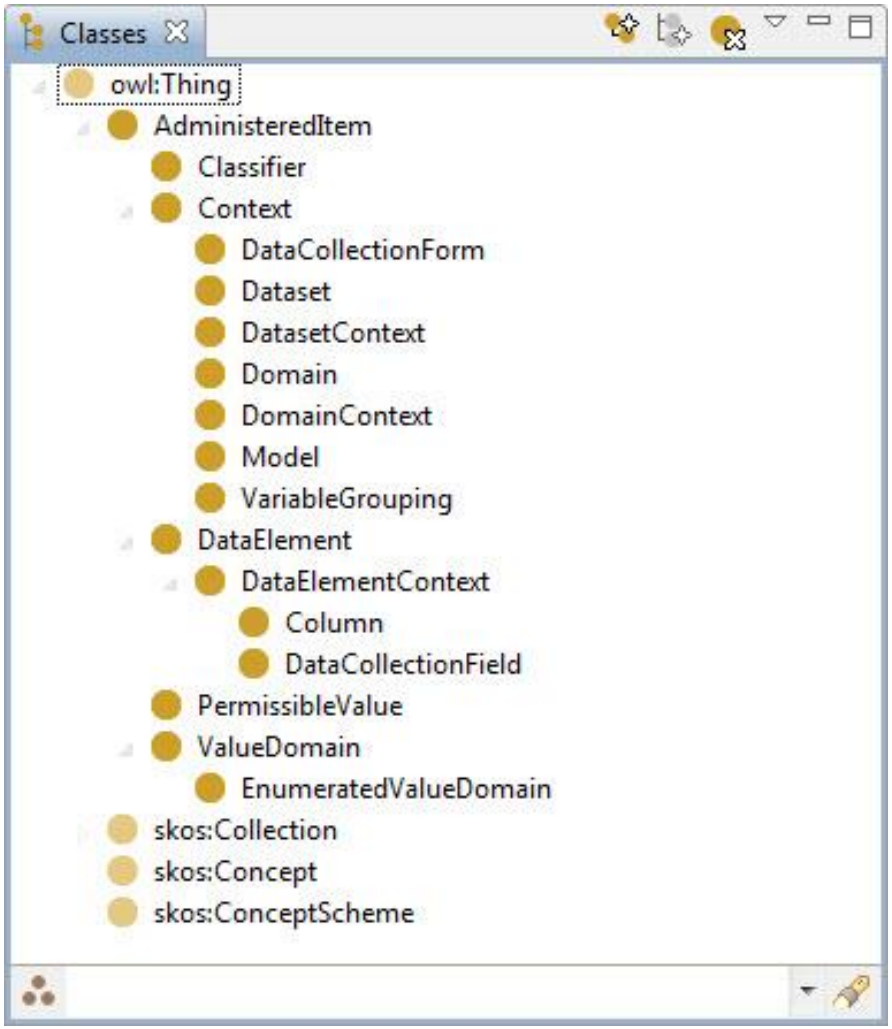
Meta-Model Hierarchy



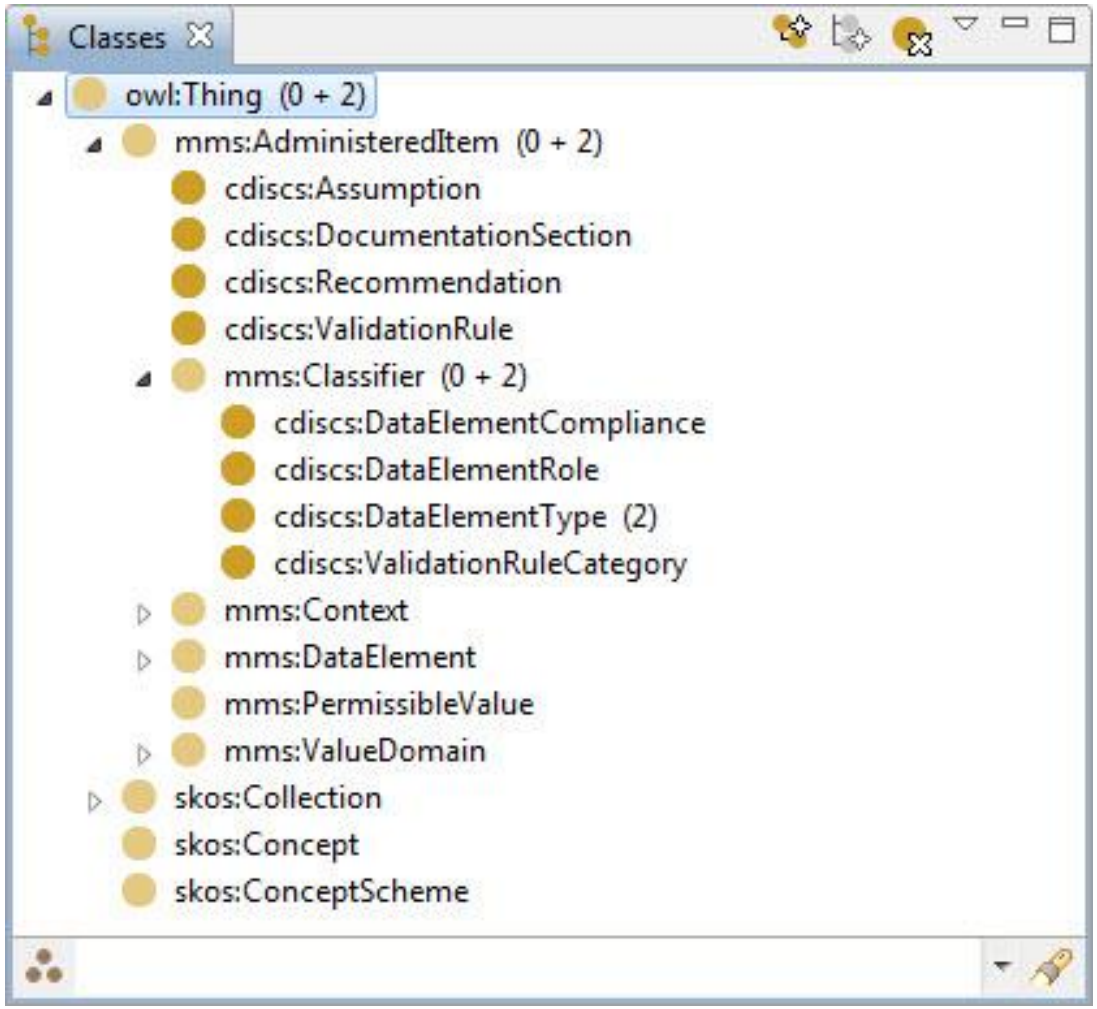
ISO 11179 Metadata Registry Std



OWL Classes: Meta-Model Schema



OWL Classes: CDISC Schema



CDISC Foundational Standards

RDF Datasets

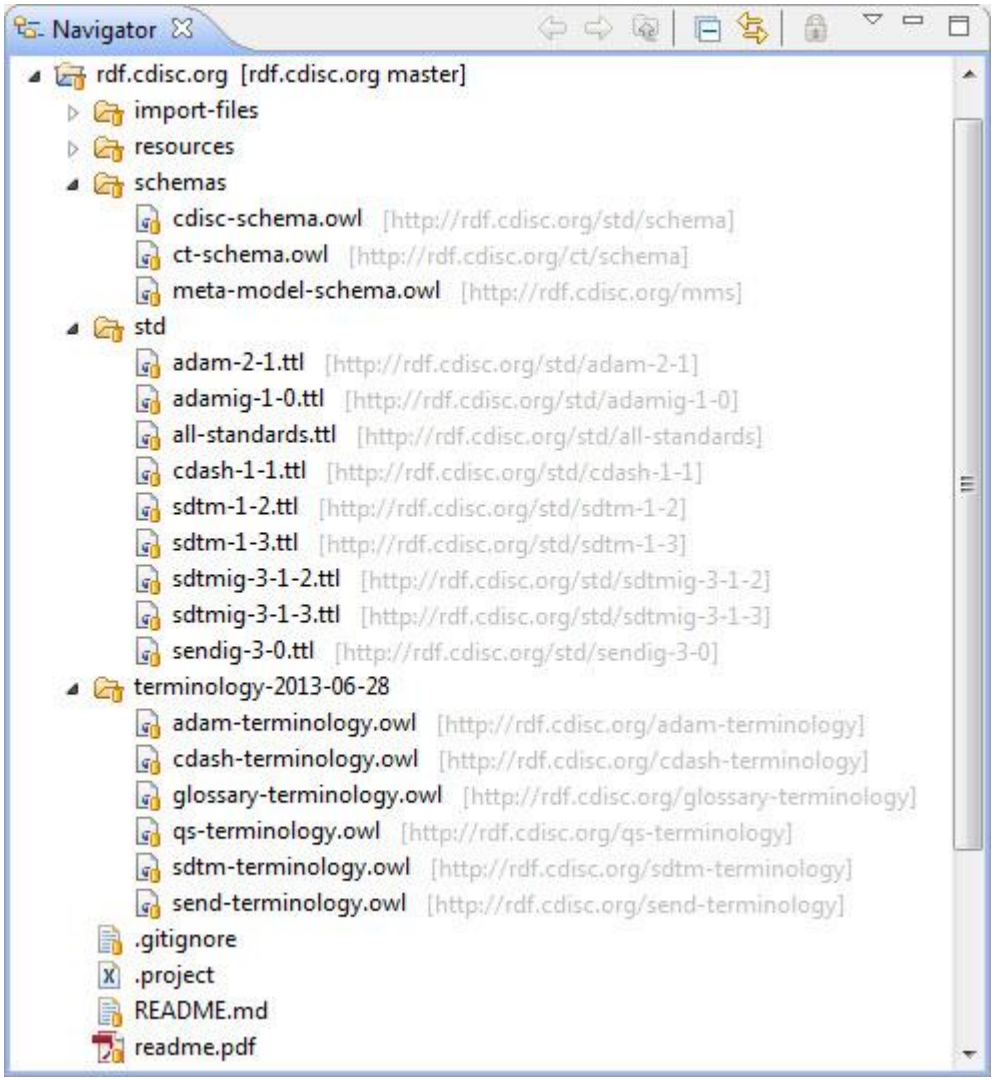
Accessing GitHub

- The first release of the Foundational Standards in RDF is available on **GitHub**

