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

*Informatique de santé — Modèle d'information — Modèle de groupe
de domaine intégré de recherche biomédicale (BRIDG)*

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 215, *Health informatics*.

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Introduction

The Biomedical Research Integrated Domain Group (BRIDG) model was developed in response to a growing global demand for solutions to help enhance the opportunities to more closely integrate medical research information with healthcare, as well as integrate information within medical research. Currently, clinical research data processes use a variety of meanings, formats, and data types that inhibit the ability and potential to more widely share, integrate, and disseminate clinical research data resulting in slowing, and in many cases, dead-ending, promising drug discovery and development processes. Vast bodies of medical knowledge data either do not exist in an electronic format that is useful for today's dynamic decision support systems or are electronic, but are locked into discrete proprietary systems. Once freed, information that is locked away in static documents and discrete databases is able to flow through the processes of medical research. In an ideal world, critical data could be read, accessed, and aggregated by any tool at any point in the process. The tools would become the effective means of communication crossing all the existing boundaries and would enable automation of many procedures that currently take place manually. Removing the time-consuming procedure of translating and transcribing data contained in dissimilar and proprietary information stores would allow scientists to focus on science and innovation.

In order for all of this to become reality, medical research data need to be machine-readable and semantically interoperable.

The BRIDG model provides an approach to remove semantic ambiguities present in the world of medical research. As a domain analysis model (DAM), BRIDG is intended to represent a shared view of the semantics of the domain of protocol-driven research and its associated regulatory artefacts. The need for this International Standard came as a result of various projects which contributed to its semantic content. These source projects 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 elements from which the concept was derived or to which the element maps.

More information about the projects contributing to the BRIDG content can be found in the BRIDG user's guide in the section entitled "Projects Contributing to the BRIDG Model" and in the BRIDG mapping spreadsheet (available at: <http://www.cdisc.org>).

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

1 Scope

This International Standard defines a set of models collectively referred to as the Biomedical Research Integrated Domain Group (BRIDG) model for use in supporting development of computer software, databases, metadata repositories, and data interchange standards. It supports technology solutions that enable semantic (meaning-based) interoperability within the biomedical/clinical research arena and between research and the healthcare arena. The clinical research semantics are represented as a set of visual diagrams which describe information relationships, definitions, explanations, and examples used in protocol-driven biomedical research. These diagrams are expressed using the iconography and grammar of the Unified Modelling Language (UML), the HL7 Reference Information Model (RIM), and a Web Ontology Language (OWL).

This International Standard establishes the links between protocol-driven research and its associated regulatory artefacts including 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 along with all associated regulatory artefacts required for or derived from this effort, including data specifically associated with post-marketing adverse event reporting.

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2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/HL7 21731, *Health informatics — HL7 version 3 — Reference information model — Release 4*

BRIDG Model, *UML-Based Comprehensive Model Diagram*¹⁾

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

adverse event

any unfavourable and unintended sign, symptom, disease, or other medical occurrence with a temporal association with the use of a medical product, procedure, or other therapy, or in conjunction with a research study, regardless of causal relationship

EXAMPLE Death, back pain, headache, pulmonary embolism, heart attack.

3.2

attribute

descriptive feature of a *class* (3.3) depicted as being contained within the class

3.3

class

concept of primary importance, i.e. the domain of interest

1) Available at <http://www.cdisc.org/bridg>.

3.4
domain analysis model
DAM

abstract representation of a subject area of interest that is the basis for development of lower-level design artefacts for computer software, databases, or data exchange standards

Note 1 to entry: In this case, the subject area of interest is protocol-driven research.

3.5
unified modelling language
UML

standardized general-purpose modelling language used to specify semantic requirements for a particular domain

3.6
web ontology language
OWL

web-based language designed for use in applications that need to process the content of information

3.7
web ontology language – description logic
OWL-DL

family of knowledge representation languages or ontology languages for authoring ontologies or knowledge bases

4 Abbreviated terms

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CDISC	Clinical Data Interchange Standards Consortium
DAM	domain analysis model ISO 14199:2015
FDA	Food and Drug Administration
HL7	Health Level Seven Inc.
NCI	National Cancer Institute
OWL	web ontology language
OWL-DL	web ontology language – description logic
RIM	Reference Information Model
SCC	Semantic Coordination Committee
UML	Unified Modelling Language

5 Overview of conceptual representations of the BRIDG model

The BRIDG model is a formal domain analysis model (DAM). DAM can be defined by the following characteristics:

- an implementation-independent view of a domain of interest;
- shared understanding of concepts;
- use of domain terminology, understandable to domain experts who may have little or no information technology knowledge, but are a primary consumers;
- unambiguous definitions;

- use of complex data types designed specifically for the domain of focus, in the case of this International Standard, the clinical research area of healthcare;
- good modelling practices;
- built by analysts and subject matter experts who develop consensus.

