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Introduction into CDISC BRIDG
Biomedical Research Integrated Domain Group

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French CDISC usergroup meeting
4th October 2016, Rennes/FR



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HEALTH SCIENCES

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Program Agenda

- 1 A little bit of history
- 2 A word about UML
- 3 Let's look into the model
- 4 Mapping example
- 5 What's new in Version 4

A little bit of history ...

.. BRIDG is getting 10 years old – or even older

(more than) 10 years of BRIDG

CDISC, HL7, NCI, FDA

- **2003-2004: CDISC and HL7 RCRIM WG** (protocol DAM)
- **2004-2005: The NCI caBIG® (and CDISC) Structured Protocol Representation Teams** (protocol DAM)
- **2005-2006: Maturation of the BRIDG Project**
(HL7 regulated submission & product labeling, CDISC all standards, and technical base for future standards)
- **2007 – 2012: BRIDG Evolution** (domain experts vs tech – rework / submodel, ISO)
- **2013 – Present: BRIDG Scope Expansion – Translational Research**
(Biospecimen, Molecular Biology, experiments)

ISO & BRIDG



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CDISC Announces BRIDG Model for Research as Final ISO Standard

May 28, 2015

Austin, TX – 28 May 2015 – The Clinical Data Interchange Standards Consortium (CDISC) is excited to announce that the International Organization for Standardization (ISO) now recognizes the collaborative Biomedical Research Integrated Domain Group (BRIDG) Model version 3.2 as a published, Final International Standard for clinical research and its link with healthcare. This standard, which had previously passed through the ISO Draft International Standard (DIS) ballot, was unanimously approved on 24 April for publication by the ISO Technical Committee (TC) 215 for Healthcare Informatics.

The **BRIDG Model** is a domain analysis model representing the realm of protocol-driven research. The BRIDG Model was initiated by CDISC in 2003 to support harmonization among the CDISC standards for clinical research and to bridge research and healthcare. Shortly thereafter, the US National Cancer Institute (NCI), Health Level Seven (HL7) and the U.S. Food and Drug Administration (FDA) joined with CDISC to collaborate on the development and maintenance of this model. BRIDG became a CDISC and HL7 standard in 2012. The BRIDG Board of Directors had also made the decision in 2010 to begin the process of advancing BRIDG to the status of an international standard through the ISO process. Through the Vienna Agreement, ISO standards are automatically adopted by the European Committee for Normalization (CEN).

Source: <http://cdisc.org/cdisc-announces-bridg-model>



ISO/TC 215 and BRIDG – October 2015

ISO/PRF 14199

50.20

35.240.80

Health informatics -- Information models -- Biomedical Research Integrated Domain Group (BRIDG) Model

ISO/PRF 14199

Health informatics -- Information models -- Biomedical Model

General information	Revisions	Corrigenda / Amendments
Document published on:		
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TC/SC: ISO/TC 215	Number of Pages: 8	

	00 Registration	20 Start of main action	60 Completion of main action	90 Decision		98 Abandon	99 Proceed
40 Enquiry stage	40.00 DIS registered	40.20 DIS ballot initiated: 3 months	40.60 Close of voting	40.92 Full report circulated: DIS referred back to TC or SC	40.93 Full report circulated: decision for new DIS ballot	40.98 Project deleted	40.99 Full report circulated: DIS approved for registration as FDIS
50 Approval stage	50.00 FDIS registered for formal approval	50.20 Proof sent to secretariat: FDIS ballot initiated: 2 months	50.60 Close of voting: Proof returned by secretariat	50.92 FDIS referred back to TC or SC		50.98 Project deleted	50.99 FDIS approved for publication
60 Publication stage	60.00 International Standard under publication		60.60 International Standard published				

35.240.80: IT applications in health care technology

Including computer tomography



ISO/TC 215 and BRIDG – October 2016

✓ ISO 14199:2015

60.60

ISO/TC 215

Health Informatics – Information models – Biomedical Research Integrated Domain Group (BRIDG) Model

General information Revisions Corrigenda / Amendments

Document published on: 2015-09-15

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Status: ✓ Published Stage: 60.60 (2015-09-17)

TC/SC: ISO/TC 215 Number of Pages: 8

	00 Registration	20 Start of main action	60 Completion of main action	90 Decision	92 Repeat an earlier phase	93 Repeat current phase	98 Abandon	99 Proceed
40 Enquiry stage	40.00 DIS registered	40.20 DIS ballot initiated: 3 months	40.60 Close of voting	40.92 Full report circulated: DIS referred back to TC or SC	40.92 Full report circulated: DIS referred back to TC or SC	40.93 Full report circulated: DIS referred back to TC or SC	40.98 Project deleted	40.99 Full report circulated: DIS approved for registration as FDIS
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35.240.80: IT applications in health care technology

Including computer tomography

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Quick word to UML ...

.. as it needs to be introduced quickly

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UML is ...

- Unified Modeling Language

- *"The Unified Modeling Language (UML) is a graphical language for visualizing, specifying, constructing, and documenting the artifacts of a software-intensive system. The UML offers a standard way to write a system's blueprints, including conceptual things such as business processes and system functions as well as concrete things such as programming language statements, database schemas, and reusable software components."* - OMG

UML diagram types

1. Structural Modeling Diagrams

Structure diagrams define the static architecture of a model. They are used to model the 'things' that make up a model - the classes, objects, interfaces and physical components. In addition, they are used to model the relationships and dependencies between elements.

1. Package Diagrams



Package diagrams are used to divide the model into logical containers, or 'packages', and describe the interactions between them at a high level ...[Learn More](#)

2. Component Diagrams



Component diagrams are used to model higher level or more complex structures, usually built up from one or more classes, and providing a well defined interface ...[Learn More](#)

3. Class or Structural Diagrams



Class or Structural diagrams define the basic building blocks of a model: the types, classes and general materials used to construct a full model ...[Learn More](#)

4. Deployment Diagrams



Deployment diagrams Deployment diagrams show the physical disposition of significant artifacts within a real-world setting ...[Learn More](#)

5. Composite Structure Diagrams



Composite Structure diagrams provide a means of layering an element's structure and focusing on inner detail, construction and relationships ...[Learn More](#)

6. Object Diagrams



Object diagrams show how instances of structural elements are related and used at run-time ...[Learn More](#)

Named as Instance Diagram
Since BRIDG 4.0

7. Profile Diagrams



Profile diagrams provide a visual way of defining light-weight extensions to the UML specification. UML profiles are often used to define a group of constructs with domain-specific or platform-specific properties and constraints, which extend the underlying UML elements ...[Learn More](#)

2. Behavioral Modeling Diagrams

Behavior diagrams capture the varieties of interaction and instantaneous states within a model as it 'executes' over time; tracking how the system will act in a real-world environment, and observing the effects of an operation or event, including its results.

