

# Governance of interoperability and standards in digital health

Version 1

IMIA BUD program

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July 2026

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# Introduction

This document is aimed at providing guidance at the strategic level on interoperability and standards in digital health.

The target group is policy organizations at national and international level. These organizations include a variety of organizations from the different sectors of healthcare such as lawmakers, ministries, professional organizations of care professionals (doctors, nurses, physiotherapists, pharmacists, etc.), developers and suppliers of health software, health institutions as a hospital or a community health organization and healthcare insurance organizations.

This document is intended to be in alignment with main international authoritative documents such as:

- WHO's National eHealth Strategic Toolkit
- European Union's Refined European Interoperability Framework
- ISO 23903 Health informatics - Interoperability and integration reference architecture- Model and framework.

## A model of interoperability and standards

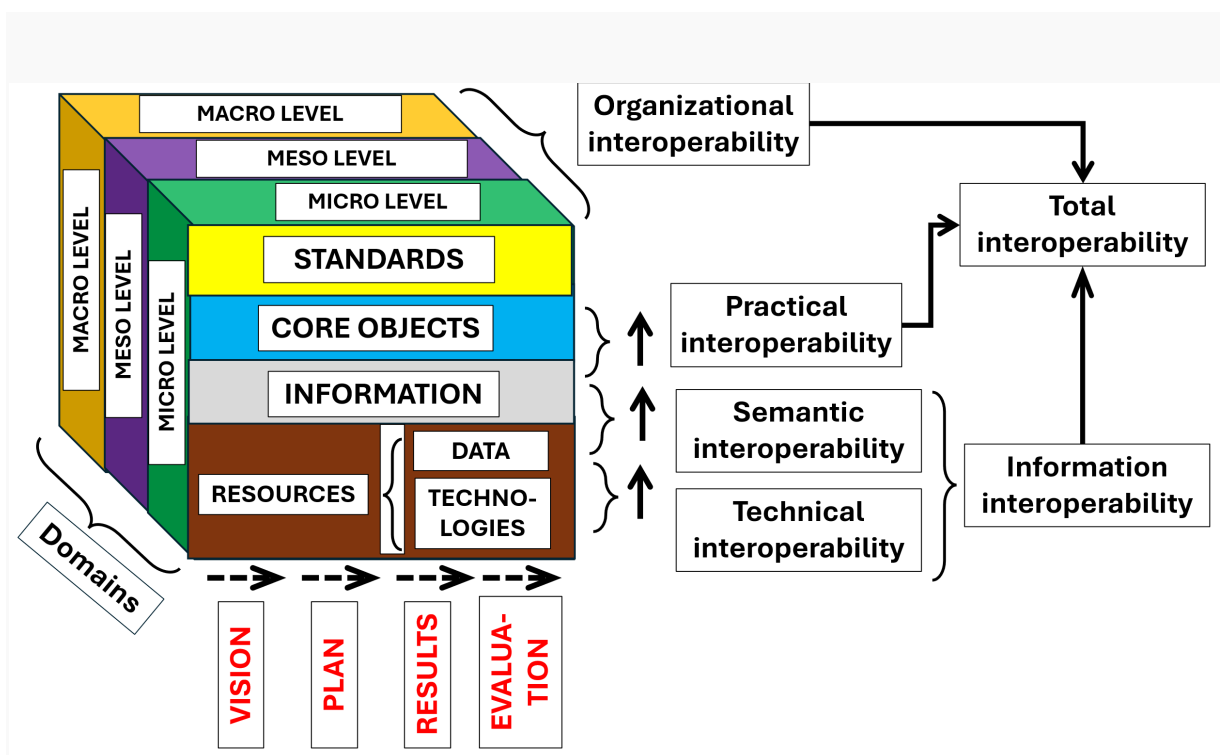


Figure 1 The interoperability Cube

When people talk about **levels of interoperability**, they're describing *how deeply* different systems (and the people behind them) can actually work together—not just technically, but in practice and in governance.

**Table 1 Levels of interoperability**

| Level          | Focus        | Core question                                                                 |
|----------------|--------------|-------------------------------------------------------------------------------|
| Technical      | Connectivity | Can systems exchange data?                                                    |
| Semantic       | Meaning      | Do communicating participants understand each other?                          |
| Practical      | Operations   | Can communicating participants actually use the information systems together? |
| Organizational | Governance   | Can organizations truly collaborate?                                          |

Practical interoperability is about whether systems can actually be used together in real-world workflows. It goes beyond “the systems can exchange data”

Organizational interoperability (healthcare) answers: “Are the institutions aligned enough to make this collaboration last?”