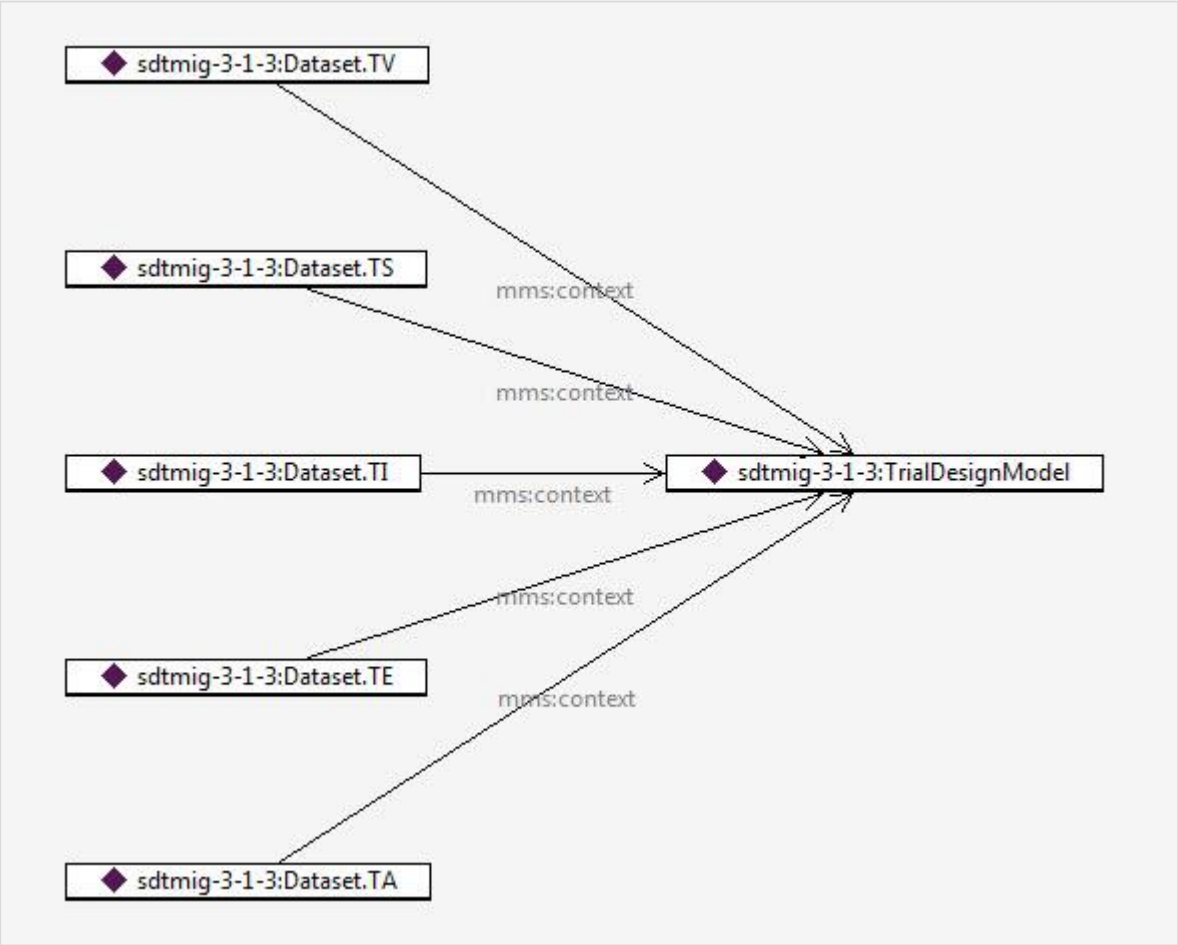
  https://github.com/phuse-org/rdf.cdisc.org

- To access the code:
  - Download a zip archive
  - Clone the project
    - Guidance in the RDF Reference Guide
    - Contact Geoff Low: glow@mdsol.com

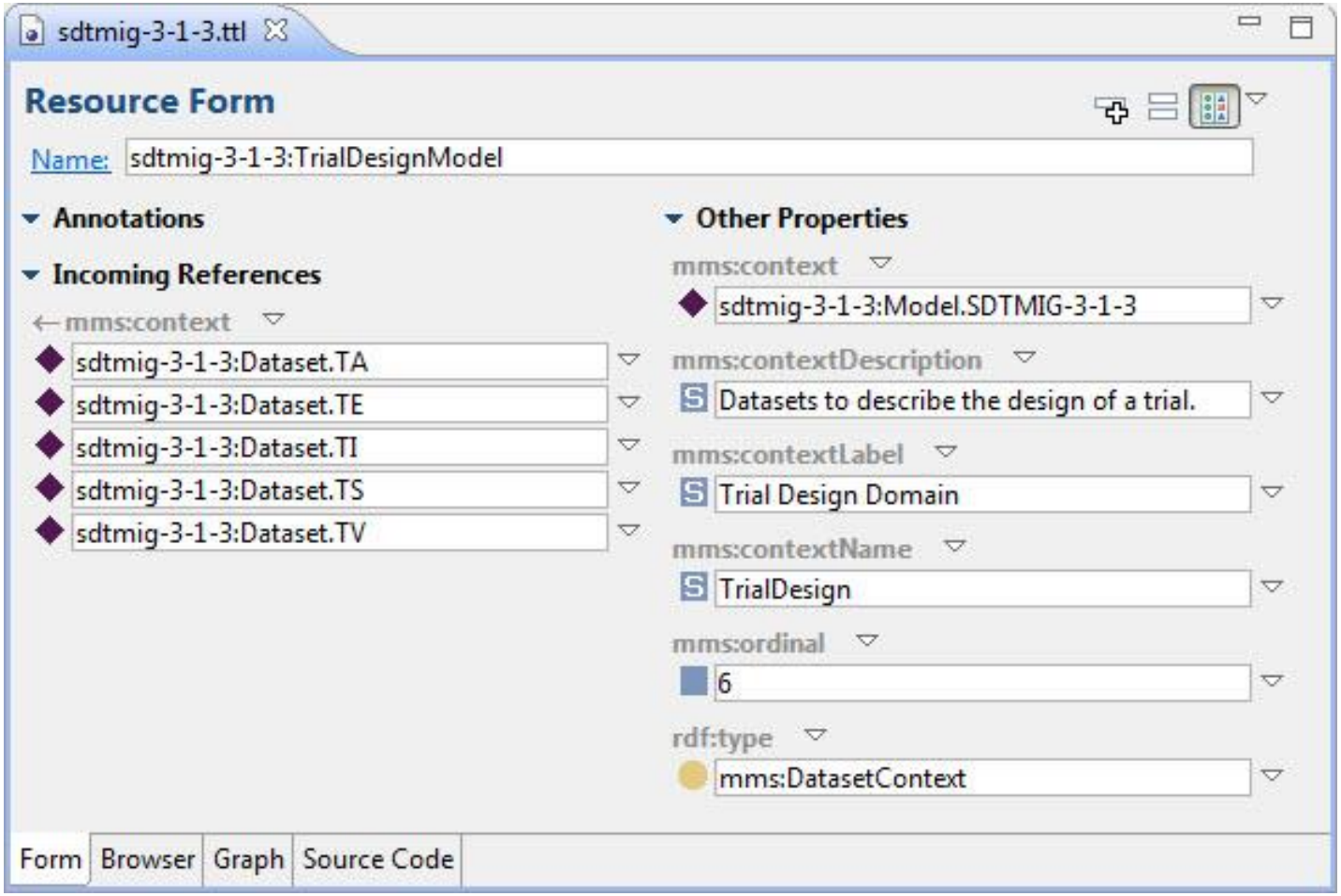
Project Structure



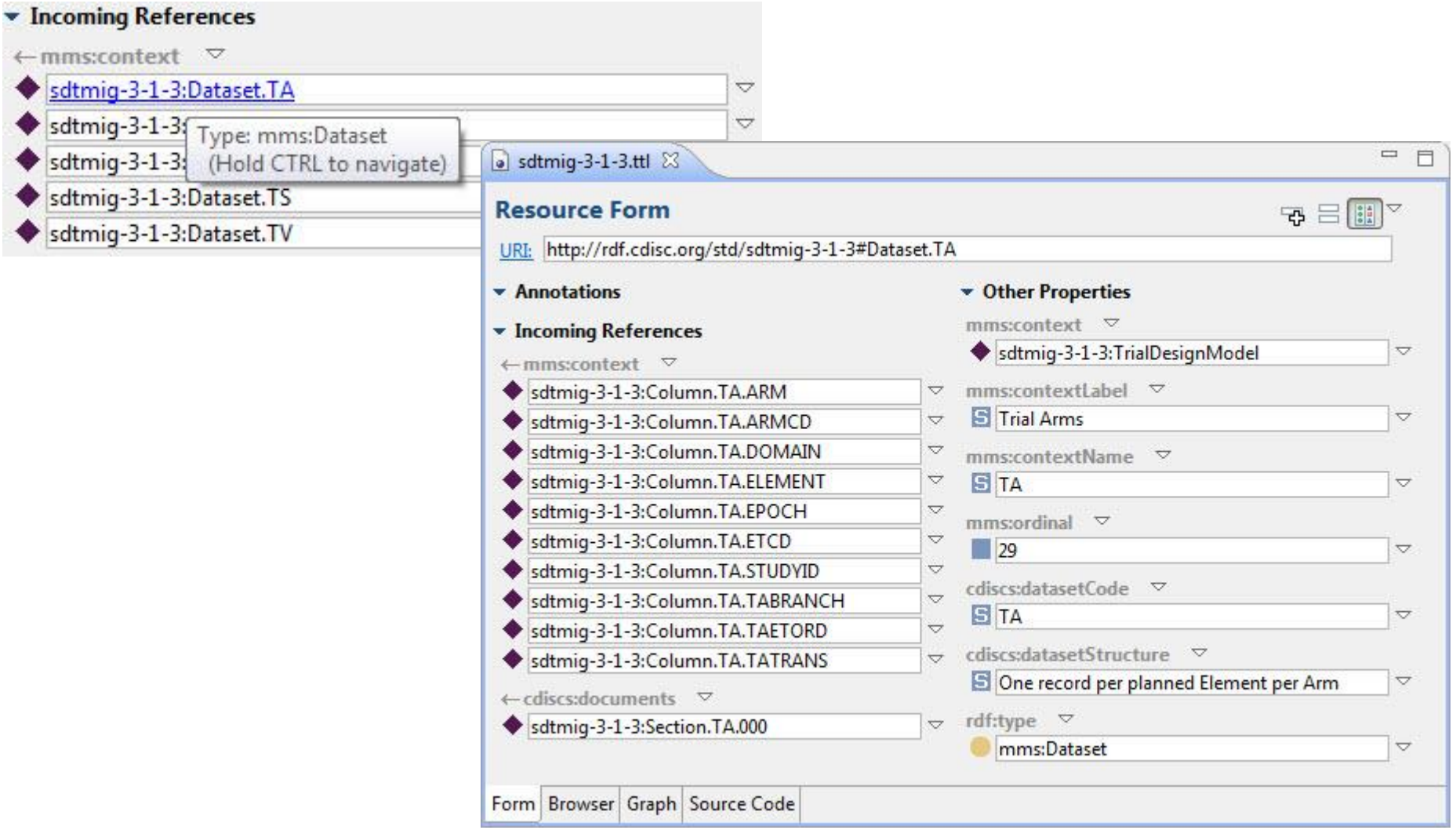
Graph Representation



Resource Form



Navigating Across Resources



RDF Text Serialization

```
sdtmig-3-1-3:Dataset.TA
      a                          mms:Dataset ;
      mms:context                sdtmig-3-1-3:TrialDesignModel ;
      mms:contextLabel           "Trial Arms"^^xsd:string ;
      mms:contextName            "TA"^^xsd:string ;
      mms:ordinal                "29"^^xsd:positiveInteger ;
      cdiscs:datasetCode         "TA"^^xsd:string ;
      cdiscs:datasetStructure    "One record per planned Element per Arm"^^xsd:string .
```

