IHE EUROPE

Integrating the Healthcare Enterprise

How to make EHDS successful?
An industry perspective

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EHDS in a nutshell – what is it and what is it about?

The European Health Data Space (EHDS) architecture is a framework that includes:

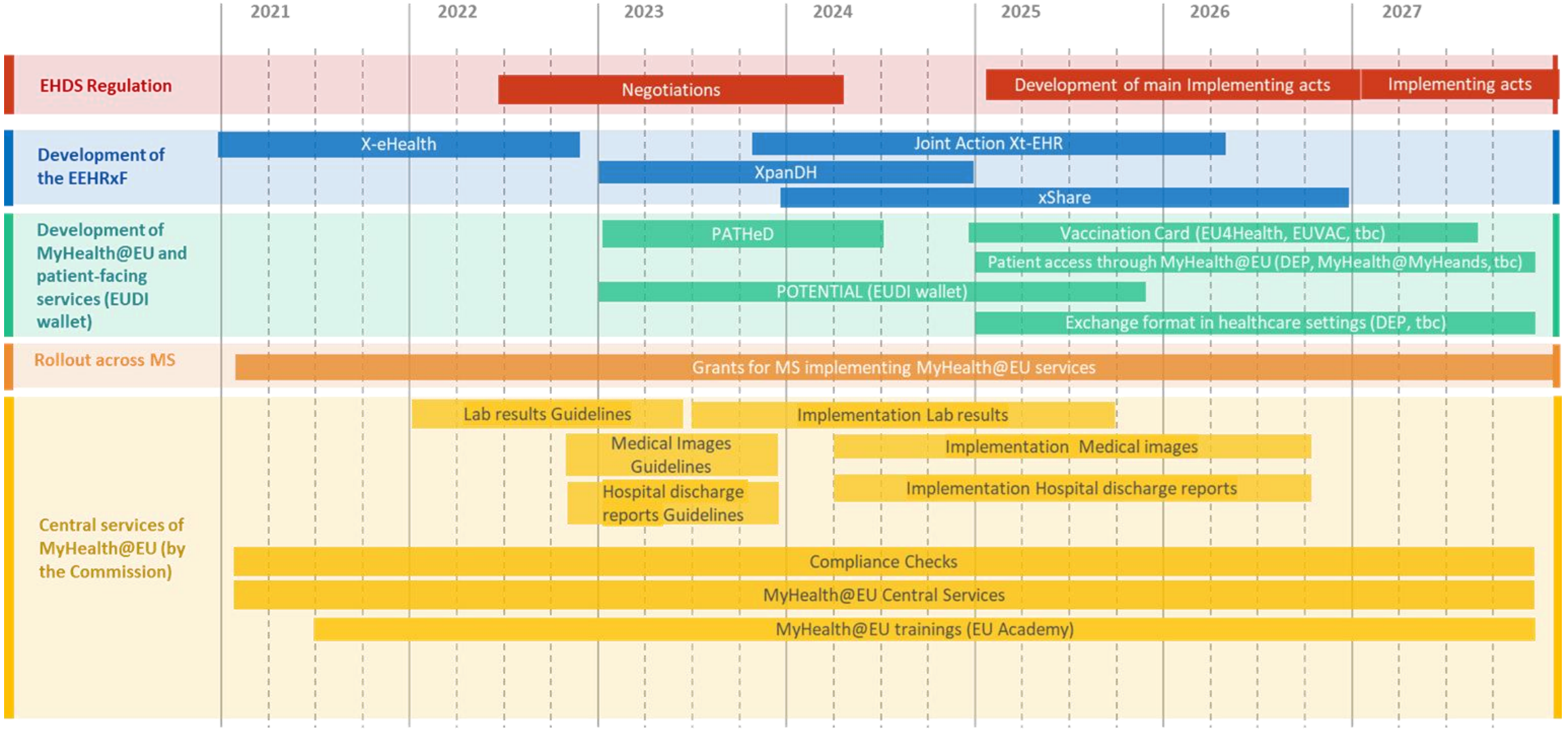
- **Rules**: A set of rules that govern the use of electronic health data
- **Common standards and practices**: A set of standards and practices that apply to the use of electronic health data
- **Infrastructures**: A secure digital infrastructure for sharing health data
- **Governance framework**: A framework that governs the use of electronic health data

The EHDS aims to:

- Give individuals more control over their electronic health data;
- **Allow healthcare providers to access patient data** with consent **across Europe (primary use);**
- Enable the **sharing of** anonymized or pseudonymised **health data for research, innovation**, and policy-making (**secondary use**);
- **Create a European single market for electronic health record systems, medical devices, and AI systems;**
- Ensure compliance with the EU's data protection standards.

