Introduction into CDISC BRIDG
Biomdecial Research Integrated Domain Group

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CD01
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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)

Source: http://bridgmodel.nci.nih.gov/about_bridg/background
ISO & BRIDG

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

ISO/PRF 14199
Health informatics -- Information models -- Biomedical Research Integrated Domain Group (BRIDG) Model

### ISO/PRF 14199

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35.240.80: IT applications in health care technology

Including computer tomography
Quick word to UML ...

.. as it needs to be introduced quickly
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 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 showing 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]

7. Profile Diagrams
   - Profile diagrams provide a visual way of defining lightweight 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 variety 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 instants 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 communication between objects at run-time, during a collaboration instance. [Learn More]

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!?
Start here
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.
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
Class & State diagrams
Class & attributes
Class & inheritance
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

• 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 is ACTIVITY driven

• Right site 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

<table>
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<th>Title Page</th>
<th>How to Read a Mapping Path</th>
<th>LSDAmv2.2.3Pus</th>
<th>SDTM IGv3.1.3x</th>
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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 version.
TAGs for classes
TAGGED VALUEs for properties
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:

\[
\text{PerformedClinicalInterpretation.value(ANY => CD).code WHERE}
\text{PerformedClinicalInterpretation > }
\text{PerformedObservation > DefinedObservation.name Code = }
\text{"assess severity" AND PerformedObservation > AssessedResultRelationship > AdverseEvent.}
\]
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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Bonnie Bredley (FDA/HL7)

CDISC

FDA

NATIONAL CANCER INSTITUTE

Oracle
Checkout the Mapping sheet ...
What’s new in Version 4
New in Version 4

• 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 (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.
Ressources
Ressources

- **HL7**: [http://www.hl7.org/special/committees/bridg/index.cfm](http://www.hl7.org/special/committees/bridg/index.cfm)
- **EA Sparxsystems**:
Integrated Cloud
Applications & Platform Services