



Interoperability Architecture. Analysis, Design and Decision Support activities 2025-2026

myHealth@myHands Intervention

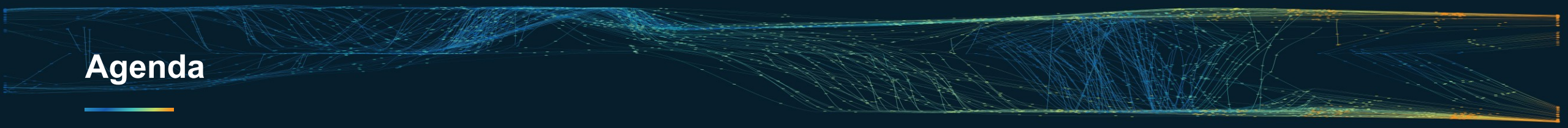
EUROPEAN COMMISSION DIGIT B2

Directorate-General for Informatics (DIGIT)

Project Officer: Mr. Catalin Moruju

interoperable
europe

Agenda



1. EIRA© & eGovERA©

2. Simplification approach

3. Relevant links



EIRA[©] & eGovERA[©]

EIRA & eGovERA

The European Commission DIGIT developed EIRA and eGovERA to **support public administrations in analysing and designing digital services** that work better together across organisations, sectors, and countries.

EIRA – Common reference framework for interoperable digital public services.



EIRA identifies the key elements that need to be considered in the analysis and design of digital public services, helping stakeholders to identify interoperability needs early, and build services that are interoperable by design.

eGovERA – Practical guidance and sector-specific architectures



eGovERA builds on EIRA by providing detailed requirements, standards and solutions to help public administrations analyse and design interoperable digital public services. It also provides specialised frameworks for specific domains (health, customs, tax)



Legal

Public Policies and Legal Instruments



Organisational

Delivery and governance model, capabilities, services and information exchanged



Semantic

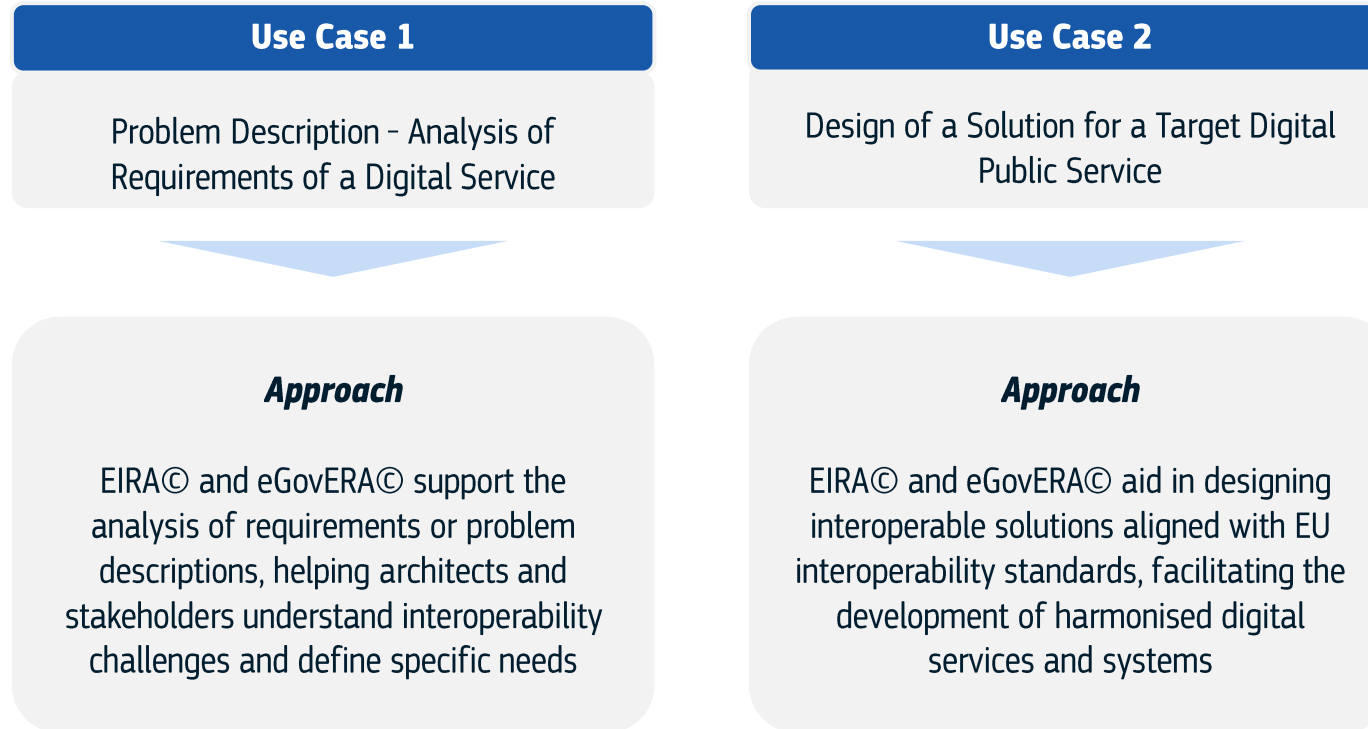
Data, metadata, ontologies, vocabularies and data representation



Technical

Back-end and front-end services, cloud infrastructure, security, monitoring, and communication protocols

