Semantic Models for CDISC Based Standards and Metadata Management

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Data Standards, PD Biometrics, Hoffmann-La Roche

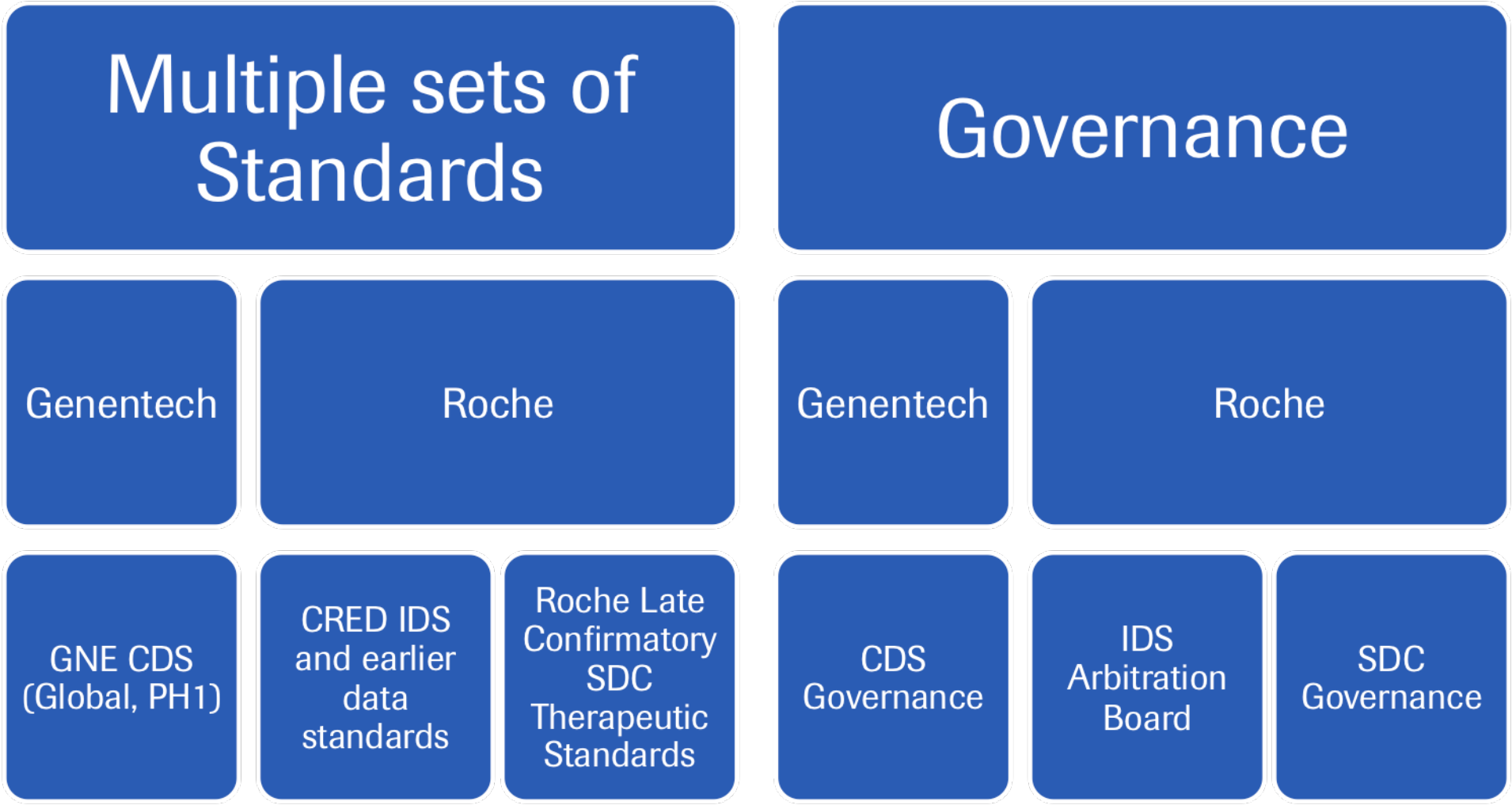
Roche Data Standards Office

Remit and Scope

- Design and manage end-to-end data standards, from protocol to submission, with supporting business processes
- Define data standards for use with gRED, pRED, and PD clinical trial data
- Drive adoption of current & future industry standards (CDISC)
- Provide lifecycle management and governance for all data standards
- Coordinate contributions to external standards bodies

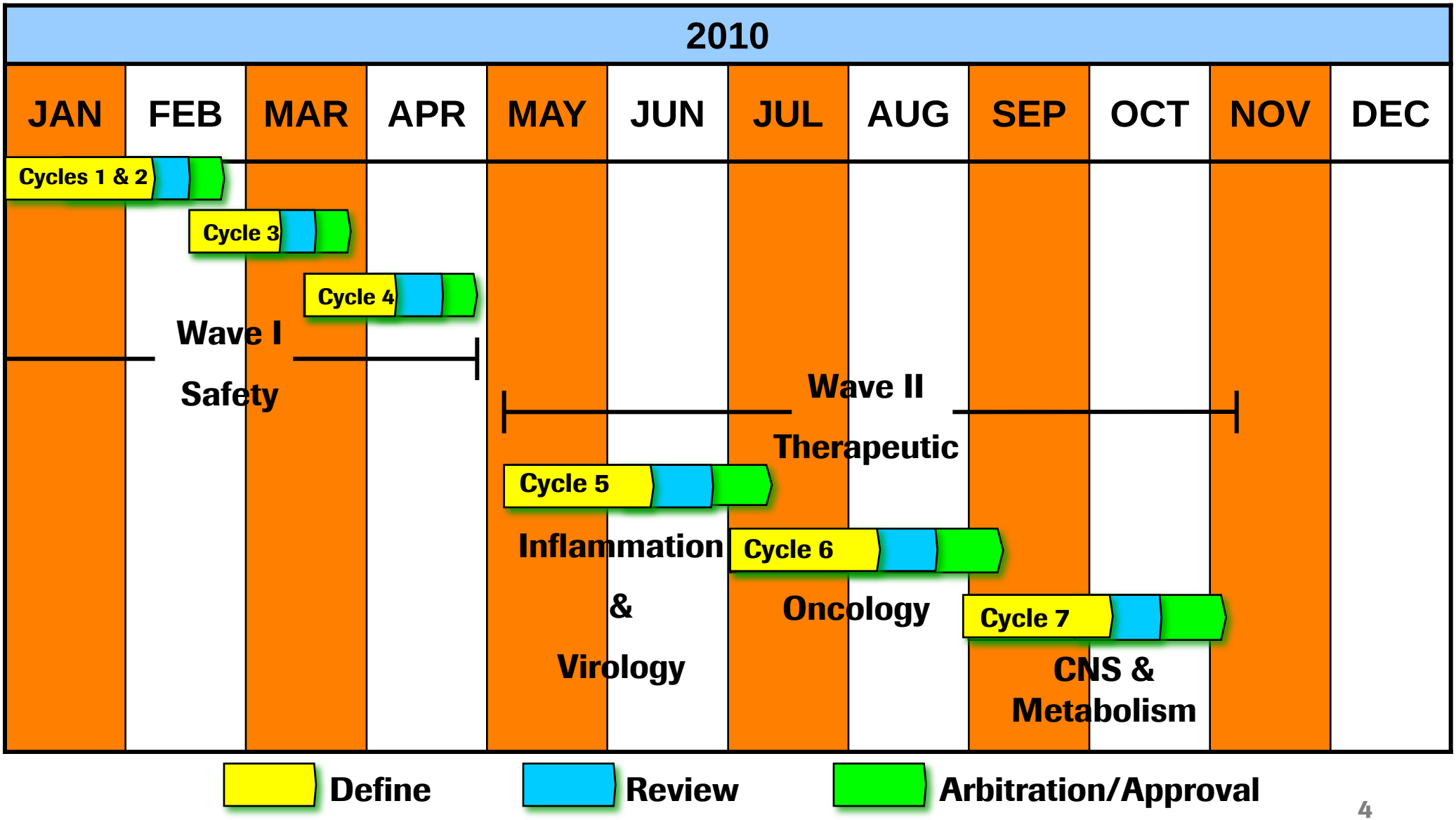
Global Data Standards Integration Initiative

Status at time of Roche-Genentech integration



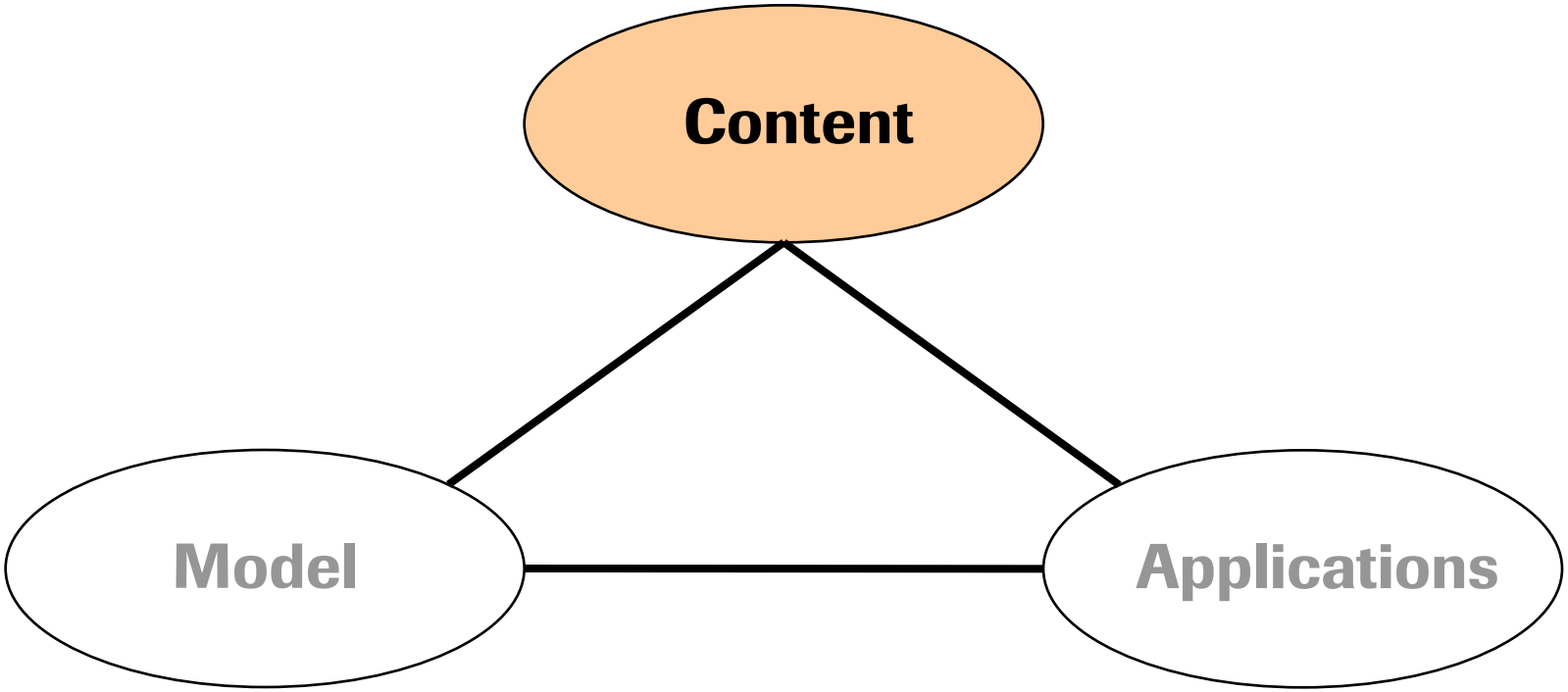
Global Data Standards Integration Initiative

Timelines



Global Data Standards Repository (GDSR)

What is in there?



Global Data Standards Repository

Content Requirements

- End-to-End **data standards** from protocol to submission cover the complete life cycle of clinical research data
  - Protocol Design
  - **Data Collection**
  - **Data Tabulation**

  } **Current Scope**

  - Data Analysis
  - Regulatory Submission
- Based on **CDISC Industry Standards**
- Objective
  - Support **consistent definition**, management, and processing of clinical research data throughout all stages of the life cycle
  - Support **data standards management**

Global Data Standards Repository

Content Elements

- Standards for data collection
  - CRF logical structure, design, layout
  - CRF fields, forms, help text, completion guidelines, annotations
- Standards for data tabulation
  - CDISC SDTM 1.2, SDTMIG 3.1.2, Controlled Terminology
  - Sponsor defined extensions
- Standards for data analysis
  - Specification of derived data elements
- Standards for consistent definitions
  - Associate data elements with defined concepts
  - Versioning and life cycle management

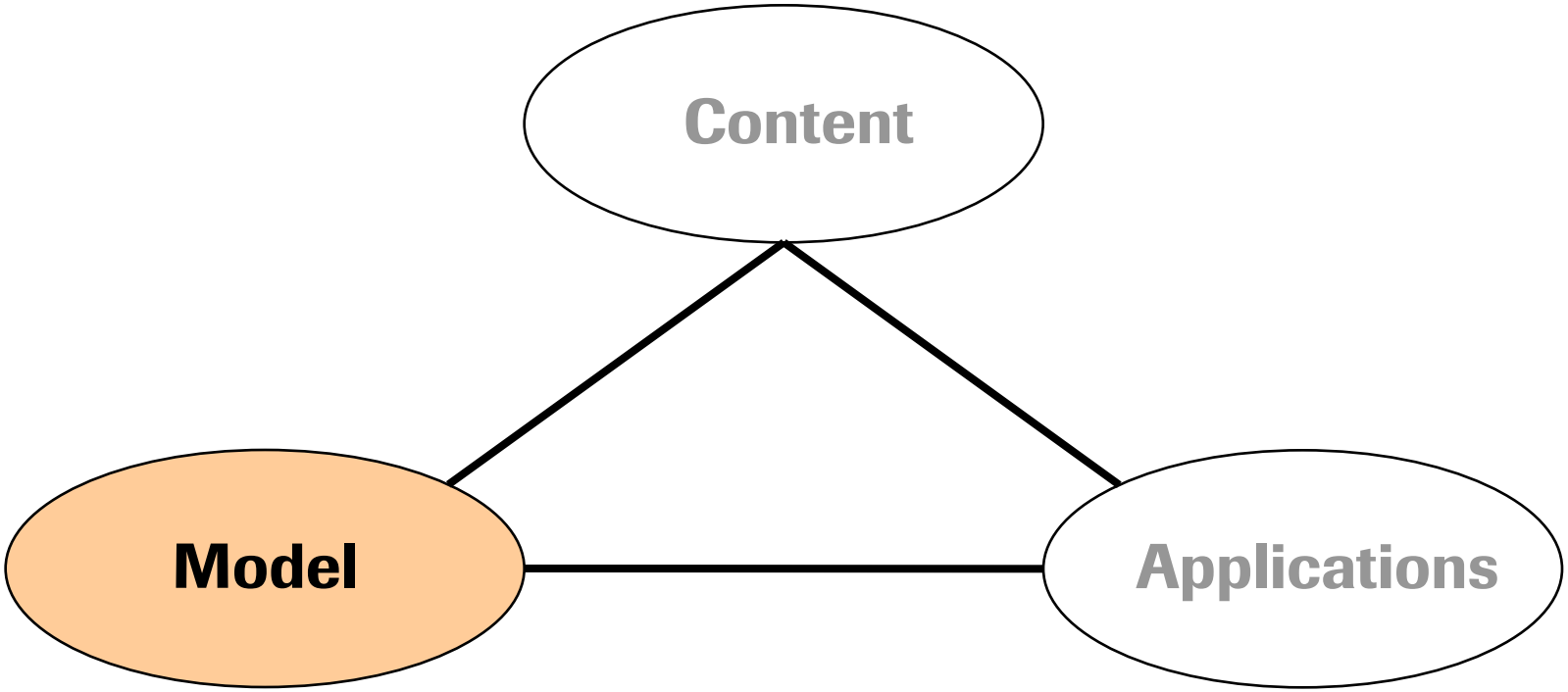
Global Data Standards

Wide Variety of Content Types

- CDISC versus sponsor defined standards
- Collected versus tabulated versus analysis data structures
- Value Level Metadata
  - Controlled Terminology
  - Lab Metadata
  - Questionnaires
- External references, e.g. NCI Thesaurus
- Sources available in Word, Excel, PDF, XML formats
- Administrative metadata, e.g. versioning and life cycle information

Global Data Standards Repository (GDSR)

How does it look like?



