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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**

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Published in Switzerland

Contents

Page

| | |
|---|------------|
| Foreword | vi |
| Introduction | vii |
| 1 Scope | 1 |
| 2 Normative references | 1 |
| 3 Terms and definitions | 1 |
| 4 Summary of the ISO 13940:2015 to FHIR R4 map | 2 |
| 4.1 Goals | 2 |
| 4.2 Approach | 2 |
| 4.3 Findings | 2 |
| 4.4 Mapping issues | 2 |
| 5 Mapping of concepts from 13940:2015 to FHIR R4 | 2 |
| 5.1 Mapping of concepts related to healthcare actors | 2 |
| 5.2 Mapping of concepts related to healthcare matters | 6 |
| 5.3 Mapping of concepts related to activities | 12 |
| 5.4 Mapping of concepts related to process | 22 |
| 5.5 Mapping of concepts related to healthcare planning | 25 |
| 5.6 Mapping of concepts related to time | 29 |
| 5.7 Mapping of concepts related to responsibilities | 35 |
| 5.8 Mapping of concepts related to information management | 39 |
| 6 Summary of the FHIR R4 to ISO 13940:2015 map | 46 |
| 6.1 Goals | 46 |
| 6.2 Approach | 46 |
| 6.3 Findings | 46 |
| 6.4 Mapping issues | 46 |
| 7 Mapping of concepts from FHIR R4 to ISO 13940:2015 | 47 |
| 7.1 Mapping of concepts related to foundation – conformance | 47 |
| 7.2 Mapping of concepts related to foundation – terminology | 49 |
| 7.3 Mapping of concepts related to foundation – security | 51 |
| 7.4 Mapping of concepts related to foundation – documents | 53 |
| 7.5 Mapping of concepts related to base – individuals | 55 |
| 7.6 Mapping of concepts related to base – entities#1 | 58 |
| 7.7 Mapping of concepts related to base – entities#2 | 61 |
| 7.8 Mapping of concepts related to base – workflow | 63 |
| 7.9 Mapping of concepts base – management | 65 |
| 7.10 Mapping of concepts related to clinical – summary | 67 |
| 7.11 Mapping of concepts related to clinical – diagnostics | 70 |
| 7.12 Mapping of concepts related to clinical – medications | 73 |
| 7.13 Mapping of concepts clinical – care provisions | 76 |
| 7.14 Mapping of concepts related to clinical – request and response | 80 |
| 7.15 Mapping of concepts related to financial – support | 83 |
| 7.16 Mapping of concepts related to financial – billing | 85 |
| 7.17 Mapping of concepts related to financial – payment | 87 |
| 7.18 Mapping of concepts related to financial – general | 89 |
| 7.19 Mapping of concepts related to specialized – public health and research | 91 |
| 7.20 Mapping of concepts related to specialized – definitional artifacts | 93 |
| 7.21 Mapping of concepts related to specialized – evidence-based medicine | 97 |
| 7.22 Mapping of concepts related to specialized – quality reporting and testing | 99 |
| 7.23 Mapping of concepts related to specialized – medication definition | 101 |
| 8 Summary of the ISO 13606-1:2019 from/to FHIR R4 map | 107 |
| 8.1 Goals | 107 |
| 8.2 Approach | 107 |
| 8.3 Findings | 107 |

