The European Health Data Space

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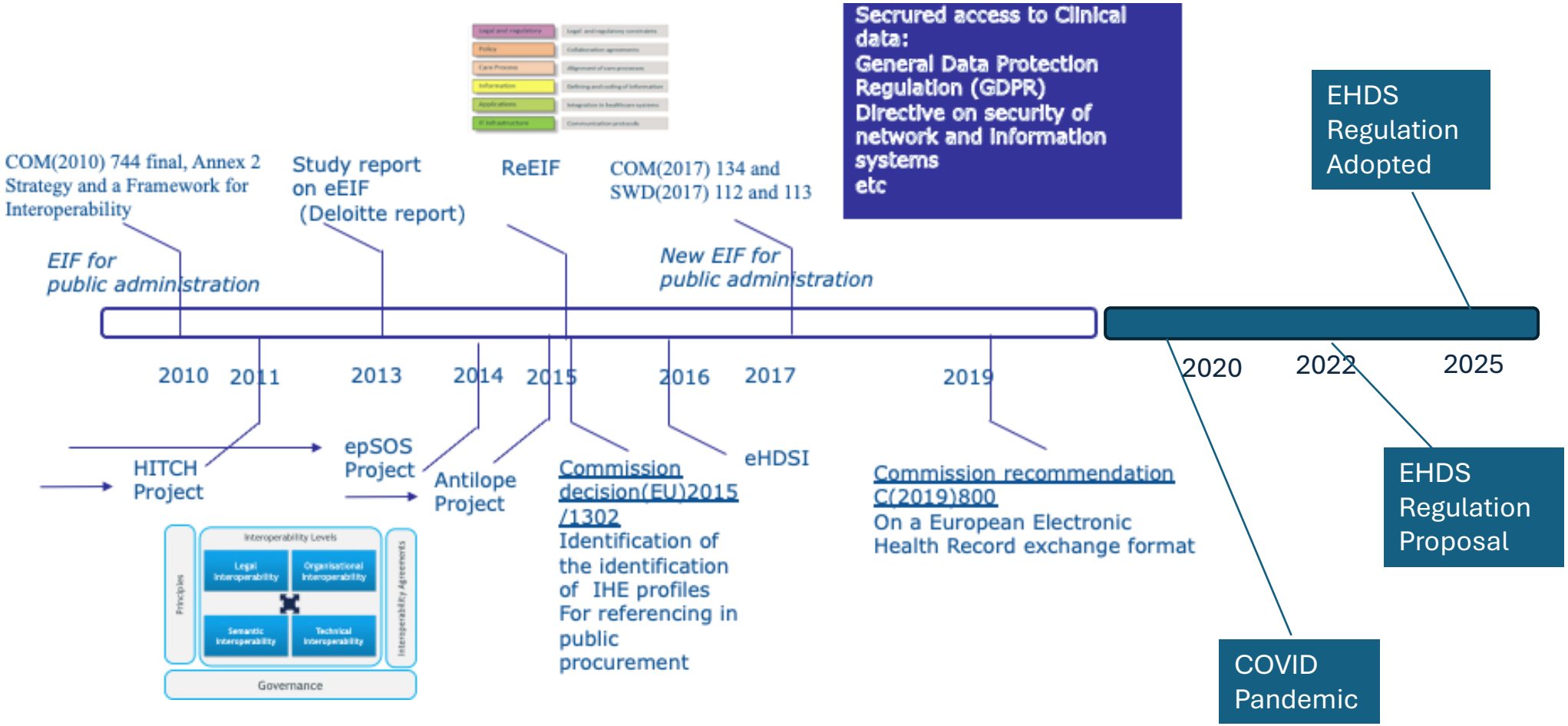
The European Health Data Space Regulation of 11 February 2025
Harnessing the value of health data

EHDS Regulation is a reality

Official Regulation Text: https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng

Effective 26 March 2025

Background

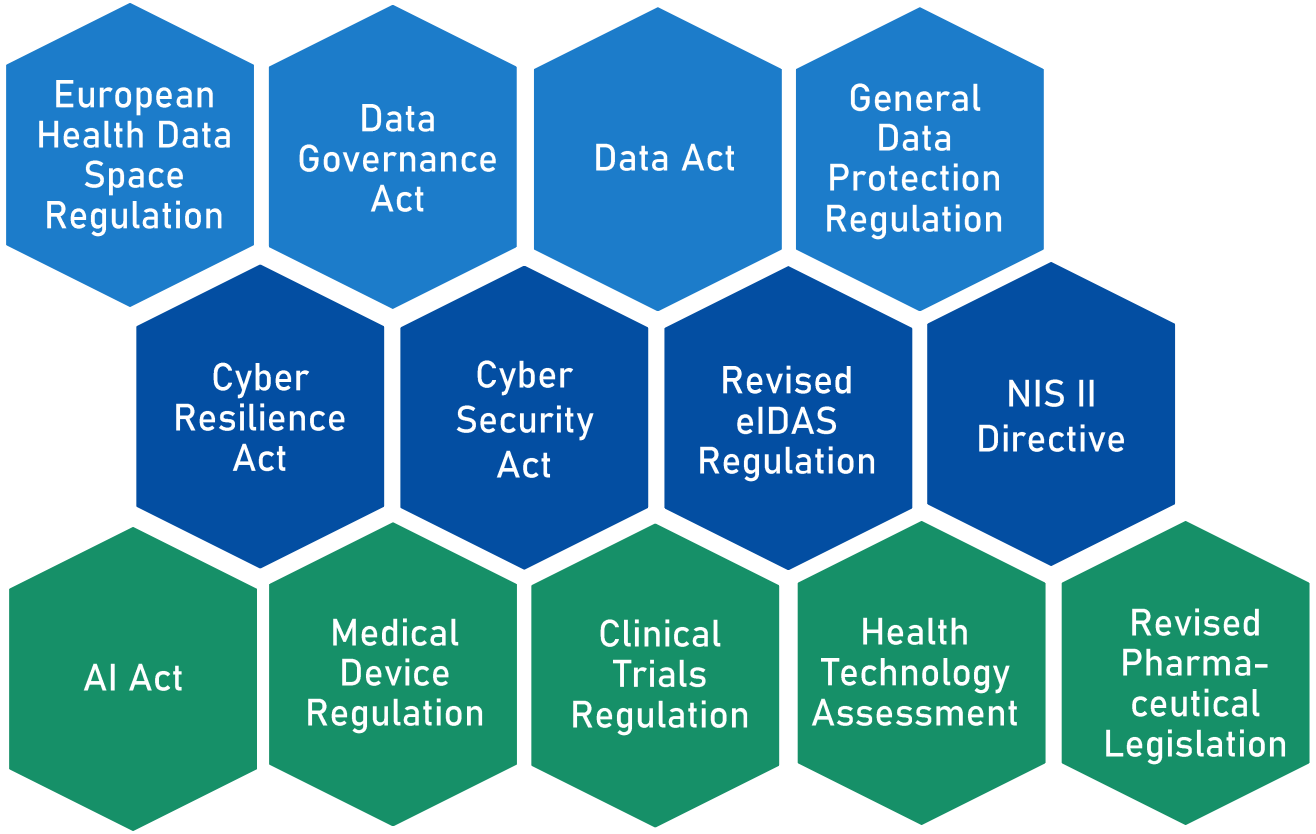

Secrured access to Clinical data:
General Data Protection Regulation (GDPR)
Directive on security of network and information systems
etc
EHDS Regulation Adopted
COM(2010) 744 final, Annex 2 Strategy and a Framework for Interoperability
Study report on eEIF (Deloitte report)
ReEIF
COM(2017) 134 and SWD(2017) 112 and 113
EIF for public administration
New EIF for public administration
2010
2011
2013
2014
2015
2016
2017
2019
2020
2022
2025
HITCH Project
epSOS Project
Antilope Project
Commission decision(EU)2015/1302
Identification of the identification of IHE profiles For referencing in public procurement
eHDSI
Commission recommendation C(2019)800
On a European Electronic Health Record exchange format
EHDS Regulation Proposal
COVID Pandemic
Interoperability Levels
Legal Interoperability
Organisational Interoperability
Semantic Interoperability
Technical Interoperability
Principles
Interoperability Agreements
Governance

Digital transformation of healthcare: the building blocks

Data availability & sharing

Security and trust

Technology and safety

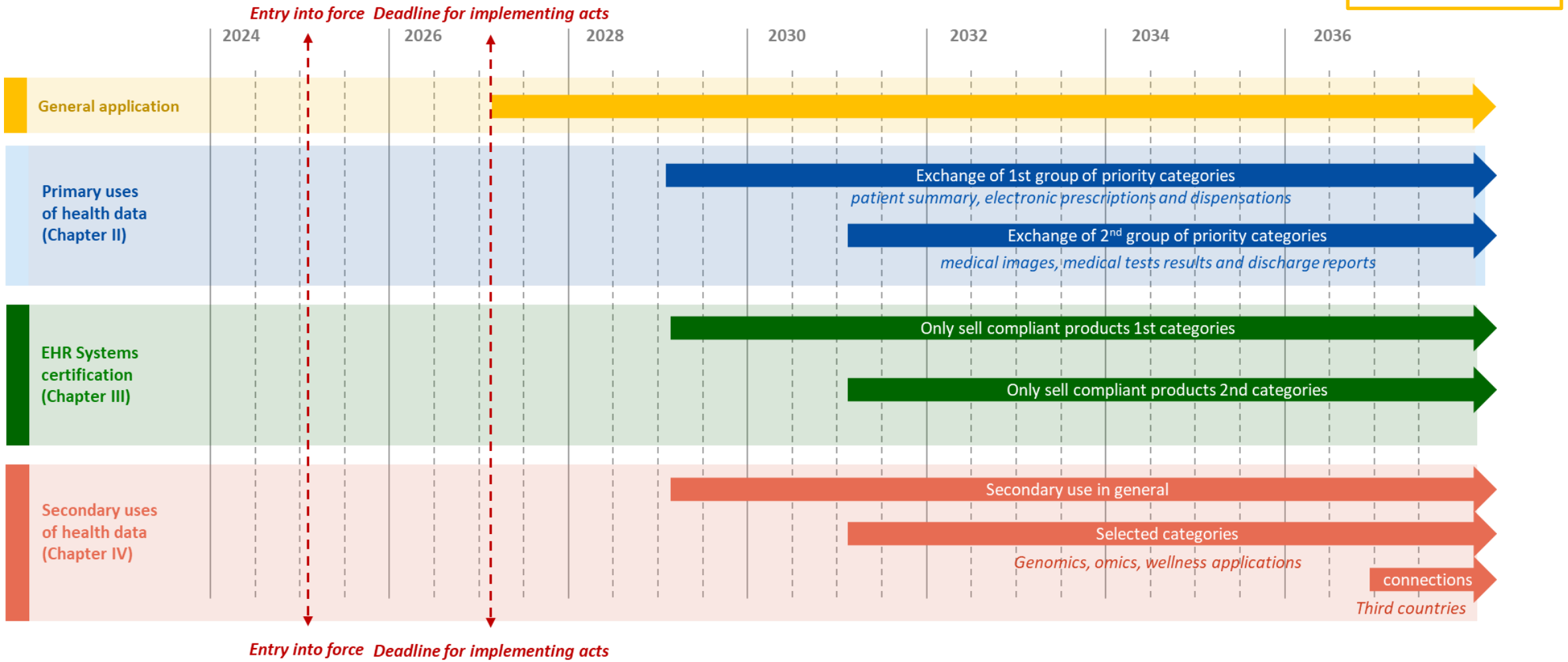


e-Health target: 100% of EU citizens access to **electronic health records** by 2030