GDSR Modeling

Objectives

- Develop a meta-model to capture and interconnect
  - Common Conceptual Domain Model
  - Data Standard Models
  - Value Level Metadata
- Represent all output of the standardization effort as structured information
  - Avoid implicit information in documents
- Capture this information in an electronic repository called the Global Data Standards Repository (GDSR)

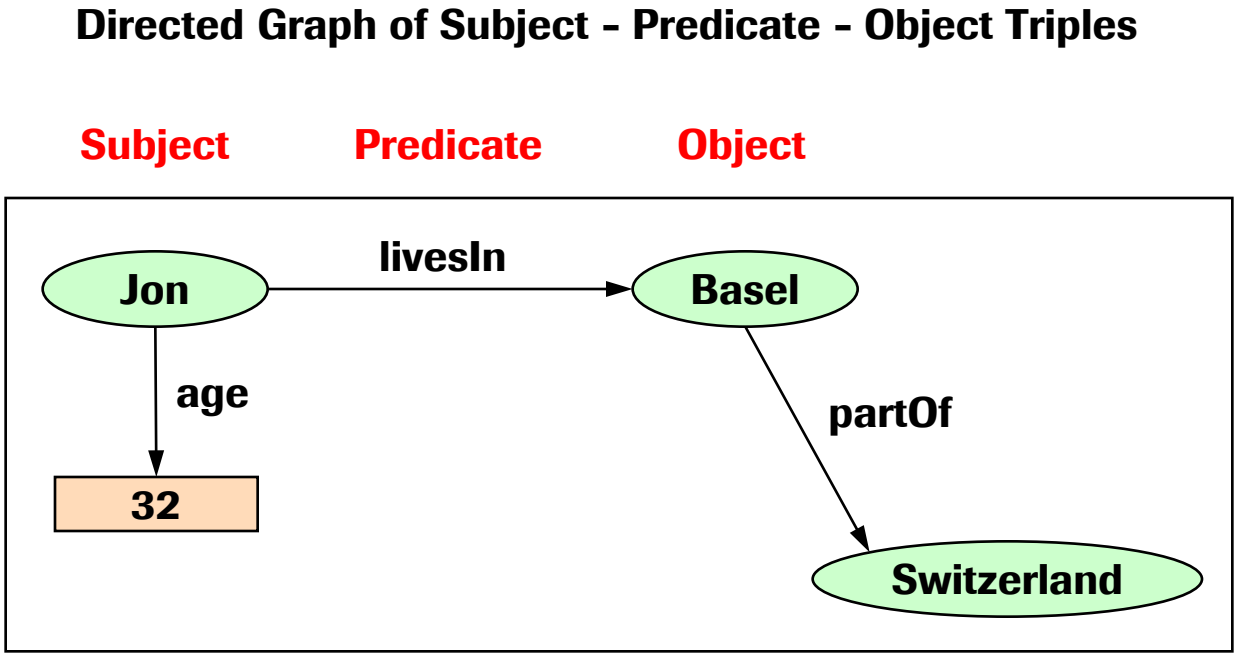
GDSR Modeling

Technology

- Candidate meta-models
  - Relational meta-data model
  - UML object-oriented model
  - Semantic model
- Advantages of semantic models and ontology frameworks
  - Easy to federate disparate types of data and meta-data (Linked Data)
  - Ontologies are increasingly based on the OWL format (e.g. NCI Thesaurus)
  - Prepare readiness to adopt the CDISC BRIDG model and SHARE repository
- Standards and Tools
  - Mature W3C standards (URI, XML, RDF, RDFS, OWL, SPARQL)
  - Availability of mature semantic modeling tools

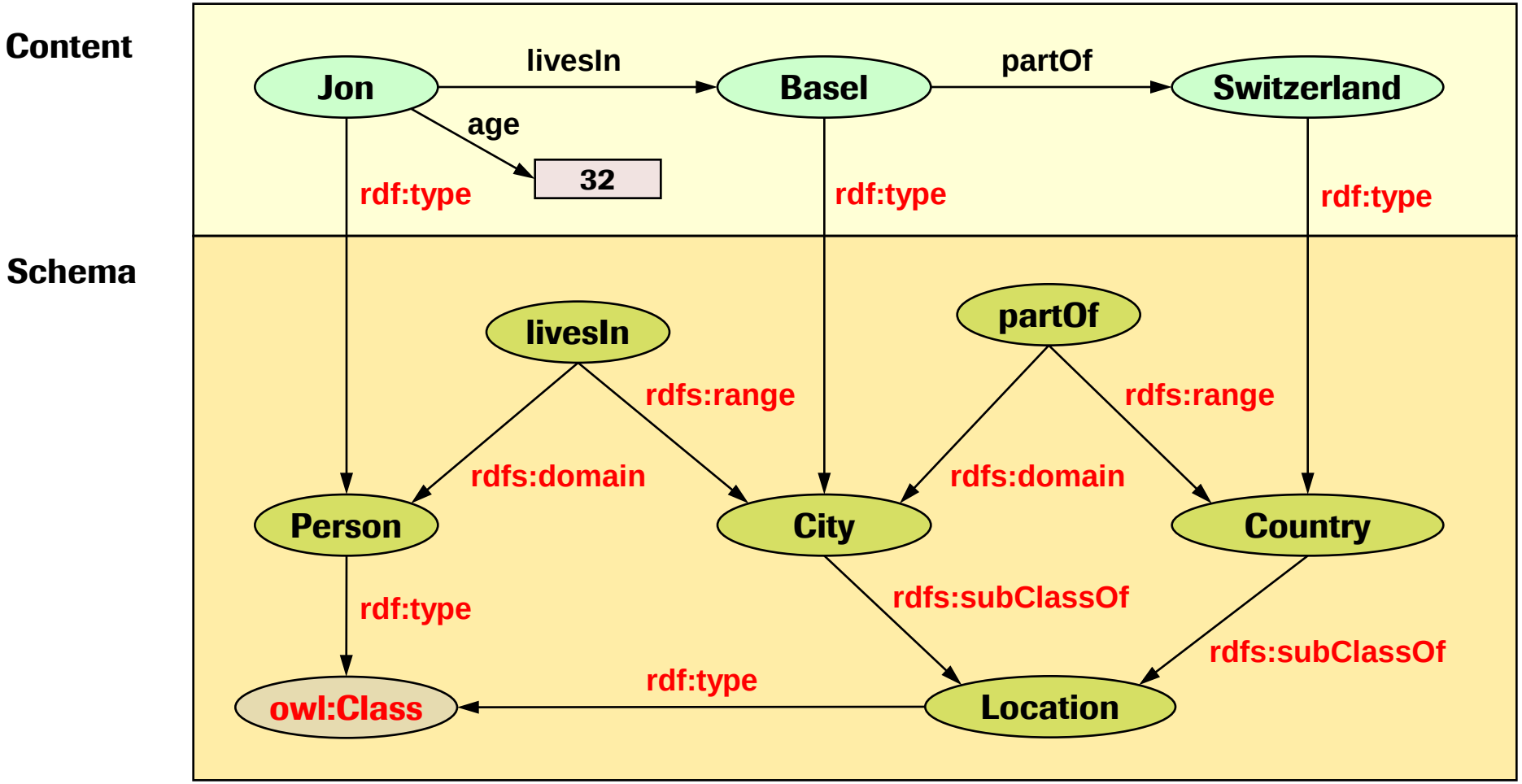
Semantic Modeling

1. RDF Graphs



Semantic Modeling

2. Content and Schema



Everything is a Triple

Semantic Modeling

3. Uniform Resource Identifiers

- In RDF everything is a triple (content and schema)
- A triple is either a <Subject Predicate Object> or a <Subject Predicate Value>
- Subjects, predicates, and objects are commonly called RDF resources
- Every RDF resource has a Uniform Resource Identifier (URI)
- Namespaces provide a convenient way to group related resources together

Uniform Resource Identifiers

Example

- Global Data Standards Repository
  - The resource representing the SDTM domain AE (Adverse Events)
    http://gdsr.roche.com/cdisc/sdtmig-3-1-2#Table.AE
  - The prefix sdtmig identifies the namespace
    http://gdsr.roche.com/cdisc/sdtmig-3-1-2#
  - The qualified name for the same resource
    sdtmig:Table.AE
- Examples from the W3C standards
  - rdf:type is the qualified name of
    http://www.w3.org/1999/02/22-rdf-syntax-ns#type
  - owl:Class is the qualified name of
    http://www.w3.org/2002/07/owl#Class

Semantic Modeling

4. Inference

- RDFS and OWL provide a set of predicates for schema modeling
  - e.g. owl:inverseOf relates two inverse properties
    <hasCitizen owl:inverseOf livesIn>
- Its meaning is defined by the way new triples may be derived from existing triples
  - Stated Triple
    <Jon livesIn Basel>
  - Derived Triple
    <Basel hasCitizen Jon>

Web Ontology Language (OWL)

Predicates

- owl:allValuesFrom
- owl:annotatedProperty
- owl:annotatedSource
- owl:annotatedTarget
- owl:assertionProperty
- owl:backwardCompatibleWith
- owl:bottomDataProperty
- owl:bottomObjectProperty
- owl:cardinality
- owl:complementOf
- owl:datatypeComplementOf
- owl:deprecated
- owl:differentFrom
- owl:disjointUnionOf
- owl:disjointWith
- owl:distinctMembers
- owl:equivalentClass
- owl:equivalentProperty
- owl:hasKey
- owl:hasSelf
- owl:hasValue
- owl:imports
- owl:incompatibleWith
- owl:intersectionOf
- owl:inverseOf
- owl:maxCardinality
- owl:maxQualifiedCardinality
- owl:members
- owl:minCardinality
- owl:minQualifiedCardinality
- owl:onClass
- owl:onDataRange
- owl:onDatatype
- owl:oneOf
- owl:onProperties
- owl:onProperty
- owl:priorVersion
- owl:propertyChainAxiom
- owl:propertyDisjointWith
- owl:qualifiedCardinality
- owl:sameAs
- owl:someValuesFrom
- owl:sourceIndividual
- owl:targetIndividual
- owl:targetValue
- owl:topDataProperty
- owl:topObjectProperty
- owl:unionOf
- owl:versionInfo
- owl:versionIRI
- owl:withRestrictions

Semantic Modeling

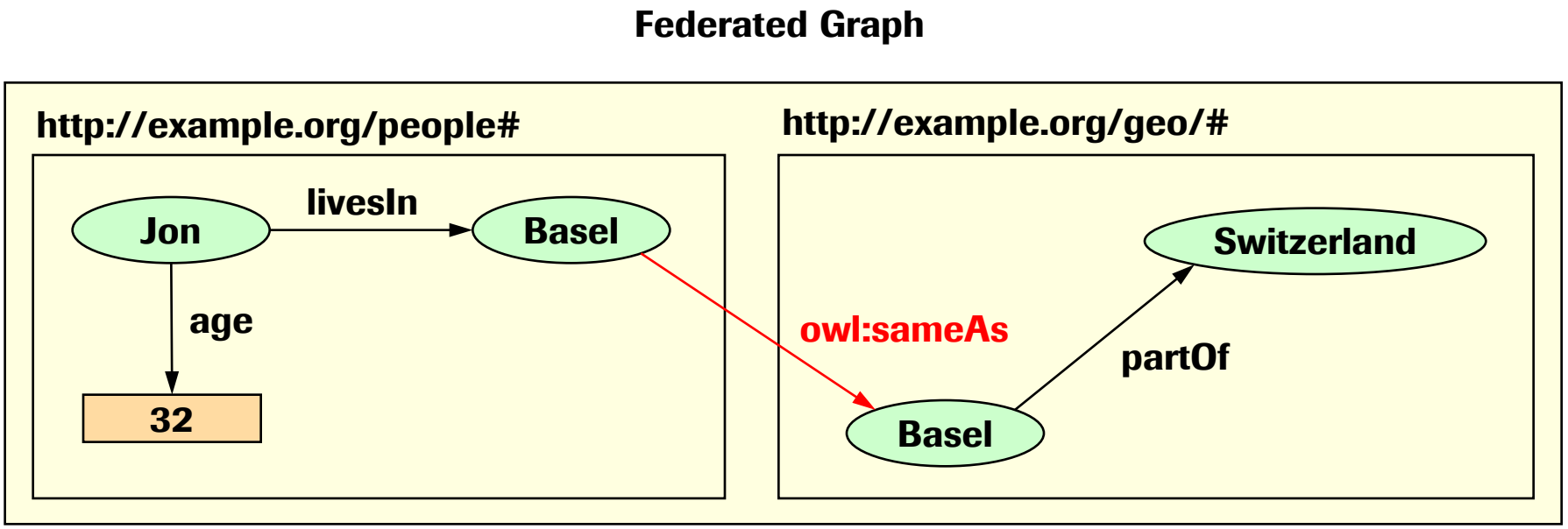
W3C Standards

- Resource Description Framework (RDF)
  - RDF defines how to express a knowledge base (content) as a directed graph of resources (set of triples)
  - Every resource has a URI and is part of a namespace
- RDF Schema (RDFS) and Web Ontology Language (OWL)
  - A set of standard predicates to build vocabularies (schemas)
  - Inference capabilities
- SPARQL Protocol and RDF Query Language (SPARQL)
  - Language to query an RDF knowledge base
- Simple Knowledge Organization System (SKOS)
  - Small footprint RDF based schema for concept models

Linked Data

Content Federation

- Semantic models in RDF format are easy to federate
- Federation of Data = Union of Triples (from both graphs)
- Use owl:sameAs to specify that two resources are equal

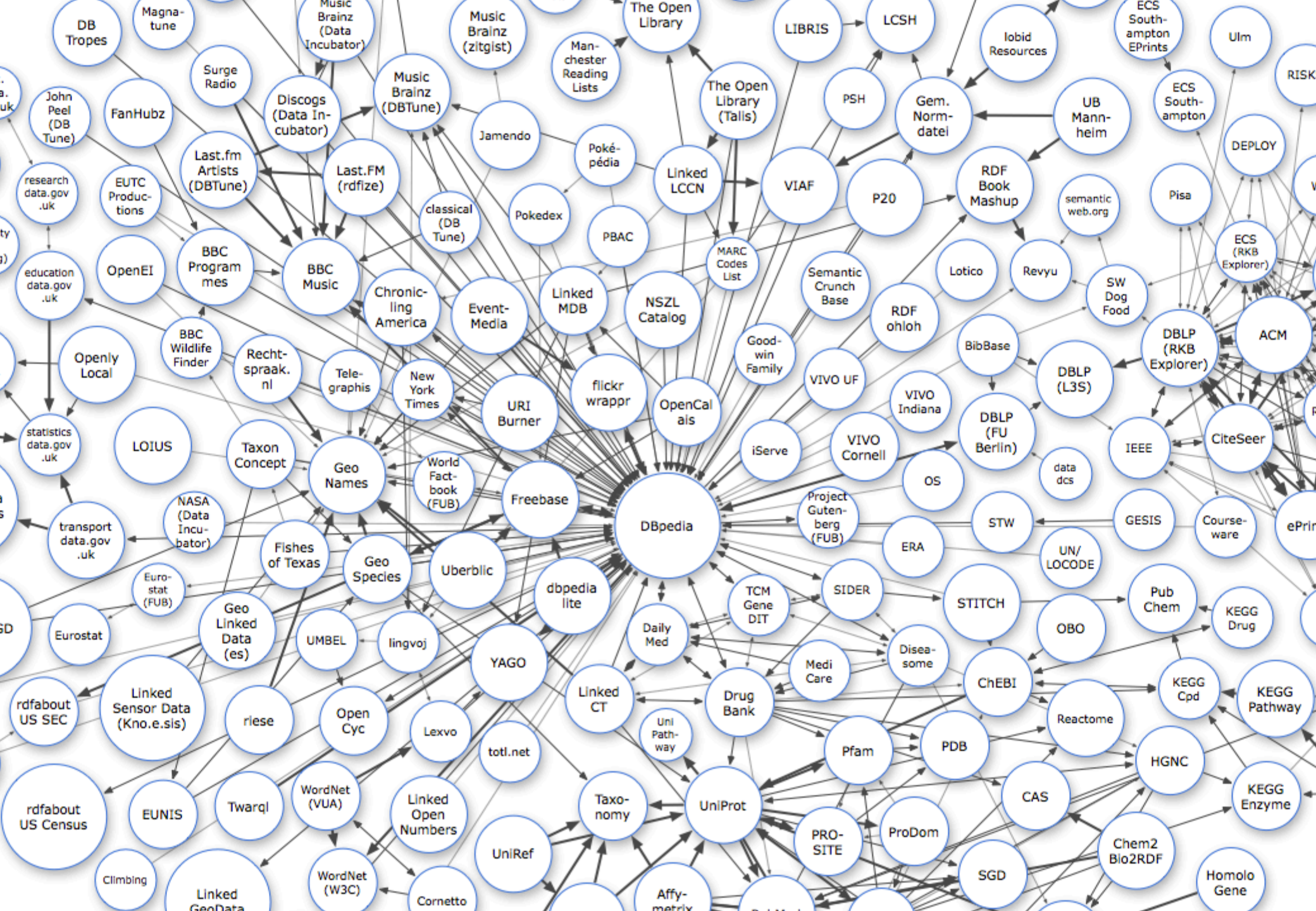


Linked Data

dbpedia.org

The DBpedia knowledge base currently describes more than 3.5 million things, out of which 1.67 million are classified in a consistent Ontology, including 364,000 persons, 462,000 places, 99,000 music albums, 54,000 films, 17,000 video games, 148,000 organisations, 169,000 species and 5,200 diseases.
The DBpedia data set features labels and abstracts for these 3.5 million things in up to 97 different languages; 1,850,000 links to images and 5,900,000 links to external web pages; 6,500,000 external links into other RDF datasets, 633,000 Wikipedia categories, and 2,900,000 YAGO categories. The DBpedia knowledge base altogether consists of over 672 million pieces of information (RDF triples) out of which 286 million were extracted from the English edition of Wikipedia and 386 million were extracted from other language editions.

