Publicly Available Specification

ISO/PAS 24305

Health informatics — Guidelines for implementation of HL7 FHIR based on ISO 13940:2015, ISO 13606-1:2019 and ISO 13606-3:2019

Informatique de santé — Lignes directrices pour l'implémentation de HL7 FHIR à partir de l'ISO 13940:2015, l'ISO 13606-1:2019 et de l'ISO 13606-3:2019

First edition
2025-07

Reference number
ISO/PAS 24305:2025(en)

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Published in Switzerland

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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).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

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

0.1 General

This document provides guidance on how four complementary international standards can be used in combination by developers of health ICT systems and infrastructures.

The goal of these four standards is to bring consistency and to maximize the smooth use of ICT by healthcare actors in the creation, representation, analysis and interoperable communication of health information, so that the use made of these main standards that represent health information is as best aligned as possible. It is therefore likely that implementers will elect to use more than one of the standards together and will benefit from guidance in how best to achieve this.

Three international standards have been published by ISO (two of which are parts of a five-part series), and one by HL7. The scope of each is summarized below. These standards environments are probably the most important to align in order to allow accelerated development and adoption of sophisticated clinical information systems and of better interoperability between them.

0.2 ISO 13940:2015

ISO 13940:2015 defines a comprehensive concept model that applies to all aspects of clinical and patient workflows, and it can therefore be considered the overarching domain model for the development of clinical information models. It specifies a concept model for continuity of care provided to any subject of care by any health system. It defines concepts representing the health status of a subject, the permissions and contractual relationships between healthcare provider organizations, plans of care and undertaken to deliver health and care. It defines the relations between these concepts, and some important areas of semantics for the values that can be provided for different properties.

0.3 ISO 13606-1:2019and ISO 13606-3:2019

The ISO 13606 series is a five-part standard series defining a high-level interoperability framework for the communication of electronic health record information. This includes a logical reference model, in ISO 13606-1, for the representation of health information within electronic health record (EHR) systems that can be communicated between heterogeneous EHR systems and with eHealth infrastructures. ISO 13606-2 formalizes the archetype concept, which is a dominant formalism for representing clinical information models. ISO 13606-3 includes an intersection of the two standards ISO 13606 and ISO 13940, by defining a set of clinical reference models as “reference archetypes” derived from ISO 13940, which are the clinical information models corresponding to the most frequently used clinical concept models that can be represented within persisted clinical information. This document makes particular use of ISO 13606-1 and ISO 13606-3. (Although not specifically included in this document, the Archetype Interchange Specification defined in ISO 13606-2 is also relevant.)

0.4 HL7 Fast Health Interoperability Resources (FHIR) Release 4

FHIR is an interoperability standard to facilitate the exchange of healthcare information between healthcare providers, patients, caregivers, payers, researchers and other actors in the healthcare ecosystem. HL7 FHIR defines generic and use case specific exchange models to communicate particular sets of health information for general support of the healthcare process. HL7 FHIR is an increasingly adopted interoperability interface specification for the communication of health information, including clinical information. It incorporates a profiling mechanism, termed FHIR Resources, that allow for the equivalent representation to clinical information models, as interface specifications suitable for specified business purposes. This document utilises FHIR Release 4, which was the most recent normative edition of this standard at the time of developing the guide. HL7 handles a wide range of healthcare exchange use cases, only some of which are relevant to the same scope as the other two standards, dealing with EHR data. This subset was used when developing this document.

0.5 The content of this document

This document focuses on three use cases for the combined use of the standards:

— the representation of continuity of care concepts conforming to ISO 13940:2015 within FHIR, and vice versa;

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— the representation of EHR extracts conforming to ISO 13606-1:2019 within FHIR, and vice versa;

— the correspondence between reference archetypes conforming to ISO 13606-3:2019 and FHIR resources.

Clause 4 summarizes the mapping from ISO 13490:2015 to HL7 FHIR, including the mapping method, findings and mapping issues that adopters can be mindful of, where the representation capability of the standards differs. Clause 5 presents the detailed mapping tables to use whenever developers of information systems that manage continuity of care, including EHR systems and healthcare provider information systems, need to generate HL7 FHIR messages to communicate certain aspects of continuity of care that are represented in the source system using ISO 13940, to another system. The mapping tables include mapping notes to indicate if the target representation covers a broader, or narrower, scope than the source representation, or to indicate that no corresponding representation exists in the target and that some of the information will not be capable of being communicated or imported. Other guidance notes are sometimes included in the tables. Clause 6 summarizes the mapping from HL7 FHIR to ISO 13490, similarly to Clause 4. Clause 7 presents the detailed mapping tables and mapping notes in that direction, to be used when developers of information systems dealing with managing the continuity of care to individuals need to ingest information from HL7 FHIR messages in order to determine the aspects of continuity of care that are included with each message.

