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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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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword

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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).

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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*.

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).

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.

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 ontololgies or knowledge bases

4 Abbreviated terms

CDISC	Clinical Data Interchange Standards Consortium
DAM	domain analysis model
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):

a) 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;

b) the HL7 representation comprises several HL7 models representing the harmonized semantics in accordance with ISO/HL7 21731 using unambiguous RIM constructs;

c) the ontological representation comprises a single OWL file and is intended to be used for semantic validation and inferencing.

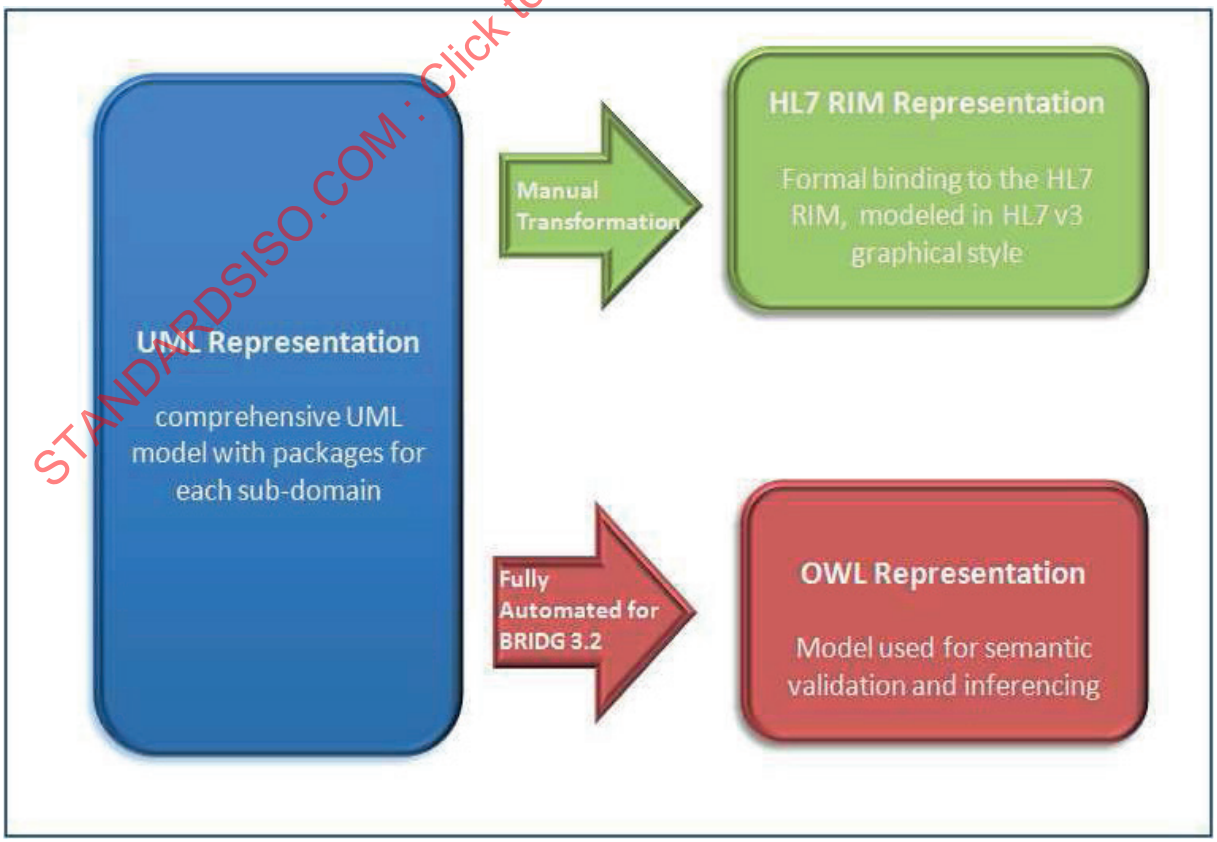

Figure 1 — Diagram depicting the BRIDG multi-representation approach

6 UML-based canonical representations

6.1 General considerations

The UML representation is considered to be the canonical representation of the BRIDG model. UML offers a variety of diagrams to visually represent the semantics. BRIDG primarily uses class and instance diagrams to visualize the data semantics of clinical research.

There is one large comprehensive UML model and six sub-domain specific model views. The comprehensive model is large and complex so the sub-domain views were created to allow for easier access and understandability. The sub-domain views which are described more fully in 6.2 are the following:

a) common;

b) adverse event;

c) protocol representation;

d) regulatory;

e) statistical analysis;

f) study conduct.

Other sub-domains may be defined as needs arise.