Linked Open Data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Music Brainz (Data Incubator)
Music Brainz (zitgist)
The Open Library
LIBRIS
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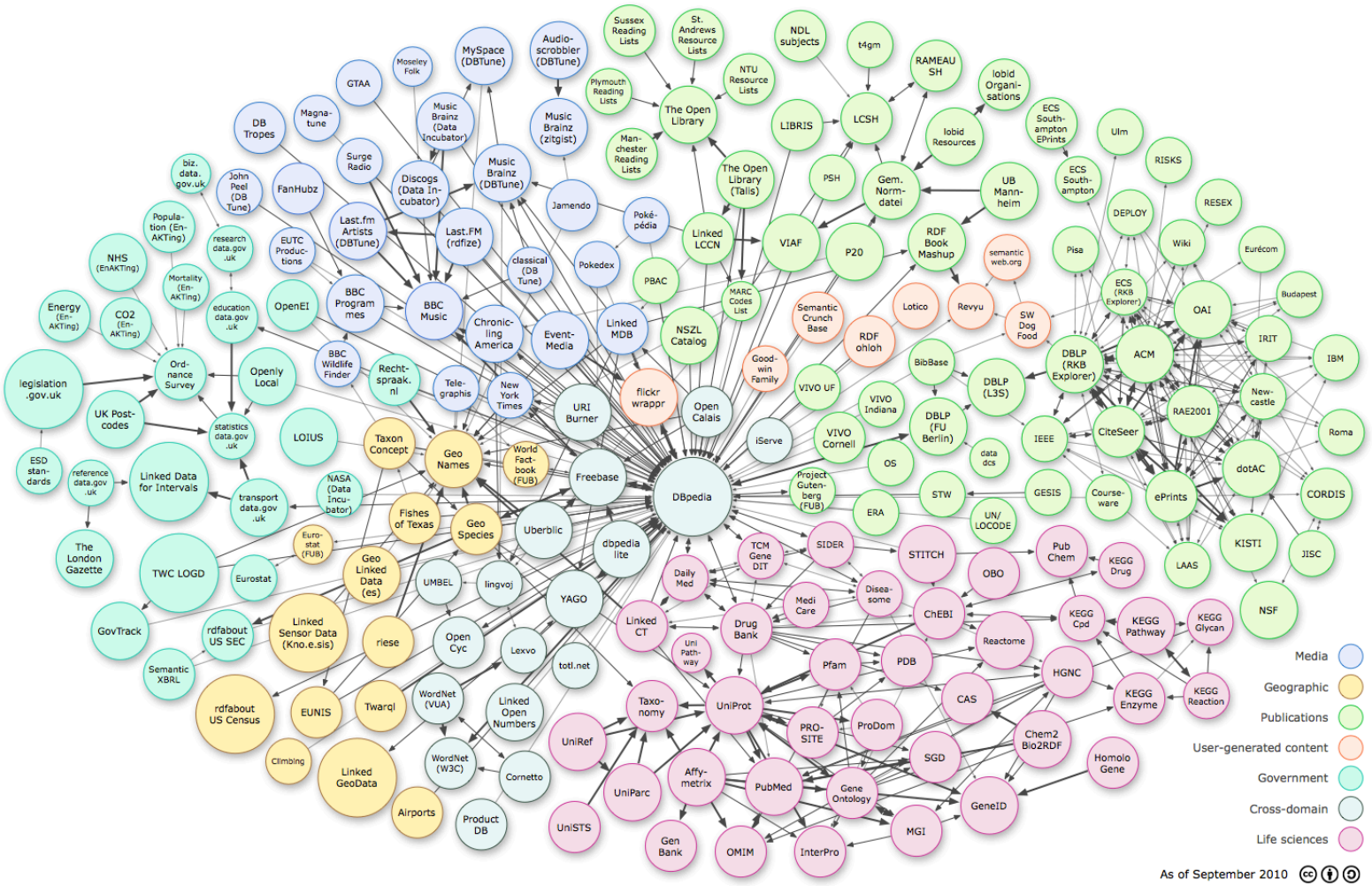
Homolo Gene

Linked Open Data (LOD) Cloud

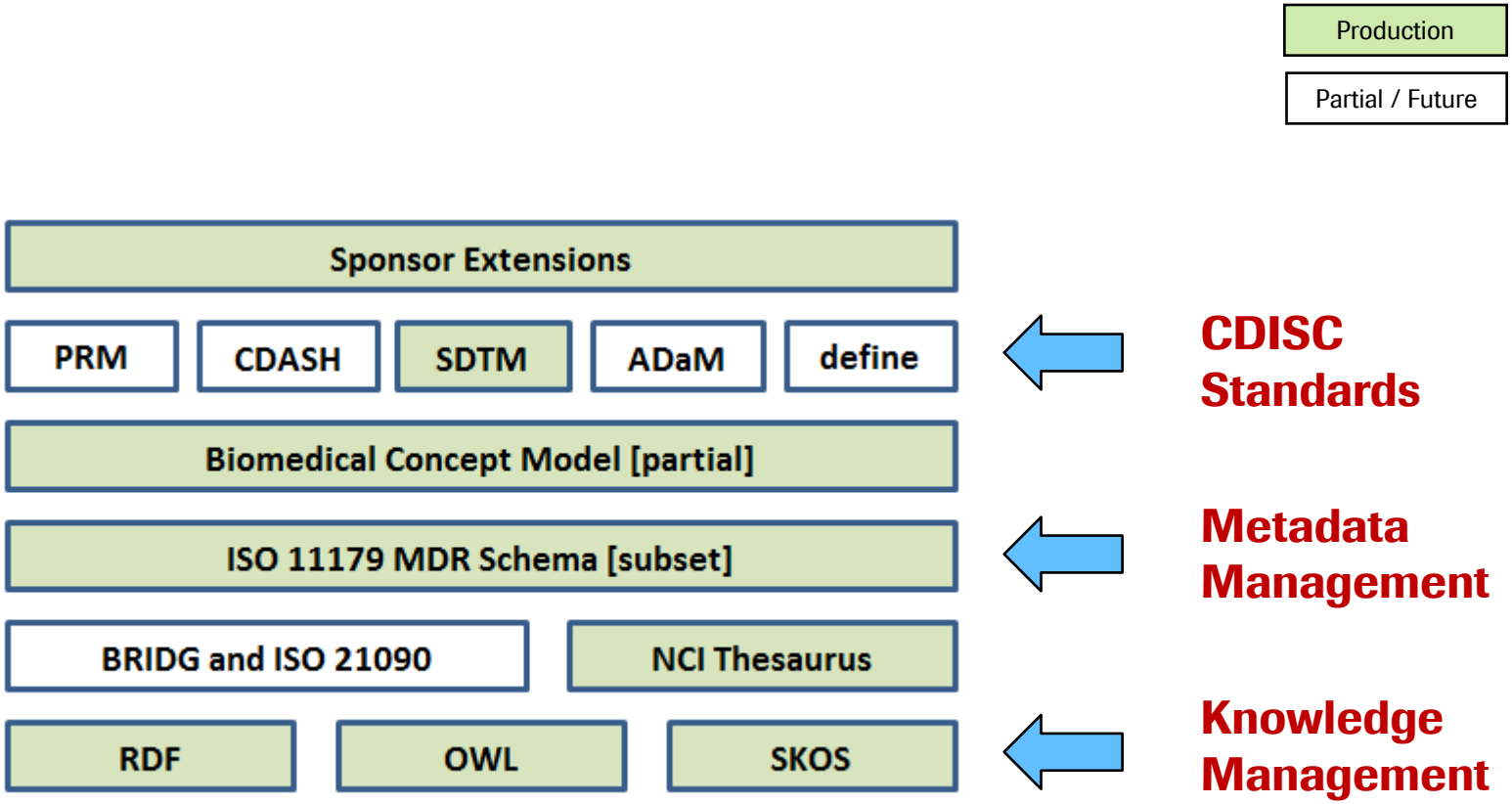
linkeddata.org



Linking Open Data cloud diagram, by Richard Cyganiak and Anja Jentzsch. http://lod-cloud.net/

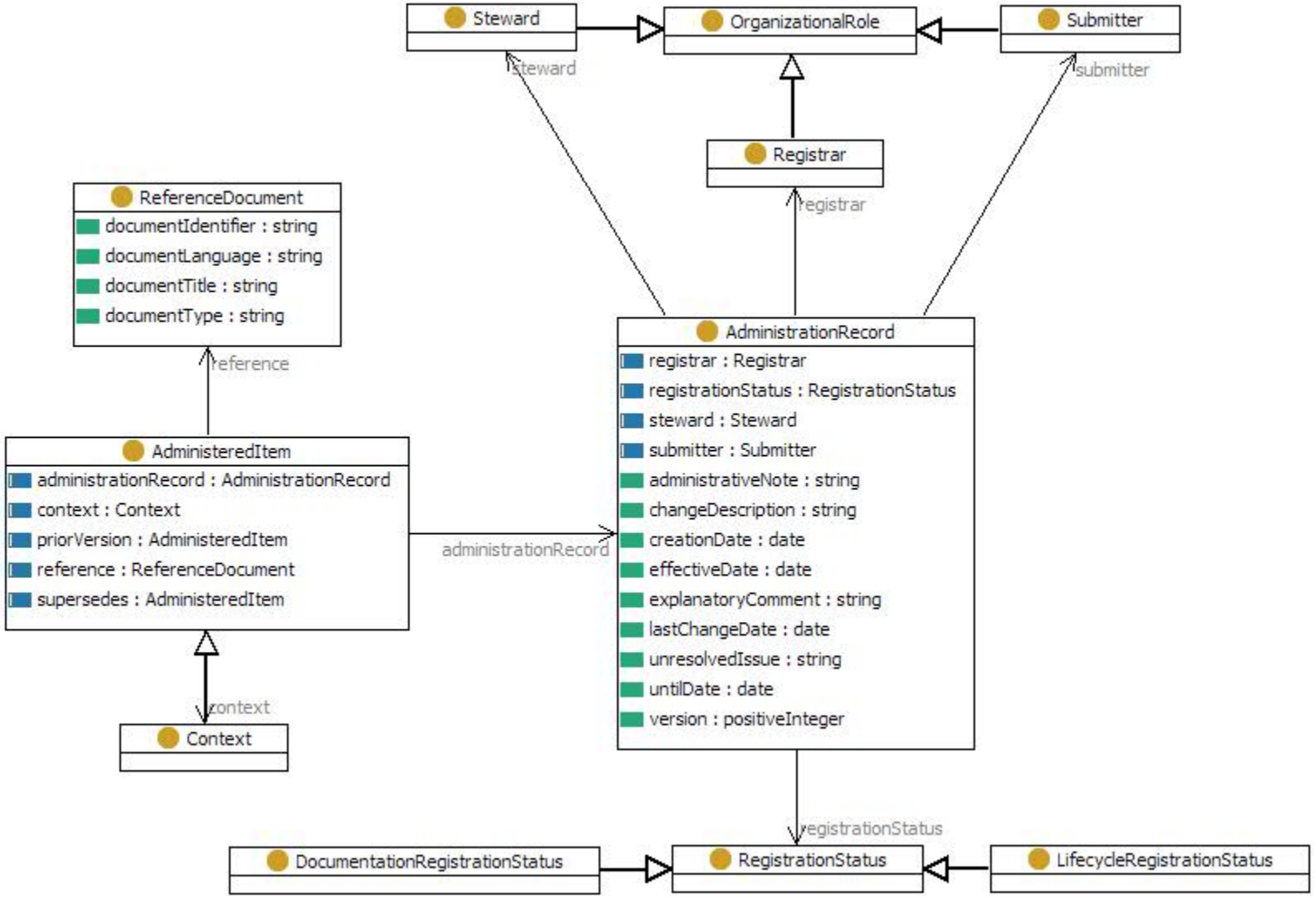
Global Data Standards Repository

Semantic Information Model



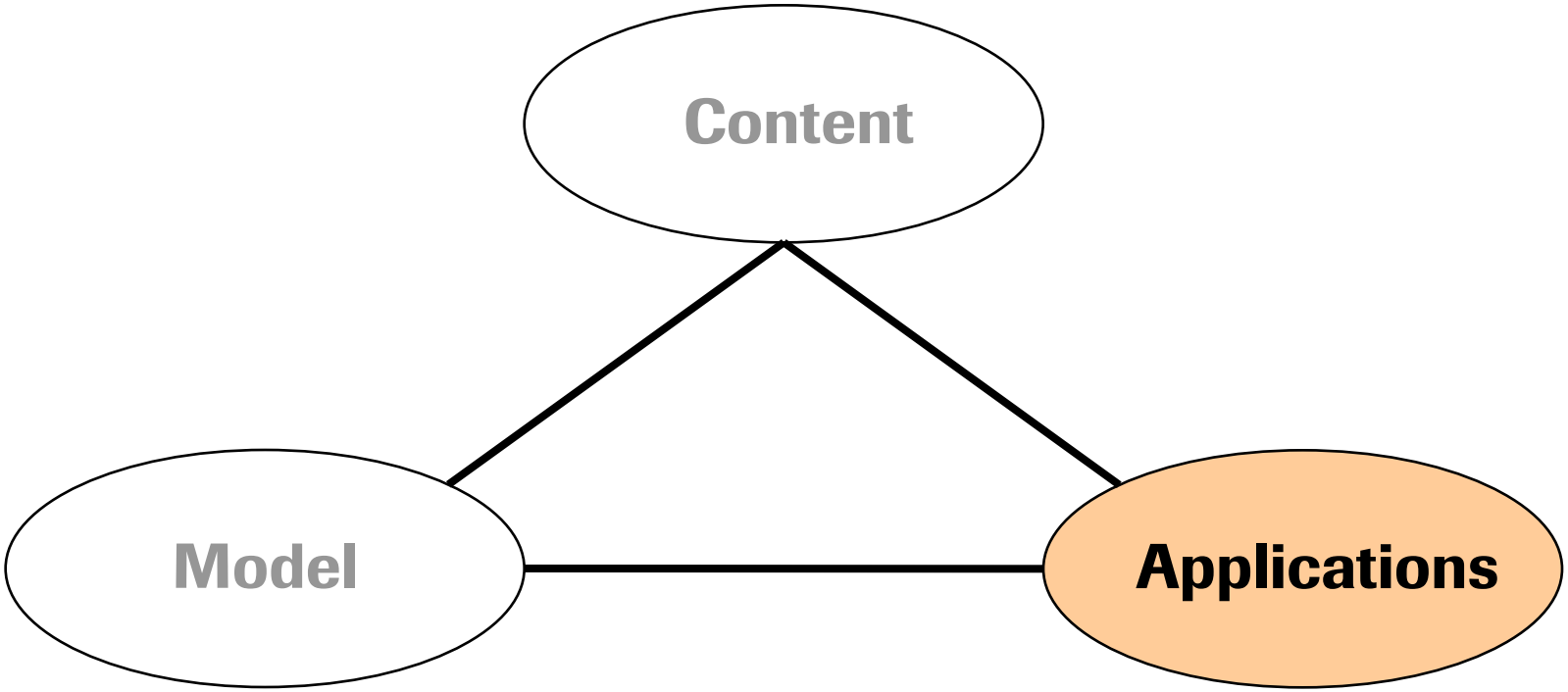
GDSR Metadata Registry Schema

ISO 11179 (partial)



Global Data Standards Repository (GDSR)

What can we do with it?