EHDS timeline

Source: European Commission



Why is the success of EHDS is important for Europe?

Medical technology innovation (launch) gap in Europe

Strengths

- Europe is the traditional epicenter for medical innovation
- R&D hubs of global vendors are located throughout the continent
- Hundreds of startups and SMEs in medtech, especially in AI
- Evidence: a patent in medical technology is filed every 30 minutes

Weaknesses

- Focus of innovation shifted to other regions: USA and China
- Innovative products are launched in Europe with multi-year delays
- Small vendors have limited opportunity for scaling

Root cause: fragmented market, regulatory and technical environment

Road to the success of EHDS

Collaboration and EU projects paving the way to EHDS standards

Work is underway to develop the **European EHR eXchange Format (EEHRxF)**.

IHE-Europe is part of the team recommending the new (**HL7 FHIR**-based) standards as the basis of the **MyHealth@EU** infrastructure.

EHTEL · HL7 Europe · CEN Health Informatics TC251 · SNOMED CT The global language of healthcare

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The Challenge

We cannot afford the cost to **stick-build** an entire new European infrastructure from scratch.

We need to address the inherent **risks** in adopting a new and **emerging** standard.

To capture the **benefits** of EEHRxF, we need to "**productize**" its adoption at **scale**.

Simply being standards-based is not enough

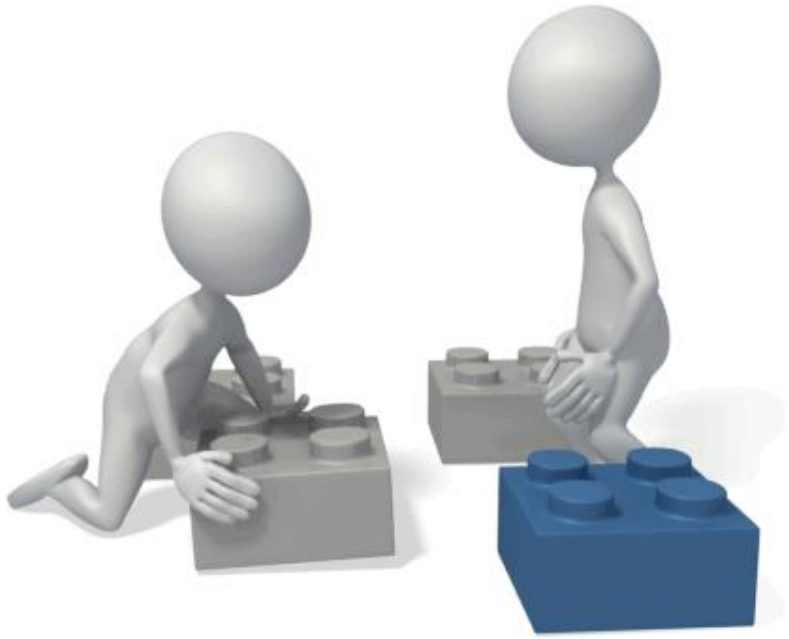
Myth

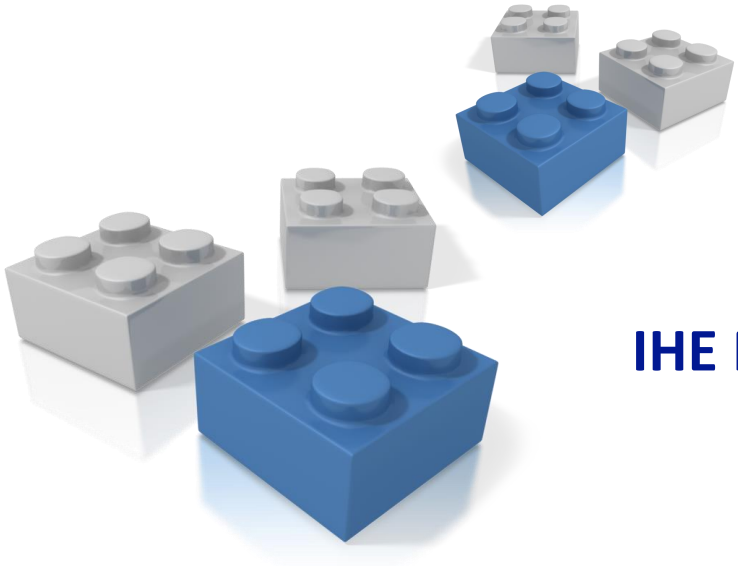
If you are standards-based, you are interoperable.

