GOVERNANCE MODEL

Final Conference, 28 September 2022

Governance framework for citizen-centric health data sharing: InteropEHRate scenarios

EMERGENCY ACCESS

S-EHR CLOUD

HCP App

www

Patient Emergency Token

Access to patient's health data in an emergency

Exchange of EHR data mediated by the citizen

HEALTHCARE ACCESS

RESEARCH ACCESS

Research definition document

S-EHR App

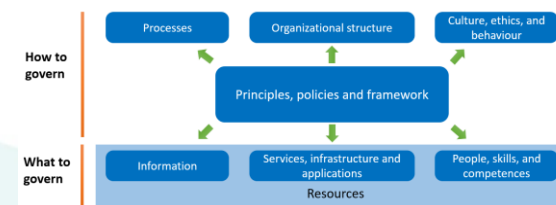S-EHR DATA CONTAINER

RESEARCH CENTER

Research Tools

Data sharing for research

Access to EHR data from primary HCP

Citizen-centric health data sharing

Governance framework for citizen-centric health data sharing
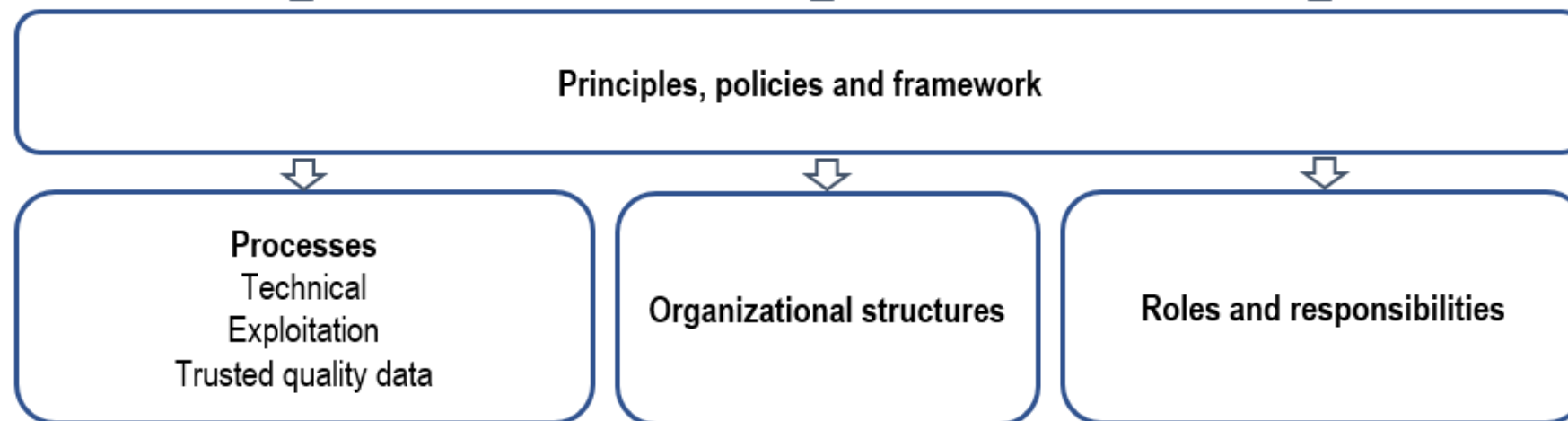
Adapted governance framework
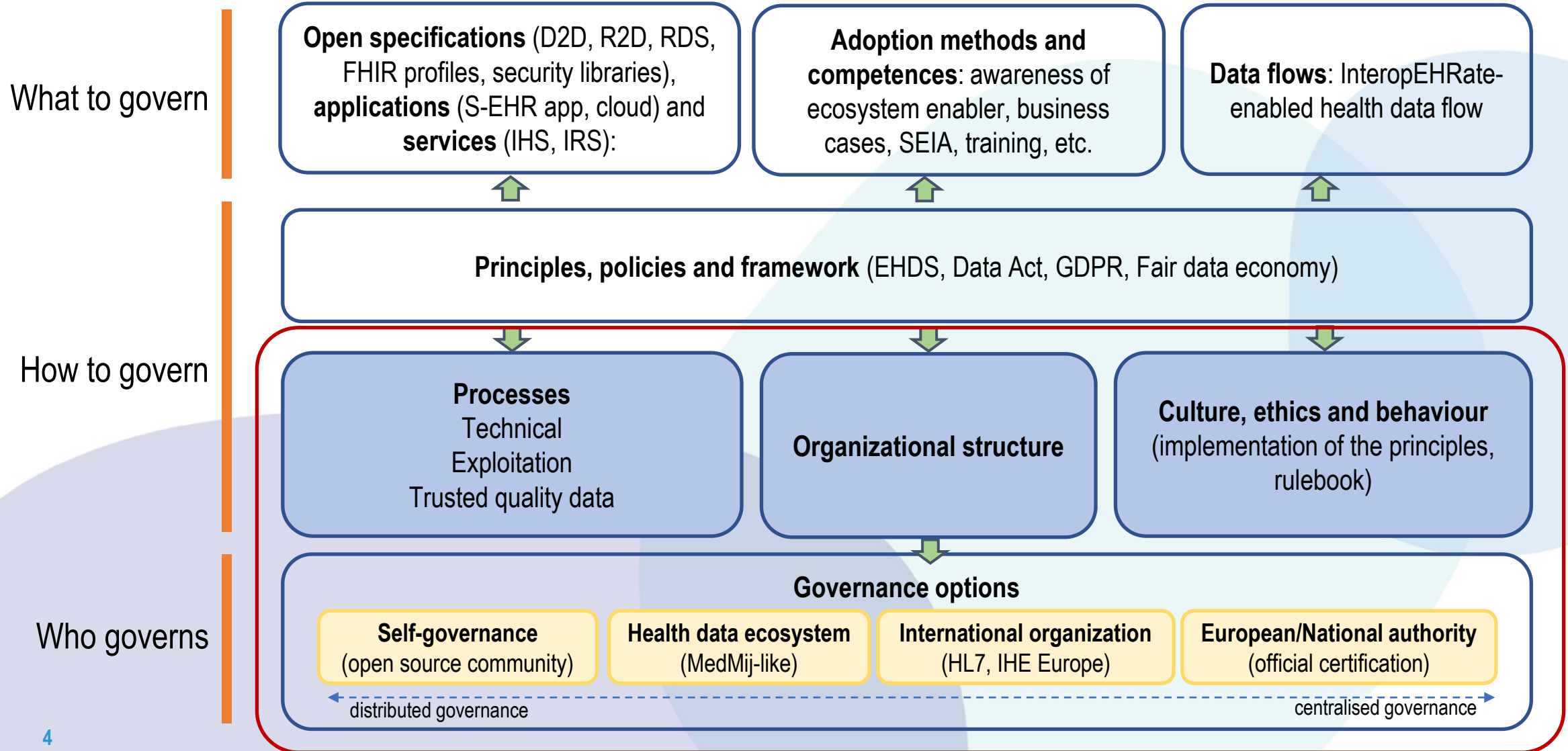
What to govern

Open specifications (D2D, R2D, RDS, FHIR profiles, security libraries), **applications** (S-EHR app, cloud) and **services** (IHS, IRS):

Adoption methods and competences: awareness of ecosystem enabler, business cases, SEIA, training, etc.