EIRA & eGovERA – Use Cases



Simplification approach

Consultation Baseline

myHealth@myHands EIRA/eGovERA Design Model: v1.0

European Interoperability Reference Architecture (EIRA[©]): v6.1.0

eGovERA[©] Business Agnostic Reference Architecture: v6.1.0

eGovERA[©] Health Reference Architecture: v6.1.0

EUDI Wallet ARF: v3.0.0

Consultation version frozen on: 3 August 2026

Available

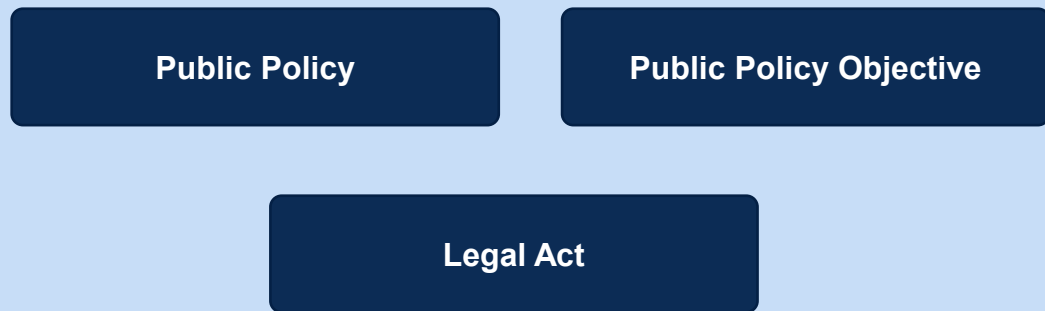
In ArchiMate format at <https://code.europa.eu/eira/eira-egovera-interventions/eira-egovera-intervention-myhealth-myhands>

As an interactive web version at <https://eira-egovera-intervention-myhealth-myhands-1e85b1.pages.code.europa.eu/?view=id-c749612380ad40a581956b5445d2912b>

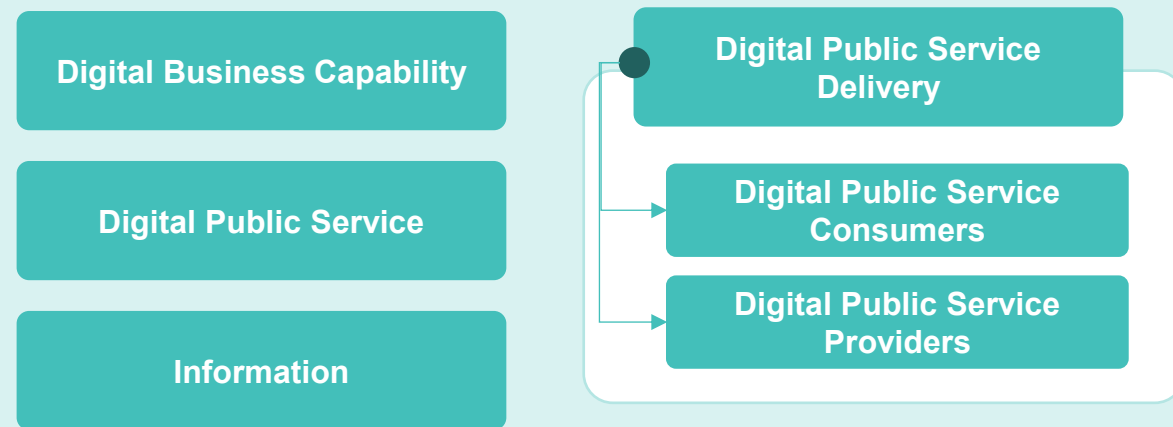
Simplification – eGovERA Core viewpoints