8. Use Case Diagrams



Use Case diagrams are used to model user/system interactions. They define behavior, requirements and constraints in the form of scripts or scenarios ...[Learn More](#)

9. Sequence Diagrams



Sequence diagrams are closely related to communication diagrams and show the sequence of messages passed between objects using a vertical timeline ...[Learn More](#)

10. Activity Diagrams



Activity diagrams have a wide number of uses, from defining basic program flow, to capturing the decision points and actions within any generalized process ...[Learn More](#)

11. Timing Diagrams



Timing diagrams fuse sequence and state diagrams to provide a view of an object's state over time, and messages which modify that state ...[Learn More](#)

12. State Machine Diagrams



State Machine diagrams are essential to understanding the instant to instant condition, or 'run state' of a model when it executes ...[Learn More](#)

13. Interaction Overview Diagrams



Interaction Overview diagrams fuse activity and sequence diagrams to allow interaction fragments to be easily combined with decision points and flows ...[Learn More](#)

14. Communication Diagrams



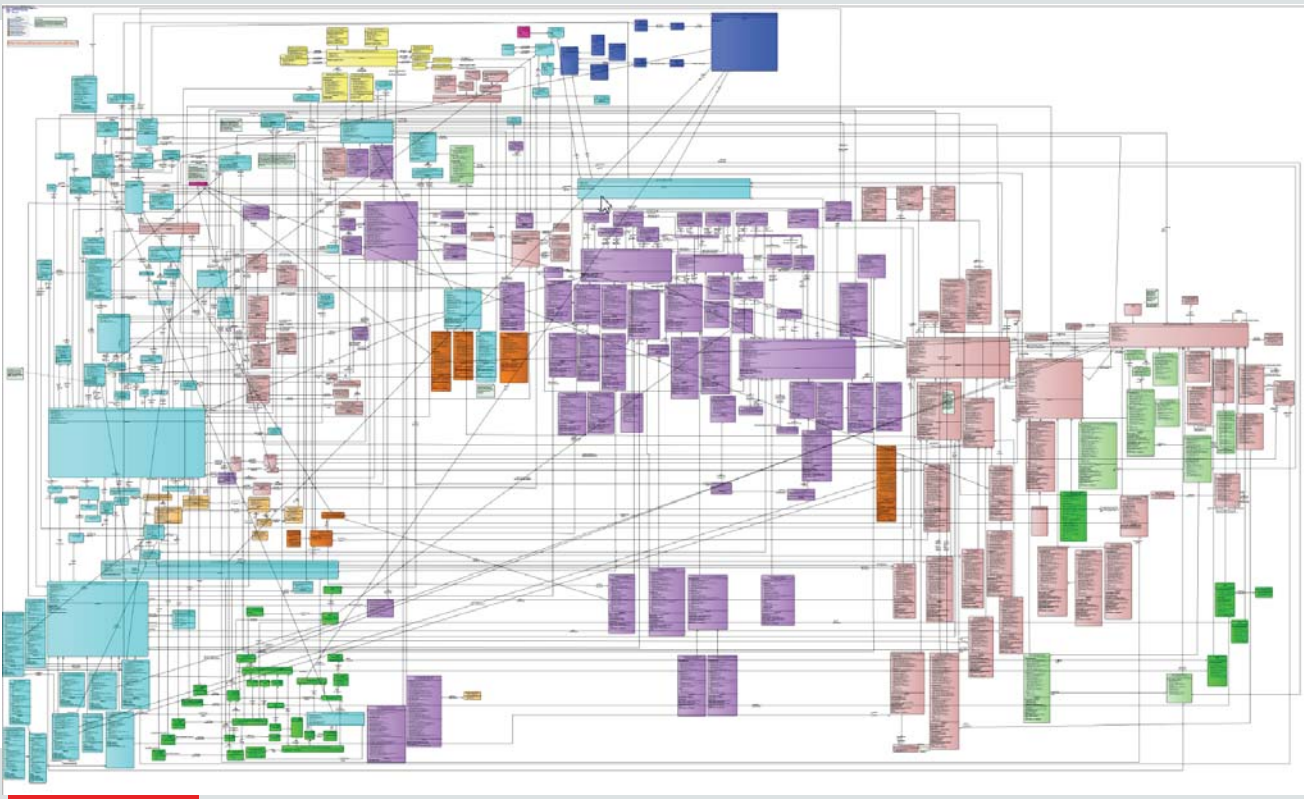
Communication diagrams show the network, and sequence, of messages or communications between objects at run-time, during a collaboration instance ...[Learn More](#)

Source: http://sparxsystems.com.au/resources/uml2_tutorial/

Let's open the model the first time

DAM (Domain Analysis Model) for Clinical Research

- Conceptual model
 - To depict behaviour/process and static/data semantics in the domain
- Subject Matter Experts can integrate and harmonize their perspectives regarding use cases, activities & information
- Abstract should be robust enough to support analysts, architects and developers
- Foundation for semantic interoperability
- Structured way for description and documentation of the requirements in a domain



Hmm, and the documentation!?



4.0: 1365



4.1: 4368



4.1.1: 930

Start here

BRIDG Biomedical Research Integrated Domain Group

BRIDG Model

<http://www.bridgmodel.org>


Release 4.0 User's Guide

27 March 2015

Biomedical Research Integrated Domain Group (BRIDG)

prepared by

BRIDG Semantic Coordination Committee (SCC)
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Smita Hastak (Samvit Solutions/NCI [C]/HL7)
Lloyd McKenzie (Gevity/NCI [C]/HL7)
Julie Evans (CDISC)
Boris Brodsky (FDA/HL7)



Name: UML-Based Comprehensive BRIDG Model Diagram
Package: BRIDG Domain Analysis Model
Version: 4.0
Author: BRIDG SCC

Legend

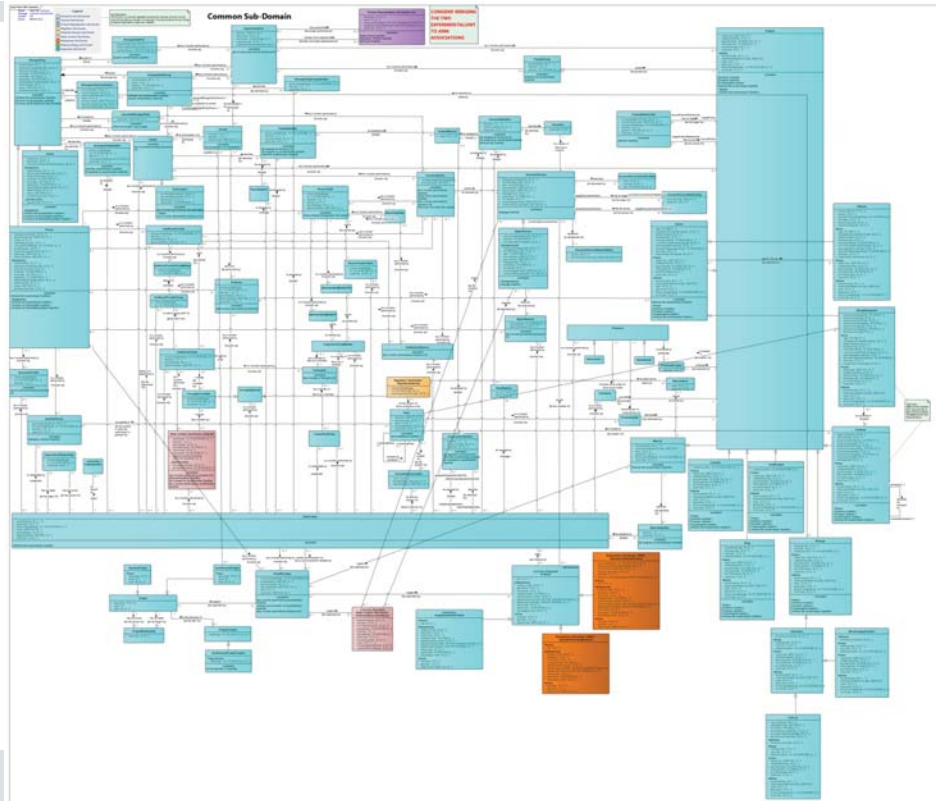
- Adverse Event Sub-Domain
- Common Sub-Domain
- Protocol Representation Sub-Domain
- Regulatory Sub-Domain
- Statistical Analysis Sub-Domain
- Study Conduct Sub-Domain
- Biospecimen Sub-Domain
- Molecular Biology Sub-Domain
- Experiment Sub-Domain