Clause 8 summarizes the mapping in both directions between the reference model of ISO 13606-1:2019 and HL7 FHIR. Clause 9 presents the detailed mapping tables from ISO 13606-1:2019 to HL7 FHIR, using the same table structure as Clauses 5 and 7. These mapping tables can enable the developer of an EHR system to communicate parts of the health information about one or more subjects of care in a way that conforms to ISO 13606-1:2019 and manifests as HL7 FHIR messages. Clause 9 presents the detailed mapping tables from HL7 FHIR to ISO 13606-1, to enable EHR information to be imported from clinical HL7 FHIR messages and represented using the ISO 13606 standard series, to then be persisted or processed by the EHR system or other receiving system in its usual way. As with the previous clause, the mapping tables indicate through comments the level of precision of the mapping and if there are areas of information content that the other standard cannot represent. Clause 9 also includes mapping tables for relevant term lists from ISO 13606-3.

Clause 10 provides guidance that explains how the reference archetypes defined in ISO 13606-3 correspond with HL7 FHIR resources, and the potential benefit of using the reference archetypes (many of which are information patterns for the continuity of care concepts that are defined in ISO 13940:2015) as the basis for defining FHIR resources and profiles. Clause 10 documents how to create FHIR resources that represent the clinical information structures within the Reference Archetypes in ISO 13606-3 that correspond to ISO 13940:2015 concepts. This is a relatively complex process, and Clause 10 provides methodological guidance on how reference archetypes can be transformed into FHIR resources, with an example FHIR profile for Health Condition is given. Clause 11 provides detailed tables guiding the representation of several example Reference Archetypes as FHIR resources.

Many of the tables in the above-mentioned clauses contain extracts of text quoted from the source standards. These have been reproduced in order to make these tables meaningful to read, and to avoid the need to frequently cross-check each row of a table with two or more source documents. Hyperlinks are provided in some rows of the tables to specific information properties of HL7 FHIR, since this document is published as an online resource. These links are being maintained permanently by HL7 and point specifically to the relevant parts of the normative version of FHIR that has been used when creating this document.

An additional standards mapping relating to archetypes and FHIR is provided in Annex A, which adds a description of the correspondence of these standards to ISO 13972. ISO 13972 is scoped on clinical information models in general, of which archetypes and some FHIR resources are examples.

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Health informatics — Guidelines for implementation of HL7 FHIR based on ISO 13940:2015, ISO 13606-1:2019 and ISO 13606-3:2019

1 Scope

This document provides guidance on how four complementary international standards can be used in combination by developers of health ICT systems and infrastructures. These standards, three published by CEN and ISO and one by HL7, are

— ISO 13940:2015,

— ISO 13606-1:2019,

— ISO 13606-3:2019, and

— HL7 Fast Health Interoperability Resources (FHIR) Release 4.

This document defines mappings between these standards: between ISO 13940 and HL7 FHIR in both directions, between ISO 13606 and HL7 FHIR in both directions, it proposes the content of an HL7 FHIR profile corresponding to the ISO 13606-1:2019 “COMPOSITION” class. It also provides guidance and worked examples of the mapping between ISO 13606-3 Reference Archetypes corresponding to ISO 13940 and HL7 FHIR.

This document also summarizes the extent to which the source concept is broader than or narrower than the best fit target concept. It also highlights mapping issues that adopters will need to be mindful of, where the representation capability of the standards differs.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13940:2015, *Health informatics — System of concepts to support continuity of care*

ISO 13606-1:2019, *Health informatics — Electronic health record communication — Part 1: Reference model*

ISO 13606-3:2019, *Health informatics — Electronic health record communication — Part 3: Reference archetypes and term lists*

HL7 FHIR, *Glossary*[1)]

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 13940:2015, ISO 13606-1:2019, ISO 13606-3:2019 and in the HL7 FHIR Glossary 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

1) http://hl7.org/fhir/help.html

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