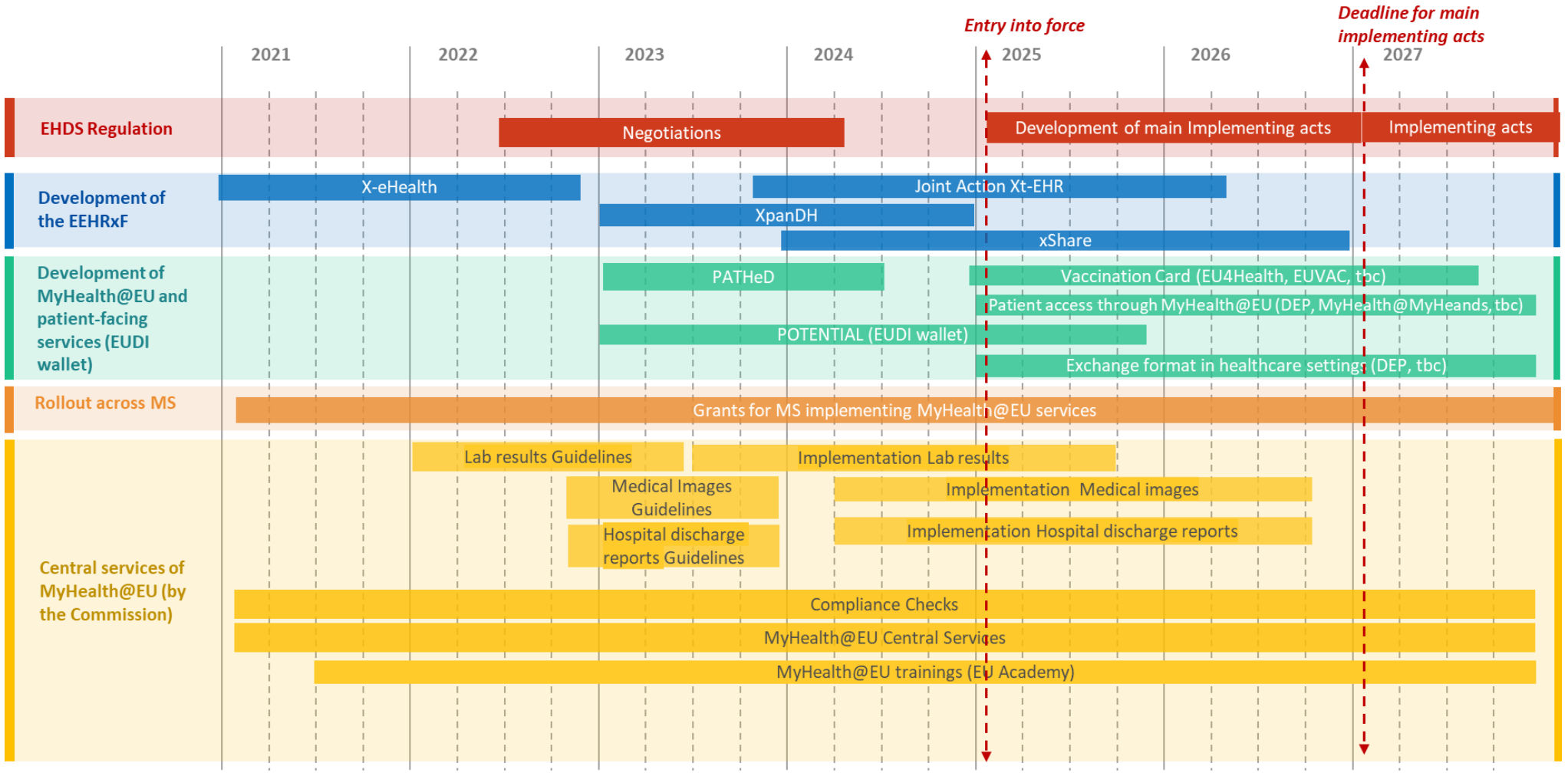
Source: Konstantin Hyppönen, European Commission

Implementation of the EHDS Regulation

Article 105

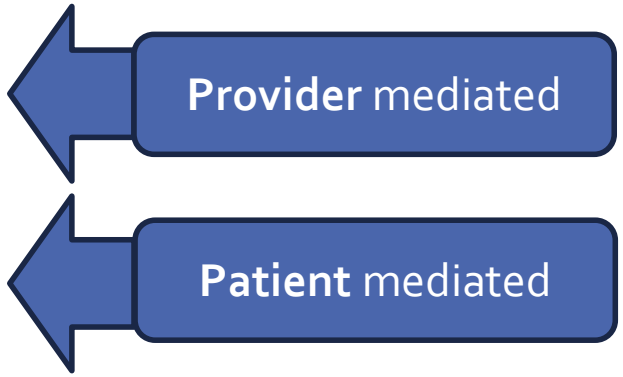


Primary uses of health data – Implementation



EHDS in a Nutshell –what is it about?

1. Primary use = use of data for the delivery of healthcare
   - Improving patients' access to their health data;
   - Ensuring seamless exchanges for continuity of healthcare – also across borders
2. Secondary use = use of data for research and public interest purposes
   - Making data available for research, policy-making etc. in a safe and secure way - also across borders
3. Requirements for electronic health record (EHR) systems
   - Creating a single market for electronic health records systems, supporting both primary and secondary use.



My health @ EU
eHealth Digital Service Infrastructure
A service provided by the European Union

HealthData@EU

Primary Use of Data

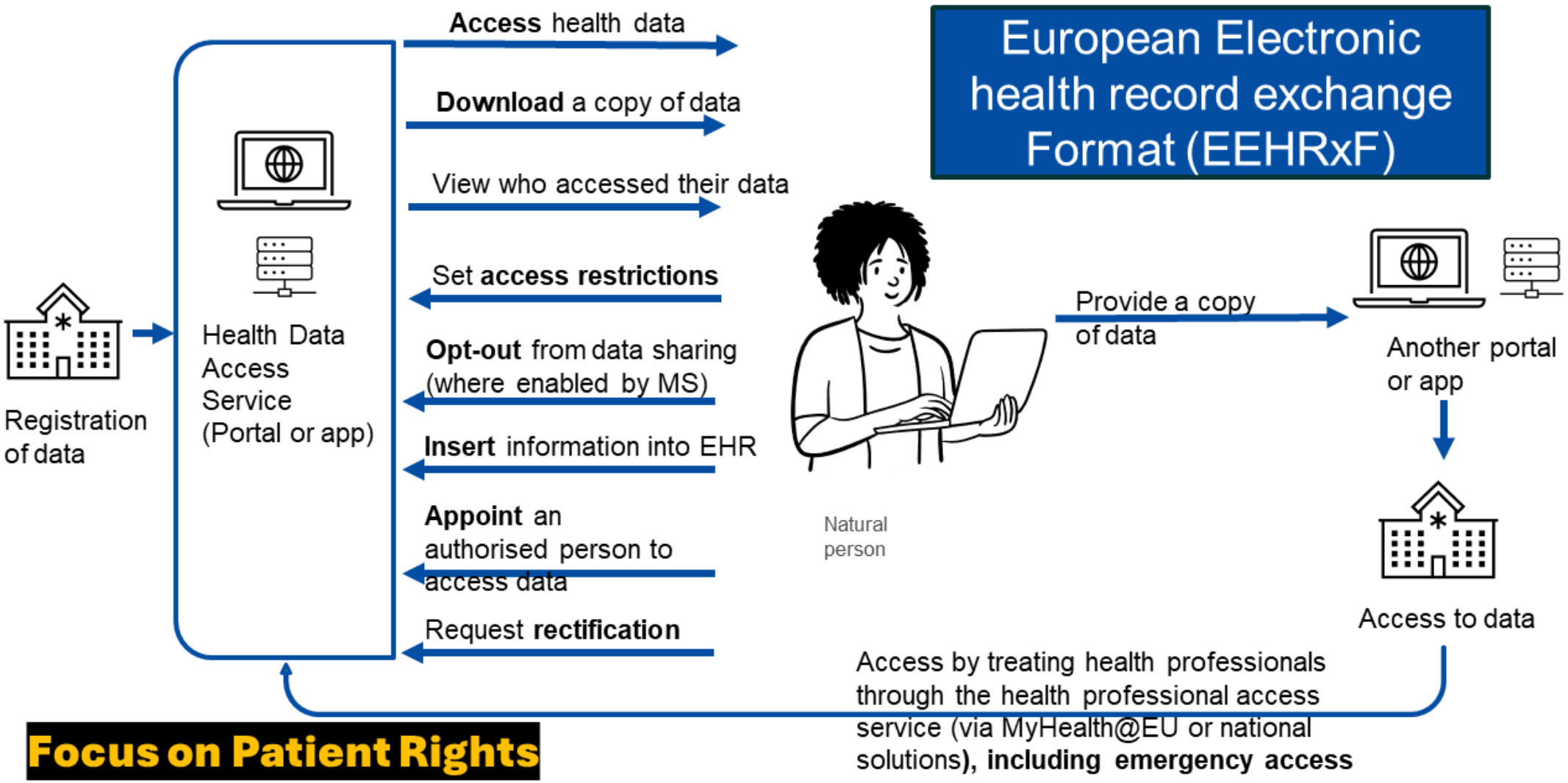
EHDS in a Nutshell –Primary use

Chapter II

How?