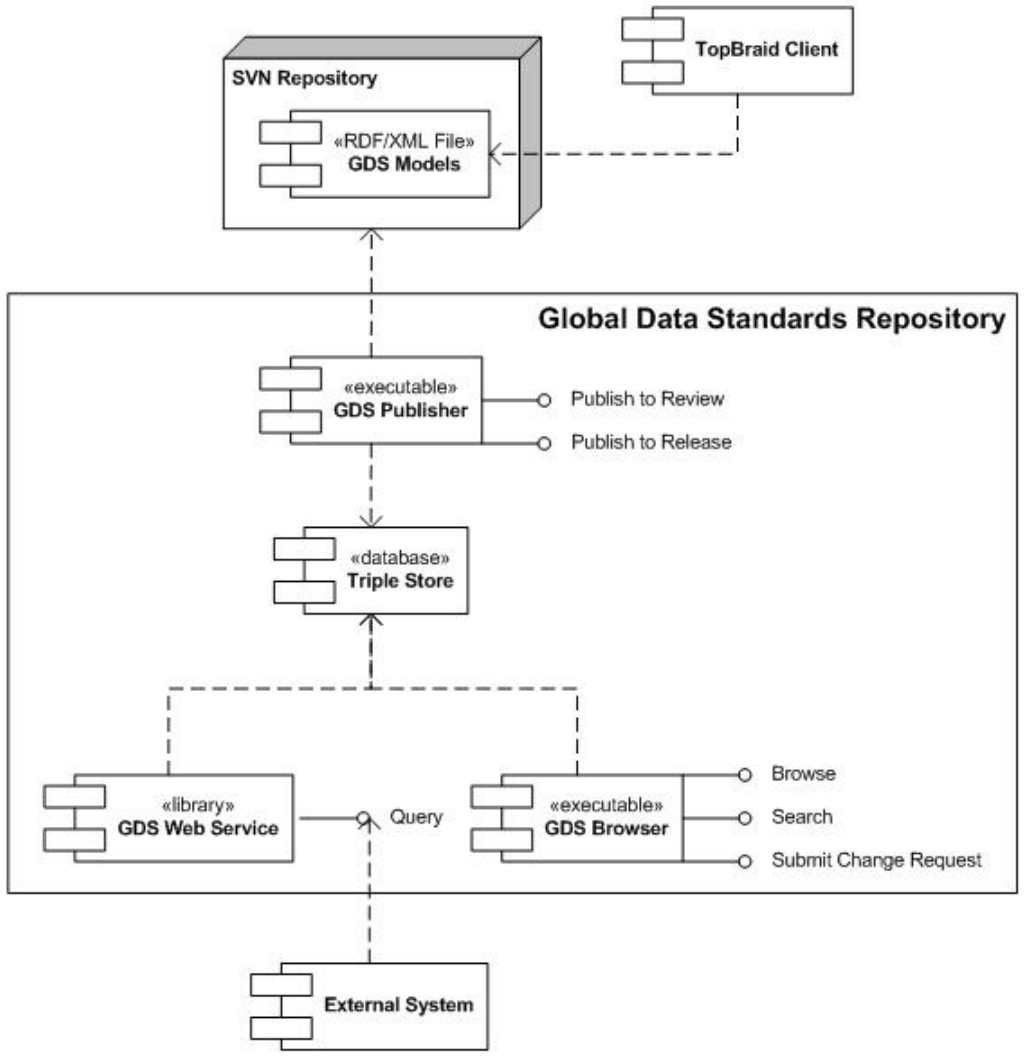
GDSR Applications

Objectives

- Provide access to the GDSR
  - As input to other systems for machine consumption
  - As a knowledge source for human consumption