View Description:
This View shows the complete BRIDG Model (current Release) and specifically shows, for each class where it's applicable, the complete set of attributes for the class, partitioning the attributes as to whether they are "local" to the class or inherited from the class super-type hierarchy.

Please Note: This comprehensive view of the BRIDG model is not intended for users to learn the model. It is created by the BRIDG modelers to ensure model integrity. It is highly recommended that you look at the sub-domain views to learn and review the concepts and relationships in the BRIDG model.

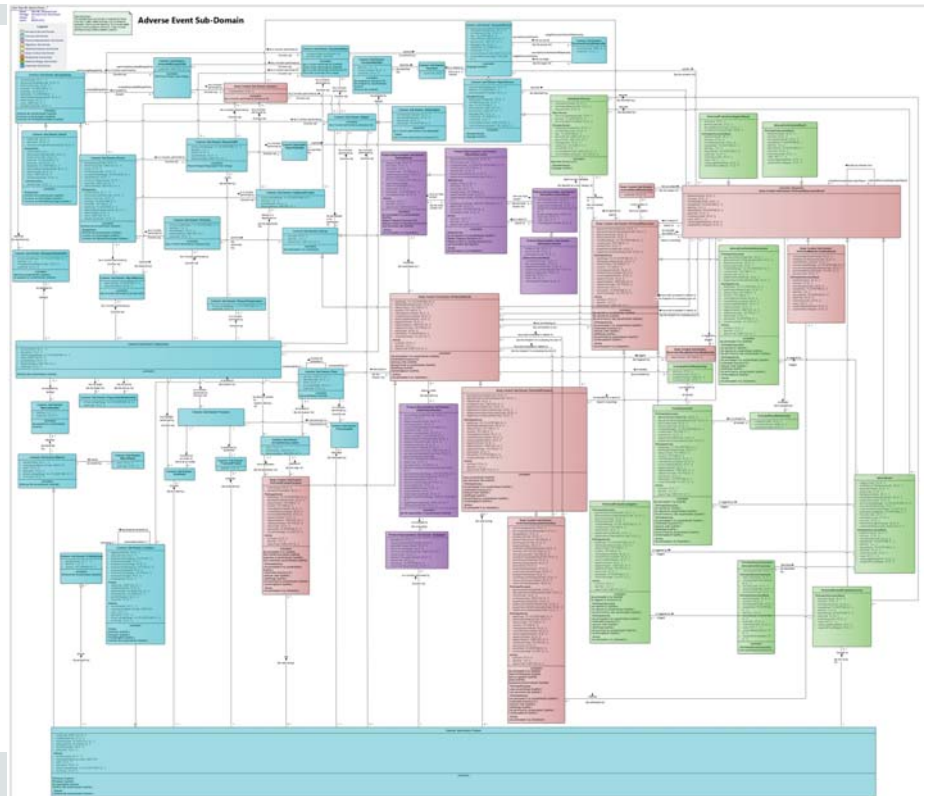


Common Sub



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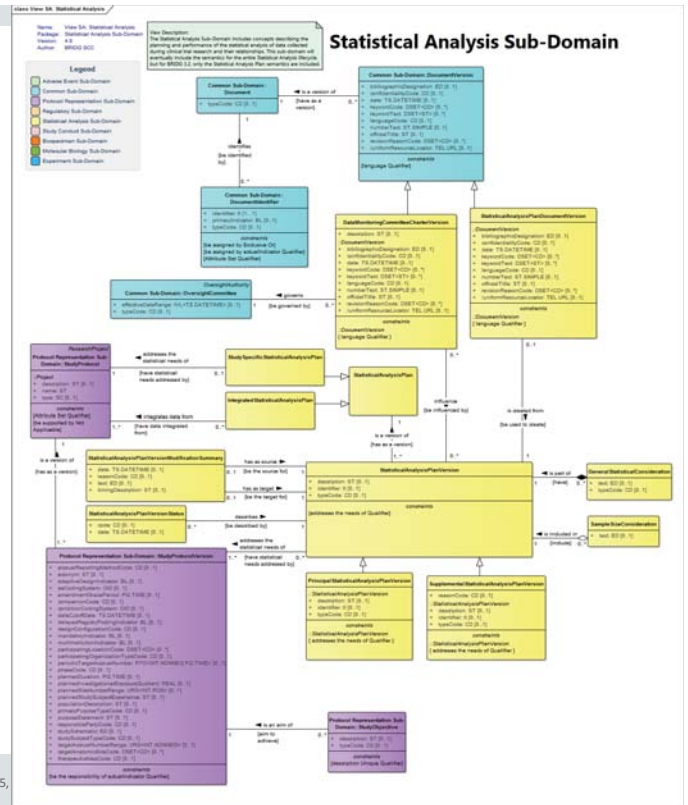
Adverse Event Sub



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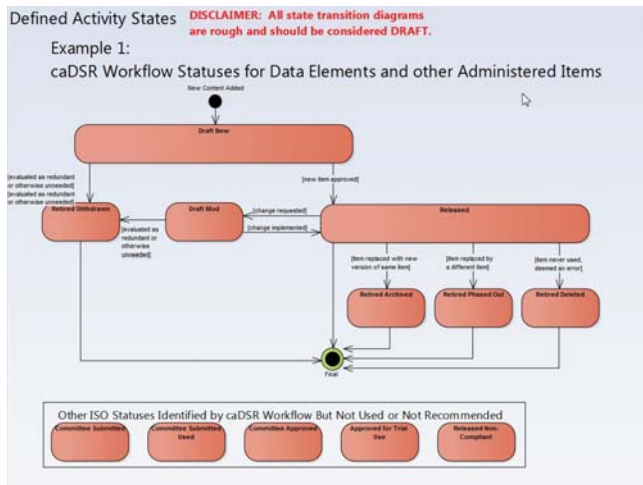
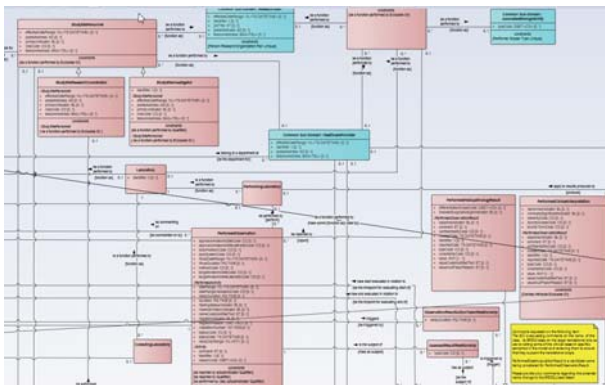
Statistical Analysis Sub Domain

