



BRIDG RELEASE INFORMATION

Forward

The BRIDG Model is a Domain Analysis Model (DAM) for biomedical research. More specifically, it is an open *shared view of the dynamic and static semantics* of a common domain-of-interest, focused on the domain of *protocol-driven research and its associated regulatory artifacts*. The BRIDG model was initiated through the Clinical Data Interchange Standards Consortium (CDISC), a global standards development organization, to ensure that the standards developed in the clinical research domain would be harmonized with each other and that they would appropriately harmonize with the HL7 Reference Information Model (RIM) to support a link between medical research and healthcare. Shortly after its initiation by CDISC, the US National Cancer Institute (NCI), Health Level 7's (HL7) Regulated Clinical Research Information Management Technical Committee (RCRIM) Work Group and the US Food and Drug Administration (FDA) joined the effort to build this model. In early 2010, the BRIDG model became a standard through the CDISC Standards Development Process. The BRIDG model is currently at Release 3.0.1, which is being balloted through the ISO Joint Initiative Council (JIC) process.

This document is being balloted through reference to the BRIDG model at www.cdisc.org/bridg, which is a dynamic model. The Clinical Data Interchange Standards Consortium (CDISC) is the lead organization for taking this standard through the ballot process.

Introduction

The Biomedical Research Integrated Domain Group (BRIDG) Model is a domain analysis model intended to represent a shared view of the semantics of the domain of protocol-driven research. This document is being balloted through reference to the BRIDG model (www.cdisc.org/bridg), which is a dynamic model.

The goal of the BRIDG Project is to produce a *shared view of the dynamic and static semantics* of a common domain-of-interest, specifically the domain of *protocol-driven research and its associated regulatory artifacts*.

A shared semantic view is essential if the clinical research community, both for itself and also as part of the larger Healthcare and life sciences communities, is to achieve *computable semantic interoperability (CSI)*, i.e. the ability for information systems to exchange at a machine-to-machine level the meaning (rather than simply the structure) of data and/or to effectively combine functionality across machine/system boundaries. Stated another way, in order to realize the various data interchange and application interactions that are known by members of the BRIDG stakeholder organizations to be requirements for CSI, a *shared view of dynamic and static semantics must be established*.

Through the efforts of the BRIDG Project, this shared view is expressed as a collection of visual diagrams which are, in turn, expressed using the iconography and grammar of the Unified Modeling Language (UML) and Health Level 7 (HL7) diagramming convention. This set of visual diagrams plus the underlying inter-diagram relationships, definitions, explanations, and examples (instance diagrams which illustrate the semantics of the diagrams in more detail) are collectively referred to as the BRIDG Model.



Biomedical Research Information Domain Group (BRIDG) Model

1 Scope

The BRIDG Model Standard is an instance of a construct often referred to as Domain Analysis Model (DAM) or “problem space model.” The term “analysis” refers to the fact that the model is specifically constructed to be *implementation-independent*, i.e. the semantics of the model are restricted to those that characterize the “problem domain” as described by domain experts. In particular, a DAM specifically excludes semantics that are introduced based on a particular “solution space” that can be built to solve the stated problem. Thus, *one or more* “solution space models” can be built to support all or part of a single problem space model. The term “domain” indicates that the semantics of the model-in-question are restricted to those that collectively define a clearly bounded domain-of-interest. In the case of the BRIDG Model, the domain-of-interest (scope) is formally defined as:

Protocol-driven research and its associated regulatory artifacts,

i.e. the data, organization, resources, rules, and processes involved in the formal assessment of the utility, impact, or other pharmacological, physiological, or psychological effects of a drug, procedure, process, subject characteristic, or device on a human, animal, or other subject or substance plus all associated regulatory artifacts required for or derived from this effort, including data specifically associated with post-marketing adverse event reporting.

This Standard does not specify the implementation details of how to use BRIDG.

2 Normative References

The BRIDG Model Standard Release 3.0.1 is available on the CDISC website at www.cdisc.org/bridg.

3 Terms and Definitions

For the purposes of the international standard, all terms and definitions can be found in the model documentation on the CDISC website at www.cdisc.org/bridg.

4 Symbols and abbreviations

For the purposes of the international standard, the following abbreviations apply.

- BRIDG – Biomedical Research Information Domain Group
- CDISC – Clinical Data Standards Consortium
- DAM – Domain Analysis Mode
- FDA – Food and Drug Administration
- HL7 – Health Level 7
- NCI – National Cancer Institute
- RCRIM – Regulated Clinical Research Information Management

5 Requirements

The requirements for this international standard came from projects that contributed semantic content to the standard. These requirements are documented in the model through the use of “tags” in each class and attribute (and many an association as well). These tags indicate the source project element from which the concept was derived or to which the element maps. More information about the projects contributing to BRIDG content can be found in the [BRIDG 3.0.1 User’s Guide](#) in the section entitled “Projects Contributing to the BRIDG Model”.