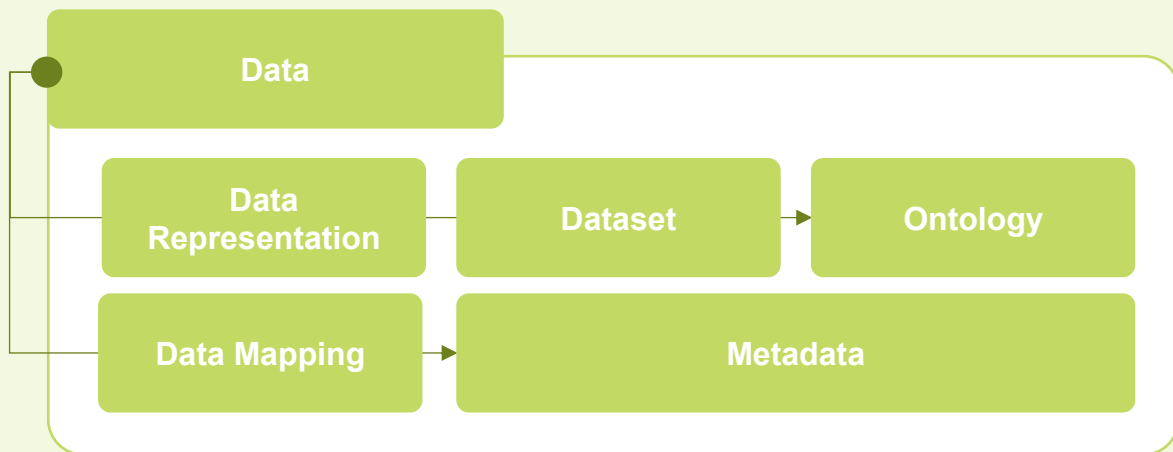
1 Legal View



2 Organisational View



3 Semantic View



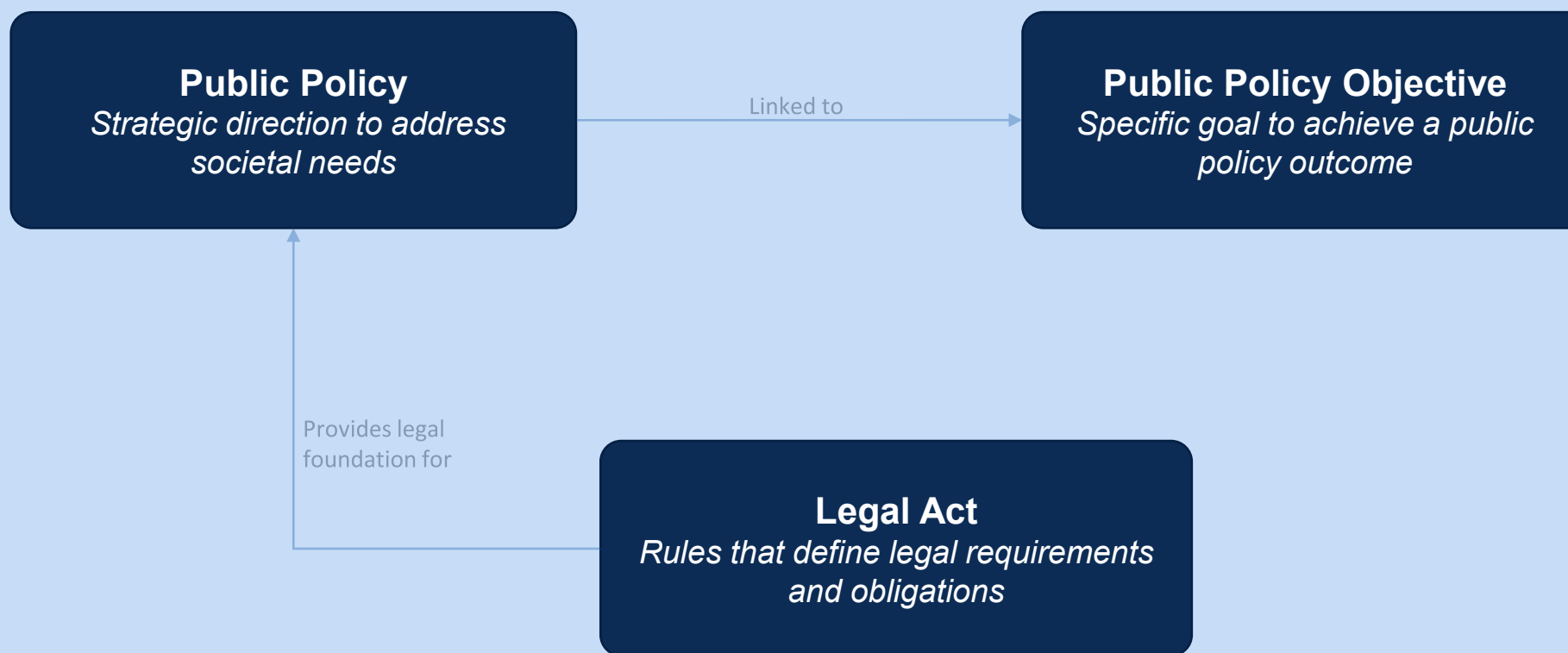
4 Technical View



Simplification – eGovERA Core viewpoints – Legal View



Defines the **legal and policy framework** that sets the rules, obligations and requirements governing the digital public service design and delivery.



Simplification – eGovERA Core viewpoints – Legal View

Public Policy

Policy Objective

Legal Act

Public Policy
Strategic direction to address societal needs

Data-driven health
decisions Public Policy

Health Cooperation and
control Public Policy

Digital transformation of
health and care Public
Policy

Digital Decade
Programme

Public Policy Objective *Specific goal to achieve a public policy outcome*

Improved access to information to strengthen evidence-based policymaking, decision-making processes, and research across public authorities, academia, and the innovation ecosystem

Online availability of key public services

Empowerment for Citizen-Centred Integrated Care

Universal Access to Electronic Health Records

Secure, cross-border access to patients' electronic health records

Simplification – eGovERA Core viewpoints – Legal View

Public Policy

Policy Objective

Legal Act

Legal Act

Rules that define legal requirements and obligations

European Binding Instruments

This view includes only the binding legal instruments specifically identified for the MyHealth@MyHands use case. Legal acts from the business-agnostic eGovERA Reference Architecture have been omitted for simplification purposes. For a comprehensive list of applicable legal acts, please refer to the ArchiMate model.

**Commission
Implementing
Regulations for the
European Digital
Identity Wallet
ecosystem**

**Implementing
regulation on
pharmacovigilance
activities**

**Implementing Decision providing the rules for the
establishment, the management and the functioning
of the network of national authorities responsible for
eHealth**

**Regulation (EU)
2024/1183 of the
European Parliament
and of the Council
amending Regulation
(EU) No 910/2014 as
regards establishing
the European Digital
Identity Framework**

**Directive on the
application of patients'
rights in cross-border
healthcare**

**Also Applicable: WHO
International Health
Regulations (2005), as
amended**

**Commission Implementing Decision laying down
technical specifications and rules for the
implementation of the trust framework for the EU
Digital COVID Certificate established by Regulation
of the European Parliament and of the Council**

**Commission
Implementing Directive
laying down measures
to facilitate the
recognition of medical
prescriptions issued in
another Member State**

**Regulation (EU)
2025/327 on the
European Health Data
Space**

**Regulation of the
European Parliament
and of the Council on
medical devices**

**Directive of the
European Parliament
and of the Council on
the Community code
relating to medicinal
products for human
use**

**Also Applicable when
Adopted: Proposal for
a regulation of the
European Parliament
and of the council
laying down Union
procedures for the
authorisation and
supervision of
medicinal products for
human use and
establishing rules
governing the
European Medicines
Agency**

Simplification – eGovERA Core viewpoints – Legal View

Public Policy

Policy Objective

Legal Act

Legal Act

Rules that define legal requirements and obligations

European Non-Binding Instruments

Commission
Recommendation on cross-border interoperability of electronic health record systems