| | | |
|-----------|---|------------|
| 8.4 | Mapping issues | 107 |
| 9 | Mapping of concepts from ISO 13606-1:2019 to FHIR..... | 108 |
| 9.1 | Mapping of concepts related to EHR Component – EHR Extract..... | 108 |
| 9.2 | Mapping of concepts related to EHR Component – Folder | 110 |
| 9.3 | Mapping of concepts related to EHR Component – Composition | 112 |
| 9.4 | Mapping of concepts related to EHR Component – Entry | 114 |
| 9.5 | Mapping of concepts related to EHR Component – Item..... | 116 |
| 9.6 | Mapping of concepts related to EHR component – Common properties of record components | 118 |
| 9.7 | Mapping of concepts related to EHR component – Base component | 118 |
| 9.8 | Mapping of concepts related to EHR component – Record component | 120 |
| 9.9 | Mapping of concepts related to EHR component – Attestation | 122 |
| 9.10 | Mapping of concepts related to EHR component – Link..... | 124 |
| 9.11 | Mapping of concepts related to EHR component – External link..... | 126 |
| 9.12 | General principles for mapping elements and data values | 128 |
| 9.13 | Mapping of concepts related to Elements and data values – Instance identifier | 133 |
| 9.14 | Mapping of concepts related to Elements and data values – URI..... | 135 |
| 9.15 | Mapping of concepts related to Elements and data values – uid | 137 |
| 9.16 | Mapping of concepts related to Elements and data values – Attachment | 139 |
| 9.17 | Mapping of concepts related to Elements and data values – SampleData..... | 142 |
| 9.18 | Mapping of concepts related to Elements and data values – Point in time..... | 144 |
| 9.19 | Mapping of concepts related to Elements and data values – Date time..... | 146 |
| 9.20 | Mapping of concepts related to Elements and data values – Date..... | 148 |
| 9.21 | Mapping of concepts related to Elements and data values – Time | 150 |
| 9.22 | Mapping of concepts related to Elements and data values – Period..... | 152 |
| 9.23 | Mapping of concepts related to Elements and data values – Timing..... | 154 |
| 9.24 | Mapping of concepts related to Elements and data values – Physical Quantity | 156 |
| 9.25 | Mapping of concepts related to Elements and data values – Coded value | 159 |
| 9.26 | Mapping of concepts related to Elements and data values – Coded simple | 161 |
| 9.27 | Mapping of concepts related to Elements and data values – Simple text..... | 163 |
| 9.28 | Mapping of concepts related to Elements and data values – String..... | 165 |
| 9.29 | Mapping of concepts related to Elements and data values – Annotation..... | 167 |
| 9.30 | Mapping of concepts related to Elements and data values – Integer..... | 169 |
| 9.31 | Mapping of concepts related to Elements and data values – Real | 171 |
| 9.32 | Mapping of concepts related to Elements and data values – Boolean..... | 173 |
| 9.33 | Mapping of concepts related to Demographics – PersonName..... | 175 |
| 9.34 | Mapping of concepts related to Demographics – TelecommunicationAddress..... | 177 |
| 9.35 | Mapping of concepts related to Demographics – LocationAddress..... | 179 |
| 9.36 | Mapping of concepts related to Demographics – Attestation info | 182 |
| 9.37 | Mapping of concepts related to value sets..... | 184 |
| 9.38 | Mapping of concepts value set – Link..... | 186 |
| 9.39 | Mapping of concepts value set – Version_status | 188 |
| 9.40 | Mapping of concepts related to value Set – Null_flavour..... | 189 |
| 10 | Challenges, constraints, and recommendations for a standardization roadmap to align the HL7 FHIR and ISO 13606-3:2019 standards..... | 190 |
| 10.1 | Purpose of this Clause..... | 190 |
| 10.2 | Importance of HL7 FHIR and ISO 13606-3:2019 alignment..... | 191 |
| 10.3 | Overview of the HL7 FHIR functional/reporting model | 191 |
| 10.3.1 | StructureDefinition and resource profiling..... | 191 |
| 10.3.2 | Meta information | 191 |
| 10.3.3 | Extension mechanism..... | 191 |
| 10.3.4 | Slicing mechanism | 192 |
| 10.3.5 | Changing knowledge and adaptability | 192 |
| 10.3.6 | Base reference models specialization | 192 |
| 10.4 | Overview of ISO 13606-3:2019 | 192 |
| 10.5 | Differences and similarities between the standards in terms of information structure composition mechanisms | 193 |
| 10.5.1 | Main concepts | 193 |

ISO/PAS 24305:2025(en)

| | | |
|---------------------|---|------------|
| 10.5.2 | Similarities..... | 193 |
| 10.5.3 | Differences..... | 193 |
| 10.6 | Benefits found from the combined use of FHIR and ISO 13606-3 | 193 |
| 10.6.1 | Enhanced semantic interoperability | 193 |
| 10.6.2 | Flexibility in data modeling..... | 194 |
| 10.6.3 | Reusability and standardization..... | 194 |
| 10.6.4 | Efficient data exchange..... | 194 |
| 10.6.5 | Enhanced clinical validity..... | 194 |
| 10.6.6 | Improved data governance and quality..... | 194 |
| 10.7 | Example of a combination of the ISO 13606-3:2019 “Health Condition” reference archetype with FHIR..... | 194 |
| 10.7.1 | General..... | 194 |
| 10.7.2 | Detailed example of combined specification..... | 195 |
| 10.7.3 | Hypothetical FHIR Profile: Health Condition | 196 |
| 11 | Mapping tables guiding the representation of reference archetypes as FHIR resources | 198 |
| 11.1 | Mapping of properties related to reference archetypes for demographic entities | 198 |
| 11.2 | Mapping of properties related to reference archetypes for clinical information specifications..... | 200 |
| Annex A | (informative) Mapping between HL7 FHIR, the ISO 13606 series and ISO 13972 | 217 |
| Bibliography | | 225 |

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Foreword

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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 13606-1:2019 and 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;