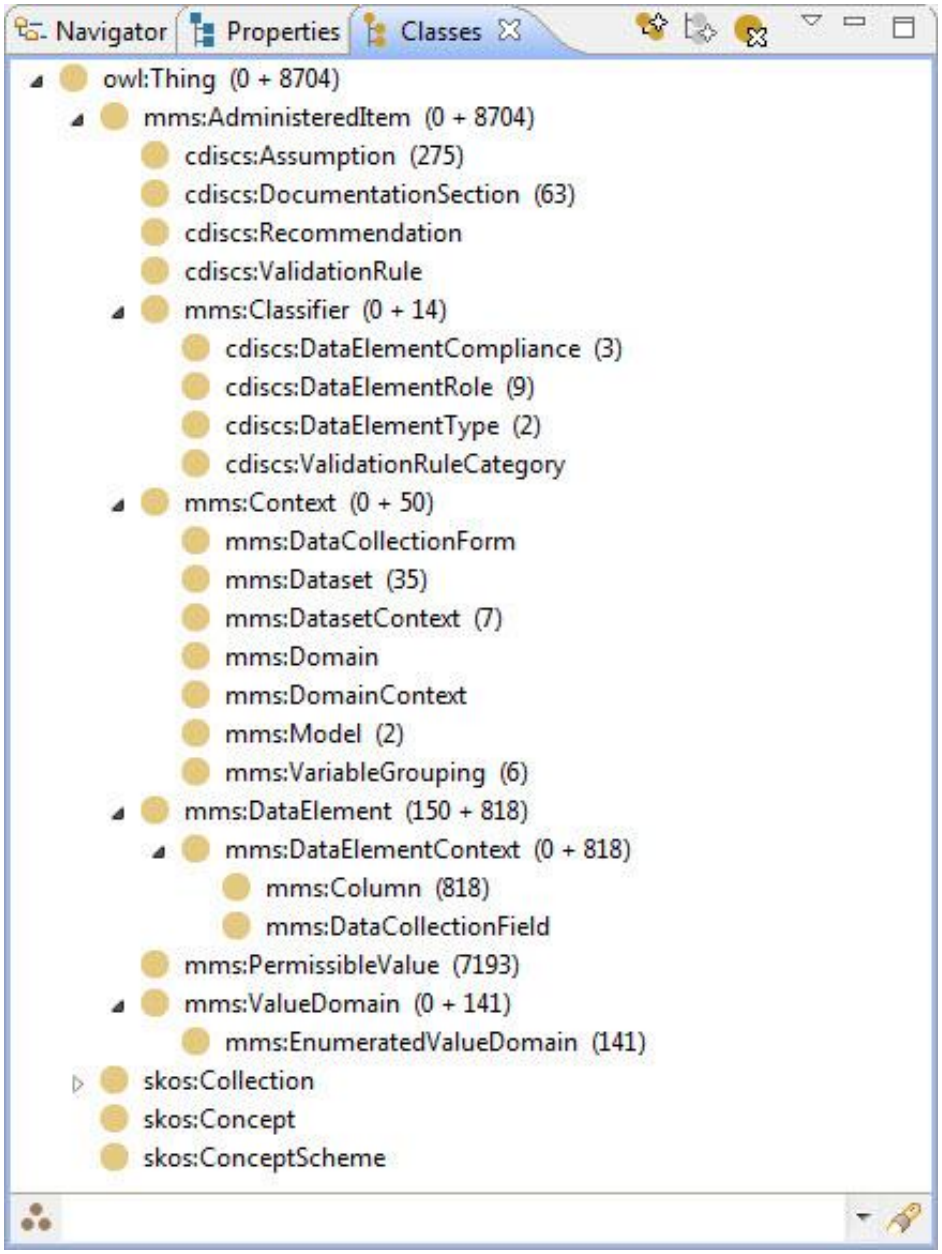
RDF Query Language

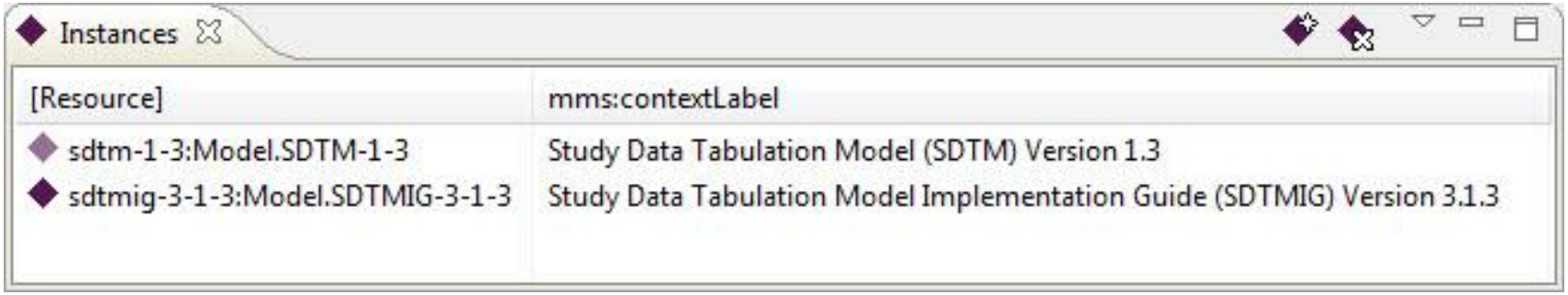
Query Editor | Query Library

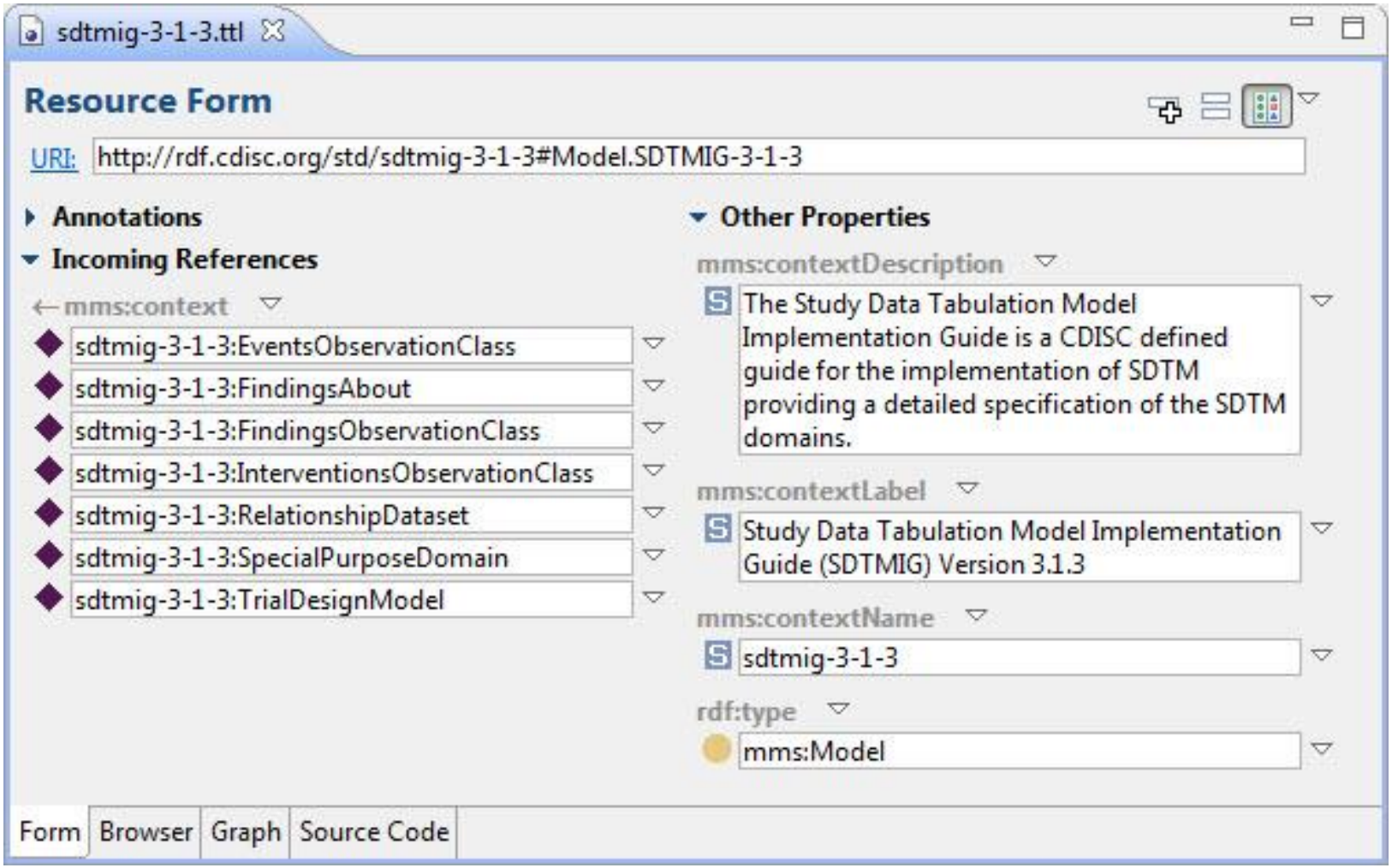
```
# Find all SDTM variables with codelist C71113
PREFIX mms: <http://rdf.cdisc.org/mms#>
PREFIX sdtmct: <http://rdf.cdisc.org/sdtm-terminology#>
SELECT ?domain ?variable ?label
WHERE {
   ?dataElement mms:dataElementValueDomain sdtmct:C71113 .
   ?dataElement mms:context/mms:contextLabel ?domain .
   ?dataElement mms:dataElementName  ?variable .
   ?dataElement mms:dataElementLabel ?label .
}
```