- Strengthening patients' rights on defined categories of their own data; Patient- and health professional-facing services to access data;
- Building on existing voluntary MyHealth@EU infrastructure, not touching upon national rules on provision of care / management of healthcare systems.

Rights of natural persons in primary use



Access services

Articles 4,11, 12, 16

- Patient-facing
  - MS to establish one or more (their choice depending on organisation of healthcare system);
  - Agnostic regarding centralised or decentralised storage;
  - Interoperable among MS (COM to provide technical specs).
- Health professional-facing
  - Access to priority categories of patients ***under their treatment;***
  - Authentication: Art. 6 eIDAS-recognised or other electronic identification that meet Art.
  - 36 common specs

Building on existing cooperation

MyHealth@EU under Cross-border Healthcare Directive

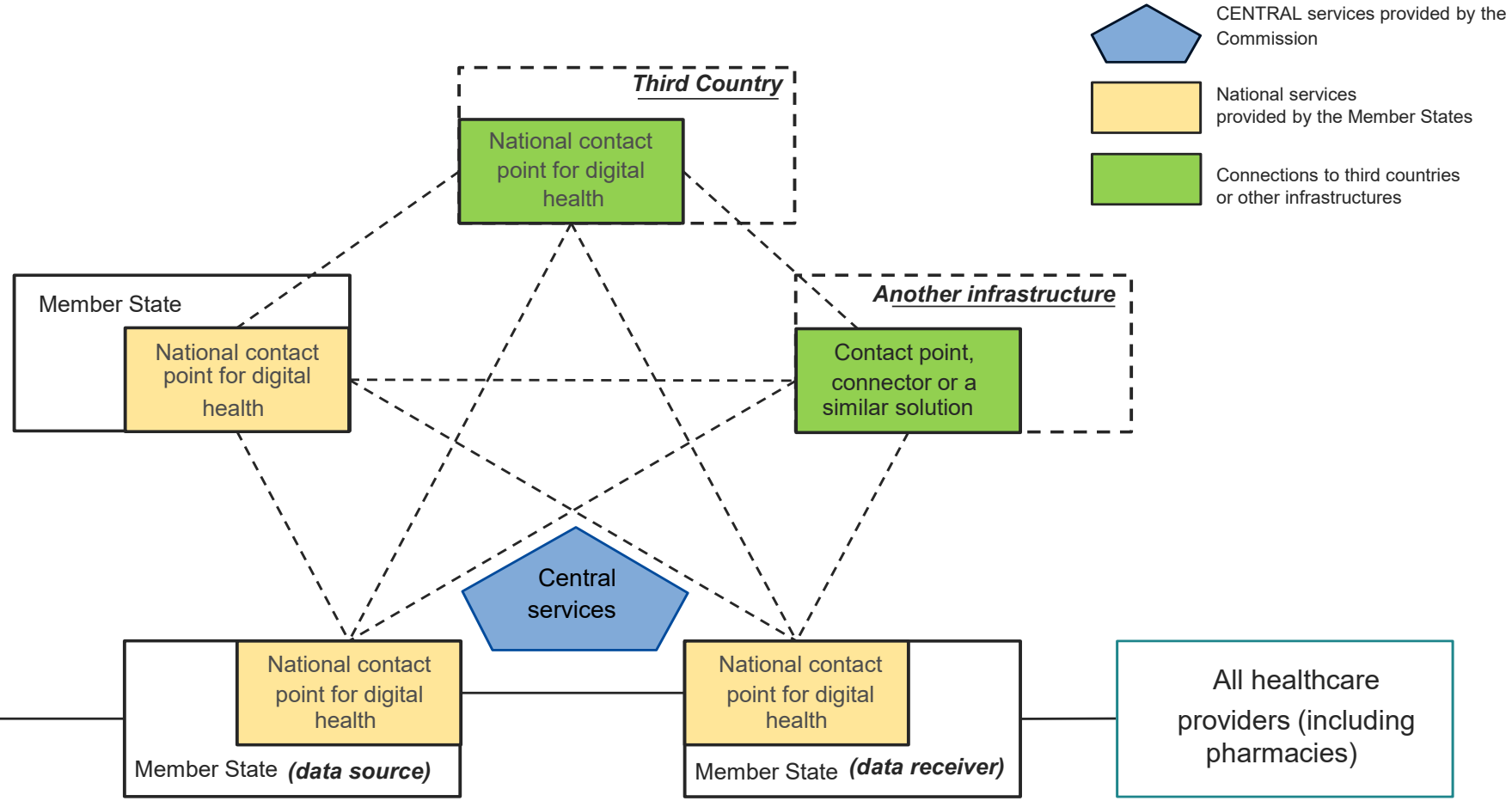
- Voluntary system for exchanging patient summaries, prescriptions and dispensations (= first group of priority categories) **16 countries** live with at least one service, up to **9 more** expected to go live with first service(s) this year

Evolution of MyHealth@EU for the EHDS

- Voluntary => mandatory
- New services
- New data categories

MyHealth@EUhigh-level architecture

Article 23



Data categories

Priority group 1:

- Patient summaries
- ePrescriptionsand eDispensations

Priority group 2:

- Medical test results: laboratory, other diagnostics, related reports
- Medical imaging: studies
- and reports Discharge reports

Additional data categories:
May be exchanged where supported

Data suppliers:
all healthcare providers.

The exchange format (EEHRxF) – Art. 15

Article 15

European electronic health record exchange format

1. By … [two years from the date of entry into force of this Regulation], the Commission shall, by means of implementing acts, lay down the technical specifications for the priority categories of personal electronic health data referred to in Article 14(1), setting out the European electronic health record exchange format. Such format shall be commonly used, machine-readable and allow transmission of personal electronic health data between different software applications, devices and healthcare providers. Such format shall support transmission of structured and unstructured health data and shall include the following elements:

   (a) harmonised datasets containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data;

   (b) coding systems and values to be used in datasets containing electronic health data;

   (c) technical interoperability specifications for the exchange of electronic health data, including its content representation, standards and profiles.

   The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 98(2).

Priority categories

Group 1

- Patient summaries
- Electronic prescriptions
- Electronic dispensations

Detailed specifications for the European Electronic Health Record Exchange Format (EEHRxF) via implementing act, building on work done following 2019 recommendation, several projects etc. => strong Member State involvement

Group 2

Articles 14, 15

- Medical imaging studies and related imaging reports
- Medical test results, including laboratory test and related reports
- Discharge reports

EHR Systems and Vendor Compliance

Chapter III

How?

- Product legislation for two components of EHR systems:
  →interoperability and logging;
- Full harmonisation for those two components;
- Approach based on new legislative framework for product legislation, incorporating recent developments from other product legislation.

What is (and is not) an EHR system?

Elements of the definition:

- combination of hardware of software or software only; allows the storage, intermediation, export, import, conversion, editing, or viewing of priority categories of electronic health data
- Not necessary to provide all of storage, intermediation, export, import, conversion, editing, or viewing functionalities to be considered as an EHR system; intended by their manufacturer to be used:
  - by healthcare providers when providing patient care;
  - or by patients when accessing their electronic health data.

Systems that only processes other kinds of data, e.g. appointment booking systems, are not EHR systems.

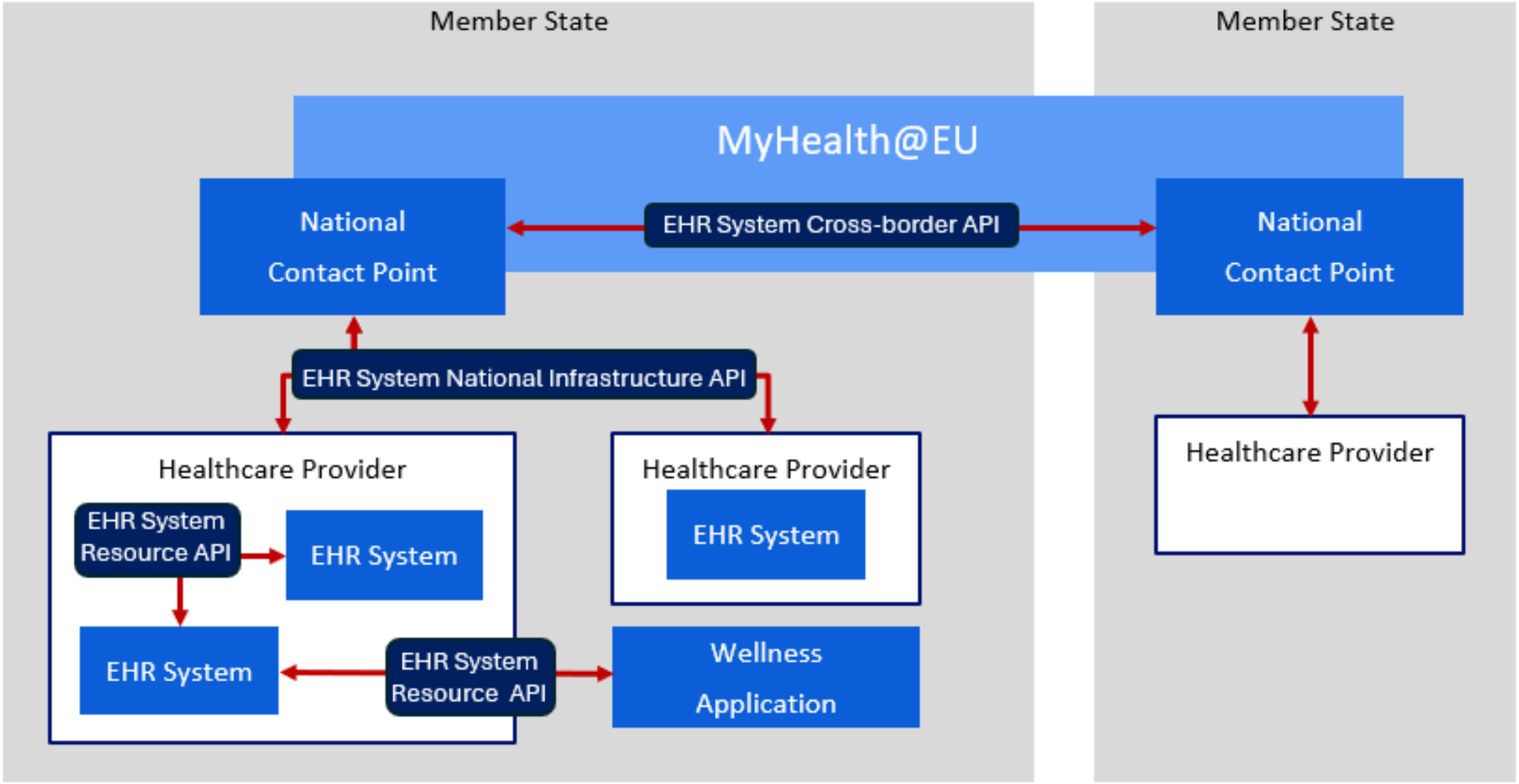
e.g. systems used by clinicians for recording notes, test results etc., up to a patient management system

E.g. an app that connects to the electronic health data access service for patient will count as an EHR system.