Global Data Standards Repository

UML Deployment Diagram



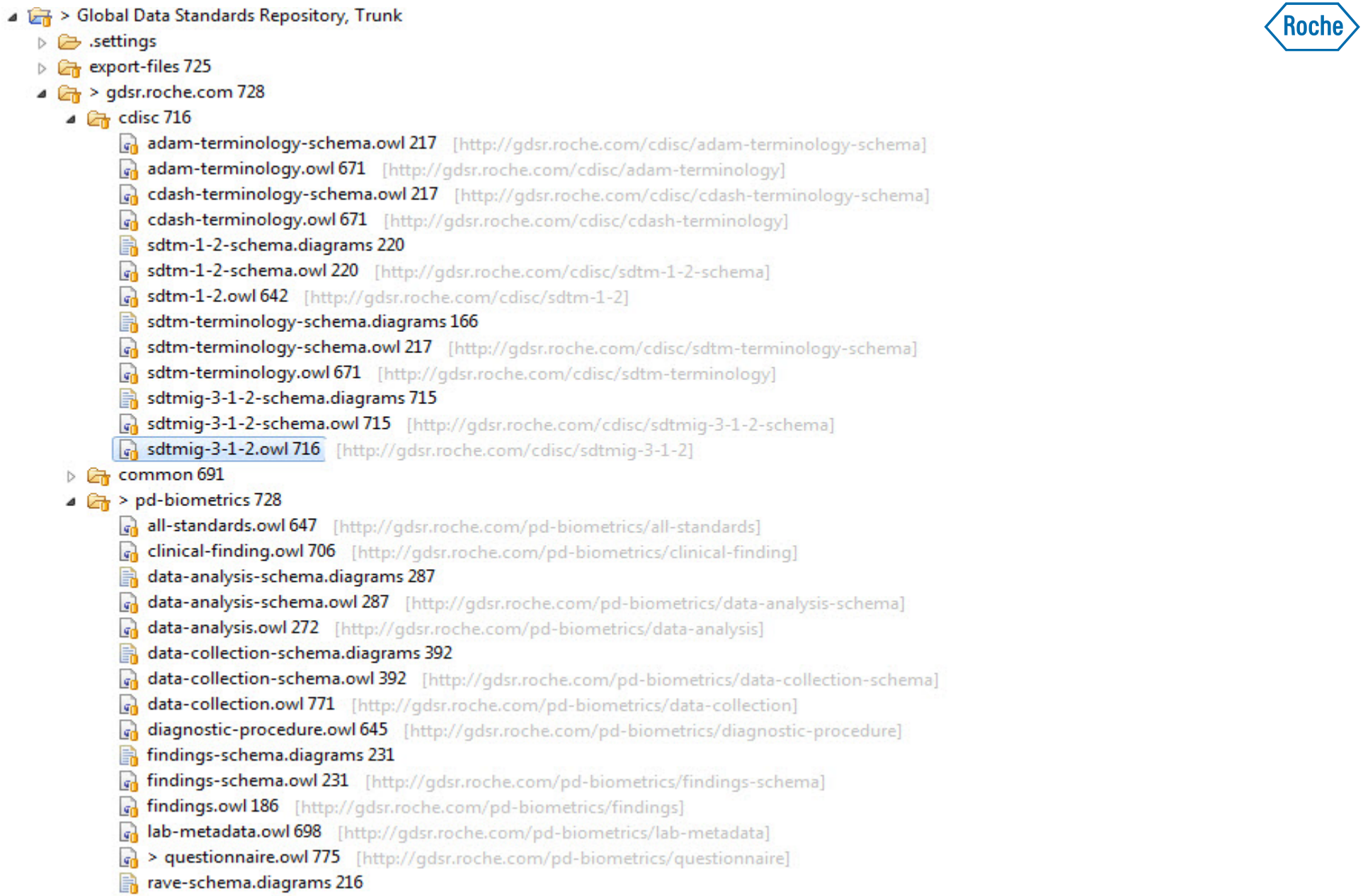
Content Management

Content Publishing

Metadata Repository

Single Point of Access

TopBraid
Semantic Modeling Workbench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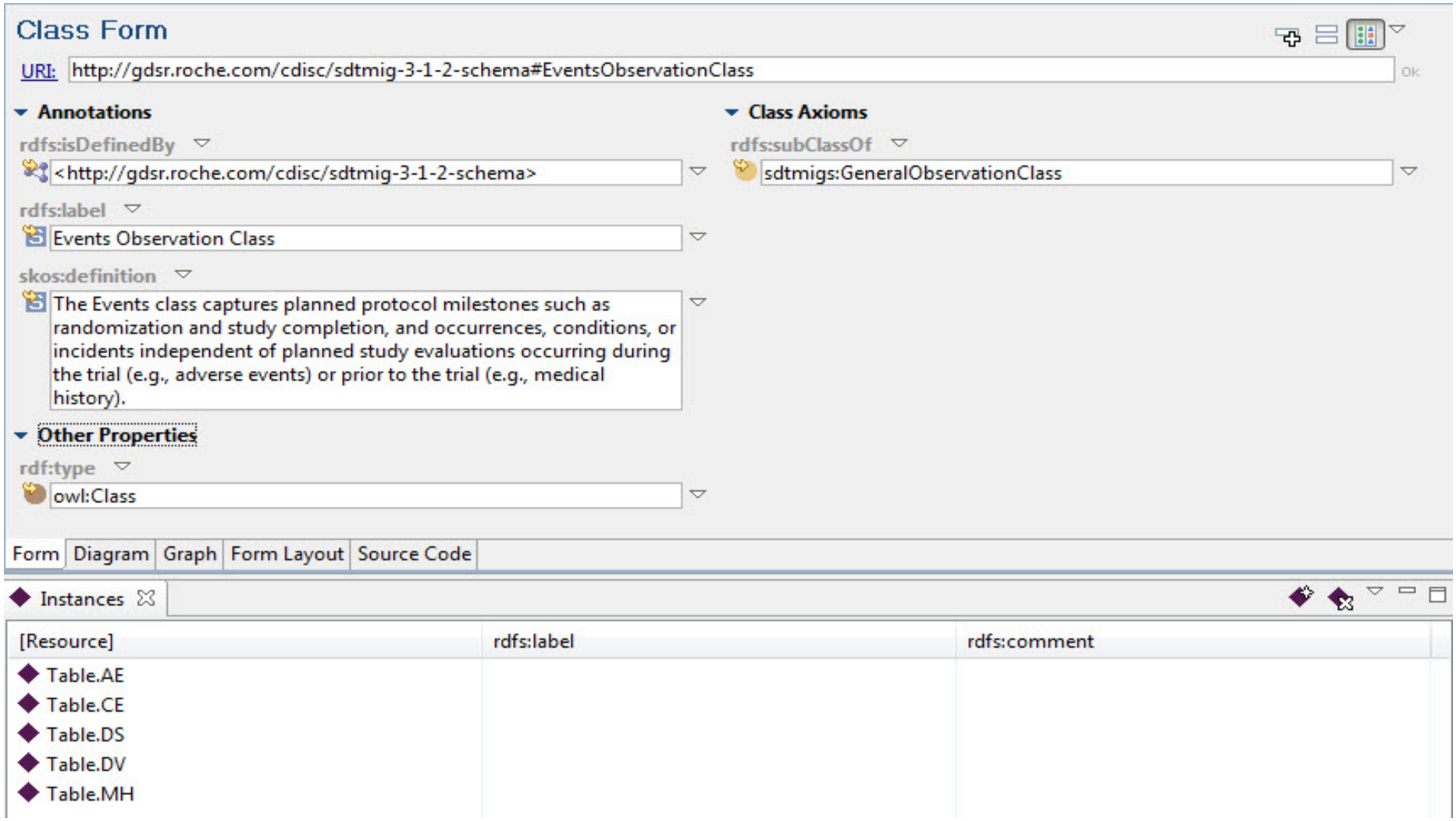
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Events Observation Class
skos:definition
The Events class captures planned protocol milestones such as randomization and study completion, and occurrences, conditions, or incidents independent of planned study evaluations occurring during the trial (e.g., adverse events) or prior to the trial (e.g., medical history).
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Table.CE
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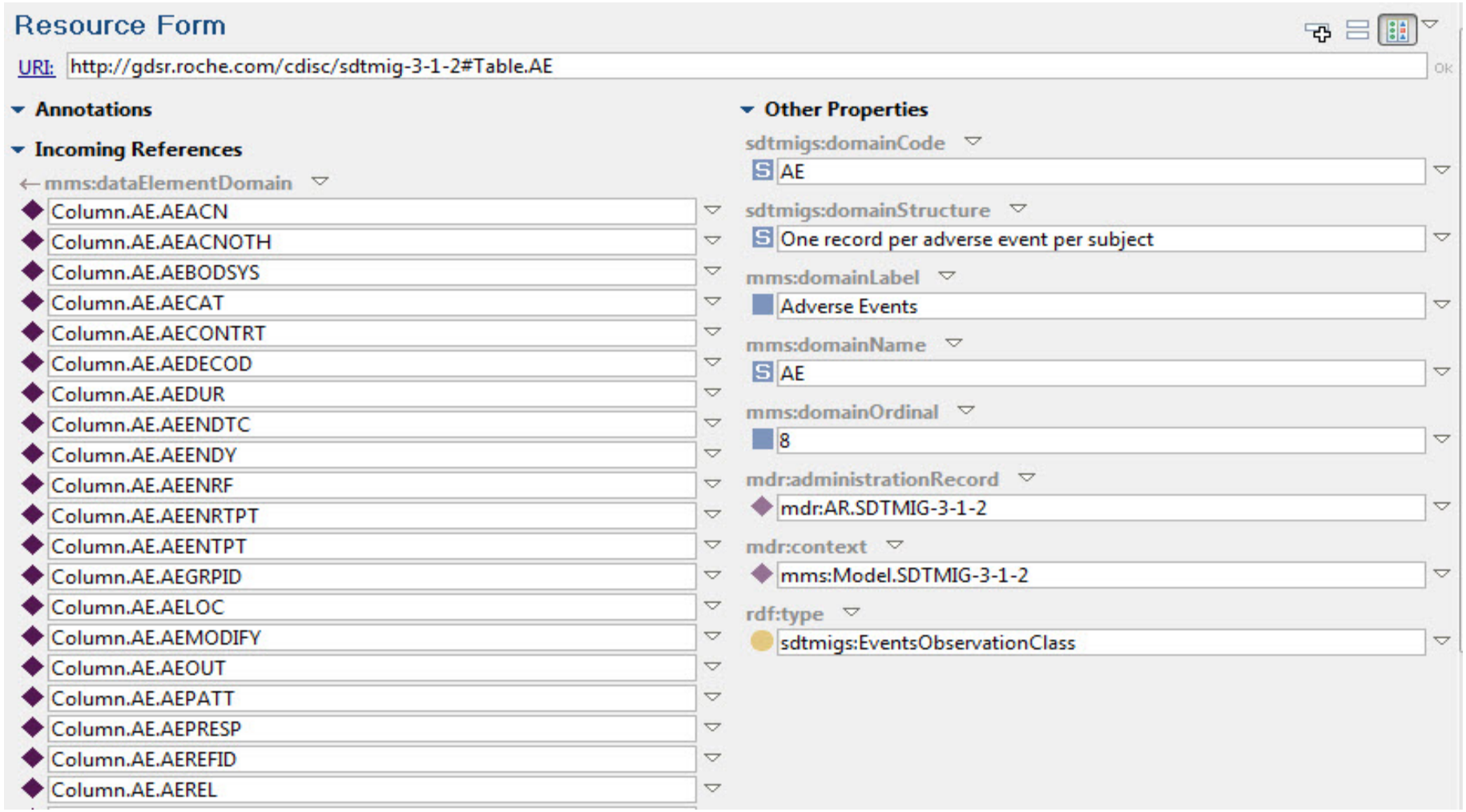
Table.DV
Table.MH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Adverse Events
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AE
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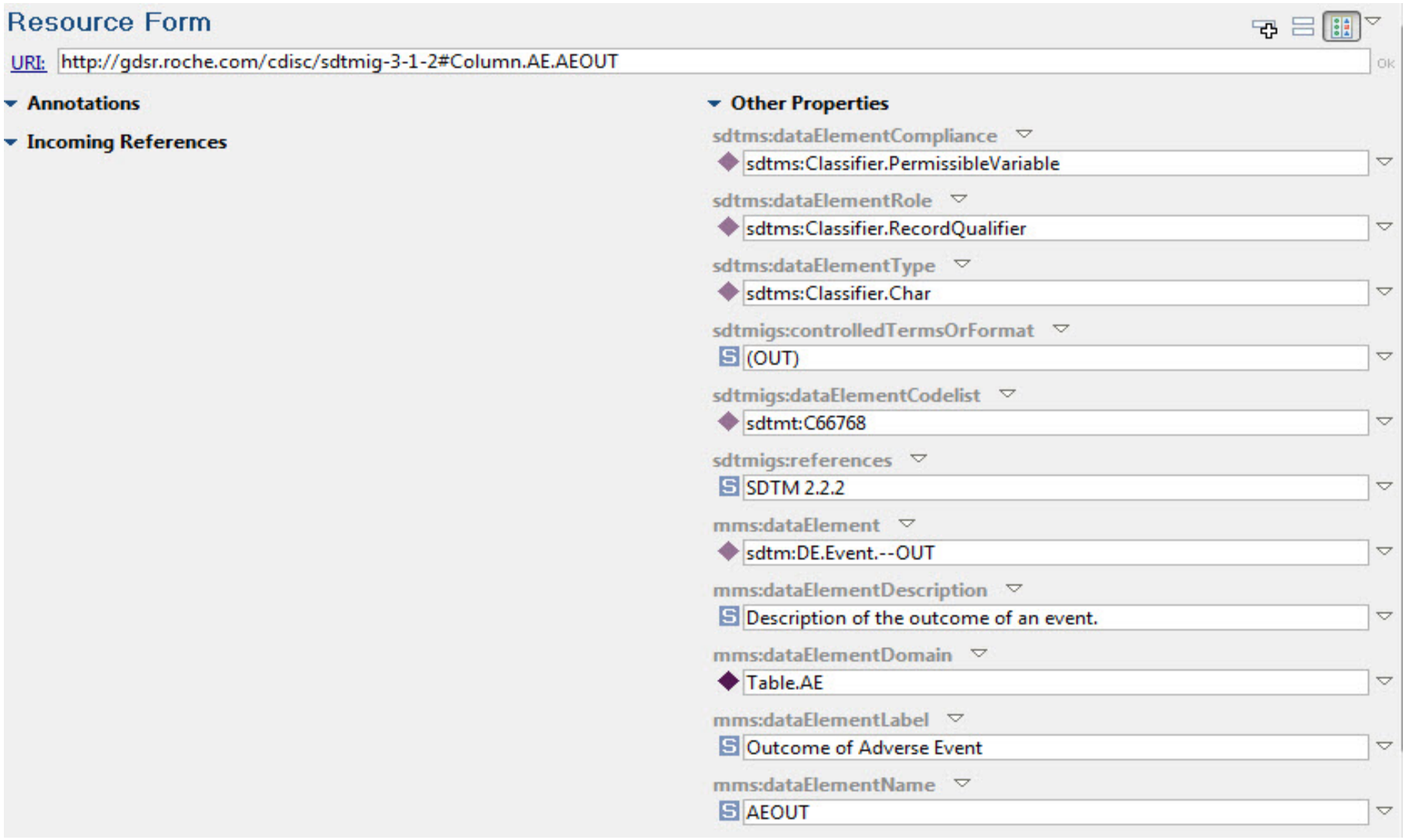
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(OUT)
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sdtmt:C66768
sdtmigs:references
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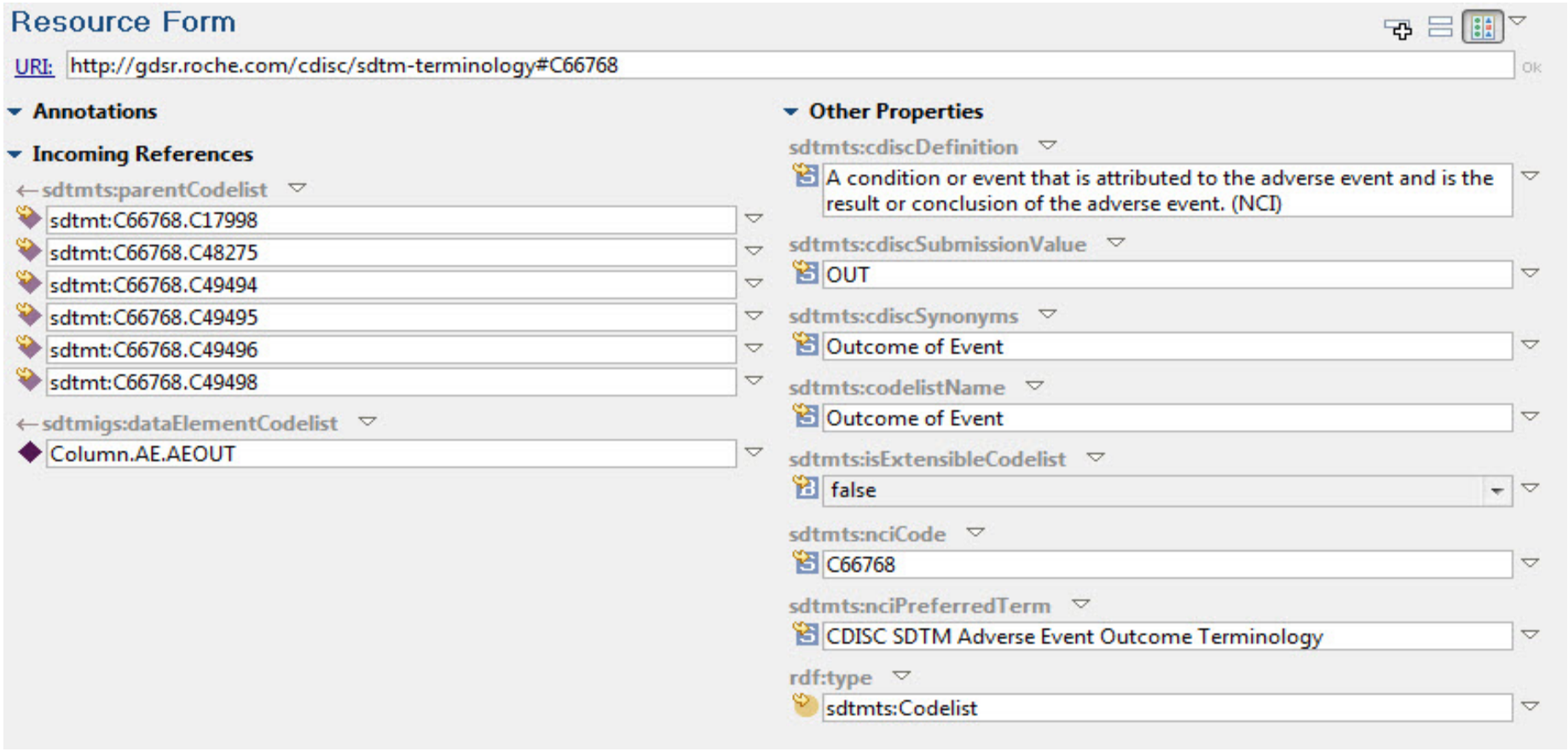
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←sdtmigs:dataElementCodelist
Column.AE.AEOUT
Other Properties
sdtmts:cdiscDefinition
A condition or event that is attributed to the adverse event and is the result or conclusion of the adverse event. (NCI)
sdtmts:cdiscSubmissionValue
OUT
sdtmts:cdiscSynonyms
Outcome of Event
sdtmts:codelistName
Outcome of Event
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CDISC SDTM Adverse Event Outcome Terminology
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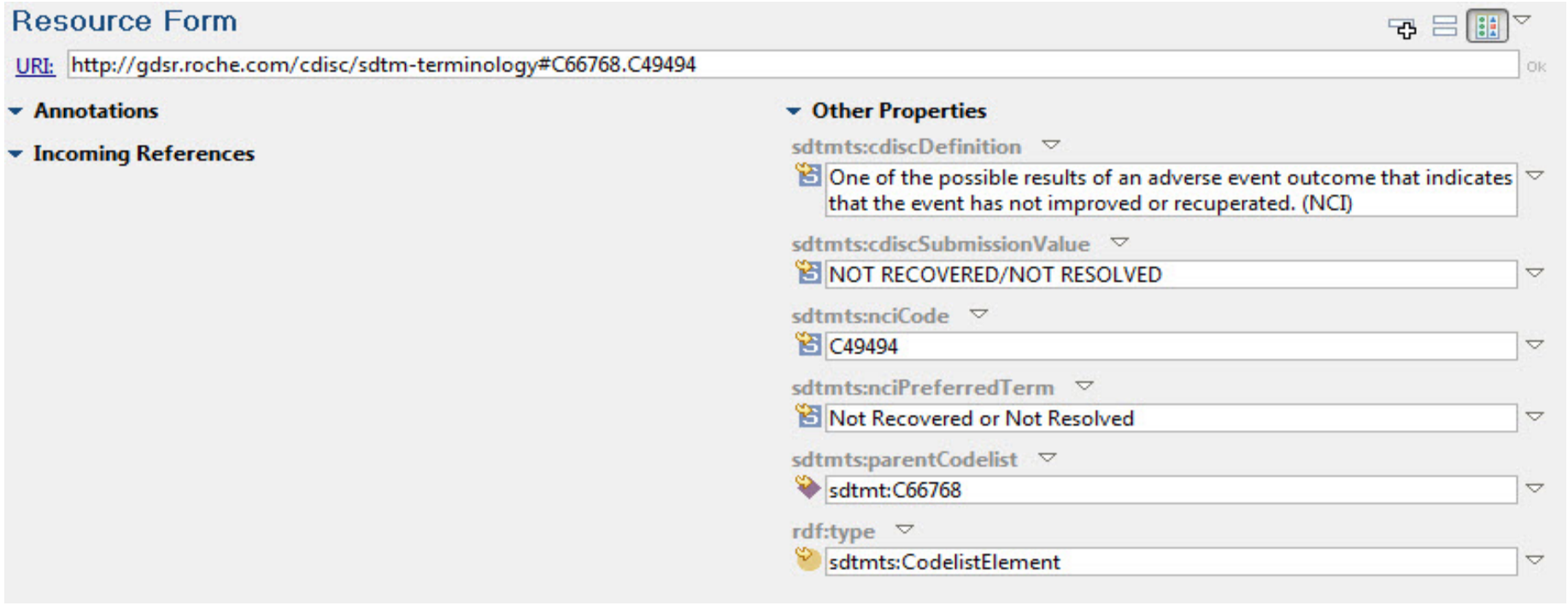
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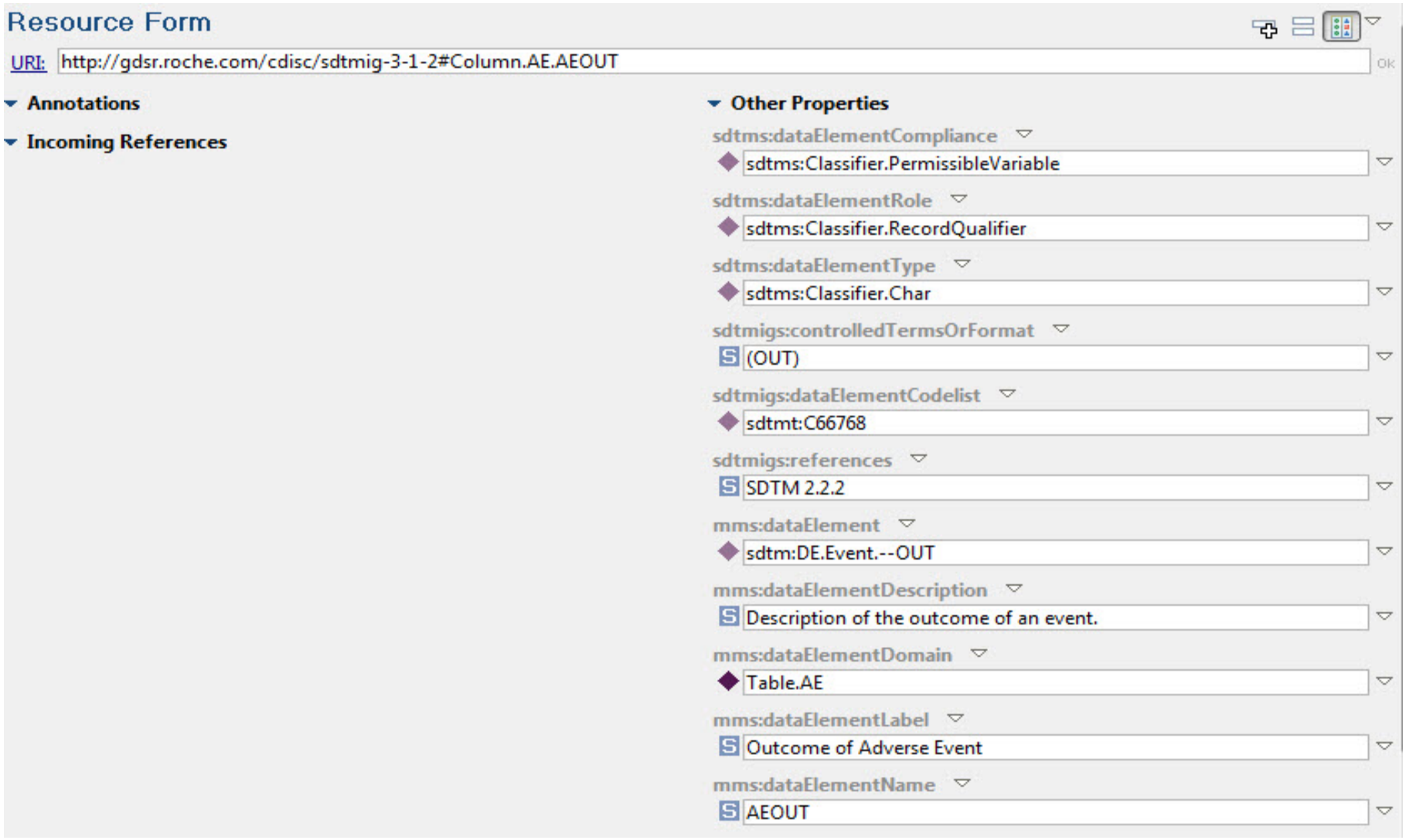
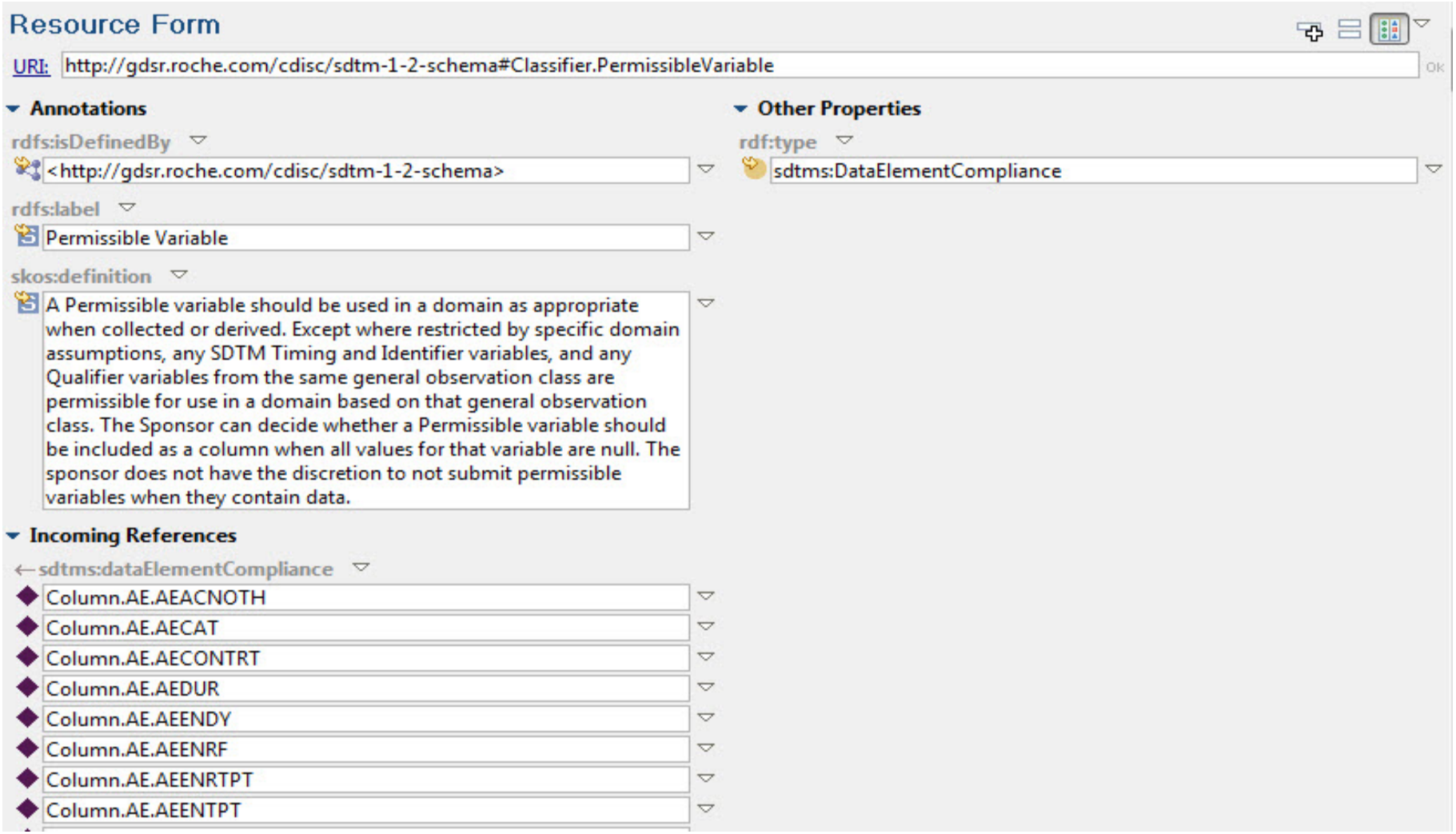
Ok
Annotations
Incoming References
Other Properties
sdtmts:cdiscDefinition
One of the possible results of an adverse event outcome that indicates that the event has not improved or recuperated. (NCI)
sdtmts:cdiscSubmissionValue
NOT RECOVERED/NOT RESOLVED
sdtmts:nciCode
C49494
sdtmts:nciPreferredTerm
Not Recovered or Not Resolved
sdtmts:parentCodelist
sdtmt:C66768
rdf:type
sdtmts:CodelistElement


Resource Form
URI:
http://gdsr.roche.com/cdisc/sdtmig-3-1-2#Column.AE.AEOUT
OK
Annotations
Incoming References
Other Properties
sdtms:dataElementCompliance
sdtms:Classifier.PermissibleVariable
sdtms:dataElementRole
sdtms:Classifier.RecordQualifier
sdtms:dataElementType
sdtms:Classifier.Char
sdtmigs:controlledTermsOrFormat
(OUT)
sdtmigs:dataElementCodelist
sdtmt:C66768
sdtmigs:references
SDTM 2.2.2
mms:dataElement
sdtm:DE.Event.--OUT
mms:dataElementDescription
Description of the outcome of an event.
mms:dataElementDomain
Table.AE
mms:dataElementLabel
Outcome of Adverse Event
mms:dataElementName
AEOUT


Resource Form
URI:
http://gdsr.roche.com/cdisc/sdtm-1-2-schema#Classifier.PermissibleVariable
Ok
Annotations
rdfs:isDefinedBy
<http://gdsr.roche.com/cdisc/sdtm-1-2-schema>
rdfs:label
Permissible Variable
skos:definition
A Permissible variable should be used in a domain as appropriate when collected or derived. Except where restricted by specific domain assumptions, any SDTM Timing and Identifier variables, and any Qualifier variables from the same general observation class are permissible for use in a domain based on that general observation class. The Sponsor can decide whether a Permissible variable should be included as a column when all values for that variable are null. The sponsor does not have the discretion to not submit permissible variables when they contain data.
Incoming References
←sdtms:dataElementCompliance
Column.AE.AEACNOTH
Column.AE.AECAT
Column.AE.AECONTRT
Column.AE.AEDUR
Column.AE.AEENDY
Column.AE.AEENRF
Column.AE.AEENRTPT
Column.AE.AEENTPT
Other Properties
rdf:type
sdtms:DataElementCompliance

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Data Tabulation

Administration Panel

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  - Findings Metadata for Measurements
  - Questionnaires
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Please select an item.

