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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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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 document 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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This document was prepared by Technical Committee ISO/TC 215 *Health informatics.*

This second edition cancels and replaces the first edition (ISO 14199:2015), which has been technically revised.

The main changes are as follows:

— in the Introduction a description was added about the difference between this document and the BRIDG model, which is predominantly represented as a large UML Model, not captured in this document;

— the main differences between BRIDG version 3.2 and BRIDG version 5.3.1 have been identified;

— a sentence was added in 9.1 indicating that all artefacts of the BRIDG model are downloadable from the BRIDG website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

The Biomedical Research Integrated Domain Group (BRIDG) Model is a collaborative effort engaging stakeholders from the Clinical Data Interchange Standards Consortium (CDISC), the HL7 BRIDG Work Group, the US National Cancer Institute (NCI), the US Food and Drug Administration (FDA), and the International Organization for Standardization's (ISO) Technical Committee on health informatics, TC 215. The BRIDG model was developed to closely integrate medical research information with healthcare, as well as integrate information within medical research. Clinical research data processes use a variety of meanings, formats, and data types that inhibit the ability and potential to share, integrate, and disseminate clinical research data, thus slowing and, in many cases, 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 can flow through the processes of medical research. In an ideal world, critical data can be accessed, read, 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. For this to become reality, medical research data must be machine-readable and semantically interoperable.

The BRIDG model provides an approach to remove semantic ambiguities present in medical research. The 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 BRIDG became clear when various source projects contributed semantic content which was not interoperable. These source projects are documented in the model using tags in each class and attribute as well as other associations. These tags indicate the source project elements from which the concept was derived or to which the element maps.

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[2] and the Download Release Packages & Browse Online page on the BRIDG website[2] for a table listing the projects that were harmonized in each version throughout BRIDG's history.[2] The background page under the About tab includes an overview of the history of the BRIDG model noting contributing projects.

Since BRIDG v3.2, there have been a few versions and many model changes. The current version, BRIDG v5.3.1, is now a complex, 300+ class model with hundreds of attributes and relationship, definitions and examples, etc., all captured in a Unified Modelling Language (UML) tool called Enterprise Architect. It is also available in an XMI format export, and is accompanied by a User's Guide, a mapping spreadsheet detailing use cases for all the semantics and a change list identifying all the changes from v3.2 to v5.3.1.

The key differences between the 2015 version of BRIDG (v3.2) and the latest version of BRIDG (v5.3.1) can be summarized as follows:

— harmonization of models, projects and standards with the BRIDG model;

— new semantics added as a result of model harmonization include a range of topics in the areas of life science, SDTM 3.1.3, 3.2 and Pharmacogenomic, Pharmacogenetics domains, clinical research organization administration, and imaging and annotation;

— artefacts updated include pertinent files from the release package for BRIDG 5.3.1 and a report detailing the differences between BRIDG 3.2 and BRIDG 5.3.1.

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

1 Scope

This document is complementary to the Biomedical Research Integrated Domain Group (BRIDG) model. It is a high-level overview of BRIDG in general and BRIDG version 5.3.1 in specific. This document also provides necessary links to artifacts that detail the changes between BRIDG v3.2 and BRIDG v5.3.1[5] and to the BRIDG Release Download page.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
adverse event
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.

[SOURCE: BRIDG Model Report, p. 15[2]]

3.2
attribute
descriptive feature of a *class* (3.3) depicted as being contained within the class

[SOURCE: BRIDG 5.3.1 User's Guide, Section 5.6.3[2]]

3.3
class
entity that represents a person, place, or thing

[SOURCE: BRIDG 5.3.1 User's Guide, Section 5.6.2[2]]

3.4
domain analysis model
DAM
abstract representation of a subject area of interest, in this case protocol-driven research, that is the basis for development of lower-level design artefacts for computer software, databases, or data exchange standards

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