- Describing the planning and performance of the statistical analysis
- Contains semantics for Statistical Analysis Plan
- Future may include entire Statistical Analysis life cycle



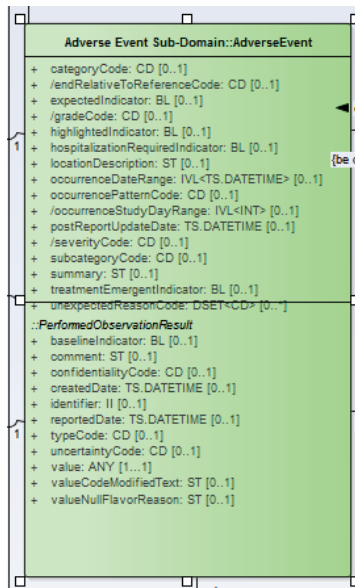
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Class & State diagrams

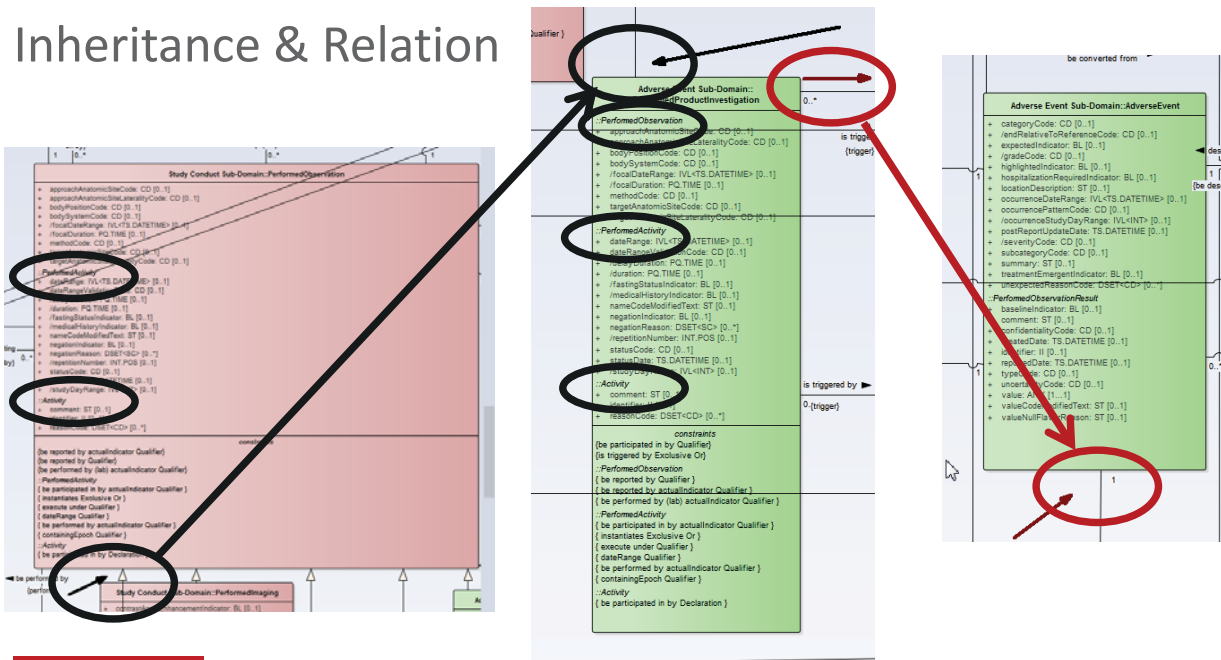


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Class & attributes



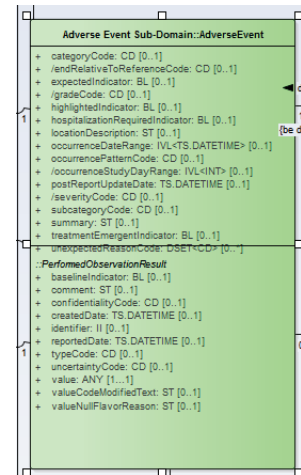
Inheritance & Relation



Data Types

Some examples – defined by HL7 ADT (Abstract Data Types)

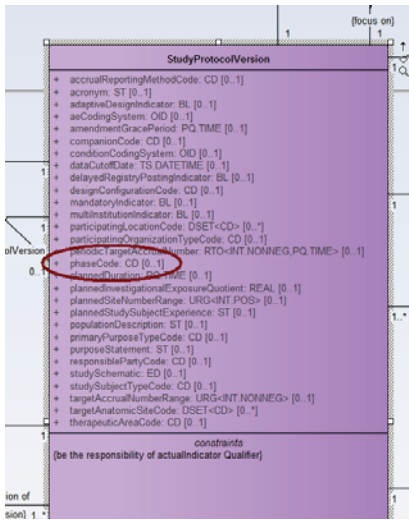
- ST, BL, INT, TS.DATETIME
- EN= Entity Name, AD = Address
- CD = Concept Descriptor (code list)
- PQ = Physical Quantity



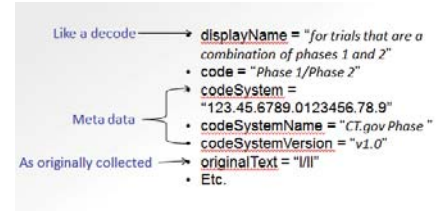
CD Concept Descriptor = code list

- A CD is a reference to a concept defined in an external code system, terminology or ontology
- Important data type as it addresses the issue of binding of vocabulary/terminology to the model
- Used in BRIDG whenever the request has been seen for a particular attribute as a need for an enumerated list of values