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      - MH - Medical History
      - AE - Adverse Events
      - CE - Clinical Events
      - DV - Protocol Deviations
      - DS - Disposition
      - YI - Site and Investigator
    - Findings Observation Class
    - Interventions Observation Class
  - Special Purpose Class
- Controlled Terminology
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  - Questionnaires
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Events Observation Class

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).

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Data Tabulation > SDTM 3.1.2 Extended > General Observations > Events Observation Class > AE - Adverse Events

Administration Panel

- SDTM 3.1.2 Extended
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    - Events Observation Class
      - MH - Medical History
      - **AE - Adverse Events**
      - CE - Clinical Events
      - DV - Protocol Deviations
      - DS - Disposition
      - YI - Site and Investigator
    - Findings Observation Class
    - Interventions Observation Class
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- Controlled Terminology
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AE - Adverse Events

Showing 1 to 50 of 67 Show 50 | All

<< < 1 2 > >>

Name	Label	Type	Role	Core
STUDYID	Study Identifier	Char 8 String	Identifier Variable	Required Variable
DOMAIN	Domain Abbreviation	Char 2 String	Identifier Variable	Required Variable
USUBJID	Unique Subject Identifier	Char 50 String	Identifier Variable	Required Variable
AESEQ	Sequence Number	Num 8 Decimal	Identifier Variable	Required Variable
AEGRPID	Group ID	Char 40 String	Identifier Variable	Permissible Variable
AEREFID	Reference ID	Char 40 String	Identifier Variable	Permissible Variable
AESPID	Sponsor-Defined Identifier	Char 200 String	Identifier Variable	Permissible Variable
AETERM	Reported Term for the Adverse Event	Char 200 String	Topic Variable	Required Variable
AEMODIFY	Modified Reported Term	Char 200 String	Synonym Qualifier	Permissible Variable

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Home | Data Collection | Data Tabulation | Resources

Data Tabulation > SDTM 3.1.2 Extended > General Observations > Events Observation Class > AE - Adverse Events > AEOUT - Outcome of Adverse Event

Administration Panel

- SDTM 3.1.2 Extended
  - General Observations
    - Events Observation Class
      - + MH - Medical History
      - − AE - Adverse Events
        - AESPID - Sponsor-Defined Identifier
        - AESER - Serious Event
        - AEENDY - Study Day of End of Adverse Event
        - AETOXGR - Standard Toxicity Grade
        - AESOD - Occurred with Overdose
        - AESTDTC - Start Date/Time of Adverse Event
        - AESLIFE - Is Life Threatening
        - AEMODIFY - Modified Reported Term
        - DOMAIN - Domain Abbreviation
        - AEENRTPT - End Relative to Reference Time Point
        - AEPRESP - Pre-Specified Adverse Event
        - AEENRF - End Relative to Reference Period
        - STUDYID - Study Identifier
        - AEPATT - Pattern of Adverse Event
        - AESCONG - Congenital Anomaly or Birth Defect
        - AESTDY - Study Day of Start of Adverse Event
        - AECAT - Category for Adverse Event

◂ back

AEOUT - Outcome of Adverse Event

Name	AEOUT
Label	AEOUT - Outcome of Adverse Event
Type	Char 40 String T
Role	Record Qualifier
Core	Permissible Variable
Suppqual Repeats	

CDISC Notes

Description of the outcome of an event.

Sponsor Notes

AEOUT is the Outcome of the adverse event represented using CDISC controlled terminology.

Roche

Data Tabulation > Controlled Terminology > CDISC Terminology > C66768 Outcome of Event

+ SDTM 3.1.2 Extended
- Controlled Terminology
  - CDISC Terminology
    - C65047 Laboratory Test Code
    - C66726 Pharmaceutical Dosage Fc
    - C66727 Completion/Reason for Nc
    - C66728 Relation to Reference Per
    - C66729 Route of Administration
    - C66731 Sex
    - C66732 Sex of Participants
    - C66733 Size
    - C66734 Domain Abbreviation
    - C66735 Trial Blinding Schema
    - C66736 Trial Indication Type
    - C66737 Trial Phase
    - C66738 Trial Summary Parameter
    - C66739 Trial Type
    - C66741 Vital Signs Test Code
    - C66742 No Yes Response
    - C66767 Action Taken with Study T
    - **C66768 Outcome of Event**
    - C66769 Severity/Intensity Scale f
    - C66770 Units for Vital Signs Resul
    - C66780 Age Span
    - C66781 Age Unit
    - C66783 CDISC System Organ Cla
    - C66784 Common Terminology Cri
    - C66785 Control Type
    - C66786 Country
    - C66787 Diagnosis Group

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Controlled Terminology

Codelist Publisher	CDISC
NCI Code	C66768
Codelist is Extensible	No
Codelist Name	Outcome of Event
CDISC Definition	A condition or event that is attributed to the adverse event and is the result or conclusion of the adverse event. (NCI)

CDISC Codelist

Showing 1 to 6 of 6 Show 50 | All << < 1 > >>

NCI Code	CDISC Submission Value	CDISC Definition	CDISC Synonym(s)	NCI Preferred Term
C17998	UNKNOWN	Not known, not observed, not recorded, or refused. (NCI)	U; Unknown	Unknown
C48275	FATAL	The termination of life as a result of an adverse event. (NCI)	Grade 5; 5	Death Related to Adverse Event
C49494	NOT RECOVERED/NOT RESOLVED	One of the possible results of an adverse event outcome that		Not Recovered or Not Resolved

- SDTM 3.1.2 Extended
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- Controlled Terminology
  - + CDISC Terminology
  - + Sponsor Terminology
- Value Level Metadata
  - Findings Metadata for Measurements
    - Measurements
      - Chemistry
      - Coagulation
      - Flow Cytometry
      - Genomics
      - **Hematology**
      - Immunology
      - Microbiology
      - Other
      - Pharmacology
      - Serology
      - Urinalysis
      - Urine Drug Screen
      - Virology
    - Unit Synonyms
    - Unit Conversions

back

Hematology Measurements

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Name	Label	Domain	--TEST	--TESTCD
ABS_NEUT_COUNT	Absolute Neutrophil Count	LB	Neutrophils	NEUT
ACANTHOCYTOSIS	RBC Morphology, Acanthocytosis	LB	Acanthocytes	ACANT
ALDER_ANOMALY_INCL	Alder Anomaly, Inclusion	LB	Alder's Anomaly	ALDANOM
ANISOCYTOSIS	RBC Morphology, Anisocytosis	LB	Anisocytes	ANISO
AUER_RODS	WBC Comment, Auer Rods	LB	Auer Rods	AUERRODS
BABESIA	Babesia	LB	Babesia	BABE
BAND_ABS	Bands, Absolute Count	LB	Neutrophils Band Form	NEUTB
BAND_PERCENT	Neutrophils, Bands, Percent	LB	Neutrophils Band Form/Leukocytes	NEUTBLE

- SDTM 3.1.2 Extended
  - General Observations
  - Special Purpose Class
- Controlled Terminology
  - CDISC Terminology
  - Sponsor Terminology
- Value Level Metadata
  - Findings Metadata for Measurements
  - Questionnaires
    - 5-D Pruritus Scale
    - Aberrant Behavior Checklist
    - Abnormal Involuntary Movement Scale
    - Addiction Research Center Inventory Questionnaire (49 Q
    - Alzheimer's Disease Cooperative Study Group - Activities
    - Anxiety, Depression and Mood Scale
    - **Asthma Control Questionnaire**
    - Asthma Quality of Life Questionnaire with Standard Activit
    - Asthma Symptom Utility Index
    - Autism Diagnostic Observation Schedule Module 2
    - Autism Diagnostic Observation Schedule Module 3
    - Autism Diagnostic Observation Schedule Module 4
    - Beck Depression Inventory - Second Edition
    - Bond-Lader Visual Analog Scale
    - Brain Cancer Module Quality of Life Questionnaire
    - Brief Fatigue Inventory
    - Brief Pain Inventory (Short Form)
    - Brief Psychiatric Rating Scale
    - Calgary Depression Scale for Schizophrenia
    - Center for Epidemiologic Studies Depression Scale (CES-I
    - Chemotherapy Convenience and Satisfaction Questionnai
    - Children's Depression Inventory 1
    - Children's Depression Inventory 2

back

Asthma Control Questionnaire

Category (QSCAT)	ACQ
Instrument Name	Asthma Control Questionnaire
Author	Juniper, Elizabeth, MCSP, Msc
Pathology	Immune System Diseases, Respiratory Tract Diseases
Therapeutic Area	Inflammation (Asthma)
Disease	Asthma
Objective	To measure the adequacy of clinical asthma control
Patient Reported Outcome (PRO)	Yes
Evaluator	

Showing 1 to 10 of 10 Show 50 | All

<< < 1 > >>

Question Short Name (QSTESTCD)	Question Name (QSTEST)	Subcategory (QSSCAT)	Evaluation Interval (QSEVLINT)	Question Narrative (QSNAR)
QS00201	Nocturnal Awakenings	SUBJECT	-P1W	On average, during the past week, how often were you woken by your asthma during the night?
QS00202	Morning Symptoms	SUBJECT	-P1W	On average, during the past week, how

+ SDTM 3.1.2 Extended
+ Controlled Terminology
− Value Level Metadata
  + Findings Metadata for Measurements
  − Questionnaires
    + 5-D Pruritus Scale
    + Aberrant Behavior Checklist
    + Abnormal Involuntary Movement S
    + Addiction Research Center Invent
    + Alzheimer's Disease Cooperative S
    + Anxiety, Depression and Mood Sca
    − Asthma Control Questionnaire
      ✓ **Nocturnal Awakenings**
        Morning Symptoms
        Activity Limitation
        Shortness of Breath
        Wheeze
        SABA Usage
        FEV1 % predicted
        FEV1 pre-bronchodilator
        FEV1 predicted
        FEV1 % predicted
    + Asthma Quality of Life Questionna
    + Asthma Symptom Utility Index
    + Autism Diagnostic Observation Scl
    + Autism Diagnostic Observation Scl
    + Autism Diagnostic Observation Scl
    + Beck Depression Inventory - Secc
    + Bond-Lader Visual Analog Scale
    + Brain Cancer Module Quality of Lif
    + Brief Fatigue Inventory

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Nocturnal Awakenings

Questionnaire	Asthma Control Questionnaire
Section	
Question Category (QSCAT)	ACQ
Question Short Name (QSTESTCD)	QS00201
Question Name (QSTEST)	Nocturnal Awakenings
Subcategory (QSSCAT)	SUBJECT
Evaluation Interval (QSEVLINT)	-P1W
Question Narrative (QSNAR)	On average, during the past week, how often were you woken by your asthma during the night?

Showing 1 to 7 of 7 Show 50 | All

<< < 1 > >>

Original Result (QSORRES)	Original Result Units (QSORRESU)	Character Result in Standard Format (QSSTRESC)	Standard Units (QSSTRESU)	Sponsor Notes
NEVER		0		
HARDLY EVER		1		
A FEW TIMES		2		
SEVERAL TIMES		3		
MANY TIMES		4		

Publishing
and
Item Level Versioning

GDSR Browser
Global Data Standards Repository Browser

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Administration Panel

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Revision Choose One Upload

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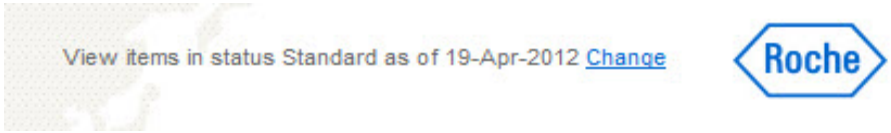
<< < 1 2 3 > >>

GDS revision number	Timestamp	Action	Registrar User ID	As of date	Status	
774	12-Apr-2012 11:53:59	Upload	wilkosm	12-Apr-2012	✔ COMPLETED	Report
777	12-Apr-2012 11:26:33	Upload	wilkosm	12-Apr-2012	✔ COMPLETED	Report
3157	11-Apr-2012 17:31:41	Upload	wilkosm	11-Apr-2012	✔ COMPLETED	Report
3135	11-Apr-2012 17:19:02	Upload	wilkosm	11-Apr-2012	✔ COMPLETED	Report
3157	11-Apr-2012 16:15:47	Upload	wilkosm	11-Apr-2012	✔ COMPLETED	Report


View items in status Standard as of 19-Apr-2012 Change


View items in status
Standard
as of
19-Apr-2012
Save
Proposed
Candidate
Standard
Retired
Superseded

Using Web Services

Export to SAS Data Sets

	Question Short Name	Question Name	Category of Question	Subcategory of Question	Evaluation Interval
32	QS001031	Disrupts group activites	ABC	HYPERACTIVITY	-P4W
33	QS001032	Stays in one position for a long time	ABC	LETHARGY	-P4W
34	QS001033	Talks to self loudly	ABC	INAPPROPRIATE SPEECH	-P4W
35	QS001034	Cries over minor annoyances or hurts	ABC	IRRITABILITY	-P4W
36	QS001035	Repetitive hand, body, or head movements	ABC	STEREOTYPY	-P4W
37	QS001036	Mood changes quickly	ABC	IRRITABILITY	-P4W
38	QS001037	Unresponsive to structured activities	ABC	LETHARGY	-P4W
39	QS001038	Does not stay in seat	ABC	HYPERACTIVITY	-P4W
40	QS001039	Won't sit still for any length of time	ABC	HYPERACTIVITY	-P4W
41	QS001040	Hard to reach, contact, get through to	ABC	LETHARGY	-P4W
42	QS001041	Cries and screams inappropriately	ABC	IRRITABILITY	-P4W
43	QS001042	Prefers to be alone	ABC	LETHARGY	-P4W
44	QS001043	Does not communicate by words/gestures	ABC	LETHARGY	-P4W
45	QS001044	Easily distractible	ABC	HYPERACTIVITY	-P4W
46	QS001045	Waves or shakes extremities repeatedly	ABC	STEREOTYPY	-P4W
47	QS001046	Repeats a word or phrase over and over	ABC	INAPPROPRIATE SPEECH	-P4W
48	QS001047	Stamps feet, bangs objects, slams doors	ABC	IRRITABILITY	-P4W
49	QS001048	Constantly runs or jumps around the room	ABC	HYPERACTIVITY	-P4W
50	QS001049	Rocks body back and forth repeatedly	ABC	STEREOTYPY	-P4W
51	QS001050	Deliberately hurts himself/herself	ABC	IRRITABILITY	-P4W
52	QS001051	Pays no attention when spoken to	ABC	HYPERACTIVITY	-P4W
53	QS001052	Does physical violence to self	ABC	IRRITABILITY	-P4W
54	QS001053	Inactive, never moves spontaneously	ABC	LETHARGY	-P4W
55	QS001054	Tends to be excessively active	ABC	HYPERACTIVITY	-P4W
56	QS001055	Responds negatively to affection	ABC	LETHARGY	-P4W
57	QS001056	Deliberately ignores directions	ABC	HYPERACTIVITY	-P4W
58	QS001057	Outbursts/tantrums if not get own way	ABC	IRRITABILITY	-P4W
59	QS001058	Shows few social reactions to others	ABC	LETHARGY	-P4W
60	QS001TS1	Total Subscale I (Irritability)	ABC	TOTAL	-P4W
61	QS001TS2	Total Subscale II (Lethargy)	ABC	TOTAL	-P4W

Export to Excel
Data Tabulation Extract

Owner	Roche PD Biometrics Global Data Standards (GDS)
Document	Data Tabulation Standards (DTS)
Release Date	03-04-2012
Status Level	Standard
Publication Date	03-04-2012

Go to
SDTM Domains
Code Lists
Terms
Lab Standards
Preferred Units
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Class	Defined By	Dataset Name	Domain Label
Special Purpose Domain	CDISC	DM	Demographics
		CO	Comments
		SE	Subject Elements
		SV	Subject Visits
Interventions Observation Class	CDISC	CM	Concomitant Medications
		EX	Exposure
		SU	Substance Use
	Sponsor	XM	Meal
		XP	Surgeries and Procedures
Events Observation Class	CDISC	AE	Adverse Events
		DS	Disposition
		MH	Medical History
		DV	Protocol Deviations
		CE	Clinical Events
	Sponsor	YI	Site and Investigator
Findings Observation Class	CDISC	EG	ECG Test Results
		IE	Inclusion/Exclusion Criterion Not Met
		LB	Laboratory Test Results
		PE	Physical Examination
		QS	Questionnaires

