|  |  |  |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  | **Release 5.0 Release Notes**  https://[www.bridgmodel.org](http://www.bridgmodel.org)  <https://bridgmodel.nci.nih.gov> |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  | 31 January 2017  ***prepared by***    Wendy Ver Hoef, Smita Hastak & Julie Evans  (Samvit Solutions/NCI [C]/HL7)  on behalf of the  HL7 Biomedical Research and Regulation (BR&R) Work Group  (formerly HL7 BRIDG and RCRIM Work Groups) |  |
|  | [Description: Clinical Data Interchange Standards Consortium](http://www.cdisc.org/)[Description: U.S. Food and Drug Administration](http://www.fda.gov/) [Description: Health Level Seven](http://www.hl7.org/)  [Description: National Cancer Institute](http://www.cancer.gov/) |  |
|  |  |  |

# 

# What’s New in Release 5.0

## General Changes in Release 5.0

BRIDG Release 5.0 is a major release that includes new semantics from three different efforts listed below plus an additional set of views of existing BRIDG semantics along with an initial draft collection of value sets for imaging-related coded attributes.

### Imaging Harmonization (including parts of DICOM)

The US National Cancer Institute (NCI) has use cases that need integration and harmonization of semantics between the clinical research domain and the imaging domain.

The focus was specifically to harmonize relevant parts of the DICOM standard and an NCI project – Annotation and Image Markup (AIM). DICOM is a widely accepted ISO standard that “addresses the exchange of digital images, and information related to the production and management of those images, between both medical imaging equipment and systems concerned with the management and communication of that information.” NCI’s AIM project has created a standard means of adding information and knowledge to an image in a clinical environment, so that image content can be easily and automatically searched.

The scope of this Imaging harmonization was limited to support the following high level use cases:

* Identification of entities – person, animal, specimen, imaging study
* Image acquisition
* Image Type (modalities – CT, MR and PET)
* Annotation & Structured Reporting

One of the key aspects of this harmonization of imaging semantics is that the BRIDG modeling team has leveraged the principles of “modeling-by-reference” which essentially means that when an established standard exists in a particular domain (like DICOM for Imaging) then not all the semantics of the referenced standard will be harmonized with BRIDG. Instead the harmonization effort will focus on aligning the common semantics between the two domains to support implementable interoperability use cases. The focus was to identify the touch points between BRIDG and DICOM to support users finding sufficient commonly used, high-level imaging concepts, link the relevant parts to the clinical research context in BRIDG, and thereby allow users to identify which imaging studies to pursue at a more detailed level in DICOM.

### Vendor Semantics

A small set of new semantics was added for trial management and monitoring. This harmonization was scoped to tracking resources, countries, and subjects in a Study, etc. One of the significant changes that was made to the BRIDG model due to the requirements brought forward from the vendor was related to change in the way BRIDG models the ”identifier” classes and attributes. In past releases, many of the identifier attributes were modeled as separate classes from the class they identified. This separate class was necessary because additional identifier semantics, e.g., type code, were needed to describe the identifier. The II (Instance Identifier) data type did not include the additional semantics. For example, in past releases, the Organization class had an association to the OrganizationIdentifier class. In BRIDG 5.0, a new data type extension, the ID (Identifier) data type, has been added as a class that can be used as a data type for identifier attributes. This new ID data type includes more properties that many identifier attributes need. As a result of adding this ID data type, eleven identifier classes were deleted since the identifier attribute was moved into the identified class.

### NCI’s Surveillance Epidemiology and End Results Reporting (SEER)

The Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute (NCI) is an authoritative source of information on cancer incidence and survival in the United States. The SEER Program registries routinely collect data on patient demographics, primary tumor site, tumor morphology and stage at diagnosis, first course of treatment, and follow-up for vital status. To learn more about SEER program, visit <https://seer.cancer.gov/>

One of the main aspect of this harmonization was addition of class called “StandardOfCareDataCollection”. This harmonization now allows the BRIDG model to support use cases where clinical data is collected about patients who are not necessarily enrolled on a clinical trial. This has introduced the touch point between clinical data and clinical research data.