CD example – taken from the BRIDG training

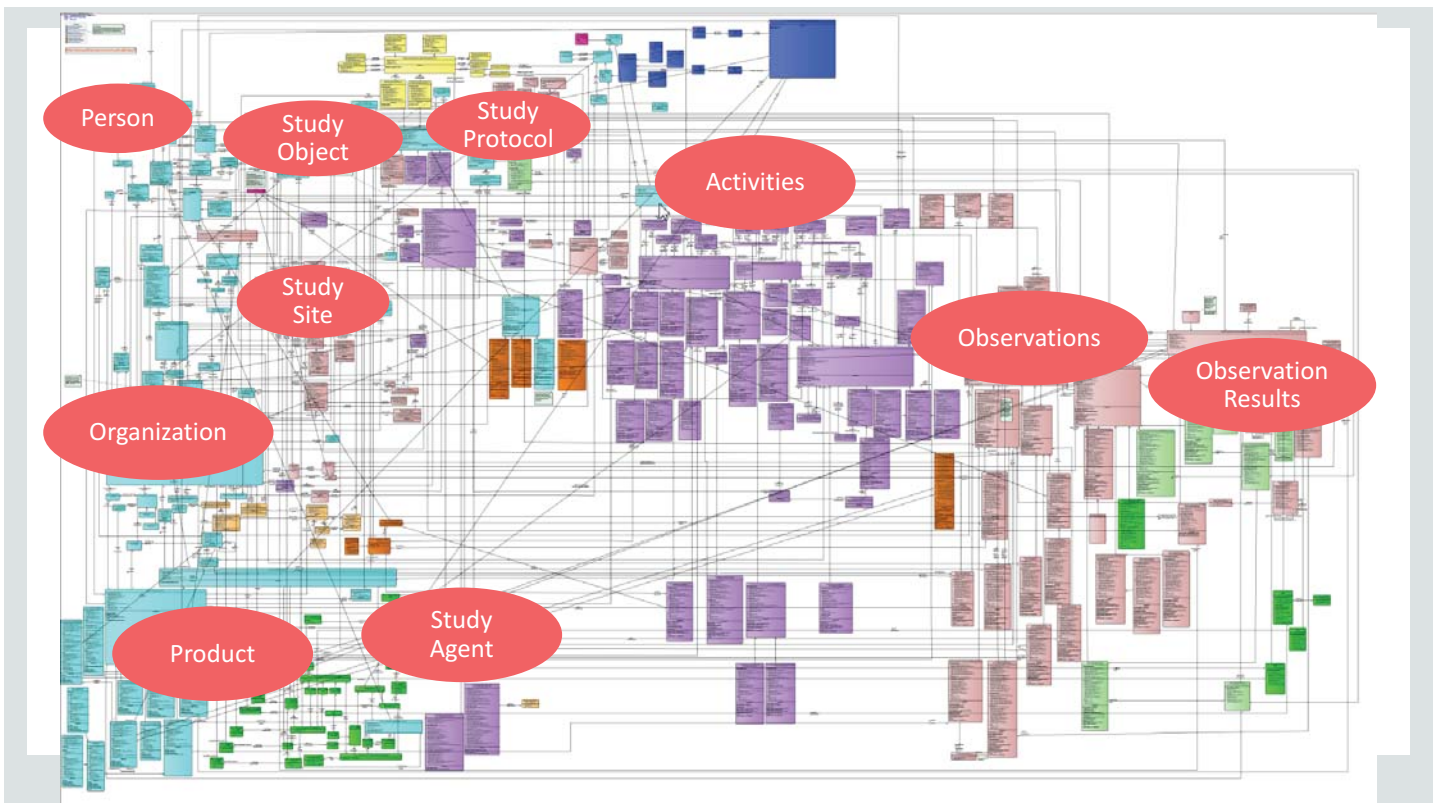
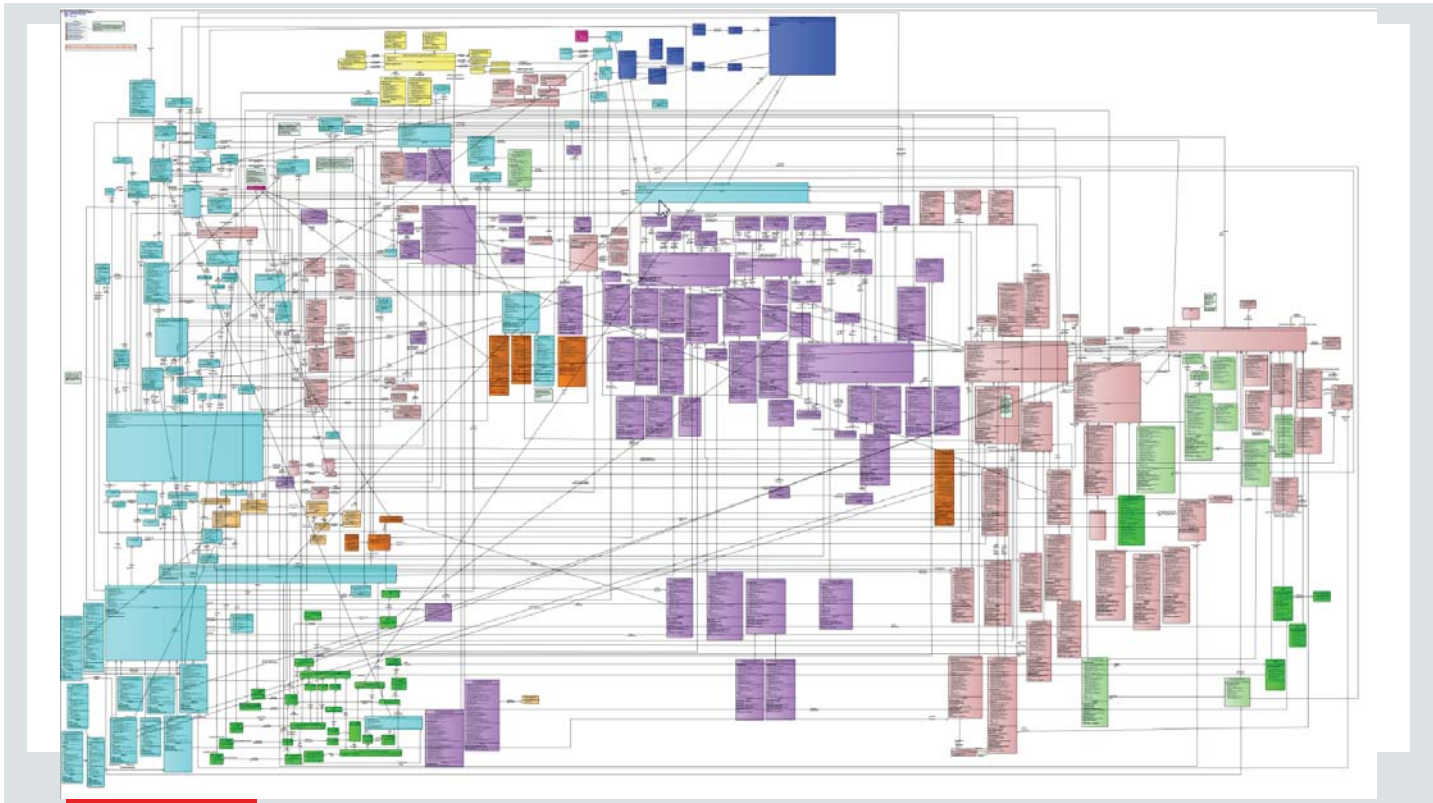


- Values for PhaseCode (defined by clinicaltrials.gov)
- N/A: for trials without phases
- Phase 0: exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, microdose studies).
- Phase 1: includes initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients
- Phase 1/Phase 2: for trials that are a combination of phases 1 and 2
- Etc.