AE
Adverse Events
Defined by CDISC
Events Observation Class

Name	Label	Type	Length	Format	Codelist	Role	Compliance	CDISC Notes
AEREL	Causality	Char	20	*		Record Qualifier	Expected Variable	Records the investigator's include NOT RELATED, UNL in the future. Check with r
AERELNST	Relationship to Non-Study Treatment	Char	200		L00005	Record Qualifier	Permissible Variable	Records the investigator's drug. May be reported as f
AEPATT	Pattern of Adverse Event	Char	40	*	L00004	Record Qualifier	Permissible Variable	Used to indicate the patte
AEOUT	Outcome of Adverse Event	Char	40	(OUT)	C66768	Record Qualifier	Permissible Variable	Description of the outcom
AESCAN	Involves Cancer	Char	2	(NY)	C66742	Record Qualifier	Permissible Variable	Was the serious event ass
AESCONG	Congenital Anomaly or Birth Defect	Char	2	(NY)	C66742	Record Qualifier	Permissible Variable	Was the serious event ass
AESDISAB	Persist or Signif Disability/Incapacity	Char	2	(NY)	C66742	Record Qualifier	Permissible Variable	Did the serious event resu
AESDTH	Results in Death	Char	2	(NY)	C66742	Record Qualifier	Permissible Variable	Did the serious event resu
AESHOSP	Requires or Prolongs Hospitalization	Char	2	(NY)	C66742	Record Qualifier	Permissible Variable	Did the serious event requ
AESLIFE	Is Life Threatening	Char	2	(NY)	C66742	Record Qualifier	Permissible Variable	Was the serious event life
AESOD	Occurred with Overdose	Char	2	(NY)	C66742	Record Qualifier	Permissible Variable	Did the serious event occu
AESMIE	Other Medically Important Serious Event	Char	2	(NY)	C66742	Record Qualifier	Permissible Variable	Do additional categories fo
AECONTRT	Concomitant or Additional Trtmnt Given	Char	2	(NY)	C66742	Record Qualifier	Permissible Variable	Was another treatment giv
AETOXGR	Standard Toxicity Grade	Char	1	*		Record Qualifier	Permissible Variable	Toxicity grade according to v3.0 (CTCAE). Sponsor shou

Code List	Label	Extensible	Submission Value	CDISC Definition
C66735	Trial Blinding Schema	true	TBLIND	The name of a code list that contains terms to define the type of blindi
C66736	Trial Indication Type	true	TINDTP	The name of a code list that contains terms to define the type of trial, e
C66737	Trial Phase	true	TPHASE	Clinical trials are broken into three or four phases: Phase I tests a new d group; Phase II expands the study to a larger group of people; Phase III group of people to measure whether the treatment actually benefits pa its risks; and Phase IV takes place after the drug or treatment has been
C66738	Trial Summary Parameter Test Code	true	TSPARMCD	Individual characteristics of a clinical trial, e.g. description of trial desig objective of trial. (NCI)
C66739	Trial Type	true	TTYPE	The type of clinical trial performed e.g. efficacy, safety. (NCI)
C66741	Vital Signs Test Code	true	VSTESTCD	The name given to the test that analyzes a particular set of vital signs in heart beat (pulse), and blood pressure. (NCI)
C66742	No Yes Response	false	NY	A term that is used to indicate a question with permissible values of ye
C66767	Action Taken with Study Treatment	false	ACN	Action Taken with Study Treatment
C66768	Outcome of Event	false	OUT	A condition or event that is attributed to the adverse event and is the r (NCI)
C66769	Severity/Intensity Scale for Adverse Events	false	AESEV	A scale that defines the degree or state of disease existing in a patient adverse event. (NCI)
C66770	Units for Vital Signs Results	true	VSRESU	The unit used to record and describe the result of a test investigating a
C66780	Age Span	true	AGESPAN	Subgroups of populations based on age. (NCI)
C66781	Age Unit	false	AGEU	Those units of time that are routinely used to express the age of a pers
C66783	CDISC System Organ Class	false	SOC	Terms at the highest level of the CDISC system organ class terminology
C66784	Common Terminology Criteria for Adverse Events	false	TOXGR	A standard terminology developed to report adverse events occurring i terminology criteria for adverse events (CTCAE) are used in study adve New Drug reports to the Food and Drug Administration. The CTCAE cont event term representing the severity of the event. (NCI)

Code List	Term	Submission Value	CDISC Definition
C66767	C17998	UNKNOWN	Not known, not observed, not recorded, or refused. (NCI)
C66767	C48660	NOT APPLICABLE	Determination of a value is not relevant in the current context. (NCI)
C66767	C49501	DRUG INTERRUPTED	An indication that a medication schedule was modified by temporarily terminat medication. (NCI)
C66767	C49502	DRUG WITHDRAWN	An indication that a medication schedule was modified through termination of a medication. (NCI)
C66767	C49503	DOSE INCREASED	An indication that a medication schedule was modified by addition; either by ch or amount. (NCI)
C66767	C49504	DOSE NOT CHANGED	An indication that a medication schedule was maintained. (NCI)
C66767	C49505	DOSE REDUCED	An indication that a medication schedule was modified by subtraction, either by strength or amount. (NCI)
C66768	C17998	UNKNOWN	Not known, not observed, not recorded, or refused. (NCI)
C66768	C48275	FATAL	The termination of life as a result of an adverse event. (NCI)
C66768	C49494	NOT RECOVERED/NOT RESOLVED	One of the possible results of an adverse event outcome that indicates that the recuperated. (NCI)
C66768	C49495	RECOVERED/RESOLVED WITH SEQUELAE	One of the possible results of an adverse event outcome where the subject recu pathological conditions resulting from the prior disease or injury. (NCI)
C66768	C49496	RECOVERING/RESOLVING	One of the possible results of an adverse event outcome that indicates that the
C66768	C49498	RECOVERED/RESOLVED	One of the possible results of an adverse event outcome that indicates that the recuperated. (NCI)
C66769	C41338	MILD	A type of adverse event that is usually transient and may require only minimal t intervention. The event does not generally interfere with usual activities of dail
C66769	C41339	MODERATE	A type of adverse event that is usually alleviated with additional specific therap interferes with usual activities of daily living, causing discomfort but poses no si harm to the research participant.
C66769	C41340	SEVERE	A type of adverse event that interrupts usual activities of daily living, or signific

Select Category | Go to Measurement Category

SDTM LBCAT Category	Measurement	SDTM LBTESTCD Test Code	SDTM LBTEST Test Name	SDTM LBSPEC Specimen
CHEMISTRY	1, 25-Dihydroxyvitamin D3, Serum	VITD3AT	1, 25-Dihydroxyvitamin D3	SERUM
	Acid Labile Subunit, Total	ACLABST	Acid Labile Subunit Total	SERUM
	Acid Labile Subunit, Total, Recalc.	ACLABSTR	Acid Labile Subunit Total, Recalculated	SERUM
	Acid Phosphatase	ACPHOS	Acid Phosphatase	SERUM
	Acid Phosphatase, Prostatic	PAP	Prostatic Acid Phosphatase	SERUM
	Albumin Index	ALBI	Albumin Index	CEREBROSPINAL FLUID
	Albumin Ratio	ALBCSR	Albumin CSF/Serum Ratio	CEREBROSPINAL FLUID, SERUM
	Albumin/Globulin Ratio	ALBGLOB	Albumin/Globulin	SERUM
	Alk. Phos., Intestine Isoenzym	ALPII	Alkaline Phos, Intestine Isoenzyme	SERUM
	Alkaline Phos., Bone Isoenzyme	ALPBI	Alkaline Phosphatase, Bone Isoenzyme	SERUM
	Alkaline Phos., Liver Isoenzyme	ALPLI	Alkaline Phosphatase, Liver Isoenzyme	SERUM
	Alkaline Phos., Placental Isoenzyme	ALPPI	Alkaline Phosp, Placental Isoenzyme	SERUM
	Alkaline Phosphatase	ALP	Alkaline Phosphatase	SERUM
	Alkaline Phosphatase, Fractionation	ALPF	Alkaline Phosphatase, Fractionated	SERUM
	Alpha Fetoprotein	AFP	Alpha Fetoprotein	SERUM
	Alpha-1 Antitrypsin, Serum Conc	A1ANTRYP	Alpha-1 Antitrypsin	SERUM
	Alternate Path Complement AH50	AH50	AH50	SERUM
	Amylase	AMYLASE	Amylase	SERUM
	Apolipoprotein B	APOB	Apolipoprotein B	SERUM
	Arterial Blood pH - pH	PH	pH	ARTERIAL BLOOD
	Bicarbonate (CO2)	BICARB	Bicarbonate	SERUM
	Bilirubin, Direct	BILDIR	Direct Bilirubin	SERUM

Instrument	SDTM QSCAT	Author
5-D Pruritus Scale	5-D PRURITUS	Elman, S; Hynan, LS; Gabriel, V; Mayo, MJ
Aberrant Behavior Checklist	ABC	Slosson Educational Publications, Inc.
Abnormal Involuntary Movement Scale	AIMS	
Addiction Research Center Inventory Questionnaire (49 Questions)	ARCI-49	
Alzheimer's Disease Cooperative Study Group - Activities of Daily Living	ADCS-ADL	
Anxiety, Depression and Mood Scale	ADAMS	
Asthma Control Questionnaire	ACQ	Juniper, Elizabeth, MCSP, Msc
Asthma Quality of Life Questionnaire with Standard Activities	AQLQ(S)	Juniper, Elizabeth, MCSP, Msc
Asthma Symptom Utility Index	ASUI	
Autism Diagnostic Observation Schedule Module 2	ADOS2	Catherine Lord, Ph.D., Michael Rutter, M.D., FRS, Pamela C. DiLavore, Ph.D., and Susan Risi, Ph.D.
Autism Diagnostic Observation Schedule Module 3	ADOS3	Catherine Lord, Ph.D., Michael Rutter, M.D., FRS, Pamela C. DiLavore, Ph.D., and Susan Risi, Ph.D.
Autism Diagnostic Observation Schedule Module 4	ADOS4	Catherine Lord, Ph.D., Michael Rutter, M.D., FRS, Pamela C. DiLavore, Ph.D., and Susan Risi, Ph.D.
Beck Depression Inventory - Second Edition	BDI-II	Beck, Aaron T, MD
Biphasic Alcohol Effects Scale	BAES	
Bond-Lader Visual Analog Scale	BL-VAS	Bond, Alyson; Lader, Malcom
Brain Cancer Module Quality of Life Questionnaire	BCM20	Osoba, D., Aaronson, N.K., Muller, M., Sneeuw, K., Hsu, M.-A.,

Asthma Control Questionnaire

QSTESTCD	QSTEST	QSEVLINT	Display Text
QS00201	Nocturnal Awakenings	-P1W	On average, during the past week, how often were you woken by your asthma during the night?
QS00202	Morning Symptoms	-P1W	On average, during the past week, how bad were your asthma symptoms when you woke up in the morning?
QS00203	Activity Limitation	-P1W	In general, during the past week, how limited were you in your activities because of your asthma?

Asthma Control Questionnaire

QSTESTCD	QSTEST	QSORRES	QSORRESU	QSSTRESC
QS00201	Nocturnal Awakenings	NEVER		0
		HARDLY EVER		1
		A FEW TIMES		2
		SEVERAL TIMES		3
		MANY TIMES		4
		A GREAT MANY TIMES		5
		UNABLE TO SLEEP BECAUSE OF ASTHMA		6
QS00202	Morning Symptoms	NO SYMPTOMS		0
		VERY MILD SYMPTOMS		1
		MILD SYMPTOMS		2
		MODERATE SYMPTOMS		3
		QUITE SEVERE SYMPTOMS		4
		SEVERE SYMPTOMS		5
		VERY SEVERE SYMPTOMS		6
QS00203	Activity Limitation	NOT LIMITED AT ALL		0
		VERY SLIGHTLY LIMITED		1
		SLIGHTLY LIMITED		2

Export to Excel
Rave Architect Loader File

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Neurological Exam

Form Policy	Study Build Optional Form
Form Layout	Mixed Form
Study Build Note	
Rave GVI Form OID	NE

Help Text

At the Screening visit, enter any findings/conditions on the General Medical History and Baseline Conditions form. After the screening visit, enter any new or worsened findings/conditions on the Adverse Event form.

SDTM Annotation(s)

Domain: ZA

ZA.ZACAT = 'NEUROLOGICAL EXAMINATION'

+ Safety
+ Across Therapeutic Area
− CNS
  − Alzheimer
    + Alzheimer Disease History
    + Modified Hachinski Ischemia Scale
    − Neurological Exam
      Timepoint
      Was a neurological examination performed?
      If Yes, date of exam
      Time of exam
      Type of neurological examination performed
      Exam performed?
      Result
      Examination category
  + Schizophrenia
+ Inflammation
+ Metabolism
+ Oncology
Ophthalmology
+ Virology

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Examination category

Data Element

Form Control	Text Field
Data Type	String
Header Text	EXAM CATEGORY

Data Collection Field

Study Build Policy	Study Build Mandatory Field
Repeating Field	No
Hidden Field	Yes
Protected Field	Yes
Study Build Conditional Field	
Study Build Alternative Field	
Study Build Value Domain	Neurological Exam Category
Study Build Value	
Study Build Note	

Rave Global Volume Integrated (GVI)

Form OID	NE
Field OID	EXAMTP
Mixed Form Log Field	Yes
Format	$100
Dictionary	
SAS Label	Examination Category
Integration Field	No
Implemented as Postfix Text	
Postfix Text	

SDTM Annotation(s)

ZA.ZASCAT

Roche

Data Collection > CNS > Alzheimer > Neurological Exam > Examination category > T

- + Safety
- + Across Therapeutic Area
- − CNS
  - − Alzheimer
    - + Alzheimer Disease History
    - + Modified Hachinski Ischemia Scale
    - − Neurological Exam
      - Timepoint
      - Was a neurological examination performed?
      - If Yes, date of exam
      - Time of exam
      - Type of neurological examination performed
      - Exam performed?
      - Result
      - ✓ **Examination category**
    - + Schizophrenia
- + Inflammation
- + Metabolism
- + Oncology
- Ophthalmology
- + Virology

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Controlled Terminology

Value Domain Attributes

Label	Neurological Exam Category
Extensible	No
Parent Value Domain	

Permissible Values

Showing 1 to 5 of 5 Show 50 | All << < 1 > >>

CRF Value	Study Build Policy
GENERAL NEUROLOGICAL	Study Build Select One Value
COGNITIVE/PERCEPTUAL NEUROPATHY	Study Build Select One Value
MOTOR NEUROPATHY	Study Build Select One Value
SENSORY NEUROPATHY	Study Build Select One Value
OTHER	Study Build Select One Value

OID	Ordinal	DraftFormName	DraftFormActive	HelpText	IsTemplate	IsSignatureRequired
ALZHX	1	Alzheimer Disease History	TRUE		FALSE	FALSE
MHIS	2	Modified Hachinski Ischemia Scale	TRUE		FALSE	FALSE
NE	3	Neurological Exam	TRUE	At the Screening visit, enter any findings/conditions on the General Medical History and Baseline Conditions form. After the screening visit, enter any new or worsened findings/conditions on the Adverse Event form.	FALSE	FALSE

FormOI	FieldOID	Ordina	DraftFieldNumber	DraftFieldName	DraftFieldActive	VariableOID	DataFormat	DataDictionaryName
ALZHX	DIAGD	1		DIAGD	TRUE	DIAGD	dd- MMM- yyyy	
ALZHX	DXDTU	2		DXDTU	TRUE	DXDTU	1	
ALZHX	SCORE	3		SCORE	TRUE	SCORE	1	NUMERIC_VALUE_V5
ALZHX								
MHIS	MMHPF	1		MMHPF	TRUE	MMHPF	$3	YES_NO
MHIS	MMHD	2		MMHD	TRUE	MMHD	dd- MMM- yyyy	
MHIS	RAINIT	3		RAINIT	TRUE	RAINIT	$3	
MHIS	MMHAM1	4		MMHAM1	TRUE	MMHAM1	$11	PRESENT_ABSENT_V1
MHIS	MMHAM2	5		MMHAM2	TRUE	MMHAM2	$11	PRESENT_ABSENT_V1
MHIS	MMHAM3	6		MMHAM3	TRUE	MMHAM3	$11	PRESENT_ABSENT_V1
MHIS	MMHAM4	7		MMHAM4	TRUE	MMHAM4	$11	PRESENT_ABSENT_V1
MHIS	MMHAM5	8		MMHAM5	TRUE	MMHAM5	$11	PRESENT_ABSENT_V1
MHIS	MMHAM6	9		MMHAM6	TRUE	MMHAM6	$11	PRESENT_ABSENT_V1
MHIS	MMHAM7	10		MMHAM7	TRUE	MMHAM7	$11	PRESENT_ABSENT_V1
MHIS	MMHAM8	11		MMHAM8	TRUE	MMHAM8	$11	PRESENT_ABSENT_V1
MHIS	TTLSCR	12		TTLSCR	TRUE	TTLSCR	2	
NE	TMPTC	1		TMPTC	TRUE	TMPTC	$60	
NE	EXAMDN1	2		EXAMDN1	TRUE	EXAMDN1	$3	YES_NO_V1
NE	EXMD	3		EXMD	TRUE	EXMD	dd- MMM- yyyy	
NE	EXTM	4		EXTM	TRUE	EXTM	HH nn	
NE	EXMTH	5		EXMTH	TRUE	EXMTH	$60	
NE	EXAMDN2	6		EXAMDN2	TRUE	EXAMDN2	$3	YES_NO_V1
NE	RSLT	7		RSLT	TRUE	RSLT	$8	NORMAL_ABNORMAL_V4
NE	EXAMTP	8		EXAMTP	TRUE	EXAMTP	$100	