What about openNCP nodes?

Article 2(2)(k)

General requirements for EHRs and system interfaces



Scope of harmonisation

Articles 26, 29, 36

EHR systems must contain two harmonised components, starting early 2029 / early 2031 for 1st/ 2ndgroup of priority categories:

Interoperability component

- Provides capability to import/export data in EEHRxFas per Art. 15

Logging component

- Provides capability to generate the logs of access as per Art. 9

Detailed specifications to be set out by COM in implementing act.

Member States remain free to have requirements on other parts of EHR systems, provided they don't interfere with the harmonised components.

How to demonstrate compliance?

Articles 39 to 41

- Self-declaration of conformity by manufacturer
  - no third-party conformity assessment as in MDR;
- However: EHR systems must pass an automated test in the ***digital testing environment*** before being placed on the market.;
- Test report becomes part of product documentation;
  - ➢ Final 'all fine' report –no obligation to disclose failed reports;
- COM to develop software package for testing environments, MS to deploy;
- What to expect from the testing environment?
  - Details to be developed, but expect simulated actions on the system:
  - Import/export transactions –checking if presentation / translation of test data is correct;
  - Logging of actions –checking if logs are generated in the right format.

EHR vendor compliance — first determine whether the product is in scope

- STEP 1 — CLASSIFY: is the software an EHR system intentionally designed to process one or more EHDS priority categories? General-purpose software is not automatically an EHR system.
- STEP 2 — IDENTIFY APPLICABILITY: Group 1 priority categories drive the first Chapter III obligations from 26 March 2029; Group 2 follows from 26 March 2031.
- STEP 3 — MAP OTHER EU LAW: identify overlaps with MDR/IVDR, AI Act, Cyber Resilience Act and other applicable legislation; EHDS allows a single EU declaration where appropriate.
- STEP 4 — DEFINE THE TWO HARMONISED COMPONENTS: European interoperability software component + European logging software component.

EHR vendor compliance — design and implementation

- STEP 5 — REQUIREMENTS BASELINE: Annex II essential requirements + Article 36 common specifications + applicable EEHRxF specifications.
- STEP 6 — INTEROPERABILITY: implement import/export of priority electronic health data in EEHRxF without features that improperly restrict authorised access, sharing, use or export.
- STEP 7 — SECURITY & LOGGING: implement identification/authentication support, reliable logging and mechanisms to review/analyse logs or connect external analysis tooling.
- STEP 8 — INTEGRATION CONTROL: demonstrate that other product components do not adversely affect the harmonised components.
- STEP 9 — CONFIGURATION/CHANGE CONTROL: preserve conformity across versions, deployments and maintenance.

EHR vendor compliance — test, evidence, declare, register

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- STEP 10 — TEST: before market placement, use the European and/or Member State Article 40 digital testing environment for the harmonised components.
- STEP 11 — EVIDENCE: include the assessment results in the Article 37 technical documentation; positive tested elements benefit from a presumption of conformity.
- STEP 12 — USER INFORMATION: prepare the Article 38 information sheet and clear instructions for use.
- STEP 13 — SELF-ASSESS: manufacturer assumes responsibility and draws up the Article 39 EU declaration of conformity.
- STEP 14 — CE MARK: affix the Article 41 CE marking in accordance with EHDS and other applicable Union legislation.
- STEP 15 — REGISTER: enter required information and test results in the EU database under Article 49 before market placement/putting into service.

EHR vendor compliance does not end at CE marking

- STEP 16 — MARKET OPERATION: maintain technical documentation and conformity as the product evolves.
- STEP 17 — COMPLAINTS: maintain complaint channels and records of complaints and non-conforming systems.
- STEP 18 — INCIDENTS: report serious incidents to relevant market surveillance authorities within the EHDS timelines.
- STEP 19 — CORRECTIVE ACTION: correct, restrict, recall or withdraw non-conforming systems and inform affected economic operators/users as required.
- STEP 20 — SURVEILLANCE: provide authorities with information/evidence and cooperate with cross-border market-surveillance actions.

Compliance is therefore a lifecycle: classify → design → validate → self-declare → register → monitor → correct → revalidate.

EHR vendor compliance — evidence pack

https://acceptance.data.health.europa.eu/ehr-systems/useful-information?locale=en

Evidence	EHDS anchor	Produced when	Purpose
Requirements/conformity matrix	Annex II + Art. 36	Design & release	Trace legal/common specifications to implementation
Architecture + component boundaries	Arts. 26, 29–30	Design	Show harmonised components and non-interference
Digital testing environment results	Art. 40	Pre-market / release	Objective automated assessment evidence
Technical documentation	Art. 37 + Annex III	Pre-market + maintained	Core compliance dossier
Information sheet + instructions	Art. 38	Pre-market	Transparency and correct use
EU Declaration of Conformity	Art. 39 + Annex IV	Pre-market	Manufacturer's legal declaration
CE marking evidence	Art. 41	Pre-market	Market conformity indication
EU database registration	Art. 49	Before market / service	EU visibility + test-result registration
Complaints/incidents/corrective records	Arts. 30, 44–45	Post-market	Lifecycle surveillance and remediation

Industry critical path — the acts that shape an EHR product

Article 40 is the evidence gateway: mandatory pre-market testing of the two harmonised software components

Commission develops open-source European test software → Member States operate compliant environments → manufacturer tests → successful result enters technical documentation.

Secondary Use of Data

Chapter IV

How?

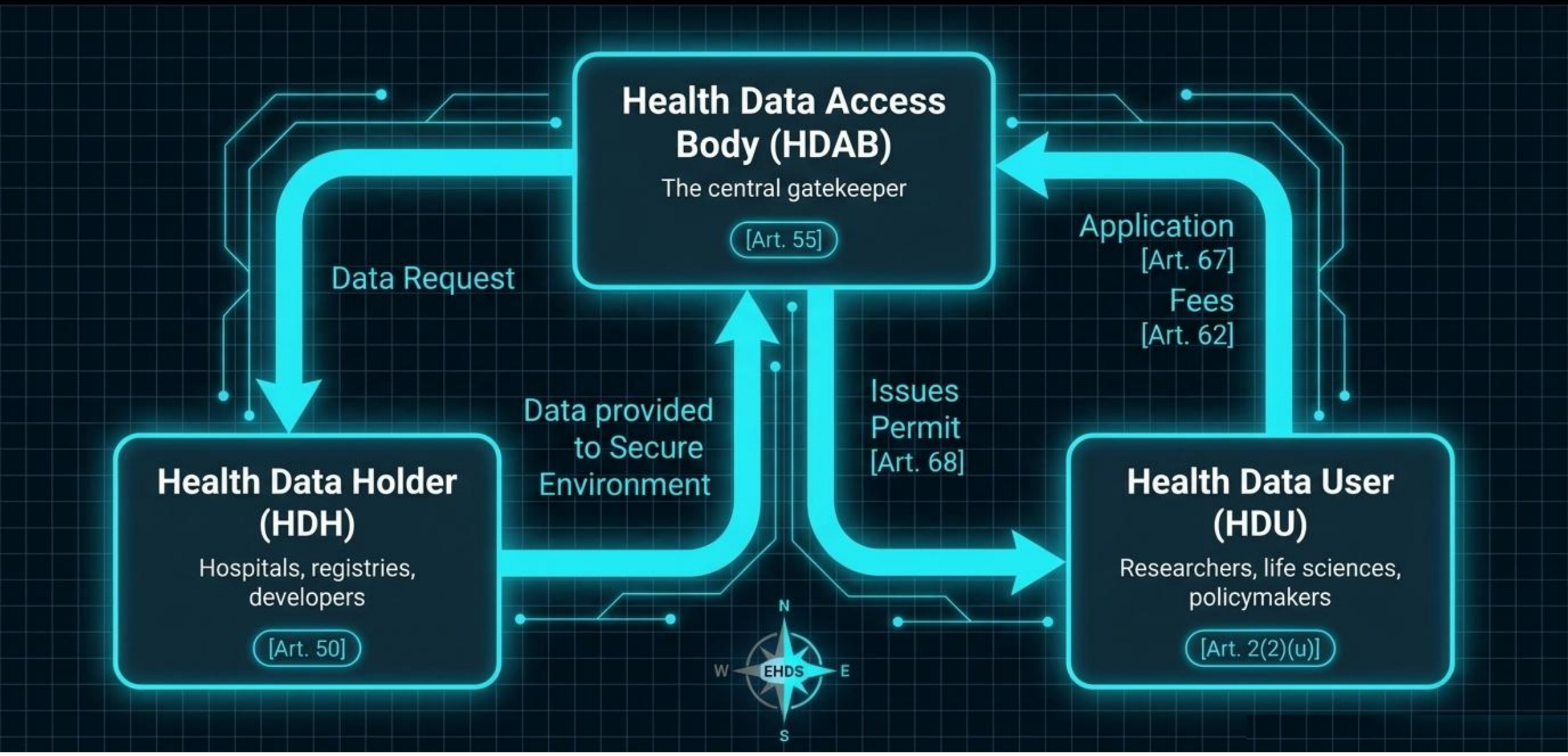
- Common European rules on who has to make which data available for which purposes and under which conditions
- Common infrastructure
- Health Data Access bodies as orchestrators
- Permits for data use, common safeguards
- Data catalogues of available datasets

The Chapter IV Secondary Use Ecosystem

A systemic view of how raw health data is legally transformed, permitted, and exported for innovation and public health.