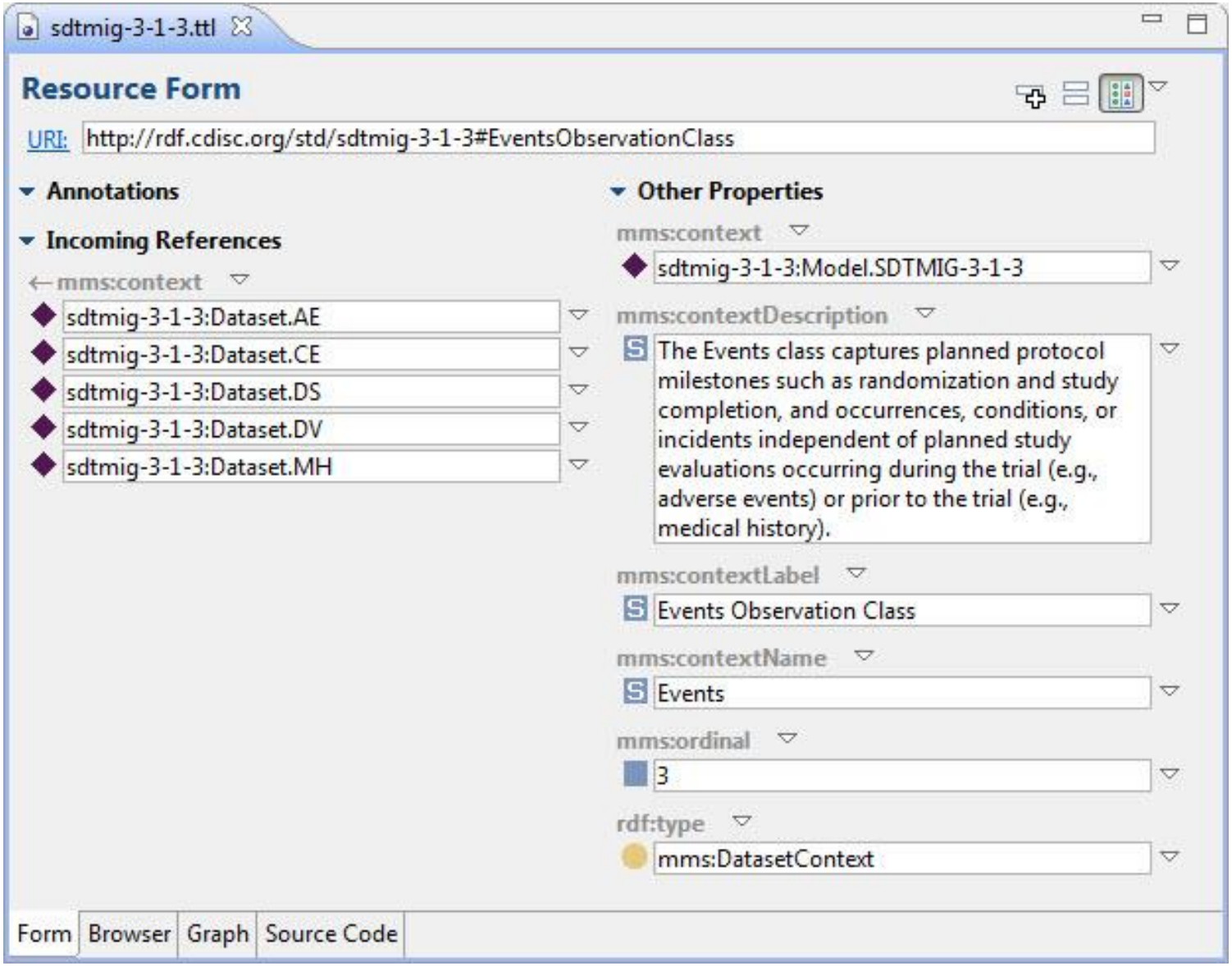
[domain]	variable	label
Concomitant Medications	CMDOSFRQ	Dosing Frequency per Interval
Exposure	EXDOSFRQ	Dosing Frequency per Interval
Substance Use	SUDOSFRQ	Use Frequency Per Interval

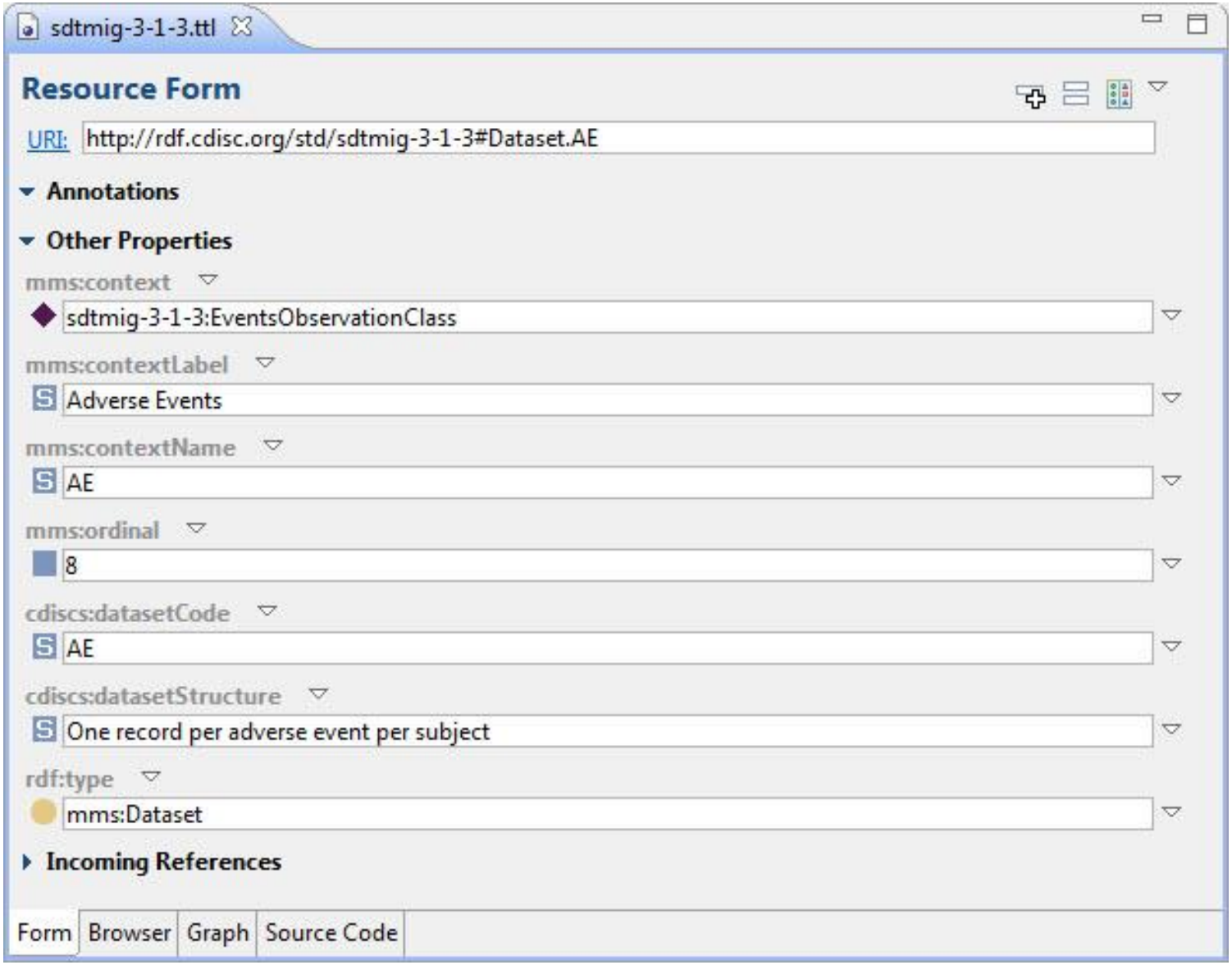
SDTM IG Walk-through

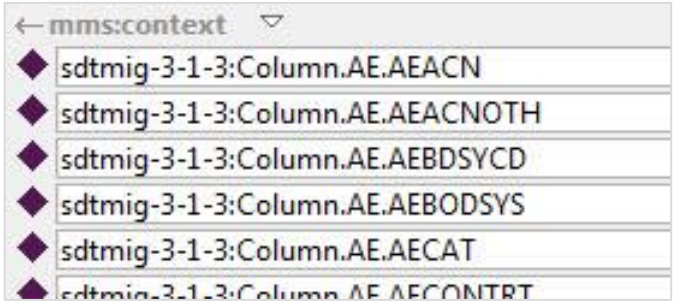

Navigator
Properties
Classes
owl:Thing (0 + 8704)
mms:AdministeredItem (0 + 8704)
cdiscs:Assumption (275)
cdiscs:DocumentationSection (63)
cdiscs:Recommendation
cdiscs:ValidationRule
mms:Classifier (0 + 14)
cdiscs:DataElementCompliance (3)
cdiscs:DataElementRole (9)
cdiscs:DataElementType (2)
cdiscs:ValidationRuleCategory
mms:Context (0 + 50)
mms:DataCollectionForm
mms:Dataset (35)
mms:DatasetContext (7)
mms:Domain
mms:DomainContext
mms:Model (2)
mms:VariableGrouping (6)
mms:DataElement (150 + 818)
mms:DataElementContext (0 + 818)
mms:Column (818)
mms:DataCollectionField
mms:PermissibleValue (7193)
mms:ValueDomain (0 + 141)
mms:EnumeratedValueDomain (141)
skos:Collection
skos:Concept
skos:ConceptScheme

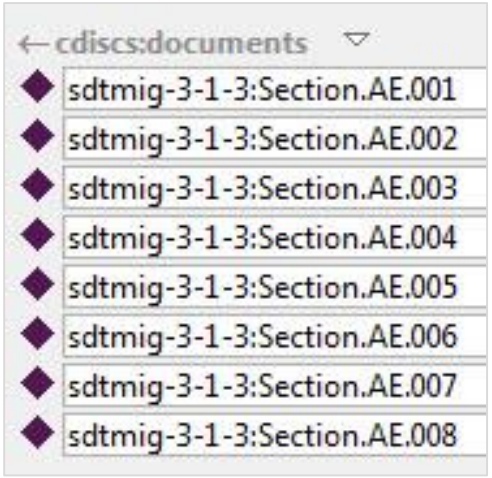

Instances
[Resource]
mms:contextLabel
sdtm-1-3:Model.SDTM-1-3
Study Data Tabulation Model (SDTM) Version 1.3
sdtmig-3-1-3:Model.SDTMIG-3-1-3
Study Data Tabulation Model Implementation Guide (SDTMIG) Version 3.1.3

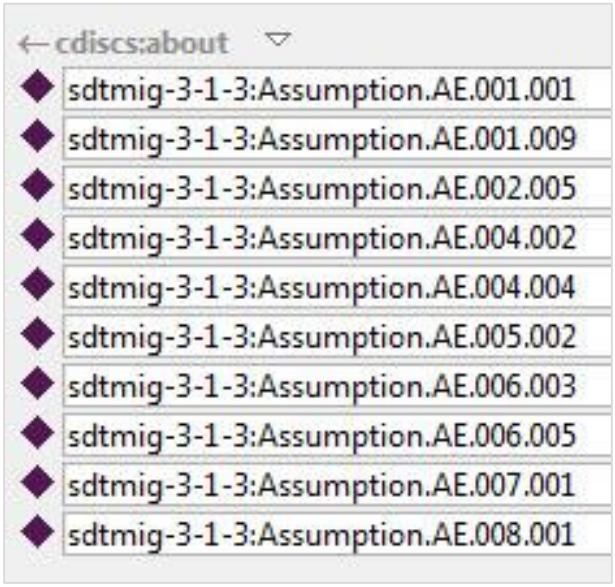

sdtmig-3-1-3.ttl
Resource Form
URI:
http://rdf.cdisc.org/std/sdtmig-3-1-3#Model.SDTMIG-3-1-3
Annotations
Incoming References
←mms:context
sdtmig-3-1-3:EventsObservationClass
sdtmig-3-1-3:FindingsAbout
sdtmig-3-1-3:FindingsObservationClass
sdtmig-3-1-3:InterventionsObservationClass
sdtmig-3-1-3:RelationshipDataset
sdtmig-3-1-3:SpecialPurposeDomain
sdtmig-3-1-3:TrialDesignModel
Other Properties
mms:contextDescription
The Study Data Tabulation Model Implementation Guide is a CDISC defined guide for the implementation of SDTM providing a detailed specification of the SDTM domains.
mms:contextLabel
Study Data Tabulation Model Implementation Guide (SDTMIG) Version 3.1.3
mms:contextName
sdtmig-3-1-3
rdf:type
mms:Model
Form
Browser
Graph
Source Code