Guidelines on good pharmacovigilance practices

European Interoperability Framework

Communication from the commission to the European Parliament, The Council, The European Economic and Social Committee and the committee of the regions on enabling the digital transformation of health and care in the Digital Single Market

*Also Applicable:
Global Public Health
Guidance*

Simplification – eGovERA Core viewpoints – Legal View

Public Policy

Policy Objective

Legal Act

Legal Act

Rules that define legal requirements and obligations

National Binding Instruments

*National Schema on access to
base registries*

*National Schema on
Cybersecurity*

*National Schema on Data
Protection*

*National Schema on eHealth
Infrastructure*

*National Schema on
eidentification*

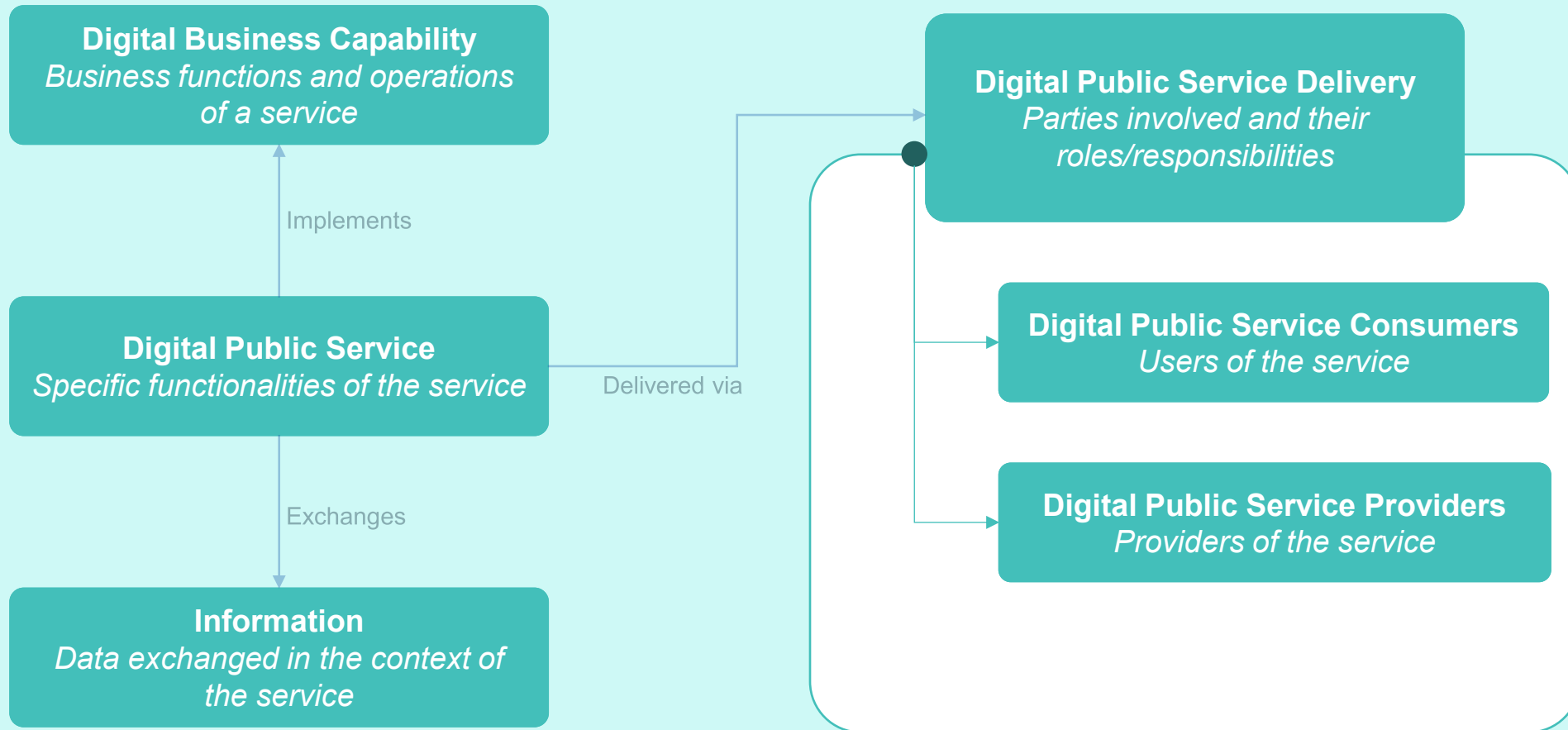
*National Legal Acts
implementing the European
Health Data Space*

*National Legal Acts on
patients' rights*

Simplification – eGovERA Core viewpoints – Organisational View



Defines the **functionalities, governance structure, and delivery model** required to achieve digital public service objectives and enable stakeholder collaboration.