## The governance processes to achieve interoperability

Since the governance processes to achieve interoperability are complex, a government should have a comprehensive and efficient system for guiding its governance processes. Such a guidance system should follow the structure of the coordination function, as explained in the European Interoperability Framework (EIF):

1. firstly the needs for communication and information are assessed, based on the needs of end-users
2. next, execution involving planning (goals with Key Performance Indicators (KPIs), objectives and resources), control measures and monitoring
3. then evaluation reveals whether the initial needs have been fulfilled in which needs have remained (effect evaluation) and whether the processes have been performed efficiently (resource evaluation)

4. finally, there is a total assessment of needs, including remaining needs and new needs, resulting in a new plan.

These 4 phases of the policy control cycle are a type of cyclic quality management that is guided by ISO 9001, the international standard for quality management.

Since governments are concerned with policies, also the cycle of the policy processes is shown in Figure 2: policy principles (expressed as the principle to start with needs), policymaking (Plan and Performance criteria), policy implementation (Execution) and policy evaluation (corresponding to Performance evaluation).

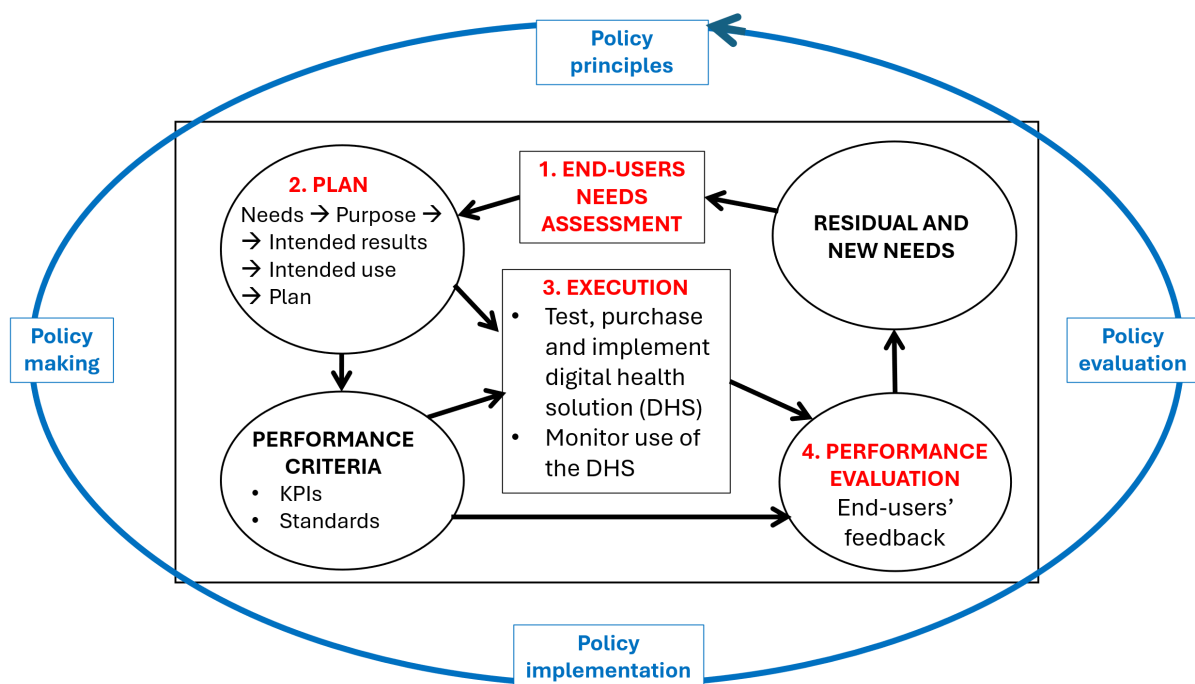


Figure 2 The governance processes to achieve interoperability

## Semantic interoperability

Semantic interoperability is defined as '*Precise meaning of exchange information which is preserved and understood by all parties*' (Literature reference: EIF). Semantic interoperability implies that data are well-formed and meaningful (reference: Floridi, *The philosophy of Information* and *The logic of Information*), that is, by definition, information. So, semantic interoperability is the process through which data acquire their meaning. It is, indeed, important that all parties understand the information. Since many different parties are involved, and there are differences in language between the involved participants, unity of language must be a focal point in interoperability governance.