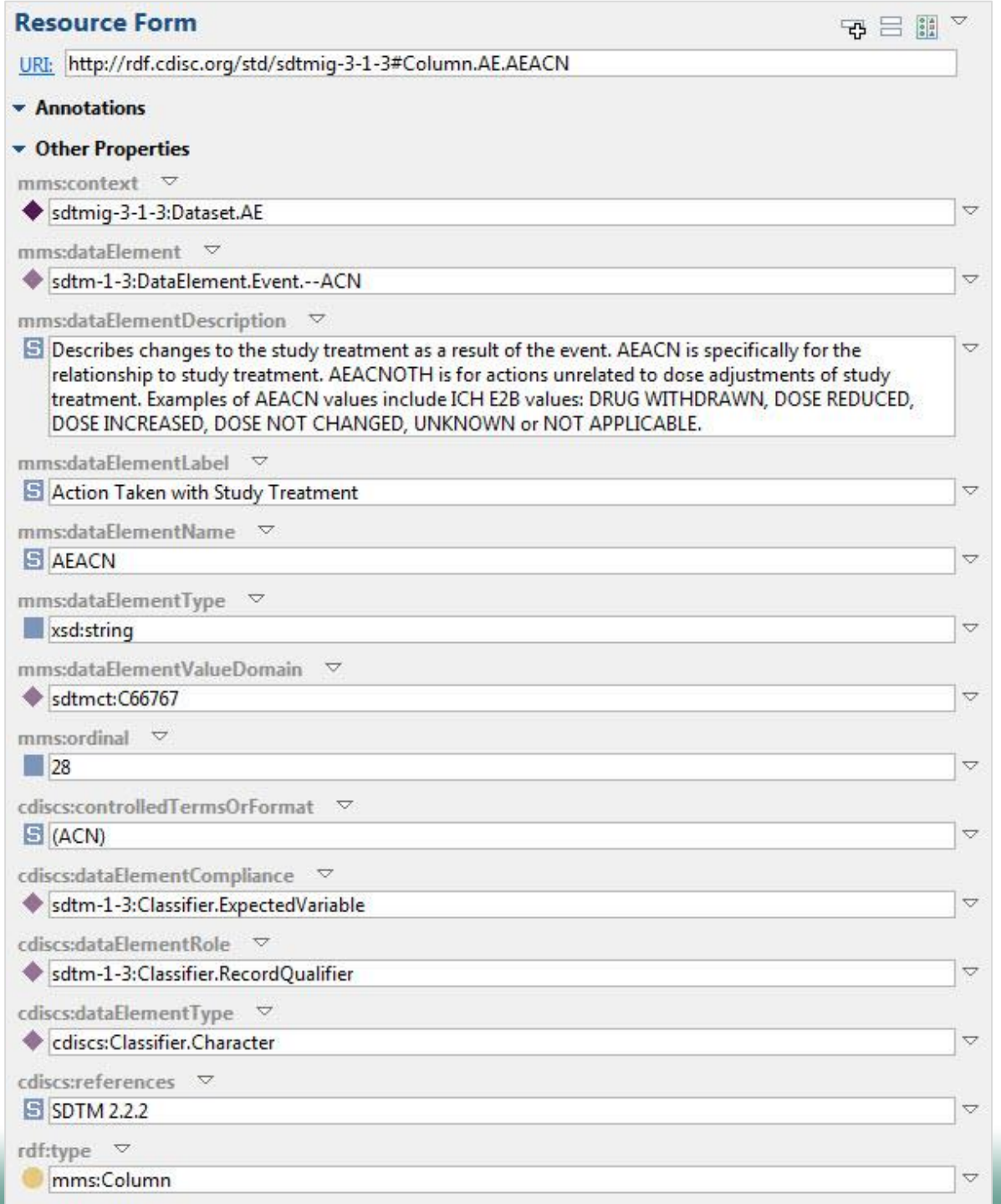

sdtmig-3-1-3.ttl
Resource Form
URI:
http://rdf.cdisc.org/std/sdtmig-3-1-3#EventsObservationClass
Annotations
Incoming References
←mms:context
sdtmig-3-1-3:Dataset.AE
sdtmig-3-1-3:Dataset.CE
sdtmig-3-1-3:Dataset.DS
sdtmig-3-1-3:Dataset.DV
sdtmig-3-1-3:Dataset.MH
Other Properties
mms:context
sdtmig-3-1-3:Model.SDTMIG-3-1-3
mms:contextDescription
The Events class captures planned protocol milestones such as randomization and study completion, and occurrences, conditions, or incidents independent of planned study evaluations occurring during the trial (e.g., adverse events) or prior to the trial (e.g., medical history).
mms:contextLabel
Events Observation Class
mms:contextName
Events
mms:ordinal
3
rdf:type
mms:DatasetContext
Form
Browser
Graph
Source Code

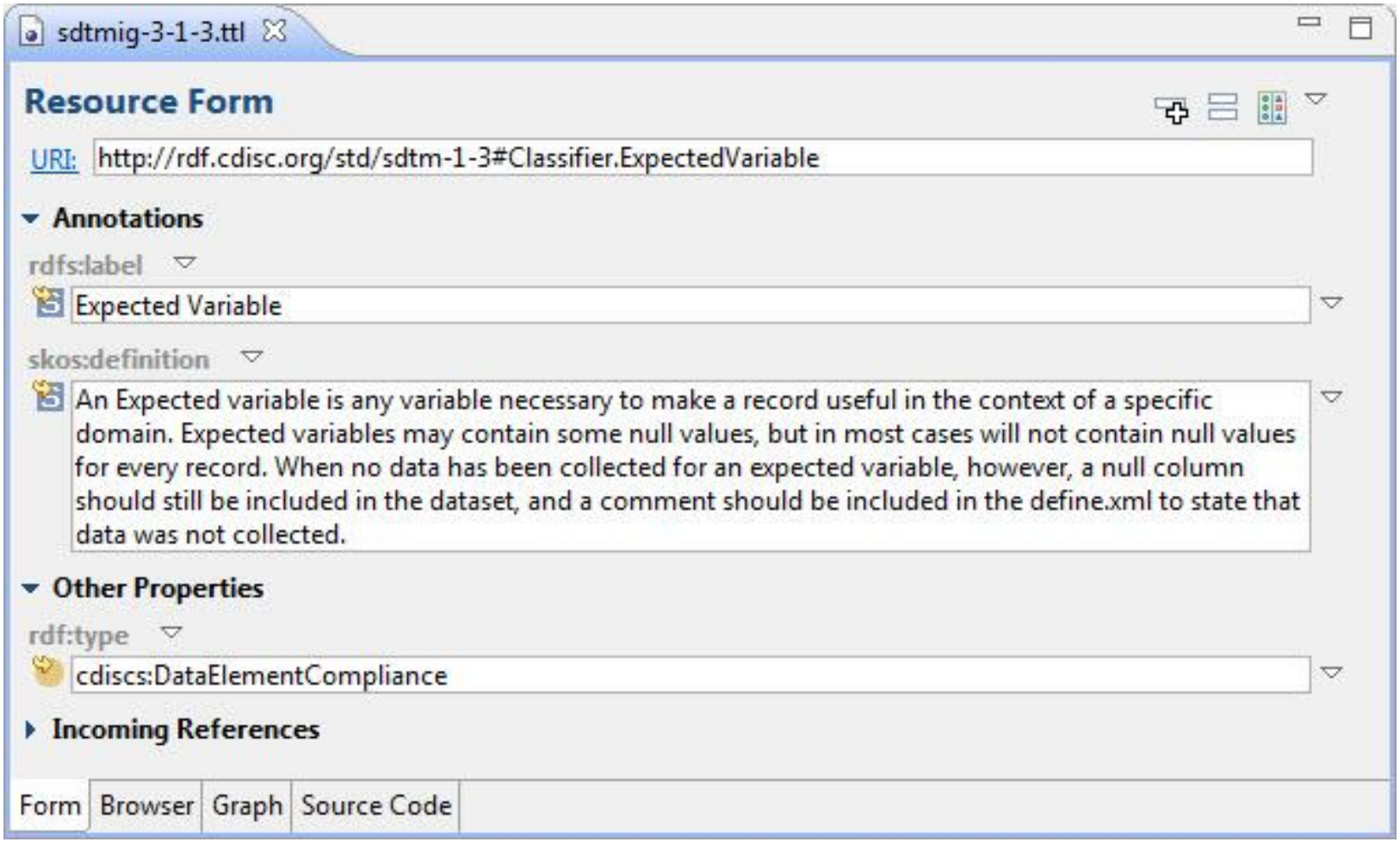

sdtmig-3-1-3.ttl
Resource Form
URI:
http://rdf.cdisc.org/std/sdtmig-3-1-3#Dataset.AE
Annotations
Other Properties
mms:context
sdtmig-3-1-3:EventsObservationClass
mms:contextLabel
Adverse Events
mms:contextName
AE
mms:ordinal
8
cdiscs:datasetCode
AE
cdiscs:datasetStructure
One record per adverse event per subject
rdf:type
mms:Dataset
Incoming References
Form
Browser
Graph
Source Code