The Stakeholder Triad

The EHDS replaces direct bilateral data brokering with a mediated, heavily regulated triad.



The Expanded Scope of Reusable Data [Art. 51]

Health Data Holders are legally obligated to make a vast array of electronic health data available. Exemptions are strictly limited to natural persons and microenterprises.

Clinical & Administrative

- EHRs & hospital discharge reports
- Insurance claims & reimbursement data

Scientific & Genomic

- Pathogen genomic data
- Human genetic/proteomic data
- Biobank databases & clinical trials

Population & Determinants

- Public health registries
- Social, environmental, and behavioral determinants of health

Digital & Device

- Automatically generated data from medical devices
- Wellness application data

[Art. 50] Member States can enact stricter safeguards for highly sensitive data (e.g., genomics).

The Boundaries of Innovation

Access is purpose-bound. The regulation explicitly defines the legal perimeter for secondary use.

Permitted Uses [Art. 53]

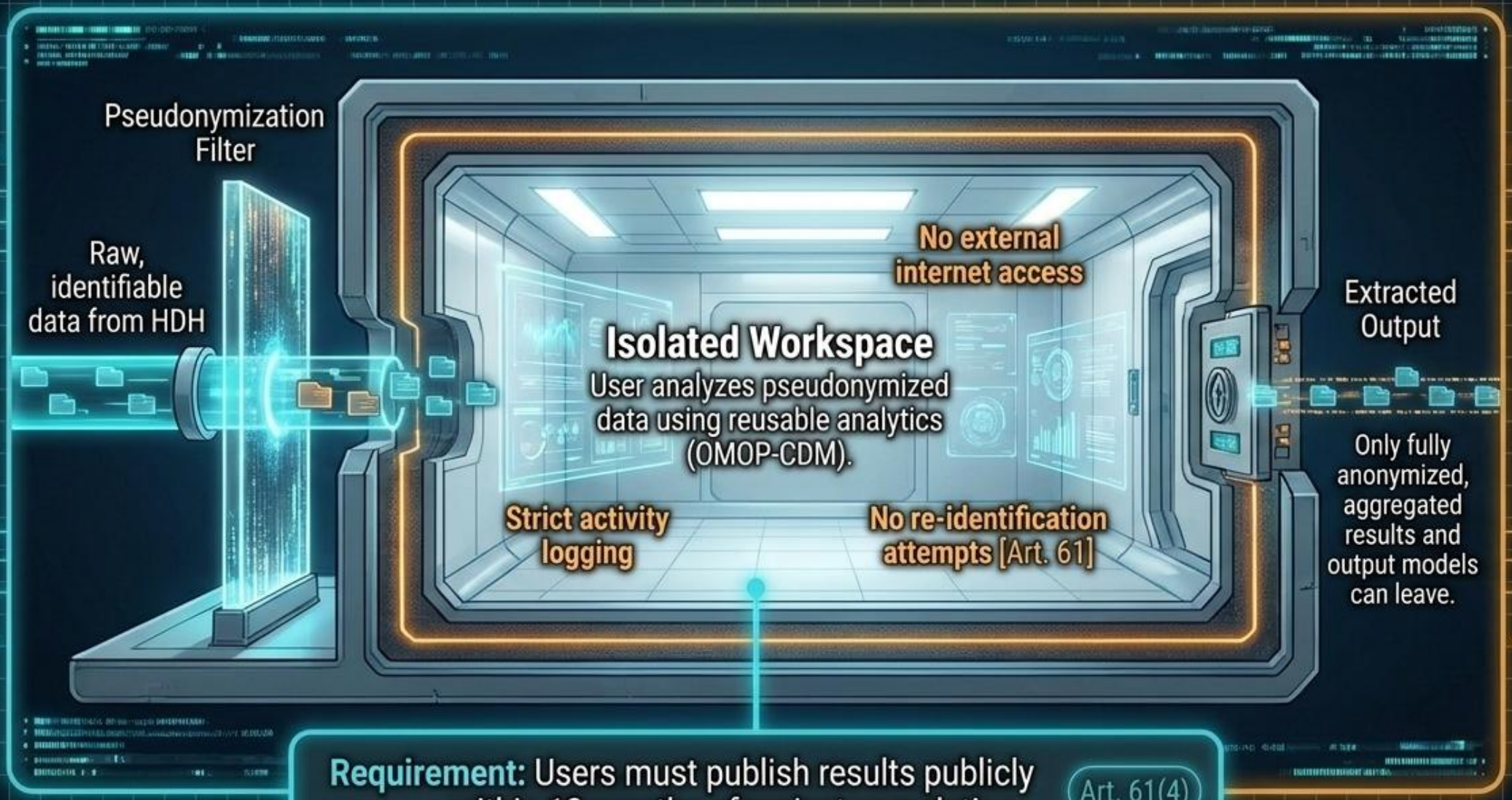
- ✓ Scientific research and technological demonstration.
- ✓ Development and innovation of healthcare products/services.
- ✓ Training, testing, and evaluating AI systems and medical devices.
- ✓ Public health, occupational health, and patient safety.

Prohibited Uses [Art. 54]

- ✗ Making decisions detrimental to a natural person.
- ✗ Advertising or marketing to healthcare professionals or patients.
- ✗ Modifying insurance premiums or credit contract conditions.
- ✗ Developing harmful products (illicit drugs, tobacco).
- ✗ Any attempt to re-identify data subjects [Art. 61].

Anatomy of the Secure Processing Environment [Art. 73]

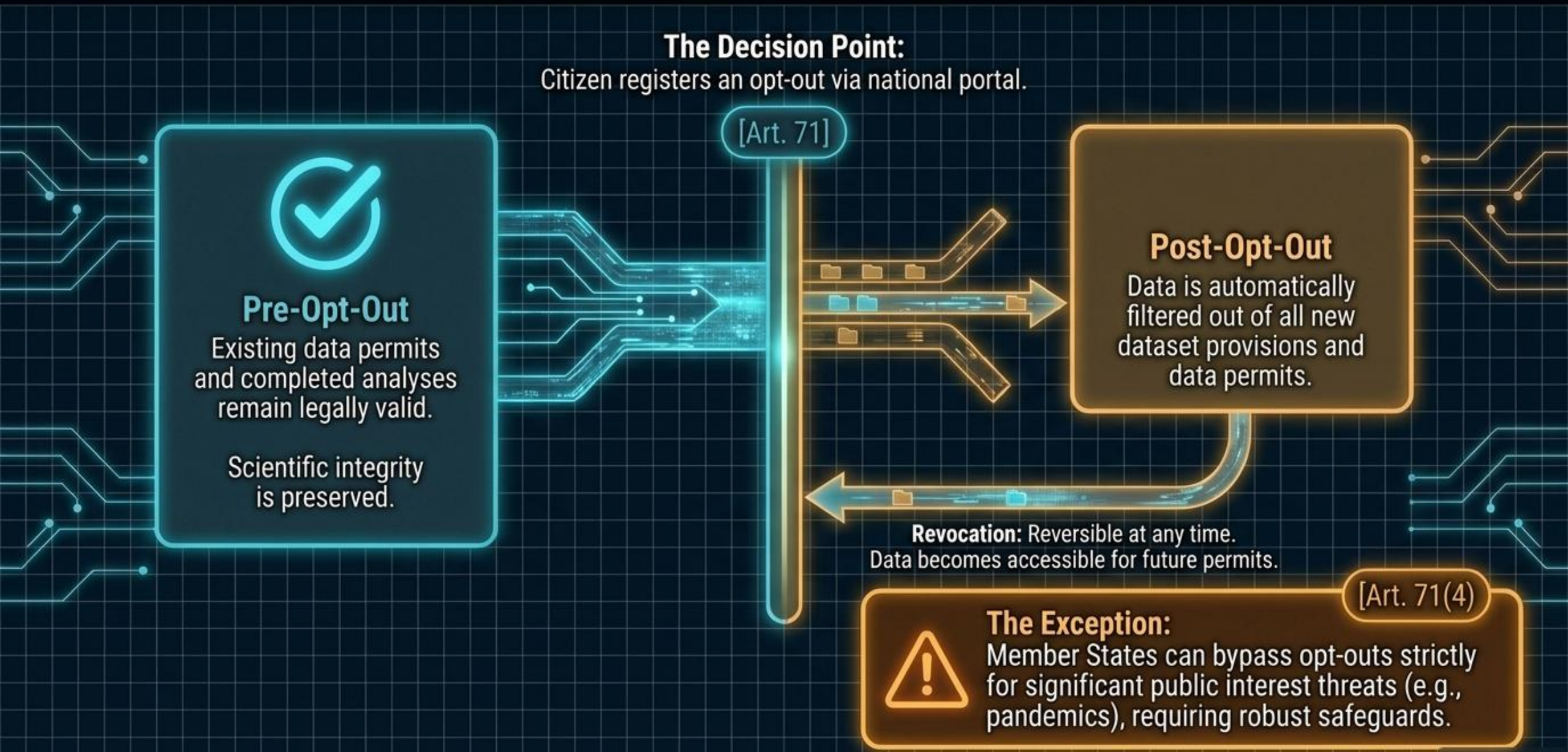
Data users do not download personal health data to their own servers. Analysis occurs exclusively within ring-fenced, HDAB-controlled digital vaults.



Requirement: Users must publish results publicly within 18 months of project completion. Art. 61(4)

Citizen Autonomy: The Opt-Out Mechanism

Individuals hold an absolute, reversible right to exclude their personal electronic health data from secondary use processing.



HealthData@EU: The Cross-Border Infrastructure

The EHDS overcomes national fragmentation by connecting harmonized national nodes into a **federated** European data ecosystem.