Reality

Interoperability relies on all the parties in the ecosystem using the **same** standards in the **same** ways.

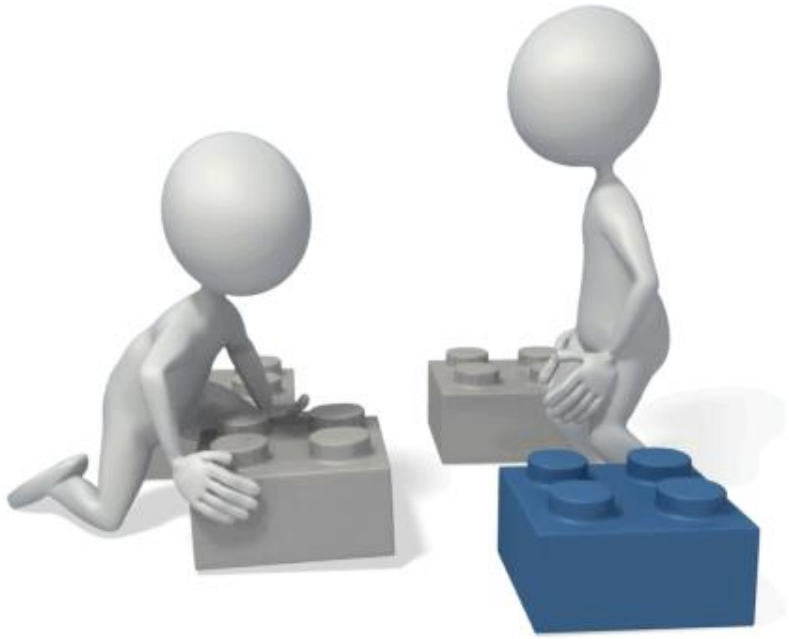
The **IHE Methodology** is a proven way to develop implementable, conformance-testable digital health specifications that “click together” like **building blocks**.

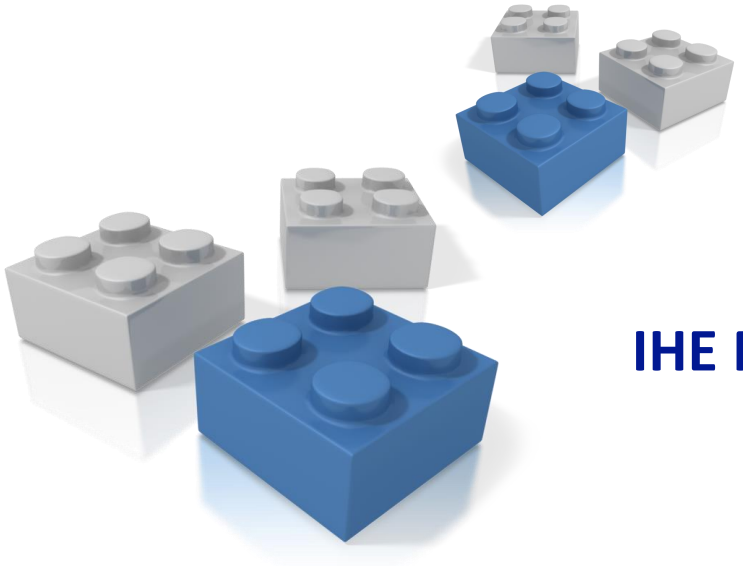




IHE Profiles

Having IHE profiles enable vendors to create digital health **products** that operationalize **assemblies** of these building blocks as collections of ***conformance-testable*** **functionalities**.