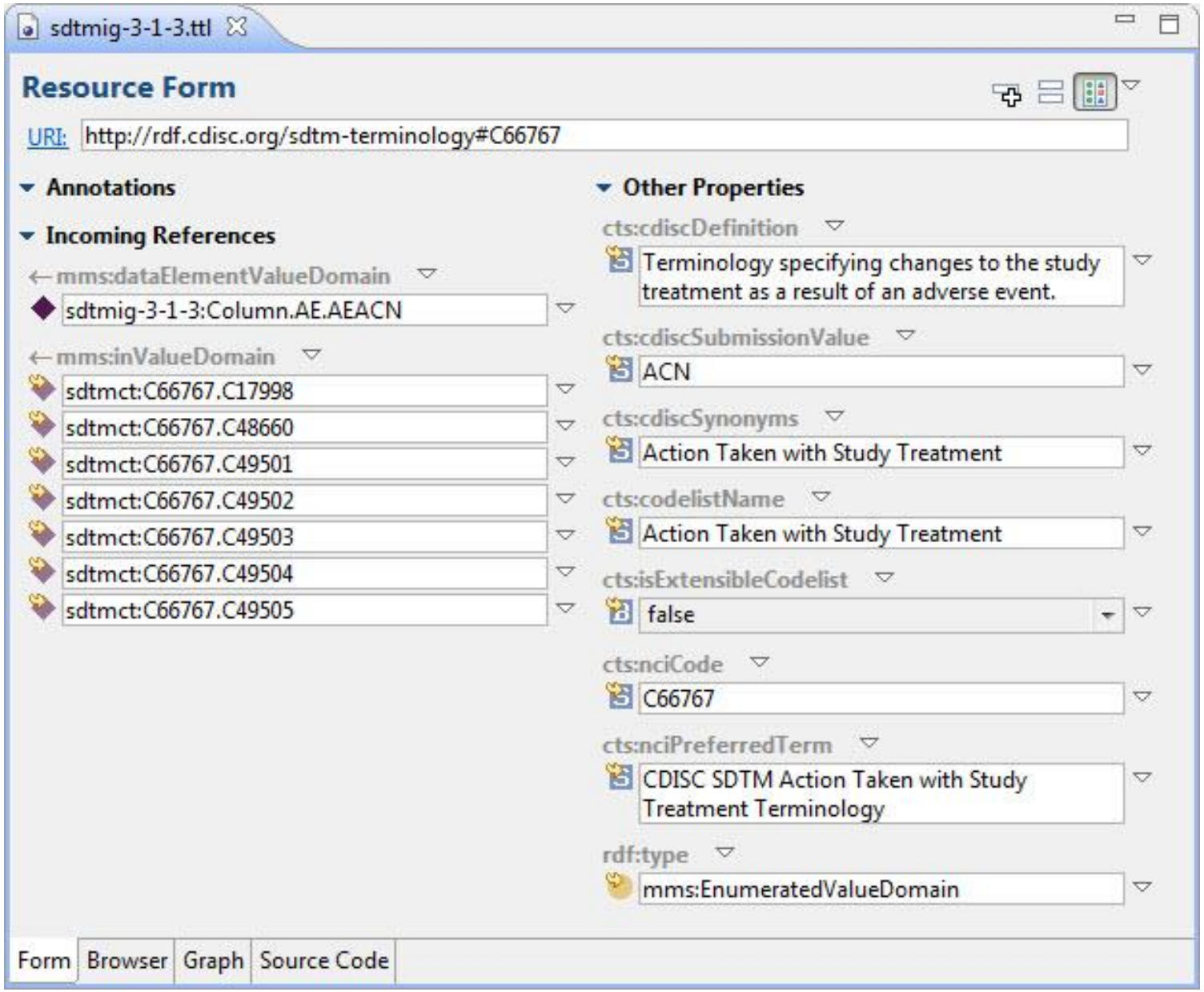

mms:context
sdtmig-3-1-3:Column.AE.AEACN
sdtmig-3-1-3:Column.AE.AEACNOTH
sdtmig-3-1-3:Column.AE.AEBDSYCD
sdtmig-3-1-3:Column.AE.AEBODSYS
sdtmig-3-1-3:Column.AE.AECAT

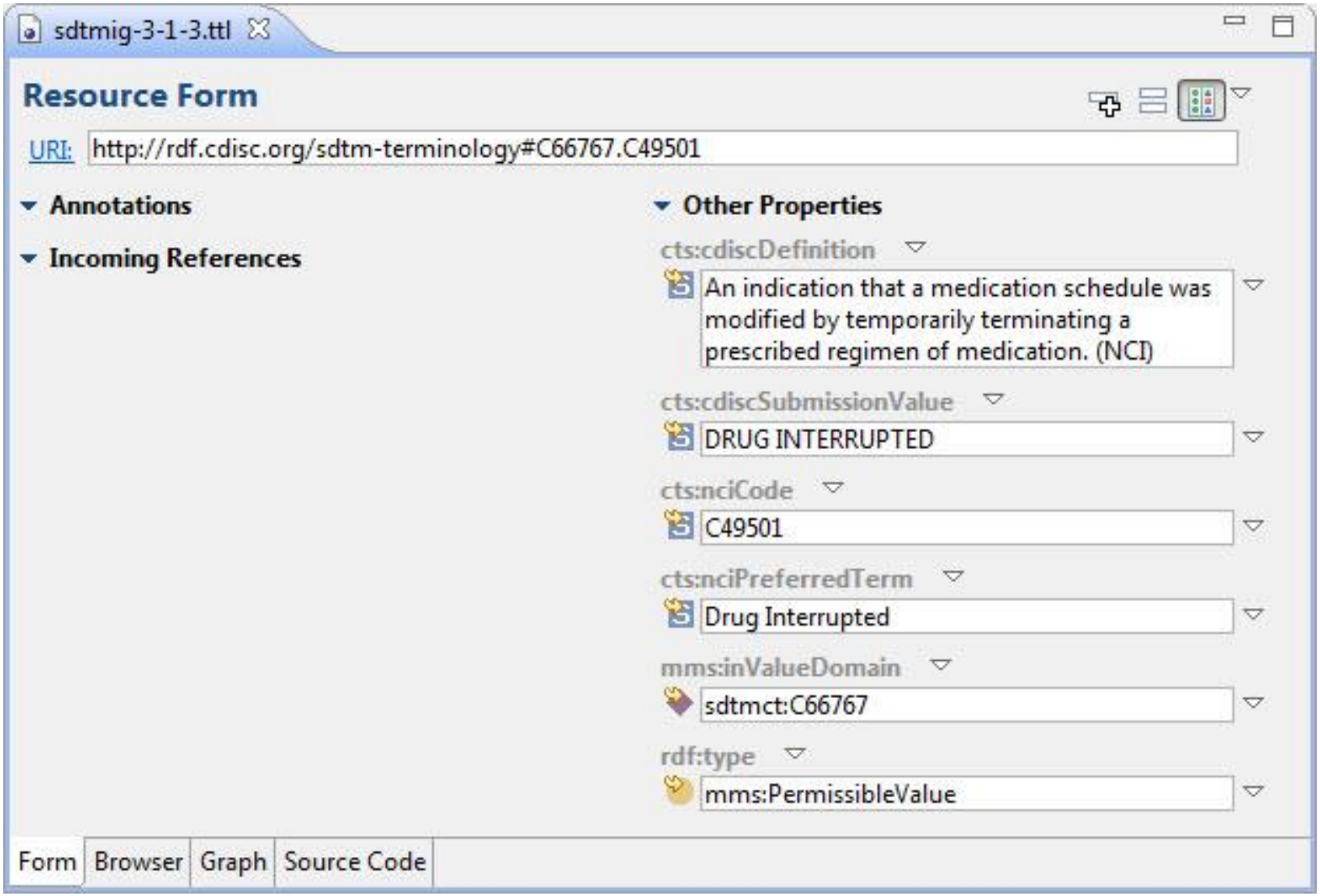

cdiscs:documents
sdtmig-3-1-3:Section.AE.001
sdtmig-3-1-3:Section.AE.002
sdtmig-3-1-3:Section.AE.003
sdtmig-3-1-3:Section.AE.004
sdtmig-3-1-3:Section.AE.005
sdtmig-3-1-3:Section.AE.006
sdtmig-3-1-3:Section.AE.007
sdtmig-3-1-3:Section.AE.008

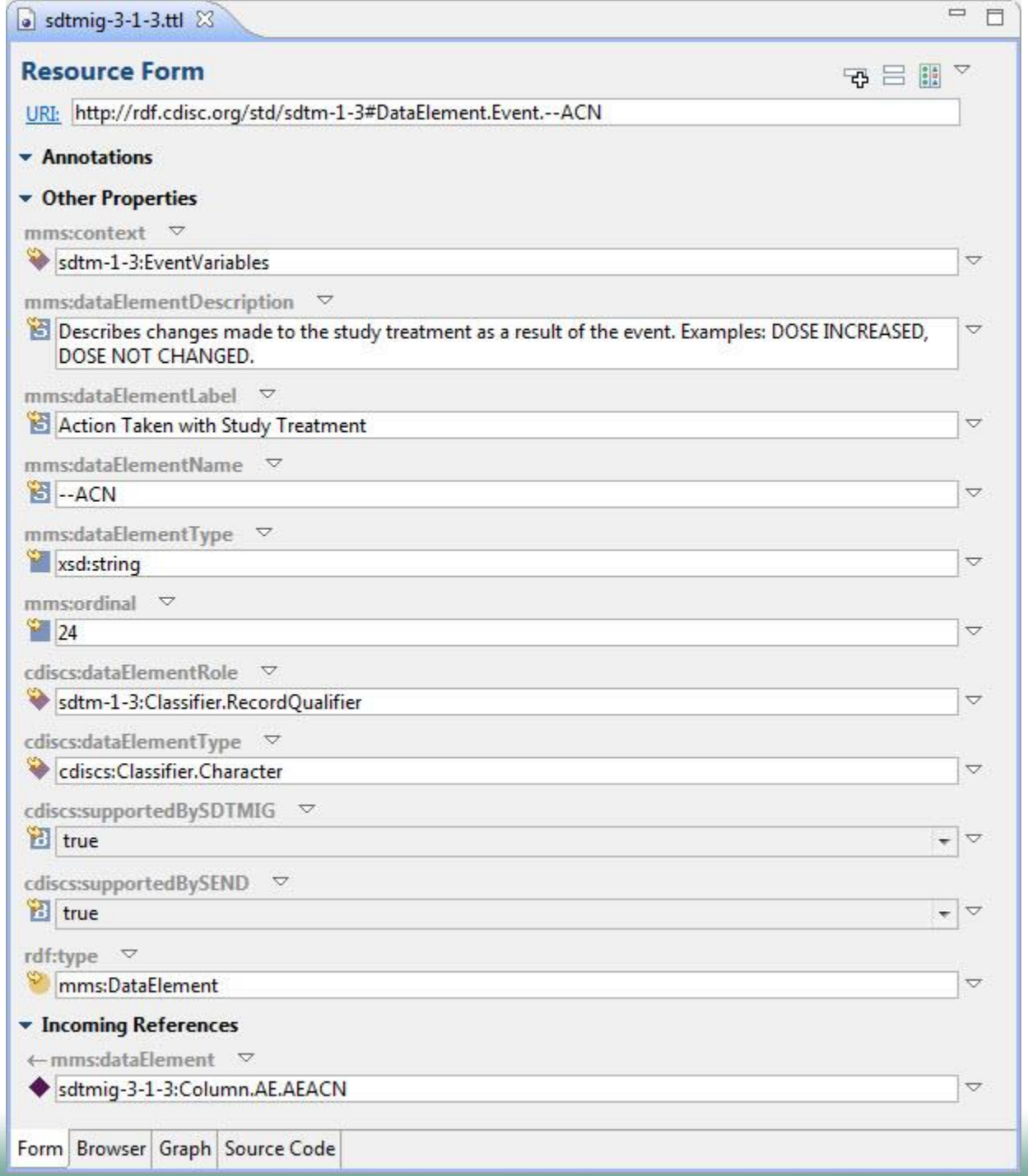

cdiscs:about
sdtmig-3-1-3:Assumption.AE.001.001
sdtmig-3-1-3:Assumption.AE.001.009
sdtmig-3-1-3:Assumption.AE.002.005
sdtmig-3-1-3:Assumption.AE.004.002
sdtmig-3-1-3:Assumption.AE.004.004
sdtmig-3-1-3:Assumption.AE.005.002
sdtmig-3-1-3:Assumption.AE.006.003
sdtmig-3-1-3:Assumption.AE.006.005
sdtmig-3-1-3:Assumption.AE.007.001
sdtmig-3-1-3:Assumption.AE.008.001