An important aspect of unity of language is the distinction between natural language and artificial language. In general, natural language is richer than artificial language. According to scientific insights and information, there is an unavoidable loss and information when natural language is transformed into artificial language.

There is a general usual implicit assumption that encoding leads to clarification of medical concept such a diagnosis. This is certainly the case for certain medical specializations. However, in the practice of healthcare, with multiple conditions and vague symptoms, a diagnosis may be better expressed in free text compared to a pre-determined codes. The decision to encode information should be the result of balancing the advantages and disadvantages of encoding.

Particular attention should be given to information for patients. Patients use natural language

## Enriching the layers of interoperability: pragmatic interoperability

The principle that digital health solution must be fit for the intended use/purpose, is expressed in the concept of pragmatic interoperability.

Pragmatic interoperability means that the data can be used correctly in the intended context to achieve the desired outcome.

For example, in healthcare:

- If Hospital A sends a blood pressure reading to Hospital B, semantic interoperability ensures both agree it's a blood pressure value in mmHg.
- Pragmatic interoperability ensures that Hospital B can actually use that value correctly in its workflows — e.g., to trigger a clinical decision support alert for hypertension, or include it in a treatment protocol — not just store it.

In other words: pragmatic interoperability is about ensuring exchanged data can be applied appropriately for its intended use.

## The function of the Interoperability Governance Cube

The Interoperability Governance Cube is aimed to provide a comprehensive tool for identifying, navigating and managing.

Each of the 24 cells in the Cube represents a whole of processes, actors, resources, etc. If a cell has a contact with another cell, this means that the processes in the cells are interrelated. So, the Cube presents the interrelations and interdependencies between processes of Interoperability Governance.

So, the Interoperability Governance Cube presents the organizational structure of entities and processes for interoperability management.

When put in the terms of informatics, this organizational structure is called an architecture. Accordingly, the Interoperability Governance Cube presents a reference architecture for interoperability management.

## Compatibility with ISO 23903

The Interoperability Governance Cube is compatible with the interoperability models in ISO 23903 (Interoperability and Reference Architecture) that also have 3 dimensions:

- domains
- processes and the composition thereof, comparable with the Interoperability Governance Cube dimension of processes
- viewpoints that have a structure similar to the Interoperability Governance Cube dimension of viewpoints.

The Interoperability Governance Cube can be considered to be a specific case of the generic umbrella models in ISO 23903. Accordingly, the use of the Interoperability Governance Cube can benefit from the applications of ISO 23903 for various areas such as information architecture, design of information systems.

Healthcare uses many specialized standards (HL7 FHIR, DICOM, ISO/EN 13606, openEHR, SNOMED CT, ICD, LOINC, etc.). ISO 23903 provides the meta-framework to integrate them while ensuring that interoperability is not just technical or semantic, but also pragmatic.

## How to use the Interoperability Cube

The Interoperability Cube is a tool for governance of interoperability.

The Cube has 3 sets of planes, each determined by 2 dimensions.

Each set of planes has a specific function for interoperability governance.

Firstly, the plane that is defined by the dimensions of domains and interoperability layers, corresponds to the Interoperability Governance Compass.

Secondly, the plane that is defined by the dimensions of processes and domains, represents the processes of collaboration of actors within and across the Legal and Operation domain. These are the processes of organizations and people to make agreements on interoperability at the care level (alignment of care processes), information level and technical level.

Finally, the plane that is defined by the dimensions of process and interoperability layers, corresponds to the interoperability governance processes in Figure 1. These governance processes are further described in the next section.

# Recommendations for using the Interoperability

This section contains recommendations for the interoperability governance processes, that are displayed in Figure 1.