The BRIDG model is a conceptual model from which detailed design level artefacts for computer-related systems can be built. At present, this domain analysis model is focused on the static (or data) semantics of the domain of clinical research that is the representation of the structures of and relationships between information within the domain. Therefore, the majority of domain semantics are represented as UML class diagrams.

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 the domain experts. The BRIDG model specifies the use of tags in each class and attribute (and many an association as well). These tags indicate the source project elements from which the concept was derived or to which the element maps.

The multiple representations specified in this International Standard are in accordance with the models specified in the BRIDG model and form an integral part of this International Standard. The following representations of the model are (see [Figure 1](#)):

- the canonical representation comprises a set of UML models (class diagrams) of all the harmonized semantics. There is one large comprehensive UML model and six sub-domain specific model views;
- the HL7 representation comprises several HL7 models representing the harmonized semantics in accordance with ISO/HL7 21731 using unambiguous RIM constructs;
- the ontological representation comprises a single OWL file and is intended to be used for semantic validation and inferencing.

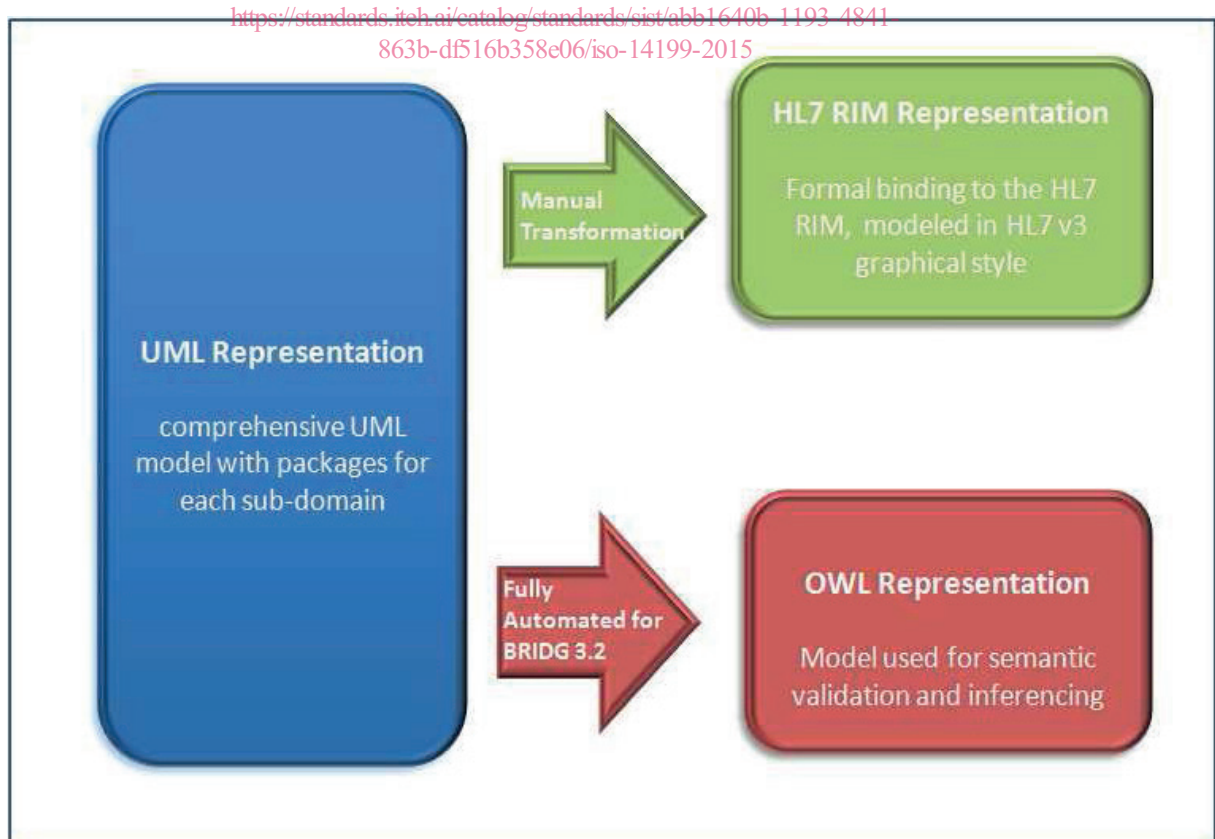


Figure 1 — Diagram depicting the BRIDG multi-representation approach