Future

Current Roche MDR

Content

- External content
  - SDTM 1.2, SDTMIG 3.1.2
  - NCI Thesaurus, CDISC Controlled Terminology
- Integrated Data Standards, Roche and Genentech
  - Safety and every Roche TA, ~ 2000 data elements
  - Data Collection and Data Tabulation
- Value level metadata
  - Lab measurements (~ 2000), Unit conversions, Questionnaires (~ 150)
- Looking at metadata for
  - SDTM Conformance Checking, Biomarker (HGNC), …

Unique Value Proposition

Convergence of Standards and Technology

- Coverage and maturity of existing CDISC standards
- Establishment of CDISC standards within the industry
- MDR based standards as a foundation for metadata driven workflow
- Upcoming role of semantic web standards and linked data principles

Roche Group R&D Pipeline

phase I (36 NMEs)

RG3639	dulanermin	cancer
RG7256	BRaf inh(2)	BRAF mutated melanoma
RG7112	MDM2 ant (2)	solid & hem tumors
RG7160	EGFR Mab	solid tumors
RG7167	CIF/MEK inh	solid tumors
RG7304	Raf & MEK dual inh	solid tumors
RG7321	PI3 kinase inh	solid tumors
RG7334	anti-PLGF Mab	solid tumors
RG7414	anti-EGFL7 Mab	solid tumors
RG7420	MEK inh	solid tumors
RG7421	MEK inh	solid tumors
RG7422	PI3 K/mTOR inh	solid&hem tumors
RG7440	AKT inhibitor	solid tumors
RG7444	FGFR3 Mab	multiple myeloma
RG7459	IAP ant (2)	solid tumors& lymphoma
RG7593	CD22 Mab ADC	hem. malignancies
RG7594	antiangiogenic	solid tumors
RG7597	anti-Her3 Mab	m. epithelial tumors
RG7686	anti-glypican Mab	liver cancer
CHU	ALK inhibitor	NSCLC
CHU	-	solid tumors
RG4934	anti-IL-17 Mab	RA
RG7185	CRTH2 antag	asthma
RG7413	Mab Beta7	ulcerative colitis
RG7432	nucleoside pol inh (9)	HCV
CHU	serine palmitoyltransf inh	HCV
RG4929	11 beta HSD inh	metabolic diseases
RG7236	Cat S antag	CV risk in CKD
RG7273	ABCA1 inducer	dyslipidemia
RG7418	anti-oxLDL Mab	sec prev CV events
RG7685	GIP/GLP-1 dual ago	type 2 diabetes
RG1578	mGluR2 antag (2)	depression
RG1662	GABA-A a5 inv ago	cogn. disorders
RG7166	triple reuptake inh	depression
RG7412	anti-Abeta Mab	Alzheimer's
RG7417	anti-factor D Mab	geographic atrophy

phase II (18 NMEs + 8 AIs)

RG1273	pertuzumab	HER2+ EBC
RG1273	pertuzumab	HER2+ mBC 2nd line
RG3502	T-DM1	HER2+ EBC
RG3616	hedgehog path inh	advanced BBC
RG3616	hedgehog path inh	operable BCC
RG3638	MetMab	mNSCLC
RG7159	GA101 anti-CD 20 Mab	NHL & CLL
RG7204	BRaf inh	met. melanoma 2nd/3rd l.ine
RG7433	navitoclax (ABT-263)	sol & hem tumors
CHU	topoisomerase I inh	gastric cancer
RG3637[1]	lebrikizumab (anti-IL13)	asthma
RG4930	OX40L Mab	asthma
RG7415	rontalizumab (IFN alpha Mab)	SLE
RG7416	anti-LT alpha Mab	RA
RG3648	Xolair	chronic idiopathic urticaria
RG7449	anti-M1 prime Mab	asthma
RG3484	HPV16	cervical neoplasia
RG7128	nucleoside polymerase inh.	HCV
RG7227	danoprevir (protease inh)	HCV
RG1512	P selectin Mab	CVD
RG7201[2]	SGLT2 inh	type 2 diabetes
RG1450	gantenerumab (A-beta)	Alzheimer's
RG1594	ocrelizumab	RRMS
RG3487	nic alpha7	Alzheimer's
RG7090	mGluR5 antag (2)	TRD
EVO	NMDA receptor antag	TRD

[1] LIP transition approved
[2] Ph3 in Japan
[3] Complete response in the US
[4] FPI Jan.2011

phase III (8 NMEs + 25 AIs)

RG105	Rituxan	NHL fast infusion
RG105[3]	MabThera	NHL sc formulation
RG435	Avastin	HER2+ BC adj
RG435	Avastin	mBC combo Herceptin 1st line
RG435	Avastin	NSCLC adj
RG435	Avastin	HER2- BC adj
RG435	Avastin	triple neg BC adj
RG435	Avastin	relapsed ovarian ca
RG435	Avastin	high risk carcinoid
RG435	Avastin	glioblastoma 1st line
RG435	Avastin	mCRC TML
RG435[3]	Avastin	mBC 2nd line
RG597	Herceptin	HER2+ BC sub cut.
RG597	Herceptin	HER2+ adj BC (2yrs)
RG1273	pertuzumab	HER2+ mBC 1st line
RG1415	Tarceva	NSCLC adj
RG1415	Tarceva	NSCLC EGFR mut 1st line
RG3502	T-DM1	HER2+ mBC 1st line
RG3502	T-DM1	HER2+ advanced mBC
RG7159	GA101 anti-CD 20 Mab	CLL
RG7159	GA101 anti-CD 20 Mab	iNHL
RG7204	BRaf inh	met. melanoma 1st line
RG1569	Actemra	ankylosing spondylitis
RG1569	Actemra	sc formulation RA
RG1569	Actemra	early RA
RG1569	Actemra	RA DMARD IR H2H
RG1439	aleglitazar	CV risk reduction in T2D
RG1658	dalcetrapib	atherosclerosis CV risk red.
RG1594[4]	ocrelizumab	PPMS
RG1678	GRI	schizophrenia negative sympt.
RG1678	GRI	schizophrenia subopt control
RG3645	Lucentis	diabetic macular edema
RG3645	Lucentis	AMD high dose

Registration (6 AIs)

RG435*	Avastin	ovarian cancer 1st line
RG435*	Avastin	mBC combo Xeloda 1st line
RG1415*	Tarceva	NSCLC EGFR mut 1st line
RG105**	Rituxan	ANCA assoc vascul
RG1569	Actemra	sJIA
CHU	EPOCH	chemo induced anemia

* in the EU
** in the US

NME
Additional Indication

Oncology
Inflammation/Immunology
Virology
Metabolic/Cardiovascular
CNS
Ophthalmology
Others

RG-No Roche Genentech managed
CHU Chugai managed
EVO Evotec

RG105 MabThera is branded as Rituxan in US and Japan

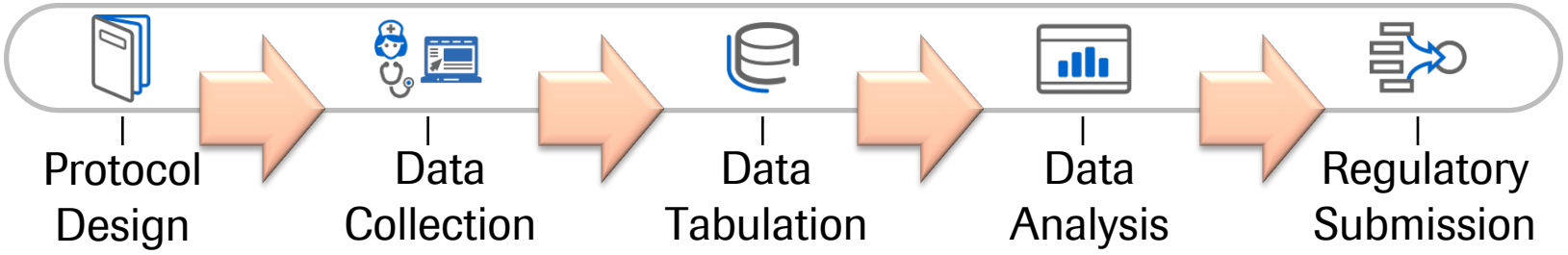
RG1569 Actemra is branded as RoActemra in EU

Status as of December 31, 2010

Biometrics Metadata Repository

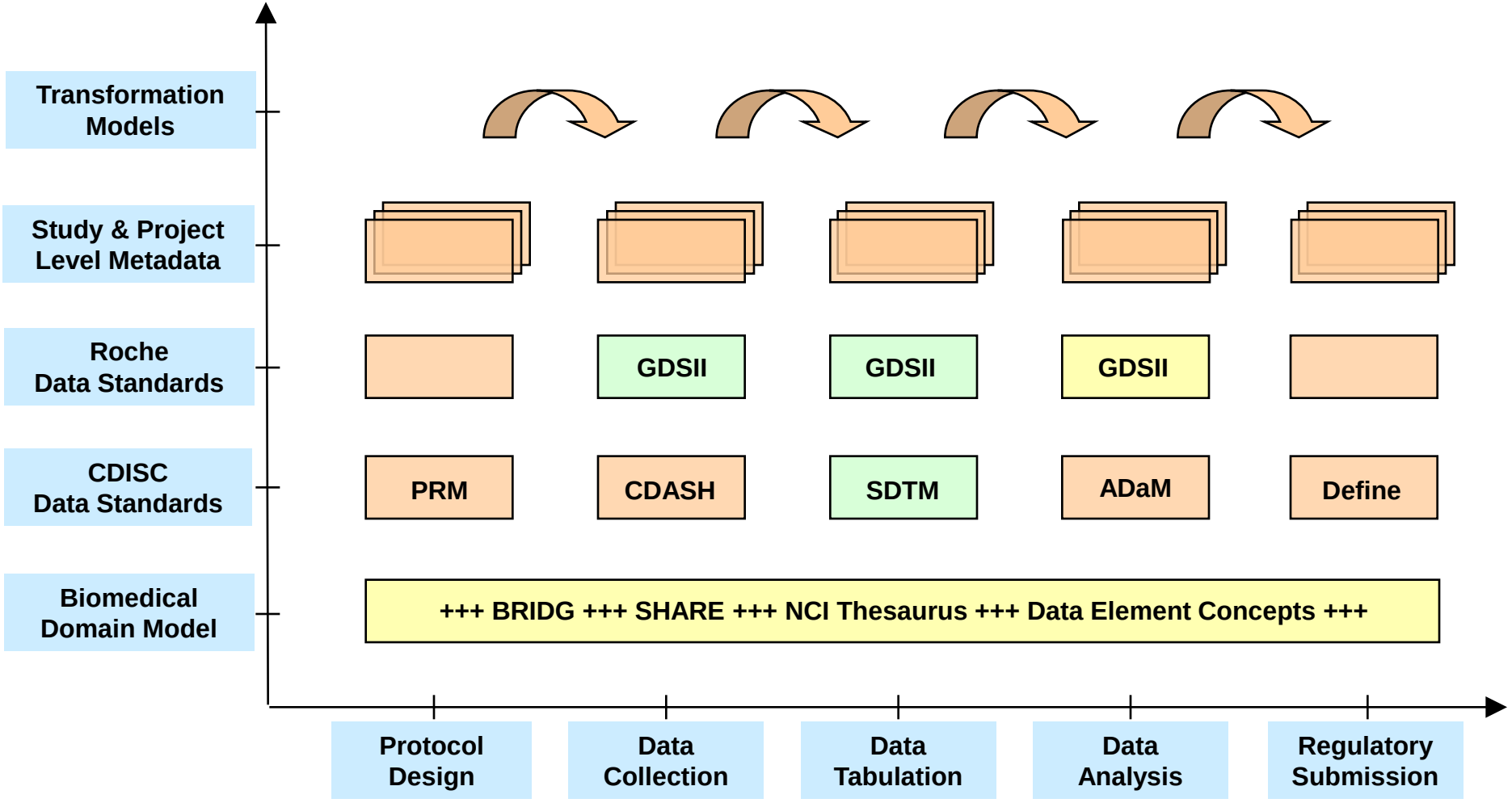
Transforming Drug Development

- To register and manage metadata for intelligent use during the design, collection, analysis and submission of our data to regulatory authorities.
- To build up a rich knowledge-base over time that includes clear and consistent definitions of all of the concepts we use and how they relate to each other.
- To accelerate the adoption of industry and internal standards.



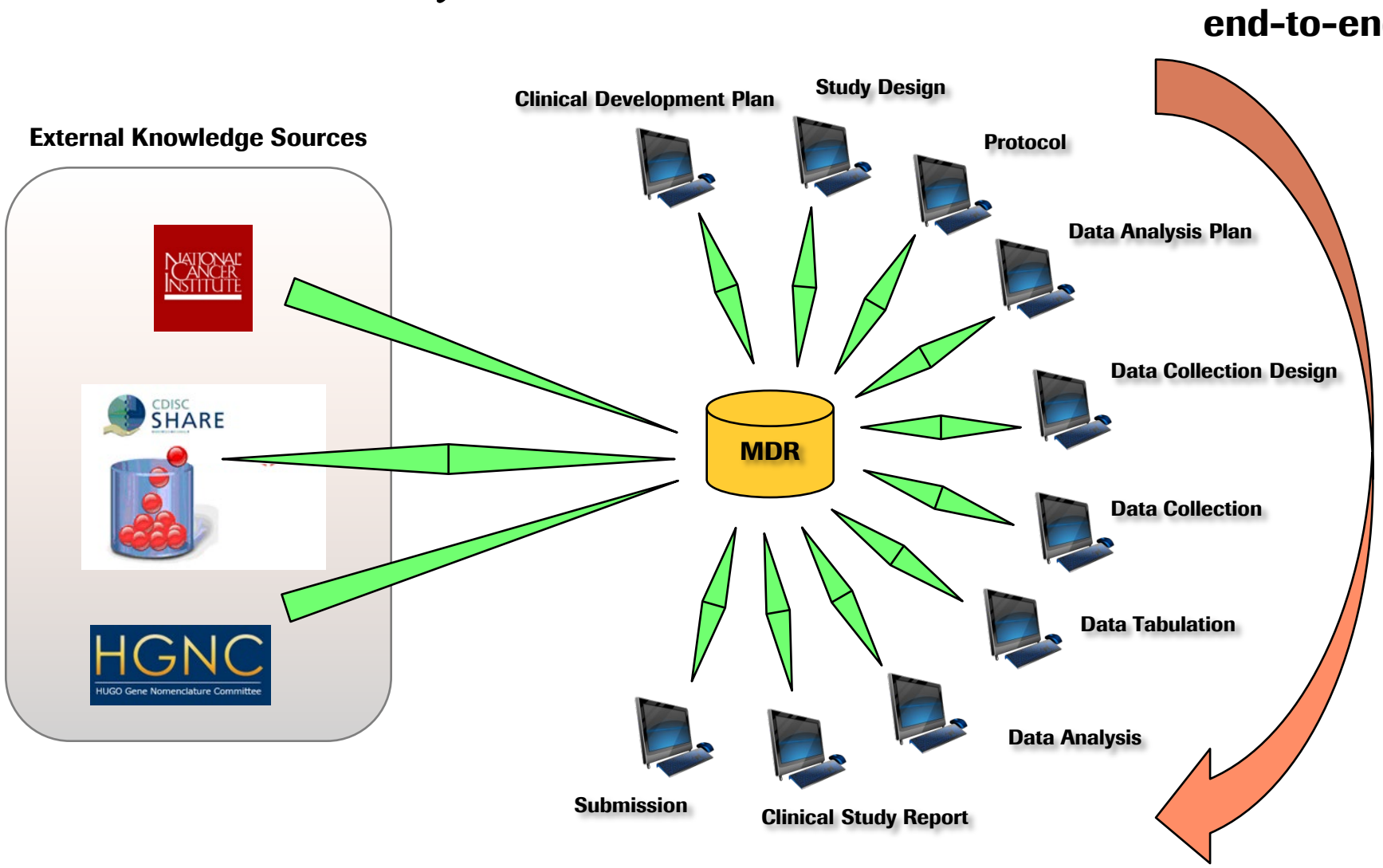
Metadata Repository

Information Architecture



Information Standards and Governance

Metadata Driven Workflow



Roche Smarter Information Management (SIM)

Key Objectives 2013 for the Roche Data Standards Office

- Refactor current MDR
  - Model driven applications
- Capture study level metadata
  - Needed for metadata driven workflow
- Metadata driven EDC build
  - Based on Trial Design Model and Schedule of Assessments
- Metadata driven SDTM transformations
  - Code generator
  - Unit test generator
  - Conformance check generator