Data flows: InteropEHRate-enabled health data flow

Principles, policies and framework (EHDS, Data Act, GDPR, Fair data economy)

How to govern

Processes
Technical
Exploitation
Trusted quality data

Organizational structure

Culture, ethics and behaviour (implementation of the principles, rulebook)

Who governs

Governance options

Self-governance (open source community)

Health data ecosystem (MedMij-like)

International organization (HL7, IHE Europe)

European/National authority (official certification)

distributed governance ← → centralised governance

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How to govern? **Processes**

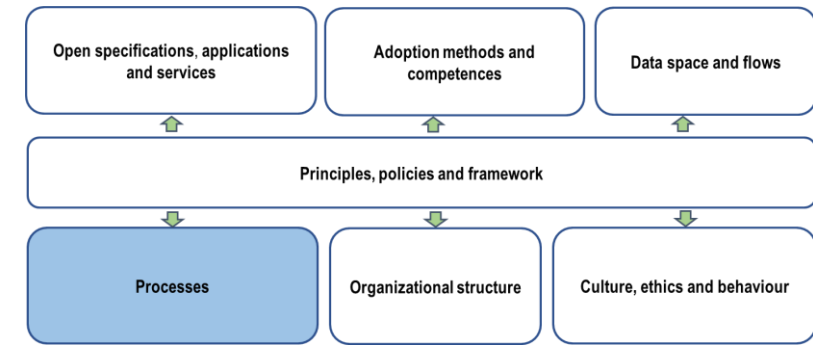**1** **Maintenance and evolution processes**

- Maintenance of exploitable assets and implementation guides
- Conformance and quality control
- Identification of shortcomings and coordination of change requests
- Evolution, test and validation of novelties
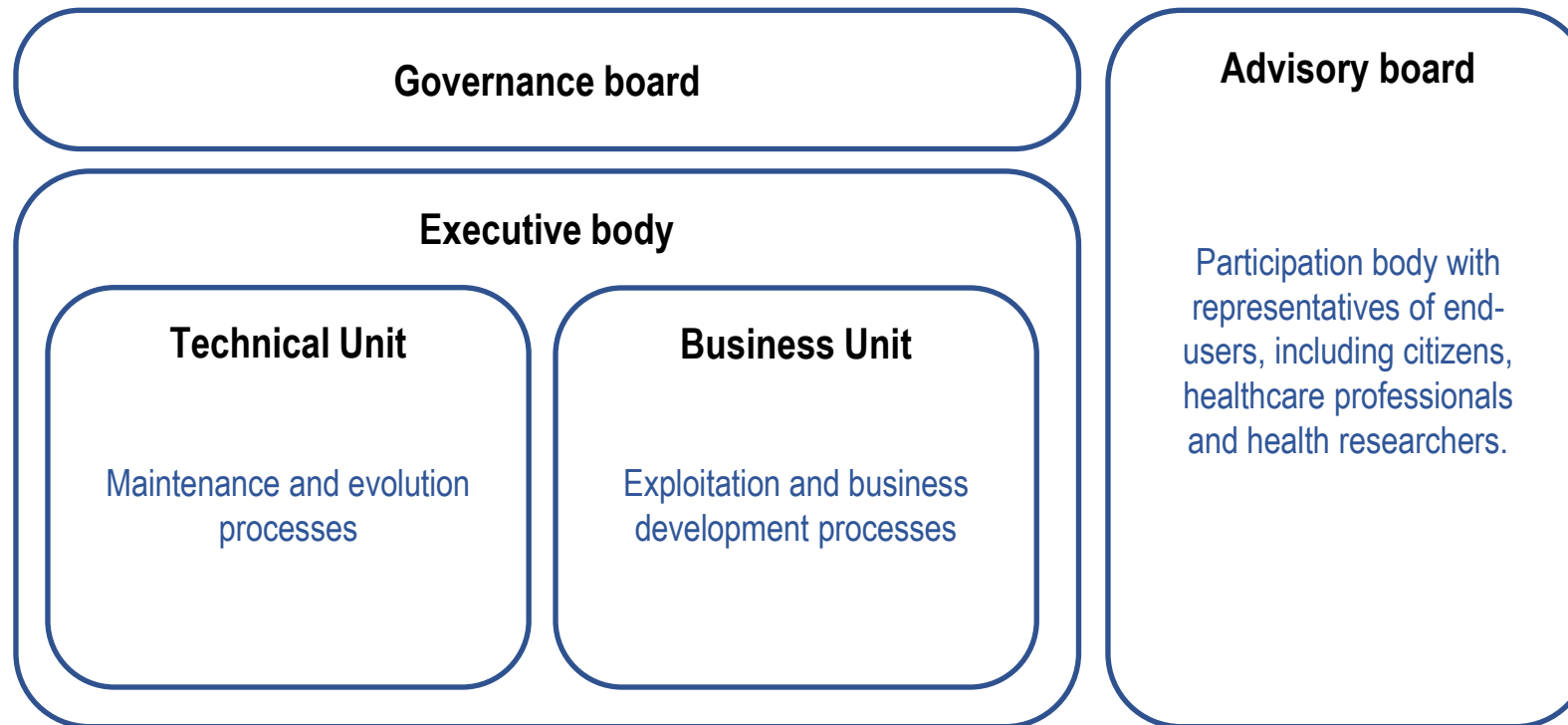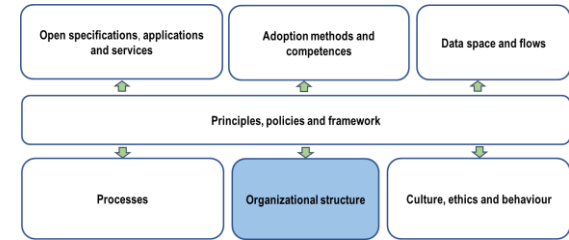- Create a testing platform
- Version management