6.2 Sub-domain UML views

6.2.1 Common

This sub-domain defines the semantics that are common to all (or most) of the other sub-domains. Most of the content not only spans clinical research, but also might be common to any healthcare-related domain analysis model and includes semantics for such things as people, organizations, places, and materials.

The common sub-domain is not intended for any one specific audience.

6.2.2 Adverse event

This sub-domain consists of safety issues involving people or products. It also includes safety-related activities during or after a research protocol such as post-market adverse event reporting.

The adverse event sub-domain is intended for those involved in safety-related activities such as detection, evaluation, follow-up, and reporting.

6.2.3 Protocol representation

This sub-domain focuses on the characteristics of a study and the definition and association of activities within the protocols. It also includes the definitions of the roles that participate in those activities.

The protocol representation sub-domain is intended for those involved in the planning and design of a research protocol. The majority of business requirements have come from those involved in clinical trial protocols.

6.2.4 Regulatory

This sub-domain was developed on the basis of the documentation required for a product submission to the US Food and Drug Administration (FDA), but not restricted to FDA. The regulatory sub-domain is intended for those involved in the creation and review of submissions to regulatory authorities (aside

from safety-related submissions which are covered in the adverse event sub-domain). The majority of business requirements come from the regulated product submission (RPS) model.

6.2.5 Statistical analysis

This sub-domain consists of the concepts describing the planning and performance of the statistical analysis of data collected during clinical trial research and their relationships.

The statistical analysis sub-domain is intended for those involved in statistical aspects of the clinical research process.

6.2.6 Study conduct

This sub-domain focuses on the activities of conducting the study as well as the results from those activities.

The study conduct sub-domain is intended for those involved in the execution of a research study. The majority of business requirements have come from those involved in clinical trials.

6.3 UML-based models and views

The BRIDG Model UML Representation includes the complete set of definitions, attributes, associations, constraints, and mappings for each class. The BRIDG model is available in the following formats.

— HTML: The html format requires an Internet browser for viewing. This format is included with this International Standard (view the html format at htto://bridgmodel.nci.nih.gov/files/BRIDG_Model_3.2_html/index.htm).

— The following formats are available in the release package via www.cdisc.org/bridg.

  — EAP file format: The EAP file format is used by the modelling software tool Enterprise Architect. 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/).

  — Microsoft Word®[2)] file format: The Word file is generated from the EAP file format using the Enterprise Architect tool.

  — XMI file format: 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.

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

7 RIM-based HL7 representation

7.1 General considerations

The HL7 Reference Information Model (RIM) is a highly abstract comprehensive information model for the “healthcare domain”. The healthcare domain is interpreted broadly encompassing such areas as

— clinical care (inpatient and outpatient),

— healthcare administration,

— reimbursement,

2) Microsoft Word is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

— community care,

— veterinary care,

— genomics, and

— imaging.

Due to its breadth, the RIM tends to use generic class, attribute, and association names that are not necessarily domain-friendly. In addition, the RIM is completely free of the constraints and business rules that apply to domain-specific models. Its purpose is to provide a single set of reference semantics that can be leveraged across all healthcare domains. Additional, more specific, models are then created with strict derivation relationships to the RIM to support the implementation of communication interfaces.

Although the RIM is, for the most part, relatively free of implementation details, it is not a DAM because as mentioned, it is not readily understandable by domain experts in any one of the listed domains (e.g. "Where are vaccinations in the RIM?", "How do I represent a provider credential?", and "Where is an SNP found?"). This arises from the requirement that the RIM be an abstraction of cross-domain semantics. However, certain BRIDG stakeholders require that BRIDG semantics be expressible in HL7 v3 XML.

Since the HL7 representation is a representational view of the semantics in the canonical representation using HL7 syntax, it is important to ensure the underlying semantics in the HL7 representation and the canonical representation are synchronized. There are no tools to automatically generate the HL7 models, therefore qualified HL7 modellers should perform this transformation manually.

7.2 RIM-based models

In the BRIDG model, the RIM-based representation is defined in accordance with ISO/HL7 21731. The RIM-based part of the BRIDG model is represented in JPEG-formatted files, which are images of the Visio®[3] (VSD) files created in the HL7 Visio tool.

The RIM-based models are represented in the following view file formats in the BRIDG release model:

— Excel®[4];

— JPEG;

— HTML.

The organization, filename conventions, and background of the content of the RIM models are given in the BRIDG RIM Representation.pdf.[1]

The mapping from UML to RIM is specified in an Excel file, (BRIDG UML to RIM Mapping.xls).[1]

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 modelling content relevant to BRIDG. This permits the expression of BRIDG semantics clearly in HL7 terms and can easily be incorporated into 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.

3) Visio is the trade name of a product supplied by Microsoft. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product named. Equivalent products may be used if they can be shown to lead to the same results.

4) Excel is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