National Contact Points (NCPs)

[Art. 75]

Organisational gateways responsible for making data available cross-border.

Interoperability Requirements

Semantic Standards: SNOMED-CT, ICD-10

Syntactic Standards: HL7 FHIR

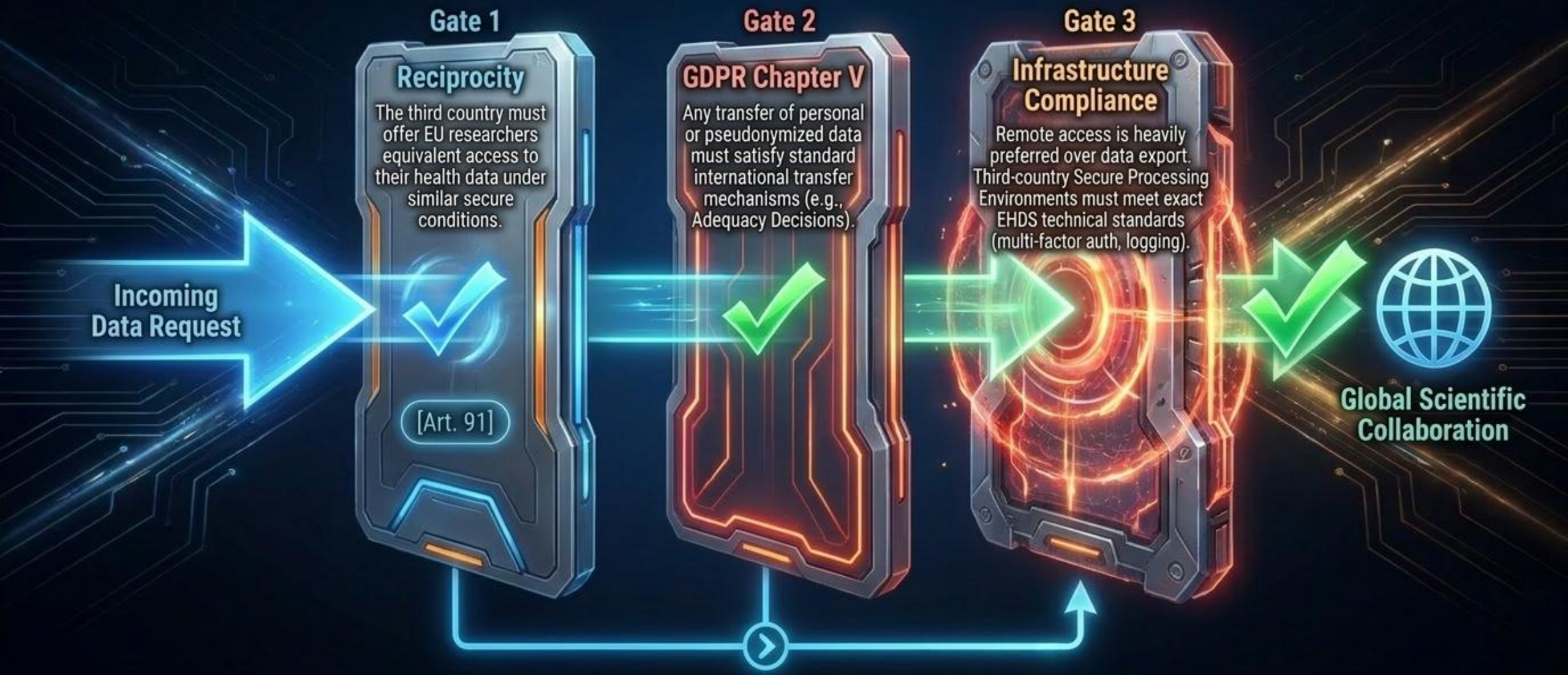
Central Platform

Managed by the European Commission, hosting the EU dataset catalogue.

[Art. 75]

Global Integration and Third-Country Access

The EHDS is designed for international scientific collaboration, but access by third countries is heavily gated by reciprocity and GDPR compliance.



Economics, Enforcement, and Penalties

Health Data Access Bodies wield significant supervisory, investigative, and punitive powers to maintain the integrity of the data space.

Economics [Art. 62]

Cost-Recovery Fee Model

- Fees charged to users must be proportionate and non-discriminatory.
- Covers only the administrative and technical costs of preparing datasets.

Enforcement [Art. 63 & 64]

Supervisory Powers:

- Auditing access logs and monitoring SPE activities.

Corrective Measures:

- Revoking permits and banning users from the infrastructure.

Punitive Fines:

- Up to €20,000,000 or 4% of total worldwide annual turnover for major structural violations (e.g., unauthorized processing, attempted re-identification).

The Implementation Staircase (2025–2035)

The transition toward full application is gradual and highly structured across a ten-year horizon.

Xt-EHR Field work
and EURIDICE SDO work

Logical Information Models

EHDS

- Harmonised datasets
- Coding systems and values
- Technical interoperability specifications

Input

HL7 FHIR

What

- Logical Information Models
  - Preferred Code Systems
- FHIR Implementation Guides
  - Value Set Bindings

Who

Xt EHR @dataspace

Member States & Stakeholders

HL7 Europe

IHE EUROPE Integrating the Healthcare Enterprise

Xt EHR @dataspace

Source: Xt-EHR Closing Event

Logical Information Models

- Logical information models (LIMs) ≈ MDA Computation-independent Models

✓ Data elements	✓ Cardinality
✓ Descriptions	✓ Preferred Code Systems
✓ Datatype	✓ Requirements
	✓ Obligations

- Tasks T6.1–T7.3 developed category-specific LIMs
- Many models and data elements are relevant in many priority categories
  - E.g. medication is relevant in all priority categories
- "Common models" group worked on alignment between logical models through the project

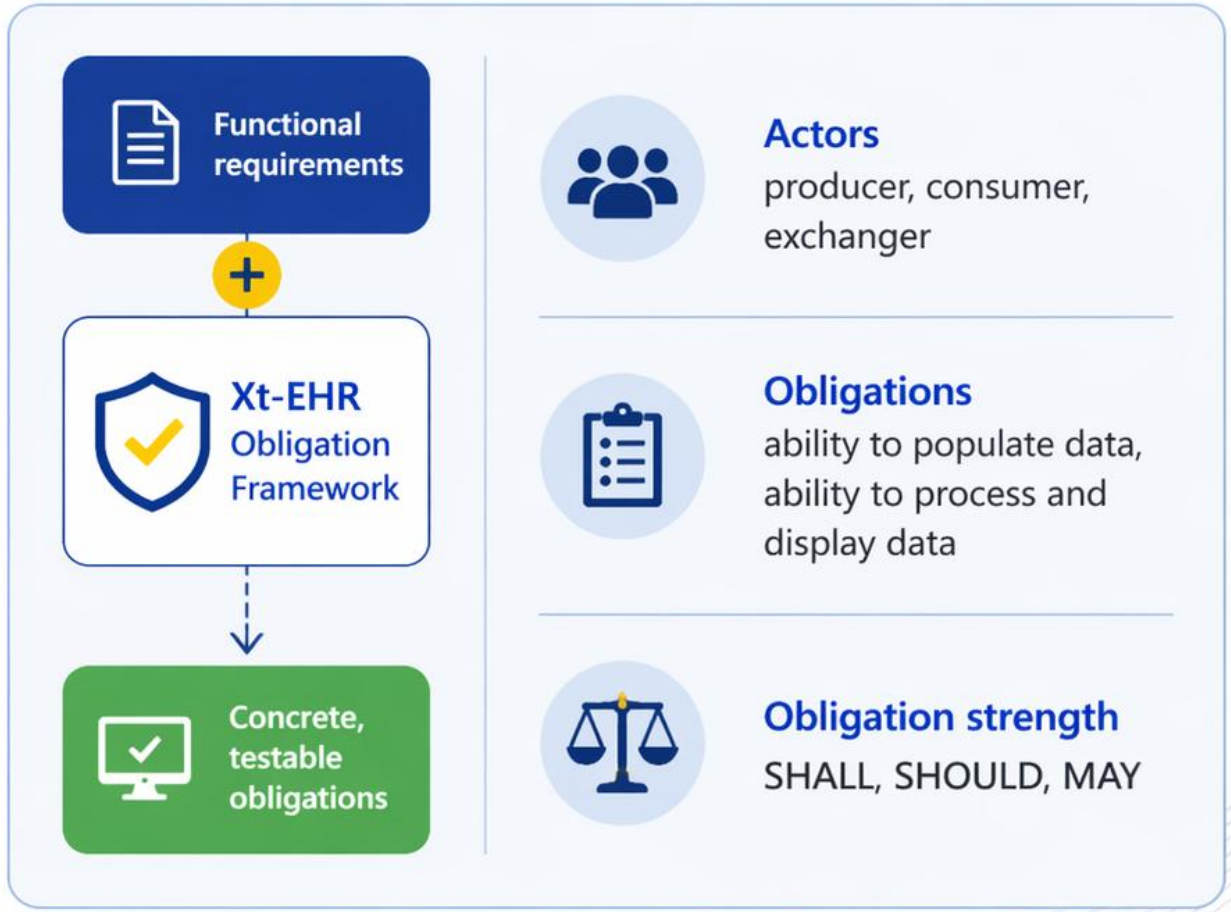
Source: Xt-EHR Closing Event

HL7 Obligation framework

Represent and additional level of requirements on the top of a structural constraints specified in the FHIR IG

Allows to specify concrete obligations of the EHR systems based on their expected function

Framework components used by the Xt-EHR project



Source: Xt-EHR Closing Event

Xt-EHR Obligations

Producer	able-to-populate	EHR system needs to demonstrate during some conformance testing process that there are some conditions under which it populates the element with a correct value. (i.e. not a data-absent-reason or equivalent.)
Consumer	process	Conformant applications SHALL/SHOULD/MAY consider the value of this element when processing the resource as specified by the IG.
	display	Conformant applications SHALL/SHOULD/MAY display the value of this element when presenting the data from the resource to a human user.
Exchanger	no-alter	This does not mean that the element value cannot change, only that changing the element value for an element marked with this obligation moves an application from being an exchanger to a Consumer and a Producer, and those obligations apply.

