



Release 5.1 Release Notes

<https://bridgmodel.nci.nih.gov>

29 March 2018

prepared by

Wendy Ver Hoef, Smita Hastak & Julie Evans
BRIDG Modeling Team
on behalf of the
HL7 Biomedical Research and Regulation (BR&R) Work Group

Note: The BRIDG Modeling Team members are funded by the US National Cancer Institute (NCI)



1 What's New in Release 5.1

1.1 General Changes in Release 5.1

BRIDG Release 5.1 is a minor release that adds semantics from the US Food and Drug Administration's Common Data Model Harmonization (CDMH) project; a new CDISC View Package, and also, several deprecated items were removed from the model as described in the BRIDG Deprecation Policy (included in the BRIDG User's Guide Section 5.8). Each of these change topics are described below.

Harmonization of the CDMH Project: The goal of the CDMH project is to build a data infrastructure for conducting research using Real World Data derived from the delivery of health care in routine clinical settings. This data infrastructure will allow researchers to simply ask research questions on much larger amounts of Real World Data than currently possible, leveraging open standards and controlled terminologies to advance Patient Centered Outcomes Research. The CDMH Project will have a BRIDG-based repository that will capture query results for de-identified aggregate and patient level data from four networks: Sentinel, PCORNet, i2b2, and OMOP.

The majority of the CDMH semantics were already present in the BRIDG Model. This harmonization added 2 new classes, 16 new attributes, and 7 new associations.

Harmonization of Anatomic Pathology Structure Report (APSR) – Work in Progress:

The BRIDG modeling team is currently working with subject matter experts (SMEs) from the HL7 Orders and Observations (O&O) Work Group and the ISO DICOM WG 26 members to harmonize the IHE's Anatomic Pathology Structured Report 2.0 (a supplement to IHE Pathology and Laboratory Medicine Technical Framework V8.0, APSR 2.0 is officially Draft for Trial Implementation IHE PaLM TF Suppl. APSR 2.0 TI (091)). The SMEs participating in this effort are some of the authors of this standard, which is based on the HL7 CDA standard. The harmonization work is in progress and work to date indicates that the majority of semantics will be supported with elements already in the BRIDG model. Some areas with existing compatibility are demographic information, medical history, procedure steps, some aspects of macroscopic/microscopic observations, and diagnostic information. At this time, the BRIDG modeling team anticipates some new elements related to anatomic pathology will be added to BRIDG and balloted in September 2018 ballot cycle.

CDISC Views Package: This is a new package in Release 5.1. There is a new view for the CDISC Lab Model. This view was built by the members of the BRIDG modeling team to facilitate the work efforts with the TransCelerate Biopharma group. The SDTM 3.1.3 view and the three sample SDTM Domain views have been moved from the Additional Focused Views package to under the CDISC Views package.

Deprecated Items Removed from Model: The deprecated items that were removed from the model are:

1. **Animal.speciesCode** - The Species of an Animal is now represented by **BiologicEntityClassification.scientificNameCode**.
2. **PlannedActivity.purpose** - This attribute is redundant and was deprecated and then removed in favor of the existing **Activity.reasonCode**.
3. **Specimen.accessionNumberText** - This semantic is more accurately derived from **SpecimenCollectionGroup.accessionNumberText** regardless of the number of specimens collected.
4. **Specimen.typeCode** - The semantic represented by the **Specimen.typeCode** attribute was clarified by the LSDAM team and actually is an identification of the activity that produced the Specimen, which means it maps to **PerformedMaterialProcessStep > DefineMaterialProcessStep.nameCode**.
5. **StudySite.accrualStatusCode** and **StudySite.accrualStatusDate** - The accrual status of a study site can overlap with the overall status of the study and study site status. The proposed solution was to eliminate the study site accrual status codes and adopt the CTRP values for study site status code.
6. Association: Each **DefinedMaterialStorage** always stores one **Specimen**. - This association was redundant since a **Specimen** can be the subject of an activity via the **Subject to Specimen** association.
7. Association: Each **PerformedAdministrativeActivity** might be performed at one **StudySite**. - This association was redundant since **StudySite** can be the subject of an administrative activity via the **Subject to Organization** association and can be a performer of an activity via the **Performer to Organization** association.

Note: The BRIDG release number on <https://bridgmodel.nci.nih.gov> is different from the HL7 BRIDG release number due to HL7 naming conventions. The corresponding release numbers are shown in the table below:

Release Date	BRIDG Website Release Name	Corresponding HL7 BRIDG Release Name
March 2018	BRIDG Release 5.1	BRIDG R4
August 2017	BRIDG Release 5.0.1	BRIDG R3
May 2017	BRIDG Release 5.0	BRIDG R3

1.2 Detailed Change Lists for Release 5.1

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

2 Files in R5.1 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](#) 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 R5.1 model is available on the BRIDG website.

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

- BRIDG 5.1 Comprehensive Domain Information Model.eap

2.1 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 5.1 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.

2.2 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 5.1 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.

2.3 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 5.1 Release Notes.pdf

2.4 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 5.1 Users Guide.pdf

2.5 BRIDG Change Lists

These documents provide a detailed list of every attribute, class, relationship and constraint that has been added, deleted or modified in the BRIDG model.

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

- BRIDG 5.0.1 to 5.1 Change List.xls

2.6 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

3 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 the following CDMH project team members:

- Mitra Rocca, FDA
- Rashedul Hasan, FDA
- Jean Duteau, Duteau Design
- Charles Yaghmour, Samvit Solutions

4 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 5.1 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 5.1 are not yet developed and therefore not part of this release package.

End of Document