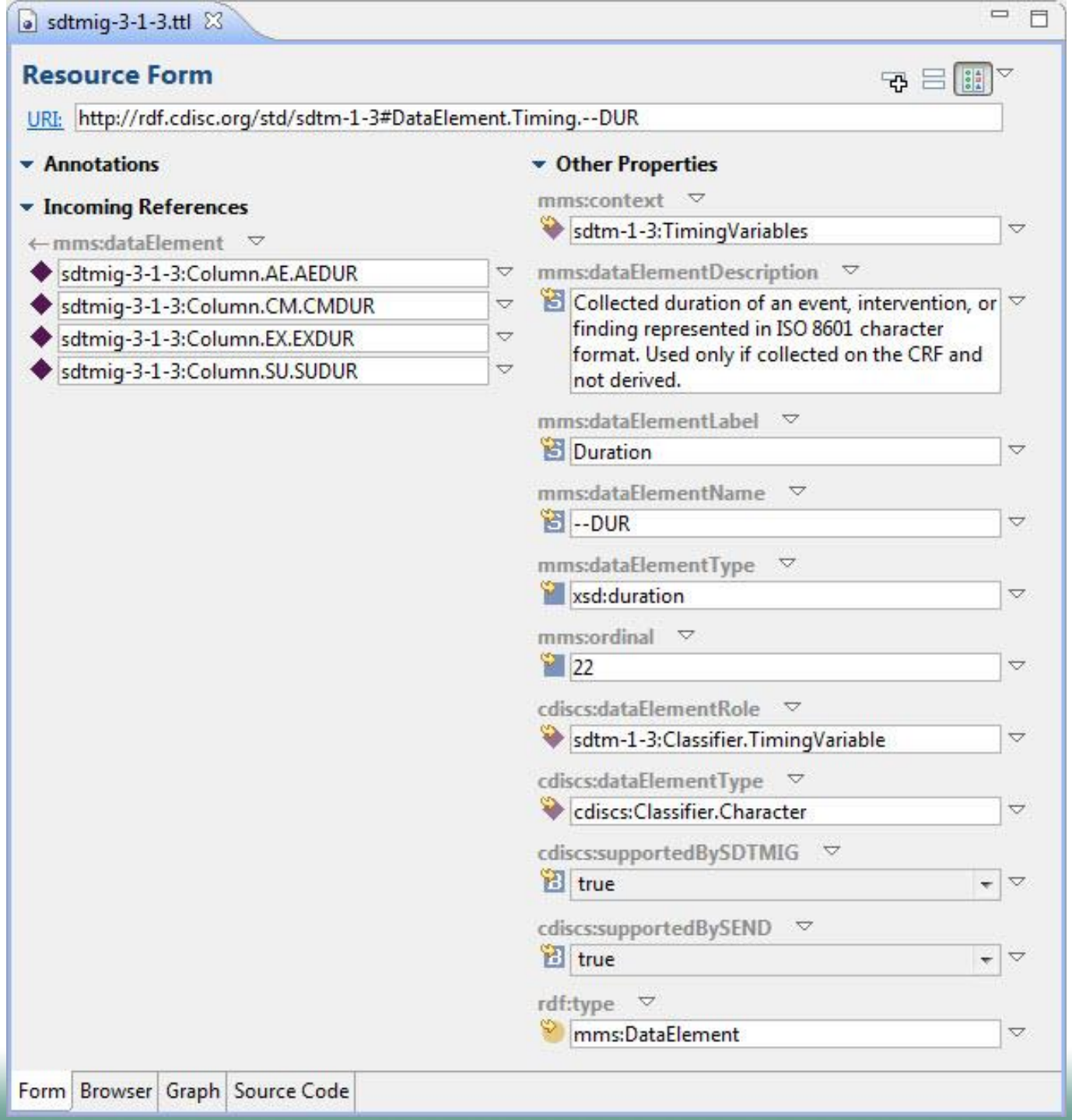

Resource Form
URI: http://rdf.cdisc.org/std/sdtmig-3-1-3#Column.AE.AEACN
Annotations
Other Properties
mms:context
sdtmig-3-1-3:Dataset.AE
mms:dataElement
sdtm-1-3:DataElement.Event.--ACN
mms:dataElementDescription
Describes changes to the study treatment as a result of the event. AEACN is specifically for the relationship to study treatment. AEACNOTH is for actions unrelated to dose adjustments of study treatment. Examples of AEACN values include ICH E2B values: DRUG WITHDRAWN, DOSE REDUCED, DOSE INCREASED, DOSE NOT CHANGED, UNKNOWN or NOT APPLICABLE.
mms:dataElementLabel
Action Taken with Study Treatment
mms:dataElementName
AEACN
mms:dataElementType
xsd:string
mms:dataElementValueDomain
sdtmct:C66767
mms:ordinal
28
cdiscs:controlledTermsOrFormat
(ACN)
cdiscs:dataElementCompliance
sdtm-1-3:Classifier.ExpectedVariable
cdiscs:dataElementRole
sdtm-1-3:Classifier.RecordQualifier
cdiscs:dataElementType
cdiscs:Classifier.Character
cdiscs:references
SDTM 2.2.2
rdf:type
mms:Column

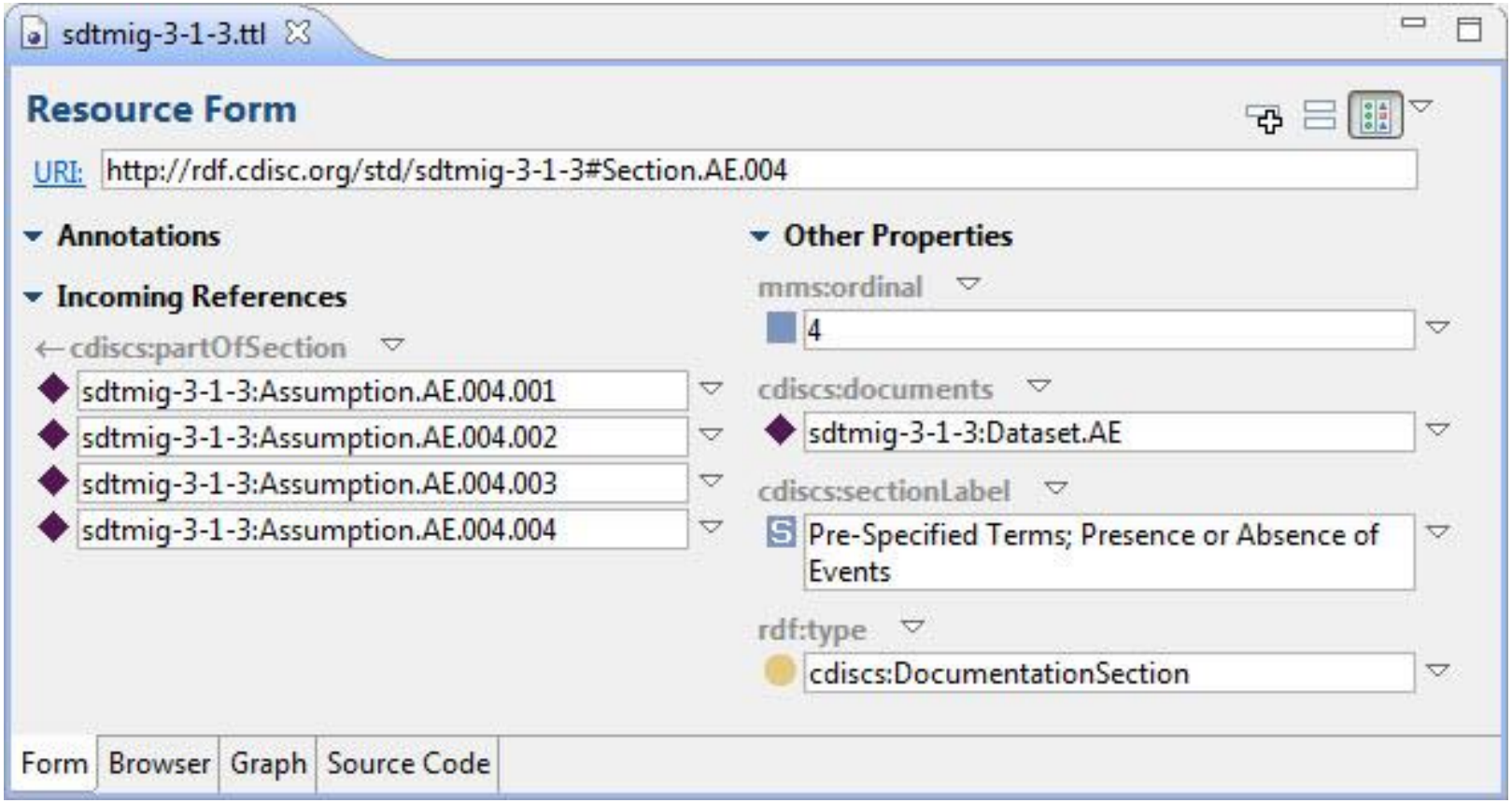

sdtmig-3-1-3.ttl
Resource Form
URI:
http://rdf.cdisc.org/std/sdtm-1-3#Classifier.ExpectedVariable
Annotations
rdfs:label
Expected Variable
skos:definition
An Expected variable is any variable necessary to make a record useful in the context of a specific domain. Expected variables may contain some null values, but in most cases will not contain null values for every record. When no data has been collected for an expected variable, however, a null column should still be included in the dataset, and a comment should be included in the define.xml to state that data was not collected.
Other Properties
rdf:type
cdiscs:DataElementCompliance
Incoming References
Form
Browser
Graph
Source Code