6 Overview of the Content of the BRIDG Model Standard

The BRIDG model consists of multiple layers that address the needs of both domain experts and technologists. In particular, there is an ‘upper layer’ of multiple sub-domain models (e.g. Protocol Representation, Study Conduct, Adverse Event, and Common) in which each sub-domain will be much more ‘user friendly,’ and a second, ‘lower’ level which will be a robust model with the appropriate conventions to ensure non-ambiguous RIM mapping. In addition, a ‘middle layer’ has been added that shows the comprehensive view of the sub-domain models. One of the components of this middle layer is an OWL representation of BRIDG. OWL (Web Ontology Language) is a knowledge representation language for authoring ontologies. OWL has been used to provide a means of validating the semantics of BRIDG against other ontologies (e.g., the HL7 Reference Information Model (RIM)). In addition, a published OWL version of BRIDG will also be maintained in the near future. Figure 1 below depicts this new Release 3.0+ approach.

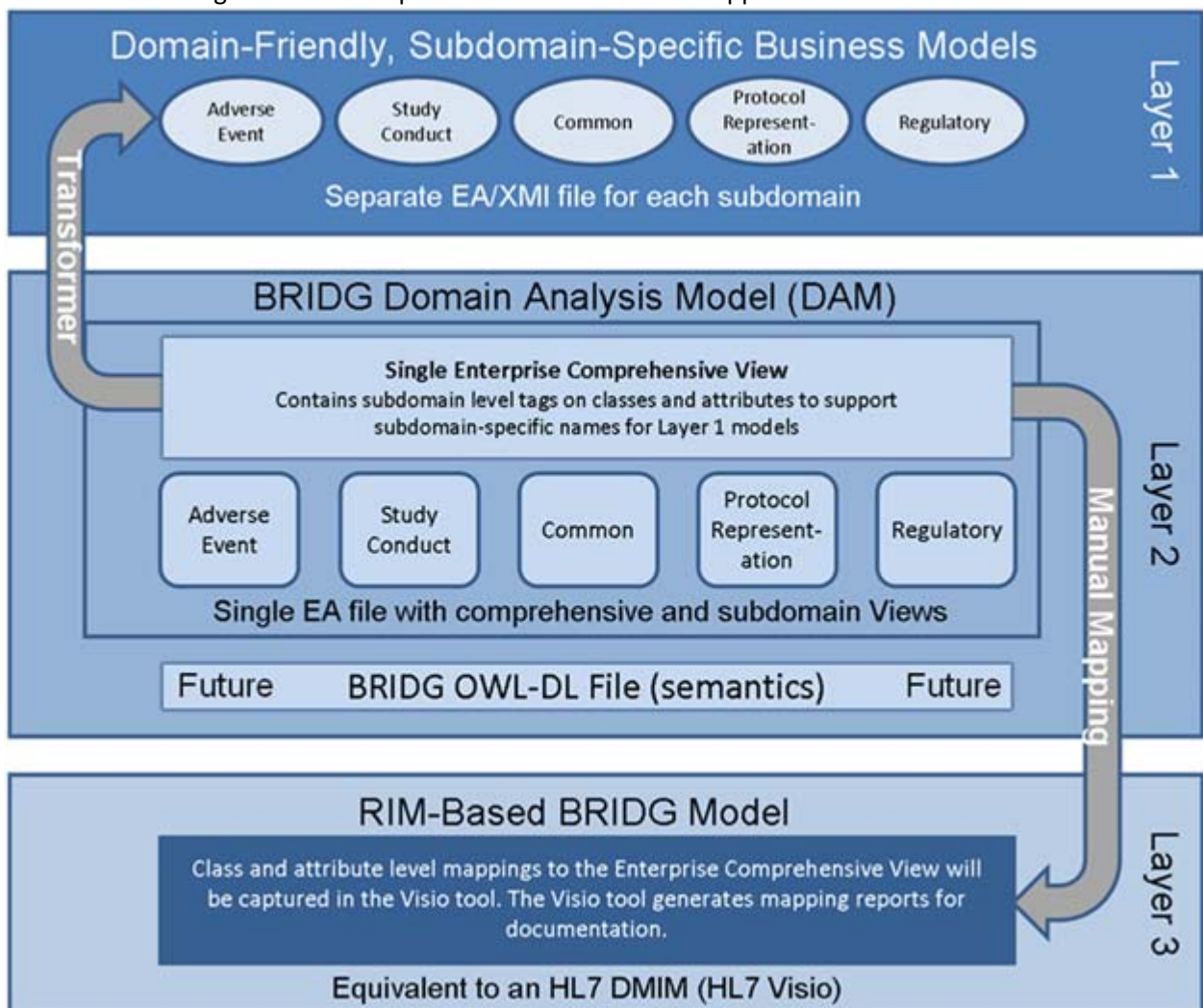


Figure 1: Diagram depicting the BRIDG Release 3.0+ approach

More detail about BRIDG and its contents is available in the [BRIDG 3.0.1 User's Guide](#). The BRIDG Release Package includes all materials collected and published as a formal release of the BRIDG model. These artifacts are gathered in a single package (ZIP file) and posted at www.cdisc.org/bridg. You can also download the model in parts as described in this document.



6.1 UML-Based Models

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

- NOTE: A viewer which enables full traversal and inspection of the complete BRIDG model can be downloaded from the Sparx Systems website: (<http://www.sparxsystems.com.au/>).

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

- BRIDG 3.0.1 Comprehensive Domain Analysis Model.EAP, which is available [here](#).
- The following sub-domain models are available [here](#):
 - BRIDG 3.0.1 Adverse Event Sub-Domain Model.EAP
 - BRIDG 3.0.1 Common Sub-Domain Model.EAP
 - BRIDG 3.0.1 Protocol Representation Sub-Domain Model.EAP
 - BRIDG 3.0.1 Regulatory Sub-Domain Model.EAP
 - BRIDG 3.0.1 Study Conduct Sub-Domain Model.EAP

6.2 RIM-based Models

The RIM-based part of the BRIDG model is represented in files with the JPEG format, which are images of the Visio (VSD) files created in the HL7 Visio Tool.

While the BRIDG HL7 models are “standard” HL7 models, they are not intended to be used directly as the foundation for exchanging messages. Instead, they serve as a basis of discussion with other HL7 groups who are modeling content relevant to BRIDG. By having the BRIDG semantics clearly expressed in HL7 terms, it will be easier to ensure that BRIDG requirements are incorporated in the various HL7 standards specifications related to the domains covered by BRIDG. For this reason, this part of the model is being presented using JPEG rather than schema, Visio, or Management Information Format (MIF) files.