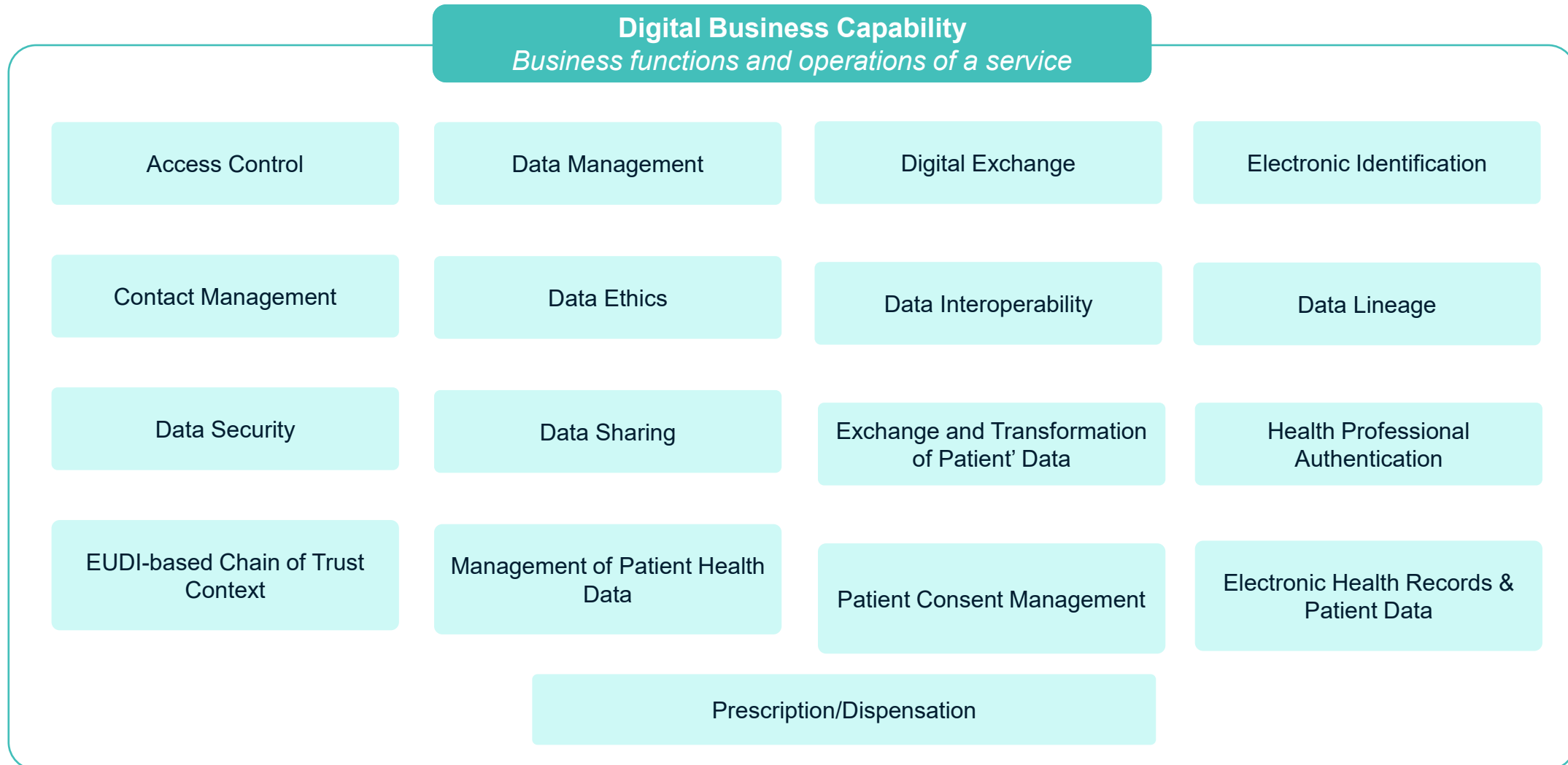
Simplification – eGovERA Core viewpoints – Organisational View