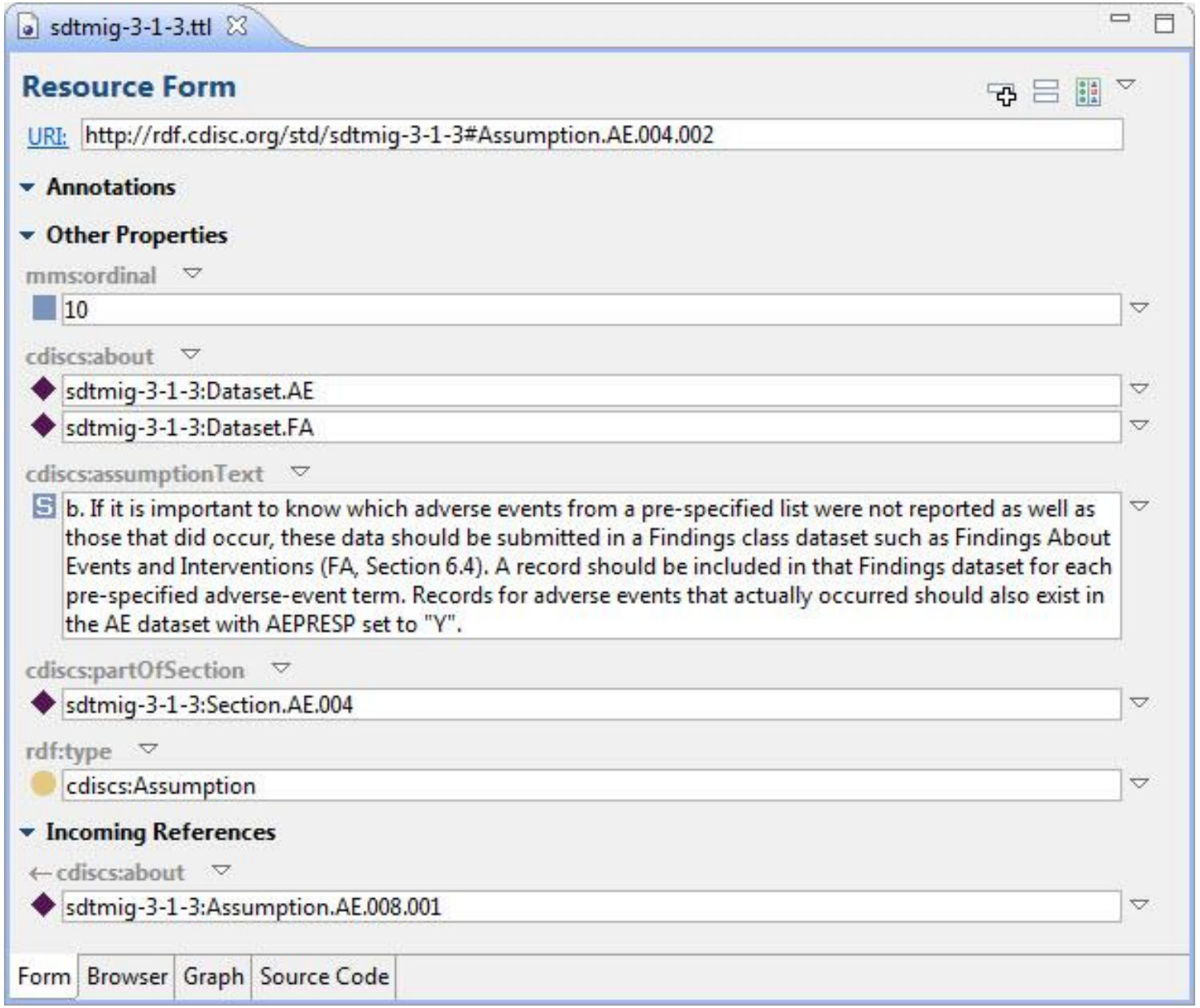

sdtmig-3-1-3.ttl
Resource Form
URI:
http://rdf.cdisc.org/sdtm-terminology#C66767
Annotations
Incoming References
←mms:dataElementValueDomain
sdtmig-3-1-3:Column.AE.AEACN
←mms:inValueDomain
sdtmct:C66767.C17998
sdtmct:C66767.C48660
sdtmct:C66767.C49501
sdtmct:C66767.C49502
sdtmct:C66767.C49503
sdtmct:C66767.C49504
sdtmct:C66767.C49505
Other Properties
cts:cdiscDefinition
Terminology specifying changes to the study treatment as a result of an adverse event.
cts:cdiscSubmissionValue
ACN
cts:cdiscSynonyms
Action Taken with Study Treatment
cts:codelistName
Action Taken with Study Treatment
cts:isExtensibleCodelist
false
cts:nciCode
C66767
cts:nciPreferredTerm
CDISC SDTM Action Taken with Study Treatment Terminology
rdf:type
mms:EnumeratedValueDomain
Form
Browser
Graph
Source Code


sdtmig-3-1-3.ttl
Resource Form
URI:
http://rdf.cdisc.org/sdtm-terminology#C66767.C49501
Annotations
Incoming References
Other Properties
cts:cdiscDefinition
An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)
cts:cdiscSubmissionValue
DRUG INTERRUPTED
cts:nciCode
C49501
cts:nciPreferredTerm
Drug Interrupted
mms:inValueDomain
sdtmct:C66767
rdf:type
mms:PermissibleValue
Form
Browser
Graph
Source Code


sdtmig-3-1-3.ttl
Resource Form
URI:
http://rdf.cdisc.org/std/sdtm-1-3#DataElement.Event.--ACN
Annotations
Other Properties
mms:context
sdtm-1-3:EventVariables
mms:dataElementDescription
Describes changes made to the study treatment as a result of the event. Examples: DOSE INCREASED, DOSE NOT CHANGED.
mms:dataElementLabel
Action Taken with Study Treatment
mms:dataElementName
--ACN
mms:dataElementType
xsd:string
mms:ordinal
24
cdiscs:dataElementRole
sdtm-1-3:Classifier.RecordQualifier
cdiscs:dataElementType
cdiscs:Classifier.Character
cdiscs:supportedBySDTMIG
true
cdiscs:supportedBySEND
true
rdf:type
mms:DataElement
Incoming References
←mms:dataElement
sdtmig-3-1-3:Column.AE.AEACN
Form
Browser
Graph
Source Code


sdtmig-3-1-3.ttl
Resource Form
URI:
http://rdf.cdisc.org/std/sdtm-1-3#DataElement.Timing.--DUR
Annotations
Incoming References
←mms:dataElement
sdtmig-3-1-3:Column.AE.AEDUR
sdtmig-3-1-3:Column.CM.CMDUR
sdtmig-3-1-3:Column.EX.EXDUR
sdtmig-3-1-3:Column.SU.SUDUR
Other Properties
mms:context
sdtm-1-3:TimingVariables
mms:dataElementDescription
Collected duration of an event, intervention, or finding represented in ISO 8601 character format. Used only if collected on the CRF and not derived.
mms:dataElementLabel
Duration
mms:dataElementName
--DUR
mms:dataElementType
xsd:duration
mms:ordinal
22
cdiscs:dataElementRole
sdtm-1-3:Classifier.TimingVariable
cdiscs:dataElementType
cdiscs:Classifier.Character
cdiscs:supportedBySDTMIG
true
cdiscs:supportedBySEND
true
rdf:type
mms:DataElement
Form
Browser
Graph
Source Code

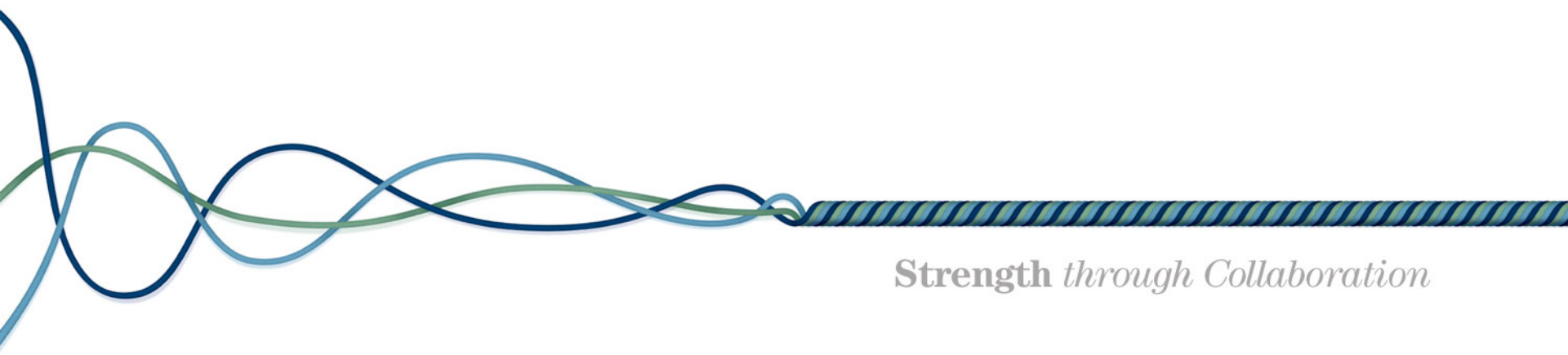

sdtmig-3-1-3.ttl
Resource Form
URI:
http://rdf.cdisc.org/std/sdtmig-3-1-3#Section.AE.004
Annotations
Incoming References
←cdiscs:partOfSection
sdtmig-3-1-3:Assumption.AE.004.001
sdtmig-3-1-3:Assumption.AE.004.002
sdtmig-3-1-3:Assumption.AE.004.003
sdtmig-3-1-3:Assumption.AE.004.004
Other Properties
mms:ordinal
4
cdiscs:documents
sdtmig-3-1-3:Dataset.AE
cdiscs:sectionLabel
Pre-Specified Terms; Presence or Absence of Events
rdf:type
cdiscs:DocumentationSection
Form
Browser
Graph
Source Code


sdtmig-3-1-3.ttl
Resource Form
URI:
http://rdf.cdisc.org/std/sdtmig-3-1-3#Assumption.AE.004.002
Annotations
Other Properties
mms:ordinal
10
cdiscs:about
sdtmig-3-1-3:Dataset.AE
sdtmig-3-1-3:Dataset.FA
cdiscs:assumptionText
b. If it is important to know which adverse events from a pre-specified list were not reported as well as those that did occur, these data should be submitted in a Findings class dataset such as Findings About Events and Interventions (FA, Section 6.4). A record should be included in that Findings dataset for each pre-specified adverse-event term. Records for adverse events that actually occurred should also exist in the AE dataset with AEPRESP set to "Y".
cdiscs:partOfSection
sdtmig-3-1-3:Section.AE.004
rdf:type
cdiscs:Assumption
Incoming References
←cdiscs:about
sdtmig-3-1-3:Assumption.AE.008.001
Form
Browser
Graph
Source Code

Questions?

CDISC Education & Events Announcements

Shannon Labout, CDISC VP Education



Upcoming Interchanges

Tokyo, Japan – July 2014

Bethesda, MD, USA – November 2014

Basel, Switzerland – May 2015

Upcoming Public Course Events

Location	Dates	Courses Offered	Registration Deadline	Discounts?	Host
Seattle, WA	26-29 Aug	SDTM, ADaM, ODM/Define-XML Combo	26 July	Expired	Axio Partners in Research
Brussels, Belgium	8-11 Sep	SDTM, CDASH, ADaM	8 Aug	Expired	Business & Decision Life Sciences
Copenhagen, Denmark	27-30 Oct	SEND, ODM, Define-XML, Dataset-XML	10 Oct	Ends 21 Aug	novo nordisk®
Beijing & Shanghai, China	TBD	TBD	TBD	TBD	TBD

- *Registration now open for some 2015 public training events.*

Public Course Schedule

- ADaM
- BRIDG
- CDASH
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  - **Good Practice in PMA Submissions for Efficient Regulatory Decision Making**
- **Date**: 21 Aug 2014, 11:00-12:30 PM EST

- **Panelists:**
  - Rhonda Facile, CDISC
  - Monika Kawohl, Accovion GmbH
  - Lex Jansen, SAS
  - **Rajesh Nair, FDA**

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- **Speaker**: Sam Hume, CDISC

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