### New Views

One of the constructive criticisms that has been voiced about the BRIDG model is that the model is very large and complex and therefore difficult to review the semantics. This is true when someone looks at the Comprehensive UML model view of the BRIDG model. The intent of that view was purely for maintenance purposes to allow the BRIDG modeling team to ensure the integrity of the model. The Comprehensive View was never intended to be the presentation to read and understand the BRIDG model. The sub-domain views were intended to be that user-friendly and consumable view to read and learn the BRIDG model. Based on the comments received during various ballot cycles, it has become clear that the sub-domain views are also too big. In response to the comments, the BRIDG members have now actively started developing small, consumable views of the BRIDG semantics. These new views are presented in a package called “Additional Focused Views”.

Following are the 5 new views added in release 5.0:

* Oncology View (in support of NCI Oncology semantics and the CDISC Oncology domains/variables)
* SDTM 3.1.3 View
* SDTM Exposure (EX) Domain View
* SDTM Disease Response (RS) View
* SDTM Vital Signs (VS) View

### Draft BRIDG 5.0 Coded Attribute Value Sets

Another set of comments the BRIDG model has received during HL7 balloting has been the lack of vocabulary binding or recommendations for the coded attributes of BRIDG. The BR&R WG members have discussed this extensively and decided upon an approach beginning with identifying candidate value sets for the various coded attributes. Gathering this information is the first step in a new effort within the BRIDG community to work toward providing vocabulary binding, a key component of semantic interoperability. It is anticipated that value set information will continue to be collected for future versions of BRIDG and that, with the support of domain experts and a community vetting process, BRIDG will eventually include some mandatory and some optional vocabulary bindings to further support our interoperability goals. With the BRIDG 5.0 release, the BRIDG modeling team has gathered an initial collection of value sets for a small set of coded attributes – those used in the Imaging Sub-Domain.

These candidate coded attributes value sets are captured in the Excel spreadsheet included in this release. (Draft BRIDG 5.0 Coded Attribute Value Sets.xls)

## Detailed Change Lists for Release 5.0

Please refer to the detailed change spreadsheets in the release package to see lists of changed, deleted, and added attributes, classes, constraints, and associations.

# Files in R5.0 Package

The BRIDG Release Package includes all materials collected and published as a formal release of the BRIDG model. In addition, this file is available at the [BRIDG web site](https://bridgmodel.nci.nih.gov/) on the Download/View Model tab, under the Download BRIDG Releases option on the left-hand navigation panel.

The UML representation of the BRIDG model is represented in Enterprise Architect from Sparx Systems (which is an .EAP file). A UML modeling tool such as Enterprise Architect supports the development of a model as a collection of process and data semantics which are represented in multiple views (e.g. Class, Instance, and State Diagrams).

NOTE: Sparx Systems provides a "FREE" Viewer version of the Enterprise Architect software --- "Enterprise Architect Viewer". This is a read-only edition and will allow you to view the BRIDG model. The Viewer is referred to as Enterprise Architect Lite and can be downloaded from <http://www.sparxsystems.com/products/ea/downloads.html>  
  
In addition, an html version of the R5.0 model is available on the BRIDG website.

The specific file name in the Release Package in this category is:

* BRIDG 5.0 Comprehensive Domain Information Model.eap

## Report of Comprehensive UML-Based Model

The release package also contains a “pdf” report for all the static elements in the BRIDG model.

The specific file name in the Release Package in this category is:

* BRIDG 5.0 Comprehensive Domain Information Model.pdf

Users and interested parties can generate similar reports for other packages by exporting from Enterprise Architect to the “pdf” format. For assistance, please refer to the Enterprise Architect Help file.

## XMI of Comprehensive UML-Based Model

Readers interested in a serialized, non-graphical version of the model can use the XMI file that is part of the BRIDG release package. It is the representation of the model that is generated by the Enterprise Architect tool as using the XML Metadata Interchange (XMI) format.