Business Capability

Public Service

Information

Service Delivery



Simplification – eGovERA Core viewpoints – Organisational View

Business Capability

Public Service

Information

Service Delivery

Digital Public Service *Specific functionalities of the service*

Emergency Access to cross-border health data

Qualified electronic signature functionality through the EUDI-Wallet

Delegation of Access Rights

Anonymisation

Patient Health Data Transformation

Generate and correct data into Electronic Health Records

Management of Access restrictions

Data Exchange

Cross-Border Audit & Traceability

Patient Consent Management via EUDI

Download a copy of personal health data

eIdentification

Cross-border Healthcare Professional Authentication

Opt-out from Data Sharing

eDelivery

eTranslation

Access to Personal Health Data Through the EUDI-Wallet

Selective Disclosure

Contact Management

Secure Access Control

myHealth@EU EUDI Wallet-Based Trust Framework

Patient Identification

Digital Immutability

Electronic Health Records

ePrescription

eDispensation

Digital Health Certificates

Patient Summary

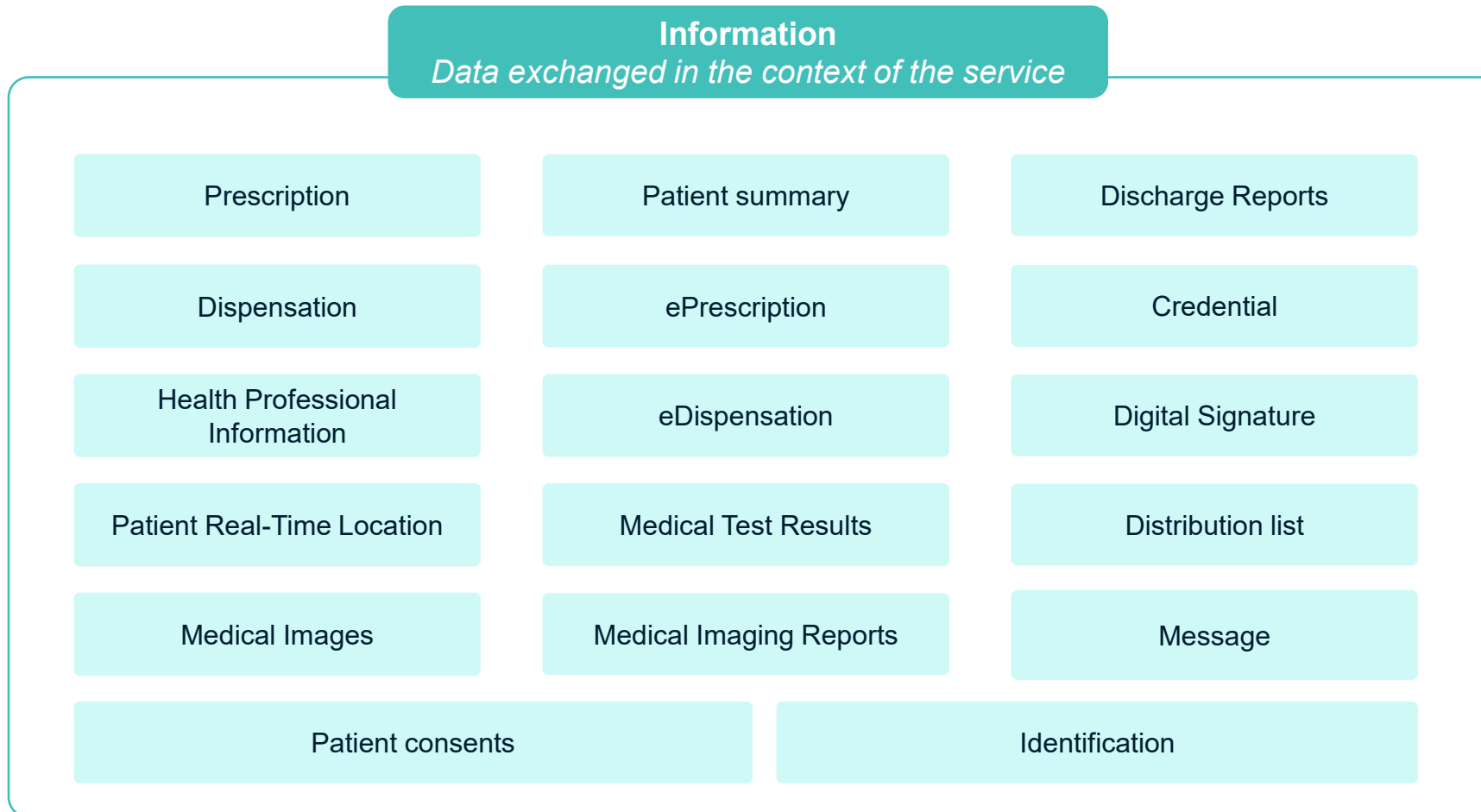
Simplification – eGovERA Core viewpoints – Organisational View

Business Capability

Public Service

Information

Service Delivery



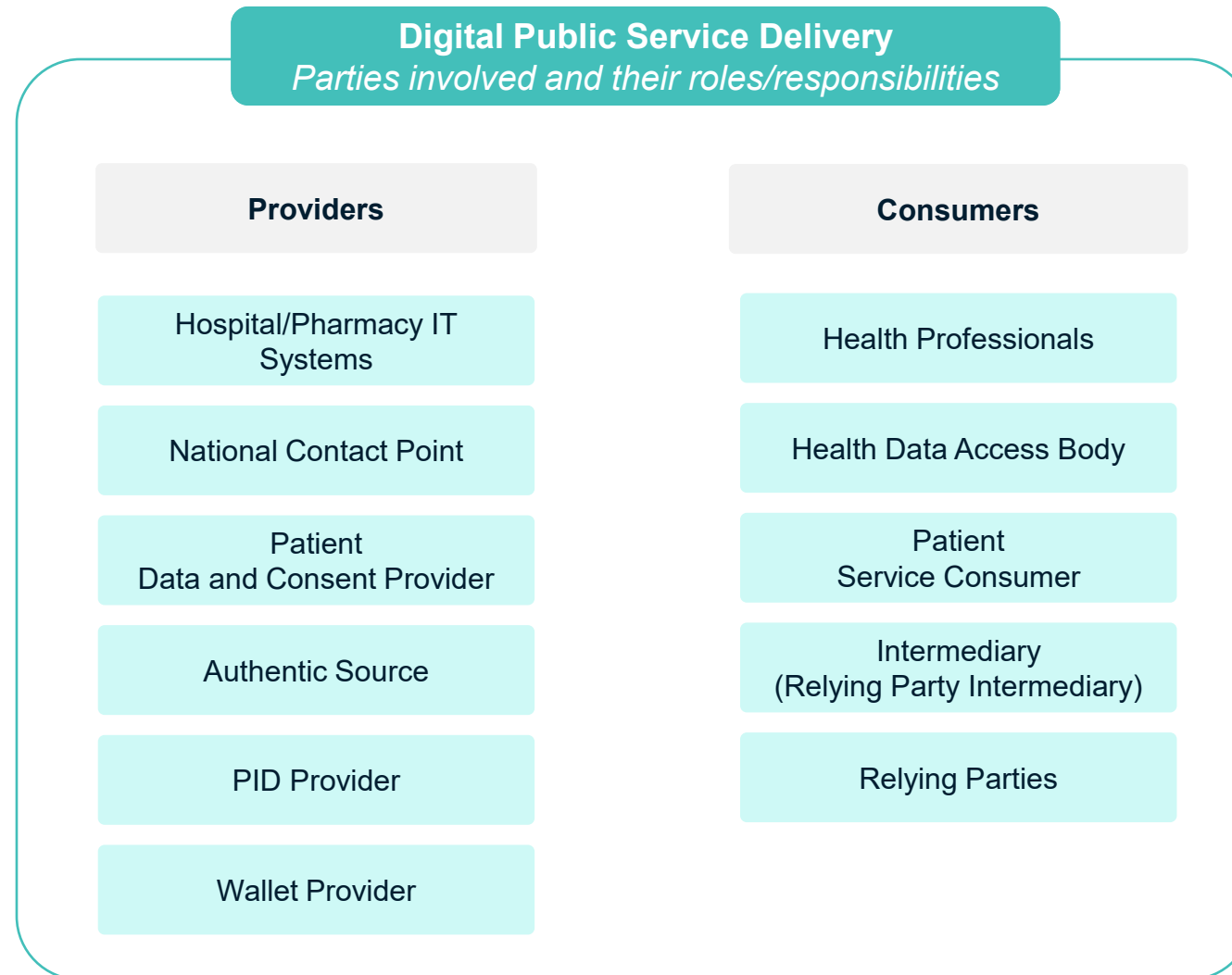
Simplification – eGovERA Core viewpoints – Organisational View