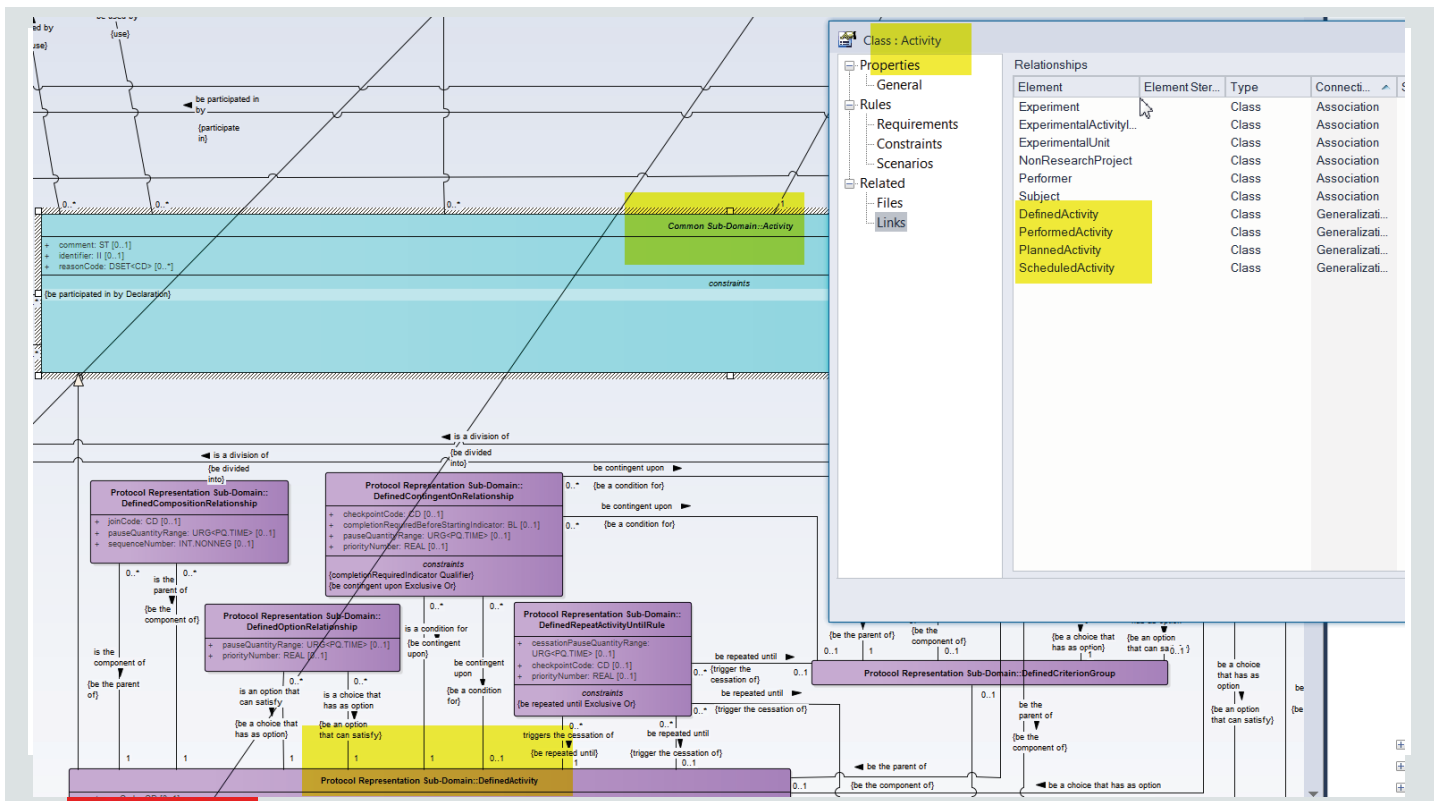
BRIDG class order has a meaning

- Model is drawn in a way to group classes together



BRIDG is ACTIVITY driven

- Right side of the BRDIG model represents all activities / acts associated with a study protocol
- 4 subtypes:
 - Defined activity (define activities during protocol Authoring)
 - Planned activity (schedule of activities for the study and potential study subjects)
 - Scheduled activity (schedule activities for an actual study)
 - Performed activity (performing those activities on the actual study subject)
- Same idea like HL7 RIMs ,moodCode' attribute of the Act class



A mapping example

Tags / tagged values

The mapping spreadsheet

BRIDG Biomedical Research Integrated Domain Group

BRIDG Mapping Spreadsheet
prepared by

BRIDG Semantic Coordination Committee (SCC)
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Smita Hastak (Samvit Solutions/NCI [C]/HL7)
Lisa Schick (Samvit Solutions/NCI [C])
Lloyd McKenzie (Gevity/NCI [C]/HL7)
Julie Evans (CDISC)
Boris Brodsky (FDA/HL7)

This document contains mappings of how source models/projects have been harmonized into the BRIDG model. Please refer to the "How to Read a Mapping Path" tab for instructions and conventions used in the mapping path column of each tab. Each source model/project version that has been harmonized with BRIDG has its own tab in the spreadsheet. Each tab indicates the specific versions of the source model /project and BRIDG model that have been harmonized. Once a harmonization is complete and that BRIDG release is finalized, mapping paths are rarely updated and may become out of date as BRIDG evolves from version to

Title Page | How to Read a Mapping Path | LSDAMv2.2.3Plus | SDTM IGv3.1.3x | PGxIG r1.0 | CTRPV3.8 | HCTv1.0 2012 | FDA HL7 SD SD DSTU2012 | Statisticsv1.0 | CTRV1.0 | CTRRv3 | NCI CRF Round 3

NCI CRF Round 3 | NCI CRF Rounds 1&2 | CTSa-HSDBv1.0 | HCTv1.0 Apr2011 | SDTM IGv3.1.2 | CDASHv1.1 | ICSRv2 | C3PRv2.9 | PSCv2.6 | caAERSv2.2 | LabViewer2.2 | CTR&R R2 | COPPA | Lab

PSC | AE | CTR&R R1 Comprehensive | SDTM IG | TDM | Study Design RMIM | HL7SP | RPS1 | C3PR | CTOM

From Mapping sheet to BRIDG

SDTM V3.1.2 to BRIDG 3.0.3

SDTM V3.1.2 (November 2008)				BRIDG R3.0.3			
SDTM Domain Prefix	SDTM Variable Name	Data Type		Class Name	Attribute Name	Data Type	Mapping Path
DM	STUDYID	Char	Unique identifier for a study.	DocumentIdentifier	identifier	II	PerformedActivity.PerformedObservation > StudyProtocolVersion > DocumentVersion.StudyProtocolDocumentVersion > Document > DocumentIdentifier.identifier
DM	DOMAIN	Char	DM: Demographics Includes information about the subject such as age, race, ethnicity, site, investigator.	StudySubject			
DM	USUBJID	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. This must be a unique number, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBJID.	SubjectIdentifier	identifier	II	Activity.PerformedActivity.PerformedObservation > SubjectIdentifier.identifier WHERE SubjectIdentifier.typeCode ="cross study identifier"
DM	SUBJID	Char	Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.	SubjectIdentifier	identifier	II	Activity.PerformedActivity.PerformedObservation > SubjectIdentifier.identifier WHERE SubjectIdentifier.typeCode ="study level subject identifier"
DM	RFSTDTCT	Char	Reference Start Date/time for the subject in ISO 8601 character format	PerformedStudySubjectMilestone	studyReferenceDateRange	IVL<TS.DATETIME>	PerformedStudySubjectMilestone.studyReferenceDateRange.IVL<TS.DATETIME> low

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Or from BRIDG to mapping ...