## Principles

- for orchestration of digital health and governance of digital health interoperability, use a coherent set of principles and policies, based on needs and standards
- for interoperability of Digital Health Solutions (DHSs), safeguard quality and safety by processes of **continuous improvement** in line with generic quality management principles and standards
- use a **people-centred, need-based and principle-based** vision, ultimately aimed at strengthening the relationship of patients with their healthcare professionals (HCPs)
- ‘**people-centred**’ means that the primary people in healthcare, patients with their HCPs, are at the centre of the digital health policies
- the ‘**needs-based**’ requirements necessitates that governments have a vision of the needs of patients and HCPs in their close healthcare interactions

## Needs of patients

- patient are simply citizens that receive healthcare services; for them, information is crucial for them to be able to cope with the disease and the challenges and stress that medical conditions generate
- citizens, they have the right to be able to manage their own life and the information on their own health, diagnosis and treatment can be essential for managing their own life;
- since the needs of patients can be very different, depending on factors such as their coping strategies, there is no digital health solution that fits all patients needs;
- some patients want to have all information, for them, access to their health information and control of the use of the information is important
- other patients may not want to be informed about all details and rely on their doctors/HCPs for their health information;
- since there is so much individual variation, patients should be enabled to decide themselves on what type of information is provided to them and how the communication with the HCP is arranged;
- also, patients should be offered the possibility to manage and control their health information and health data by using their own health data repository; this information system strategy can be helpful as a complement to the usual strategy of storing the patient data at the location where the data is created (such as a hospital); there are concerns of clinicians that patients could misunderstand the medical data; doctors could help patients to understand the medical data such as discharge letters

- so, there must be an additional system of trust and communication between patients and doctors to ensure that the patient information is managed appropriately if patients have a leading role in this
- and patients should be offered the possibility to choose between alternatives and HCPs should help them to make the right choice, as a part of the care

## Needs of healthcare professionals

- healthcare professionals (HCPs) need medical information to be able to treat the patient
- also, the medical information itself is an element in the provision of care because the information enables patients to participate at the HCP's partner in a collaborative effort to benefit the patient's health state
- for an HCP who treats a patient, it is often difficult to obtain medical information from the patient's history when the patient has been treated elsewhere; if patients have control their health data, they can provide such information immediately during their visitor consultation, e.g. when such information is online

## Plan

- throughout planning, use the principle that the patients and their HCPs are the primary end-users of digital health solutions and define the intended use of an interoperable DHS accordingly
- differentiate plans by the various settings of healthcare; distinguish between different types of healthcare, e.g. general care, specialist care, emergency care, collective prevention
- for each digital health solution, the intended use of an interoperable DHS is basic; the intended use of a DHS comprises the primary process of healthcare (such as diagnosis, therapy as explained in ISO 13490) and the people (patients, family-and-friends, HCPs)
- make clear how the intended use of an interoperable DHS would satisfy the needs
- identify barriers to patient engagement and develop strategies to empower patients for equity and inclusivity
- if there is not sufficient insight into patients needs, stimulate strategies to identify these needs and translate the needs of patients and their HCPs into practical concepts of the intended use of digital health solutions
- use a structured approach of continuous improvement with cyclic processes
- evidence-based decision-making means that the decisions in the interoperability quality control cycle should be based on evidence; the quality of evidence is measured by accepted scientific indicators such as the type of publication and peer-review.

## Performance criteria

- stimulate the development and application of needs-based Key Performance Indicators (KPIs) to guide interoperability processes

- identify standards by considering the **intended use of standards** with regard to interoperability, that is: since interoperability processes imply health software system integration, focus on software integration standards
- for quality and safety, consider standards that link user needs to the processes of health software system integration with emphasis on risk management (example: IEC 62304)
- use internationally recognized standards to translate the **intended use of a DHS** into use-based **requirements** that are, in turn, transformed into technical **specifications**
- standards for governance/management of interoperability contain requirements
- technical standards contain specifications
- recognize the relevance and importance of standards that have been developed by different organizations and support initiatives to align and integrate these standards for transparent governance of interoperability
- if there is a lack of standards, initiate and/or support movements for translating the needs of patients and HCPs into use-based requirements for digital health solutions.

## Execution

- execute the Plan with explicit reference to standards for health software development
- since execution consists of testing, purchasing and implementing digital health solutions, this is in the development stage of the health software life cycle;
- the whole of testing, purchasing and implementing is the execution process (a separate process in the governance cycle)
- for the execution process, a well-informed and evidence-based decision must be made with regard to relevant standards;
- if the digital health solution includes a module that has a medical function, medical device regulations and standards apply such as the EU's Medical Device Regulation (MDR) and the internationally supported harmonized standards such as ISO 13485

## Evaluation

- validate against use-based requirements
- collect end-users feedback
- assess residual needs and new needs.