Business Capability

Public Service

Information

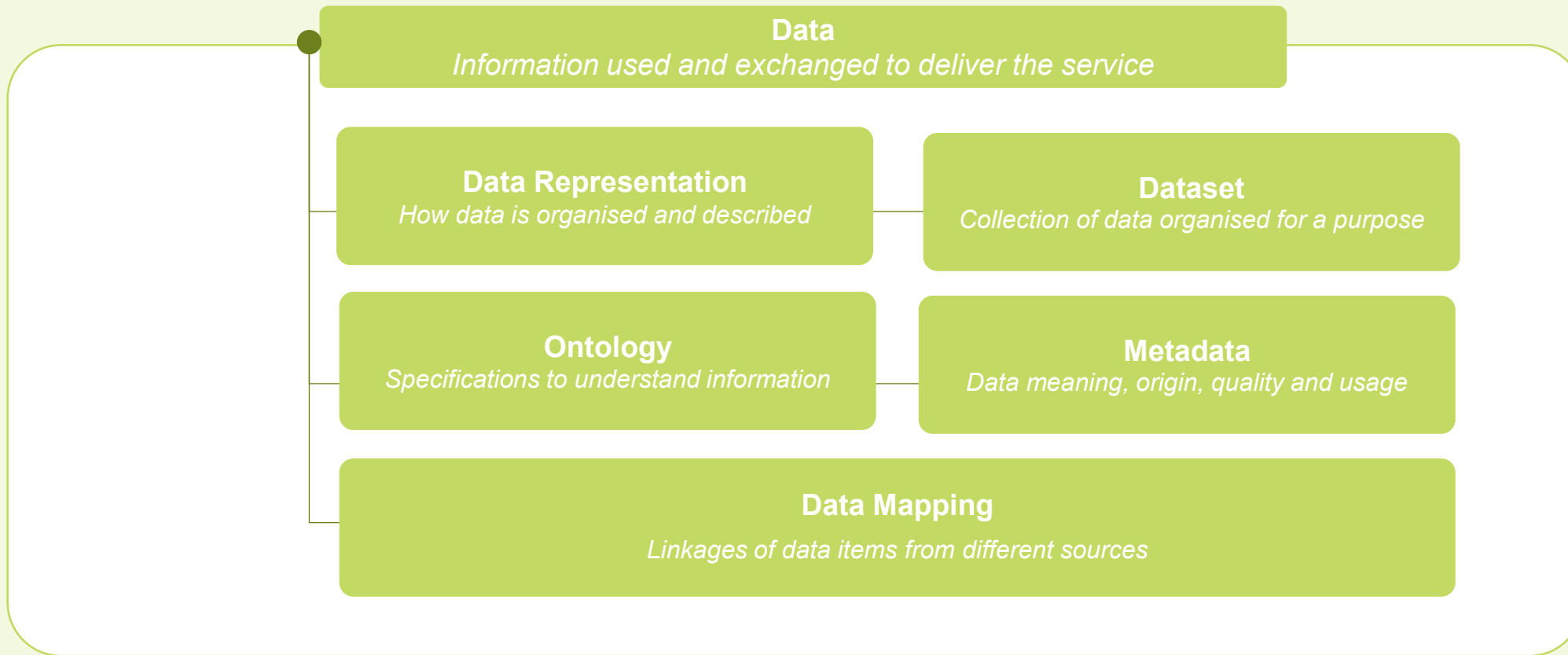
Service Delivery



Simplification – eGovERA Core viewpoints – Semantic View



Defines the **information exchanged** within the digital public service and ensures that all stakeholders interpret and use it consistently.



Simplification – eGovERA Core viewpoints – Semantic View

Data Representation

Dataset

Ontology

Metadata

Data mapping

Data Representation

How data is organised and described

Data and Document Representation and Serialisation

JSON

JSON-LD

CBOR (RFC 8949)

XML

PDF/A-3

Semantic Web Standards and Languages

RFD

SHACL

GraphQL

RDF Schema (RDFS)

SPARQL

OWL2

EUDI Wallet Semantic and Credential Representation

EUDI Wallet
Semantic Model

Authentication
Artefact

Consent Artefact

Credential
Artefact

Signature Artefact

SD-JWT

ISO mdoc /
ISO/IEC 18013-5

Simplification – eGovERA Core viewpoints – Semantic View

Data Representation

Dataset

Ontology

Metadata

Data mapping

Dataset

Collection of data organised for a purpose

Patient Summary
Dataset

ePrescription
Dataset

eDispensation
Dataset

Discharge
Reports Datasets

Medical Test
Results Dataset

Medical Images
Dataset

Medical Imaging
Reports Dataset

Patient Inserted
Dataset

Patient Consent
Dataset

Research Dataset
(Anonymised/Pseudonymised)