2 **Exploitation and business development processes**

- Identifying change management processes for standards and specifications, engaging the user and stakeholder community.
- Certification, audit processes.
- GDPR compliance considerations
- Sustainability, business model and financial resources

3 **Data space and flows**

- Trust-building among data holders and subjects
- Trusted quality of data
- Development of the ecosystem rules

Open specifications, applications and services	Adoption methods and competences	Data space and flows
Principles, policies and framework		
Processes	Organizational structure	Culture, ethics and behaviour

How to govern?

Organizational structure


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Governance board

Executive body

    Technical Unit
    Maintenance and evolution processes

    Business Unit
    Exploitation and business development processes

Advisory board

    Participation body with representatives of end-users, including citizens, healthcare professionals and health researchers.
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Governance options

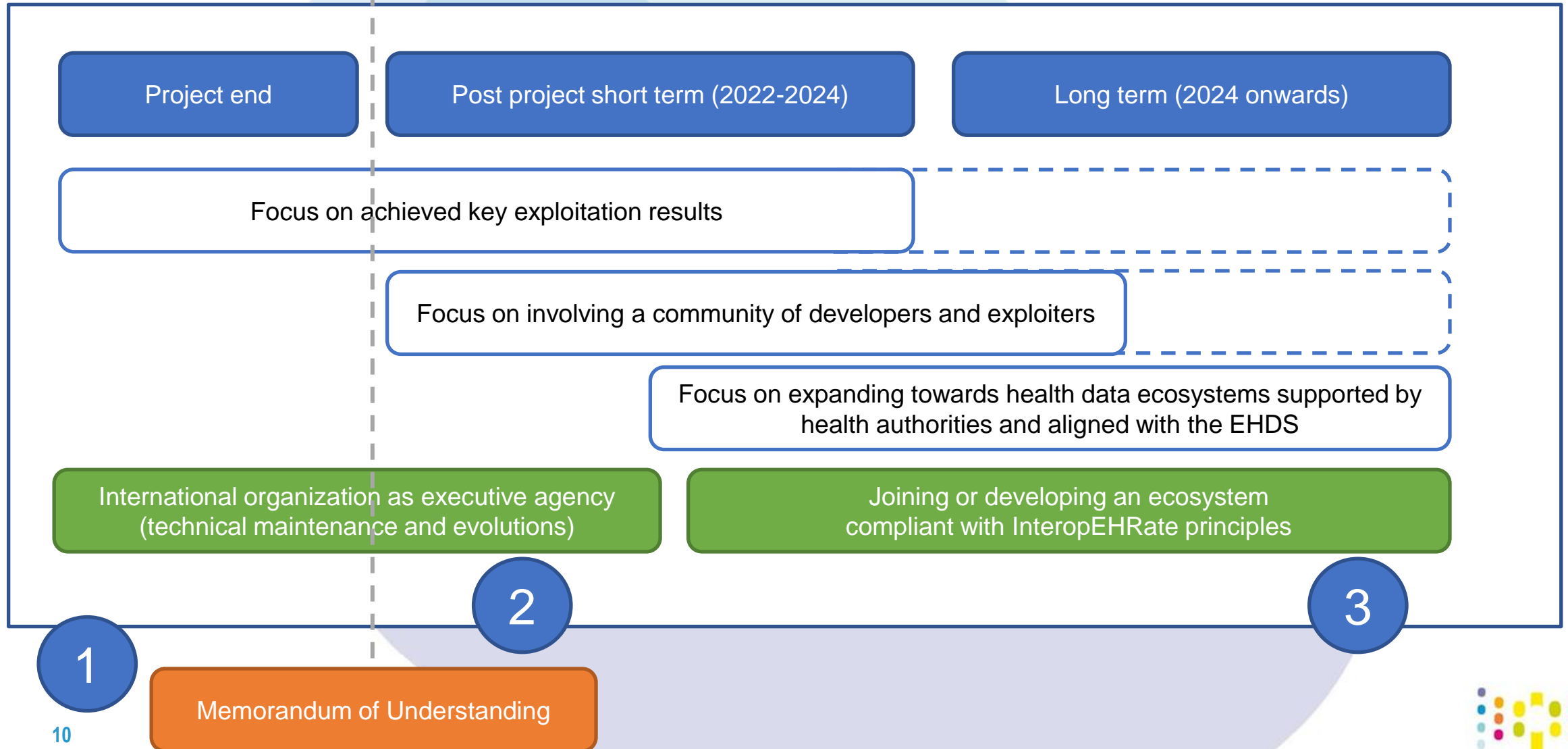| Attributes	Self-governance	Health data ecosystem	International organization	European / National Authority
Keyword	Open source community	Integration in a health data ecosystem	Development of standards	European / National certification / label
Approach	Bottom-up	Middle-out	Middle-out	Top-down
Public-private partnership	Mainly private	Mixt	Mainly private	Public
Industry participation	Open	Limited	Open	Limited

Governance options

- A **self-governed** community-based organization is in line with the open-source nature of InteropEHRate assets, attractive to create a developers' community and open to the collaboration of multiple organizations.

- An existing **international organization**, like an SDO, is an optimal candidate to host and manage the technical components of InteropEHRate. It would require to review how the exploitation and data flow assets are governed and managed.

- Direction and support from **European / National health authorities** would bolster InteropEHRate in a phase where it has already shown value at scale in reference sites.

- An **ecosystem** model of applications or health data exchanges is not foreseen as immediate governance model.

Proposed governance model of InteropEHRate

Proposed governance model: evolving configuration

Project end	Post project short term (2022-2024)	Long term (2024 onwards)

Focus on achieved key exploitation results

Focus on involving a community of developers and exploiters

Focus on expanding towards health data ecosystems supported by health authorities and aligned with the EHDS

International organization as executive agency (technical maintenance and evolutions)	Joining or developing an ecosystem compliant with InteropEHRate principles

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2

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Memorandum of Understanding

Thank you!

InteropEHRate

EHR in people's hands across Europe

www.interopehrate.eu