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TAGs for classes TAGGED VALUEs for properties

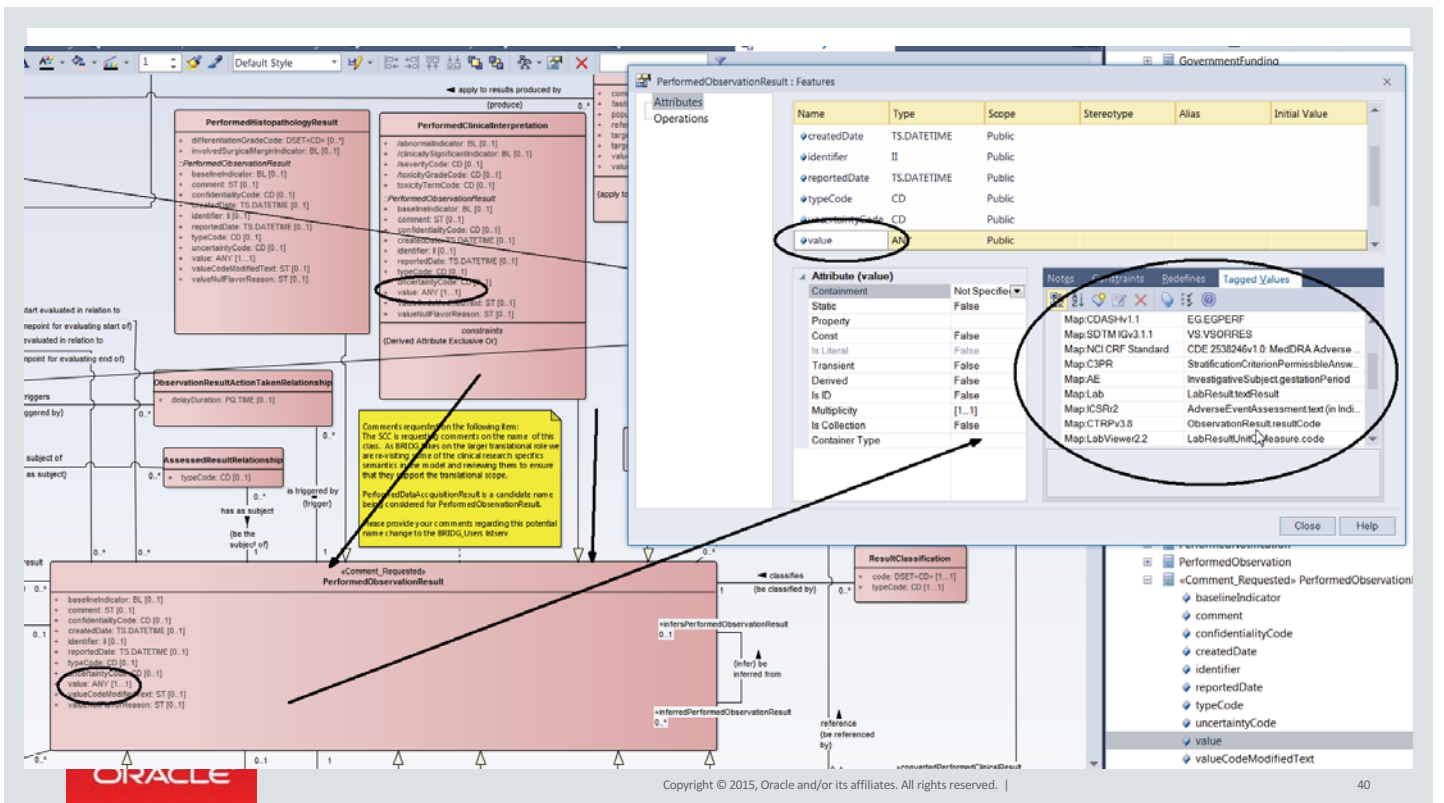
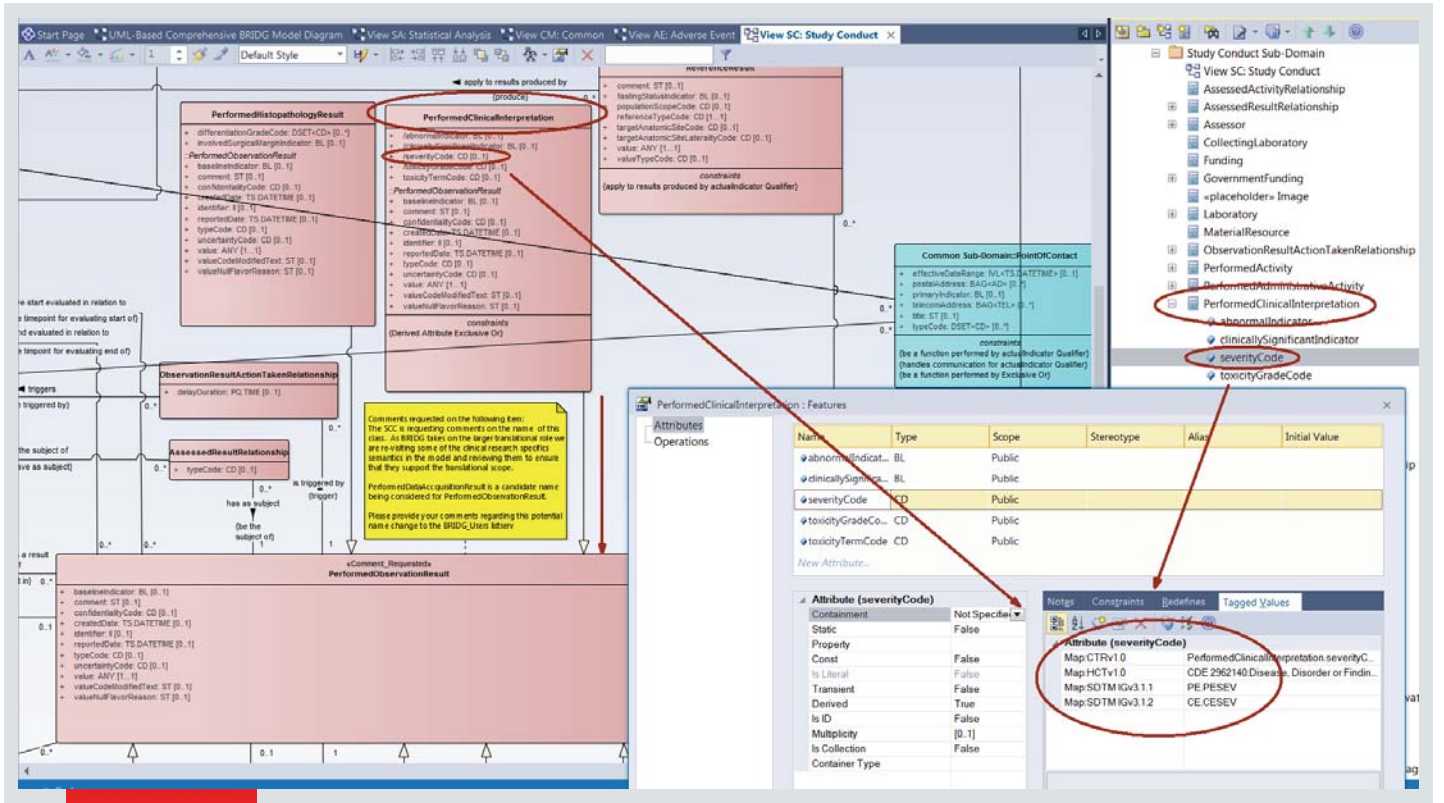
The screenshot shows the Oracle UML modeling tool interface. On the left, a class diagram for 'AdverseEvent' is visible. The 'Properties' pane shows a list of properties, with 'severityCode' highlighted. The 'Tagged Values' tab is selected, showing a list of tagged values for 'severityCode'. On the right, the 'Class (AdverseEvent)' details pane is open, showing the class definition, definition, examples, and notes. Red circles highlight the 'severityCode' property in the class diagram, the 'Tagged Values' tab, and the 'Class (AdverseEvent)' details pane.