IHE Profiles

Main steps of IHE methodology:

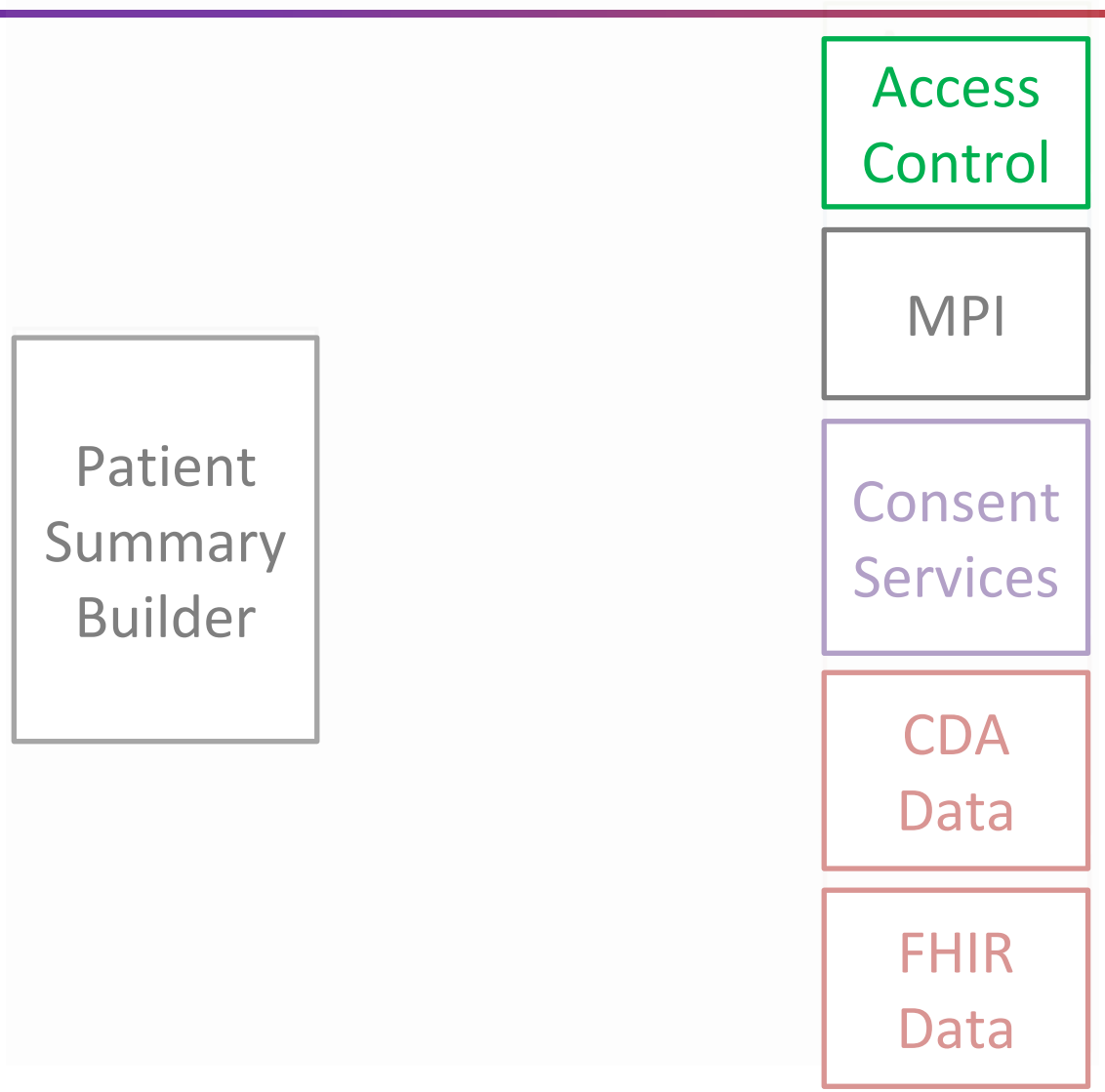
- **Step 1:** Profile creation based on applicable standards
- **Step 2:** Testing through the testing continuum
  - Plugathon
  - Connectathon
  - Projectathon
- **Step 3:** Establishment of a conformity testing platform

Example:

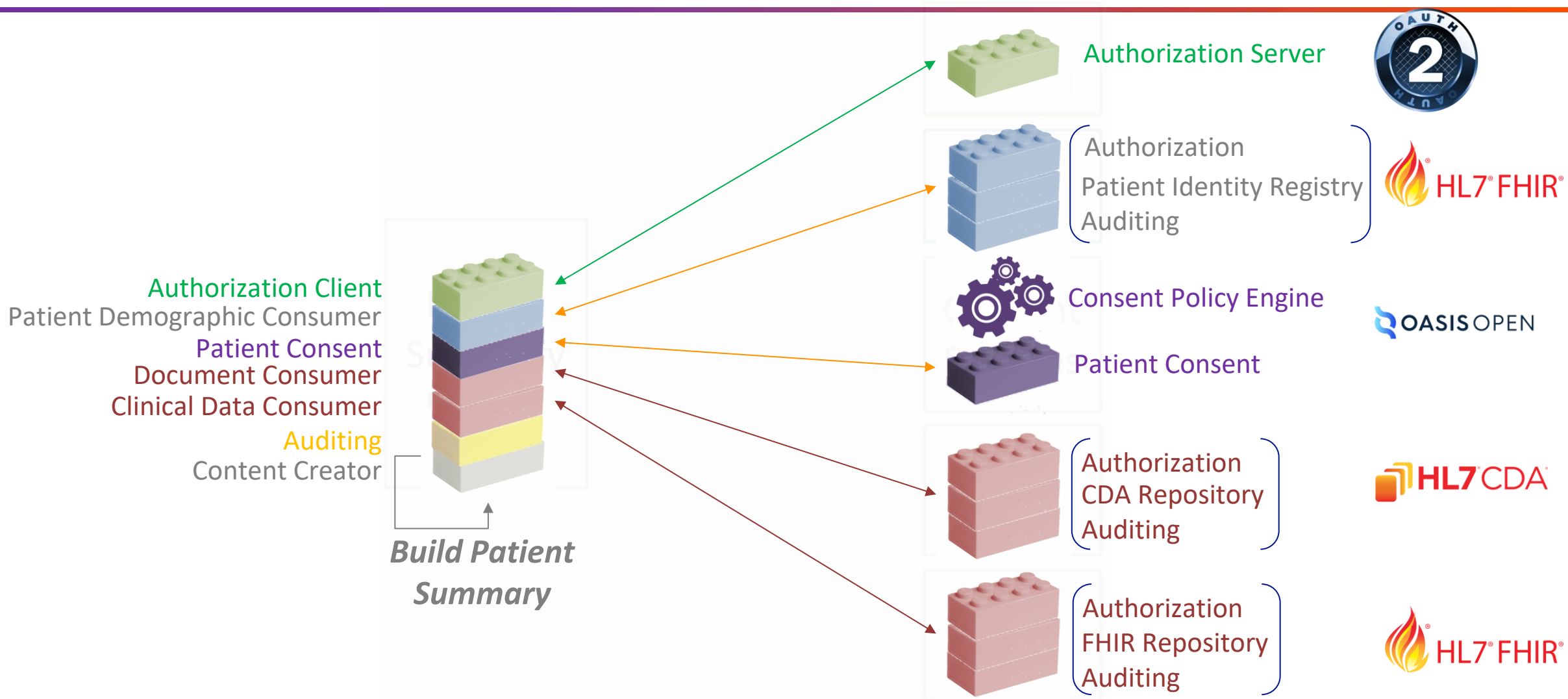
A digital health product needs to support on-demand generation of an **EEHRxF-conformant Patient Summary** document. It must be able to:

- ❑ Authorize **access** to the patient's health data
- ❑ Establish the patient's enterprise-wide **identifier**
- ❑ Obtain their data from legacy **CDA** repositories (respecting consent)
- ❑ Obtain their data from **FHIR** repositories (respecting consent)
- ❑ Build the **on-demand** summary.

Jurisdictional Shared Services



Jurisdictional Shared Services



The value of IHE family in the success of EHDS

IHE INTERNATIONAL Integrating the Healthcare Enterprise

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Key stakeholders

Industry

Establish conformance testable standards and standardized means for testing

Bring new EHDS compliant products to market

Create pathways for integrating existing products

European Commission

Continue to support projects towards EHDS enablement

Create implementing acts that support all stakeholders in achieving “plug and play” interoperability

Member states

Enact appropriate national legislation

Leverage the existing experience of industry in interoperability testing

Support initiatives for EHDS adoption by users

Citizens

Be conscious about their health and health data

Demand access to the highest standard of care

If done well, EHDS is a unique opportunity for

- Global vendors to introduce their products to a single European market
- European startups and SMEs to scale up
- Health care providers to gain efficiency
- Patients to receive the highest standard of care

Thank you for your attention

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