The RIM-based models are in the BRIDG RIM Model directory of the Release Package. The document summarizing the background on the content of the RIM models, how they're organized, filename conventions, etc. is:

- BRIDG RIM Representation.pdf

The RIM-based models are available [here](#).

6.3 Report of Comprehensive UML-Based Model

The release package also contains a rich text format (RTF) report for all the static elements in the BRIDG model. This was generated from the Enterprise Architect file and can be viewed with Microsoft Word.

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

- BRIDG 3.0.1 Comprehensive Domain Analysis Model.RTF

This report is available [here](#).

Users and interested parties can generate similar RTF reports for other packages by following the steps listed below:

- Highlight the desired package in the Project Browser.
- Right click on the package and select Documentation -> Rich Text Format (RTF) Report.



- Click Switch Generator.
- For Output Filename, click the browse (...) button to locate the folder and file name in which you wish to save the RTF report.
- Select the desired items you wish to appear in the RTF report from the “For each Object Include” section.
- To include the diagrams in the RTF report, click the “Embed Diagrams in Document” box under “Options”.
- Select the desired “Diagram format” from the radio buttons.
- Click Create under the “Document” section.
- A success message will appear when generation is complete.

6.4 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 somewhat-less-than-standard XML Metadata Interchange (XMI) format.

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

- BRIDG 3.0.1 Comprehensive Domain Analysis Model.xmi

This XMI file is available [here](#).

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

6.5 Release Notes

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

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

- BRIDG 3.0.1 Release Notes.doc

The Release Notes are available [here](#).

6.6 User’s Guide

Each release package contains an up-to-date version of this document.

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

- BRIDG 3.0.1 User’s Guide.doc

The Release Notes are available [here](#).

6.7 BRIDG Domain Analysis Static Model Style Guide

This document provides guidance to developers of domain analysis models which contribute to and are harmonized with the BRIDG Static Model; provides guidance to the BRIDG Semantic Coordination Committee (SCC) for use in developing the BRIDG Static Model, and to serve as a set of rules by which the BRIDG and contributing sub-domain models can be assessed to be well-formed.

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

- BRIDG Domain Analysis Static Model Style Guide HTML (folder)
- BRIDG Domain Analysis Static Model Style Guide.docx
- BRIDG Domain Analysis Static Model Style Guide.EAP
- BRIDG Domain Analysis Static Model Style Guide.pdf

The Style Guide is available [here](#).