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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

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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).

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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.