Notes can direct further Example Notes for Severity Code Point to PerformedClinicalInterpretation

NOTE(S):
Derived from the maximum severity observed during the course of the AdverseEvent;
PerformedClinicalInterpretation.value(ANY=>CD).code
WHERE PerformedClinicalInterpretation >
PerformedObservation > DefinedObservation.nameCode =
"assess severity" AND PerformedObservation >
AssessedResultRelationship > AdverseEvent.

The screenshot shows the Oracle UML modeling tool interface with a table of objects. The search bar at the top contains 'PerformedClinicalInterpretation'. The table has columns for Object, Type, Stereotype, Scope, Status, Phase, Created, and Modified. The 'AdverseEventSeriousness' and 'PerformedClinicalInterpretation' rows are highlighted with red circles.

Object	Type	Stereotype	Scope	Status	Phase	Created	Modified
✓	Note		Public	Proposed	1.0	01.07.2012	02.07.2012
✓	Note		Public	Proposed	1.0	01.07.2012	21.08.2012
✓	Note		Public	Proposed	1.0	01.07.2012	01.07.2012
✓	Note		Public	Proposed	1.0	19.08.2012	24.08.2012
✓	Note		Public	Proposed	1.0	01.07.2012	24.08.2012
AdverseEventSeriousness	Class		Public	<none>	1.0	29.06.2010	05.03.2015
PerformedClinicalInterpretation	Class		Public	<none>	1.0	25.07.2007	27.09.2013



Hmmm



Study Data Tabulation Model Im

Mapped Group Name	Mapped Element Name
AE	AESEV

BRIDG Model
<http://www.bridgmodel.org>
Release 4.0 Release Notes
27 March 2015
Biomedical Research Integrated Domain Group (BRIDG)
prepared by
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Julie Evans (CDISC)
Boris Brodsky (FDA/HL7)

Mapping

Type	Review by	Status	Comments / Issues / Rationale	Mapping Path / Derivation	Class Name
Supported		Applied		AdverseEvent.severityCode	AdverseEvent
teD...	TS.DATETIME	Public			
	CD	Public			
e	CD	Public			
	ST	Public			
entL...	BL	Public			
pnC...	DSET<CD>	Public			

Attribute (severityCode)

Not Specified
False
False
False
False
True
False
[0..1]
False

Notes Constraints Redefines Tagged Values

Attribute (severityCode)

- Map:CDASHv1.1 AE AESEV
- Map:AE AdverseEvent.gradeOrSeverity
- Map:SDTM IGV3.1.1 AE AESEV
- Map:PSCv2.6 AdverseEvent.description
- Map:SDTM IGV3.1.2 AE AESEV
- Map:CTrv1.0 AdverseEvent.severityCode



Checkout the Mapping sheet ...



What's new in Version 4.x

New in Version 4.0

- LS DAM – Life Sciences Domain Analysis Model
 - Hypothesis driven basic and pre-clinical research as well discovery sciences
 - Collaborative engagement between NCI, HL7 Clinical Genomics WG
 - was a sibling to BRIDG for a few years
 - Integration into BRIDG to support semantic interoperability
- 3 new sub domains
 - Biospecimen
 - Experiment
 - Molecular Biology

New in Version 4.0 (cont.)

- CDISC SDTM 3.1.3
 - Include changes / add in SDTM 3.1.3 like cover of changes in trial design, inclusion of TA Oncology
- CDISC SDTM PGx (v 1.0 Domains)
 - Pharmacogenomics & Pharmacogenetics
 - Focus on genetic data for human and viral studies

BRIDG 4.0

- With the release of BRIDG 4.0, the scope of BRIDG is now officially expressed as “**basic, pre-clinical, clinical, and translational research and associated regulatory artifacts**”.
- 4.0 is the first release of BRIDG as a translational research model and therefore some of the newer sub-domains are not fully fleshed out as yet.

BRIDG 4.1

22 MAR 2016

- With **BRIDG 4.0** the scope of the BRIDG model **changed to encompass the larger translational research domain**, rather than just representing the clinical research domain.
- **Comments on this larger model** were provided **by the FDA and the Clinical Genomics community** and were resolved over the course of the last year.
- Some comments are still outstanding and will be resolved with the addition of a new subject-matter-expert-friendly view in a future release.
- Additional changes were added to the model on behalf of a vendor who is using a BRIDG-based model in a clinical trials application

BRIDG 4.1.1

2 AUG 2016

- BRIDG Release 4.1.1 is a minor release that addresses comments from the HL7 May 2016 Informative Ballot (BRIDG R2).
- The ballot brought forth 16 comments, 10 of which were deemed to be persuasive or persuasive with modifications, according to the HL7 ballot process.
- These comments resulted in a **small number of minor changes to the User's Guide and the UML Model**. Specific changes are documented in the change list contained in the release package.

Ressources

Ressources

- BRIDG home: <http://bridgmodel.nci.nih.gov/>
- HL7: <http://www.hl7.org/special/committees/bridg/index.cfm>
- EA Sparxsystems:
- UML Tutorial: http://sparxsystems.com.au/resources/uml2_tutorial/

- ISO TC-215:
http://www.iso.org/iso/home/store/catalogue_tc/catalogue_tc_browse.htm?commid=54960&published=on&development=on

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