Secure Processing Environment (SPE)
Dataset

Terminologies, classifications, ontologies and common data models

Specifications to understand information

SNOMED CT

LOINC

ICD-10/ ICD-11

ATC WHO

OMOP-CDM

Simplification – eGovERA Core viewpoints – Semantic View

Data Representation

Dataset

Ontology

Metadata

Data mapping

Metadata

Data meaning, origin, quality and usage

Metadata Catalogue

Descriptive
Metadata

Structural
Metadata

Administrative
Metadata

mDoc Credential
Metadata

HealthDCAT-AP
Metadata

MyHealth Metadata and Semantic Fabric

Provenance
Metadata

Content
Metadata

Access
Metadata

Context
Metadata

Connection
Metadata

Quality
Metadata

myHealth FHIR Metadata Catalogue Solutions

FHIR DocumentReference

FHIR StructureDefinition

FHIR ImplementationGuide

FHIR Encounter

FHIR AuditEvent

FHIR Consent

FHIR Composition

FHIR EpisodeOfCare

FHIR Condition

FHIR OperationOutcome

FHIR Provenance

FHIR ValueSet

FHIR CapabilityStatement

FHIR Document

FHIR Observation

FHIR ConceptMap

EEHRxF Profiles

FHIR Subscription

FHIR Security Labels

FHIR Patient

FHIR Practitioner

FHIR Organisation

FHIR Collection

Simplification – eGovERA Core viewpoints – Semantic View

Data Representation

Dataset

Ontology

Metadata

Data mapping

Data Mapping

Linkages of data items from different sources

Patient Summary
Mapping

ePrescription
Mapping

eDispensation
Mapping

Discharge report
Mapping

Medical Test
Results Mapping

Medical Imaging
Reports Mapping

Medical Images
Mapping

Patient Inserted
Data Mapping

Patient Consent
Mapping

Semantic
Mapping Rule

Context-Specific
Dataset Mapping

Patient Identity
Mapping

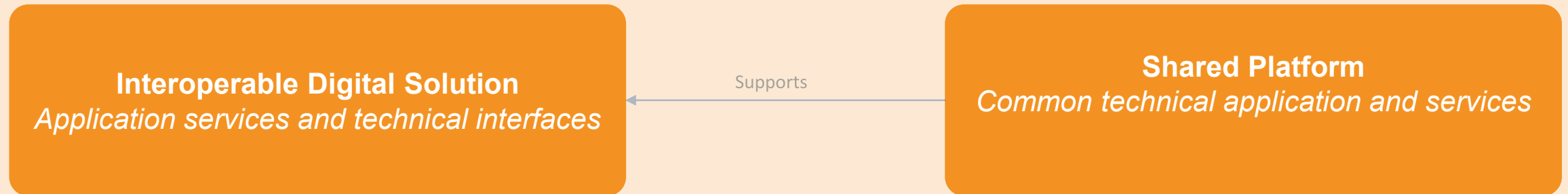
Health
Professional
Mapping

HealthDCAT-AP Dataset Mapping

Simplification – eGovERA Core viewpoints – Technical View



Defines the **applications, technologies, and infrastructure** required to implement and operate the digital public service.



Simplification – eGovERA Core viewpoints – Technical View

Interoperable Digital Solution

Shared Platform

Interoperable Digital Solution

Application services and technical interfaces

Application Presentation Enablers

Citizen Health
Application

Healthcare
Professional
Portal

Patient Portal

Wallet-Based Patient
Access

Credential
Verification Service

Patient Identity
Resolution

Consent and Access
Authorization

Patient Health Data
Retrieval

Health Record
Presentation

Clinical Data Transformation and
Mapping

Shared Platform

Common technical application and services

API Enablers

Pan-European Health
Data Access Enablers

Artificial Intelligence
Enablers

Analytics Enablers

Pan-European Health
Data Context and
Provenance Enablers

Security Enablers

Containerization
enablers

Dataspace Enablers

Health Credential and
Wallet Integration
enablers

Pan-European Health
Consent Enablers

Privacy Enablers

Data Exchange
Enablers

Data Management
Enablers

Observability and
Monitoring Enablers

Test Enablers

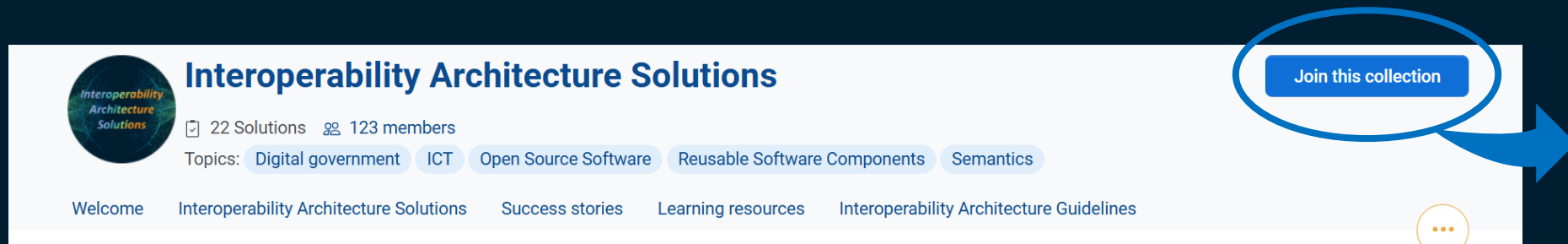
Translation Enablers

Trust Enablers

User Experience
Management Enablers



Relevant links



Interoperability Architecture Solutions

22 Solutions 123 members

Topics: Digital government ICT Open Source Software Reusable Software Components Semantics

Welcome Interoperability Architecture Solutions Success stories Learning resources Interoperability Architecture Guidelines

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success stories**

**Learn about
EIRA and
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DIGIT-EIRA@ec.europa.eu

The background features a complex, symmetrical pattern of glowing green and blue lines and particles. These elements form a central, diamond-like shape with intricate, branching structures extending towards the left and right edges. The lines are thin and delicate, while the particles are small, bright dots that create a sense of depth and movement. The overall effect is reminiscent of a microscopic view of a crystal or a complex network of fibers.

Thank you

interoperable europe

innovation ∞ govtech ∞ community

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