The specific file name in the Release Package in this category is:

* BRIDG 5.0 Comprehensive Domain Information Model.xmi

NOTE: There are known problems with this format and, as such, the XMI version of the BRIDG Model is not considered to be canonical.

## Release Notes (this file)

The release package also contains a summary of changes made from the previous version of BRIDG.

The specific file name in the Release Package in this category is:

* BRIDG 5.0 Release Notes.pdf

## User’s Guide

This document covers the background and organization of the BRIDG Project as well as detailed description of the content and use of the BRIDG Model.

The specific file name in the Release Package in this category is:

* BRIDG 5.0 Users Guide.pdf

## BRIDG 4.1.1 to 5.0 Change Lists

This document provides a detailed list of every attribute, class, relationship and constraint that has been added, deleted or modified in the BRIDG model.

The specific file name in the Release Package in this category is:

* BRIDG 4.1.1 to 5.0 Change List.xls

## BRIDG Mapping Spreadsheet

This document provides a mapping of the classes and attributes (or other kinds of data elements) from source project models to classes, attributes, and associations in the BRIDG model. This document also includes additional information such as the full path of mappings for when a source concept spans more than one BRIDG class; “where clause” criteria or conditions that may apply to mappings; source model elements deemed implementation-specific; and source model elements that remain as gaps in BRIDG.

The specific file name in the Release Package in this category is:

* BRIDG Mapping Spreadsheet.xls

## Draft Collection of Vocabulary/Value Set Information for BRIDG 5.0 Imaging-Related Coded Attributes

This document provides a collection of enumerated value sets, links to value sets available online or other reference information for value sets for coded concepts in the new BRIDG 5.0 Imaging Sub-Domain. Gathering this information is the first step in a new effort within the BRIDG community to work toward providing vocabulary binding, a key component of semantic interoperability. It is anticipated that value set information will continue to be collected for future versions of BRIDG and that, with the support of domain experts and a community vetting process, BRIDG will eventually include some mandatory and some optional vocabulary bindings to further support our interoperability goals.

The specific file name in the Release Package in this category is:

* Draft BRIDG 5.0 Coded Attribute Value Sets.xls

# Acknowledgements

The BRIDG model would not be possible without the expertise and generous support of the project team members and subject matter experts that are the source of the BRIDG semantic content.

The BRIDG modeling team worked closely with a DICOM subject matter expert who provided the Imaging, DICOM and NCI AIM expertise to this harmonization effort. We thank Dr. Clunie for his extensive contributions to the BRIDG Imaging Sub-domain.

* David Clunie, MBBS (PixelMed, Inc., DICOM Editor)

The BRIDG modeling team also worked closely with the following three individuals representing vendor semantics harmonized from a clinical trials management model:

* Hugh Glover (PAREXEL Informatics / Blue Wave Informatics)
* Julie James (Blue Wave Informatics / PAREXEL Informatics)
* Jean-Henri Duteau (PAREXEL Informatics / Duteau Design)

# Known Issues

1. With the harmonization of LS DAM in BRIDG 4.0, many new life sciences structures were added in the BRIDG model. Most of these newer semantics are still not fleshed out in BRIDG 5.0 to the same level of detail as the clinical research structures. The domain expertise for life sciences research lies in the HL7 Clinical Genomics (CG) work group and that group has recently started developing a CG Domain Information Model (DIM). The BRIDG modeling team plans to work closely with the CG modeling team to ensure that the Molecular Biology sub-domain semantics of BRIDG are represented in the new CG DIM. It is likely that eventually, the Molecular Biology sub-domain will be removed from the BRIDG model and BRIDG will point to the CG DIM as a reference model for clinical genomics with harmonization of common semantics at the touch points.
2. The HL7 RIM and OWL representations of BRIDG 5.0 are not yet developed and therefore not part of this release package.

**End of Document**