Source: Xt-EHR Closing Event

Xt-EHR Obligations

Aa Term	Requirement Level	Definition
SHALL	Mandatory	Means that the definition is an absolute requirement of the specification.
SHOULD	Recommended	Means that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.
MAY	Optional	Means that an item is truly optional.

Omission of a SHALL element may be permitted only where the corresponding capability is **permanently out of scope** for the system. Such omission must be accompanied by a **clear, explicit and verifiable written justification.**

Source: Xt-EHR Closing Event

EHDS Guidelines for manufacturers of wellness applications

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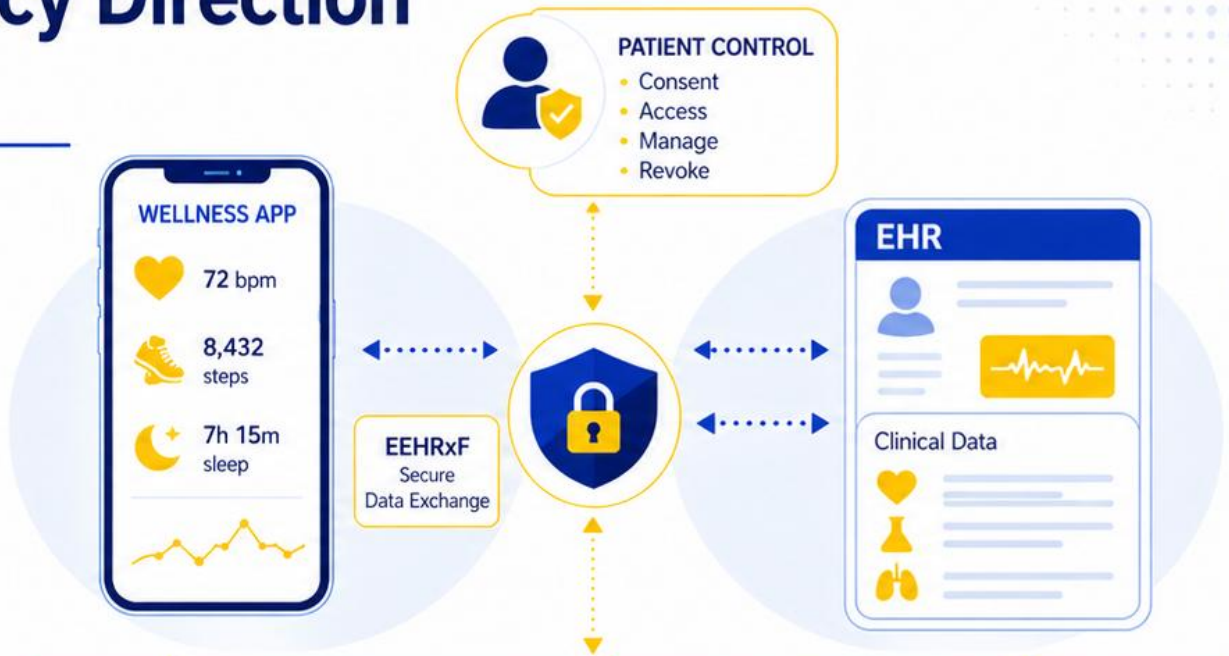
Wellness Apps in EHDS: Policy Direction and 10 Recommendations

Controlled integration, trust, and person-centred innovation

- EHDS acknowledges that more health-related data is generated by consumer and patient-facing applications and devices, but this data is often continuous, high-volume, and not automatically validated for clinical decision-making.
- The proposed approach is to keep a clear separation between priority EHR data and wellness app data, while allowing controlled integration of clinically relevant evaluations into the EHR.
- Security, logging, provenance, and patient control must remain consistent with EHDS requirements when wellness data is exchanged.
- Recommendations 1–3: enable patient-inserted data, reflect the distinct role of wellness apps versus EHR systems, and support mutual identification between compliant apps and EHR systems.
- Recommendations 4–7: issue manufacturer guidance, build on CEN-ISO/TS 82304-2 and Label2Enable, consider an EHDS label, and provide digital testing environments and tools.
- Recommendations 8–10: encourage manufacturers to claim interoperability, consider voluntary compliance pathways for consumer-used medical devices, and unlock person-centred self-care through EEHRxF-based data flows.



1–3 FOUNDATION

1. Patient-inserted data
2. Distinct role of wellness apps
3. Mutual identification

4–7 IMPLEMENTATION

4. Manufacturer guidance
5. Build on CEN-ISO/TS 82304-2 and Label2Enable
6. Consider an EHDS label
7. Digital testing environments and tools

8–10 IMPACT

8. Encourage interoperability claims
9. Voluntary compliance pathways for consumer-used medical devices
10. Unlock person-centred self-care via EEHRxF-based data flows

Source: Xt-EHR Closing Event

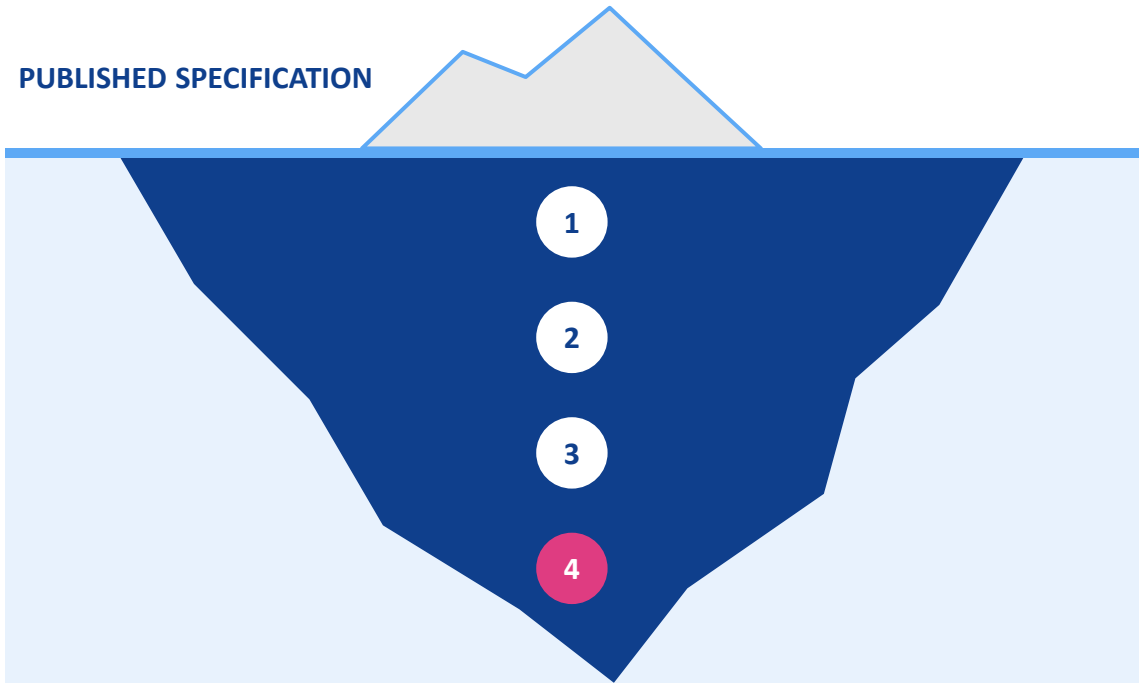
Xt-EHR is not the comitology baseline

- Xt-EHR deliverables are project outputs and useful technical background; they are not legal specifications and they do not determine the text adopted through comitology.
- The Commission drafts EHDS implementing acts under the empowerments in Regulation (EU) 2025/327. The Article 98 committee (comitology) of Member State representatives gives its opinion under the examination procedure of Regulation (EU) 182/2011.
- The legally operative baseline is the final Commission implementing act published in the Official Journal — not an Xt-EHR deliverable, Support Centre artefact or stakeholder consensus document.
- Accordingly, the implementation roadmap should track the comitology text and adopted act directly, while using Xt-EHR/Support Centre/standards work only as technical inputs or implementation accelerators.
- Xt-EHR LIMs are currently being revised and source HL7 FHIR IGs are being revisited

What is EURIDICE?

- **EURIDICE is a joint HL7 Europe and IHE-Europe initiative** that promotes convergence on European interoperability specifications.
- Focused on well-architected and implementable specifications **developed** or **formally endorsed by both organizations** proposed for use in establishing the EHDS.
- EURIDICE (Pronunciation: **eu̯.ry.dí.kɛ:)** stands for European Interoperability Specifications for Digital Solutions in Healthcare

Real implementation requires more than published data specifications



1 — Implementation detail
agreed terminologies · APIs · security · examples …

2 — Validation
conformance artefacts · test assertions · interoperability testing

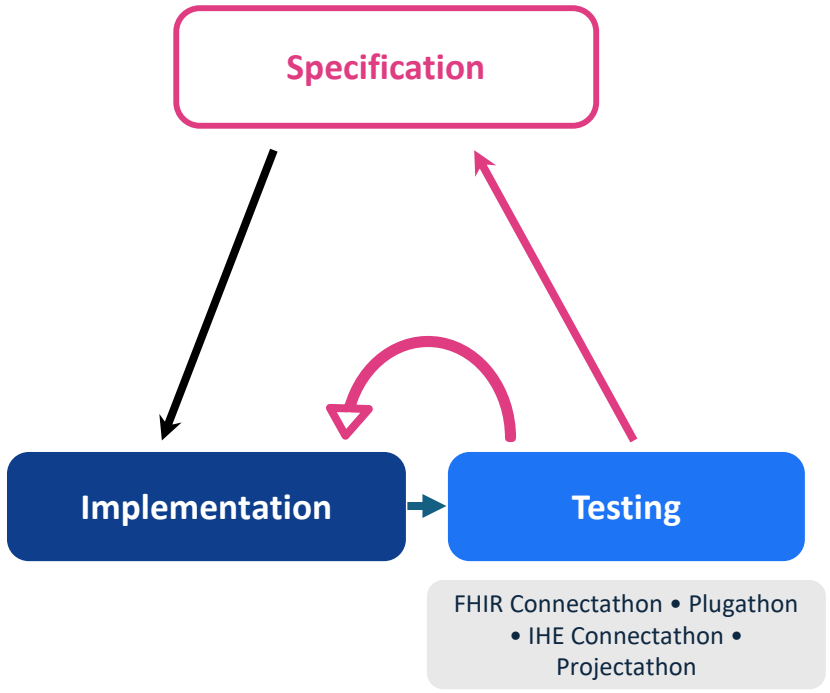
3 — Resolution
issue management · clarification · defect correction

4 — Controlled applicability
releases · authoritative adoption · effective dates · transitions

Implementation evidence → Maintenance → New release → Adoption decision

A sustainable lifecycle needs to addess all of them.

