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**Health informatics — Interoperability  
and integration reference architecture  
— Model and framework**

*Informatique de santé — Architecture de référence d'interopérabilité  
et d'intégration — Modèle et cadre*

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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](http://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](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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](http://www.iso.org/members.html).

This corrected version of ISO 23903:2021 incorporates the following corrections:

- [Figure E.1](#) has been corrected.

# Introduction

## 0.1 Preface

This document supports the integration of a) specifications from different domains with their specific methodologies, terminologies and ontologies including specific specification style as well as b) systems based on those specifications. Enabling the use-case-specific identification and consistent, formal representation including constraints of necessary components with their specific concepts and their relationships, this document facilitates the deployment of existing standards and systems, the analysis and improvement of specifications under revision as well as the design of new projects.

This document provides an overview of the Interoperability and Integration Reference Architecture (first introduced in the 1990s as the Generic Component Model – GCM<sup>[1][2]</sup>), providing scope, justification and explanation of key concepts and the resulting model and framework. It contains explanatory material on how this Interoperability and Integration Reference Architecture is interpreted and applied by its users, who might include standards writers and architects of interoperable systems, but also systems integrators.

The ongoing organizational, methodological and technological paradigm changes in health and social care result in health systems transformation toward P5 (personalized, preventive, predictive, participative precision) systems medicine as fully distributed, highly dynamic, strongly integrated, multi-disciplinary (or multi-domain) intelligent ecosystems, comprising both structured systems, communities governed by rules, and combinations thereof<sup>[3]</sup>.

## 0.2 Interoperability levels

Interoperability (see 3.16) has evolved during the last 30 years from structured messaging (e.g. EDI, HL7<sup>®1)</sup> messaging) over sharing concepts [e.g. openEHR<sup>®2)</sup> Archetypes, ISO 13940<sup>[4]</sup> (system of concepts to support continuity of care)] – both representing the data/information exchange paradigm – to cooperation at application level (e.g. Web services). All those solutions focus on information and communication technologies (ICT) systems interoperability using ICT terminologies and ontologies for representing data, information, or even concepts and knowledge, thereby distinguishing the three interoperability levels: a) foundational, b) structural, and c) semantic interoperability.

On the move towards digital health, ICT systems get more closely integrated in the real world business process. This move requires supporting advanced, knowledge-level and business process focused interoperability between all principals acting in those ecosystems such as persons, organizations, devices, applications, components, or objects to achieve the common business objectives. As knowledge, methodologies and terminologies of the domains involved in the business case and represented through those domains' ontologies, but also individual contexts, abilities and capabilities are highly different, they must be shared and adapted in advance or dynamically at runtime, enabling adequate cooperation of actors and systems involved. [Table 1](#) summarizes the different interoperability levels<sup>[5]</sup>.

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