Testing validates both implementations and the specifications



1 — Specification validation
Are the artefacts internally consistent and technically valid?

2 — Conformance testing
Does an implementation satisfy the adopted requirements, using that baseline's test suite?

3 — Cross-system interoperability testing
Can independently developed implementations exchange and process information consistently?

4 — Feedback to maintenance
Do findings reveal defects, ambiguities or inconsistent artefacts?

Testing produces evidence for maintenance. For the specifications as well as for the implementations.

The IG ecosystem for EHDS

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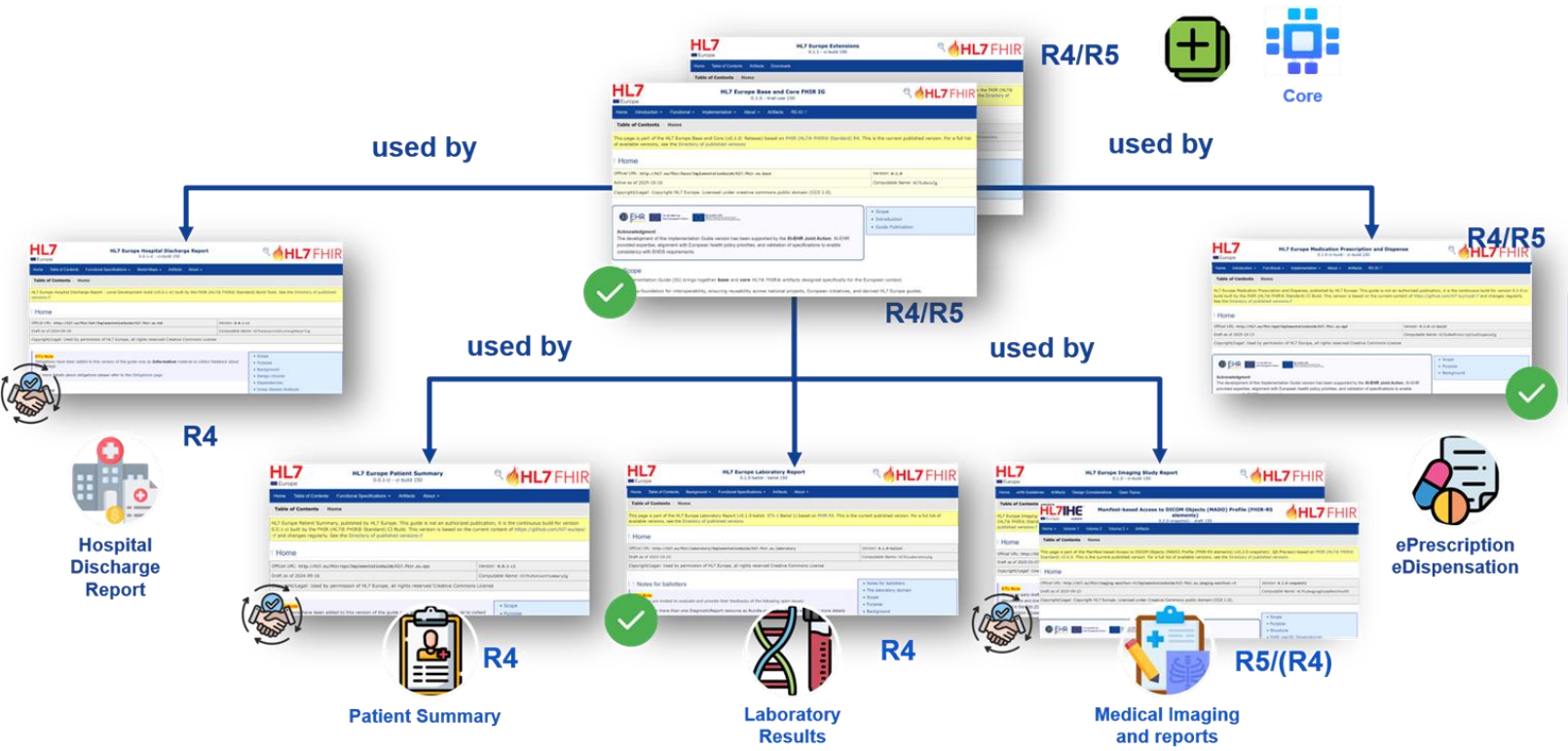
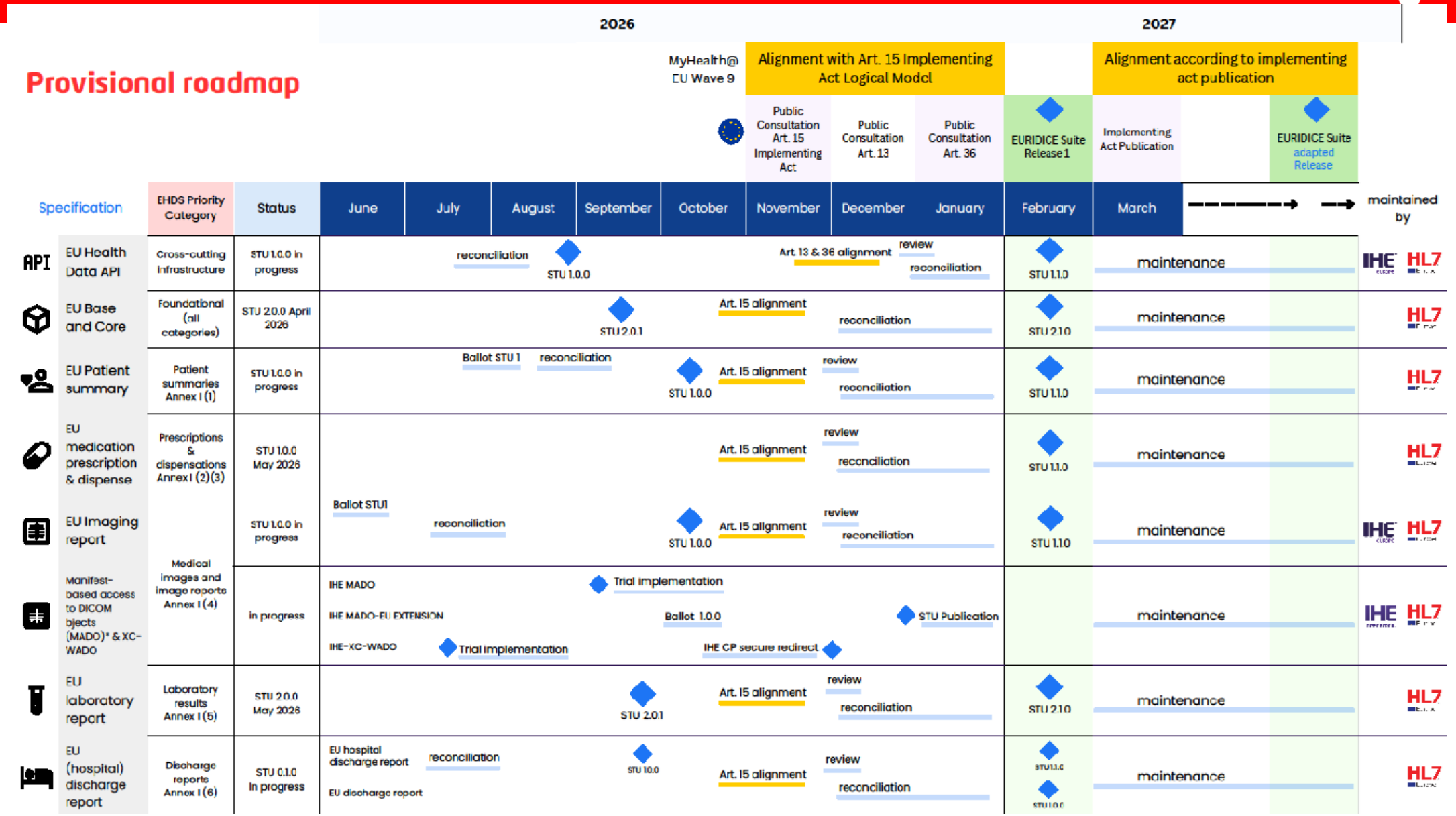
Content



Used by

Services

Provisional roadmap



Next SDO in-person events

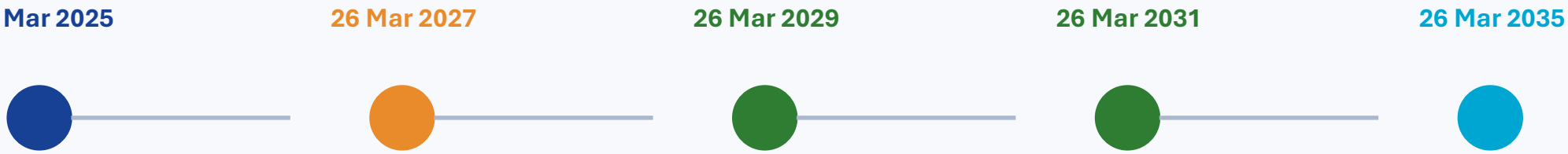
- HL7 Europe Working Group Meeting,
  Malaga, Spain
  - 16-20 November 2026

- IHE-Europe Connectathon Week,
  The Hague, Netherlands
  - 19-23 April 2027

Road toward implementation

EHDS is a staged implementation programme

The Regulation entered into force in 2025; operational obligations phase in through 2035.



What counts as an “implementing act”?

A. Key deadline package

Nine topics are explicitly highlighted by the Commission as key implementing acts due by 26 March 2027. This is the most useful denominator for programme planning.

B. Other operational acts

Examples include cross-border identification/authentication (Art. 16), EHDS Board operation (Art. 92), labels, testing specifications and other detailed rules.

C. Future / conditional acts

The Regulation also empowers recurring updates, optional extensions and case-specific implementing decisions (e.g., connections to infrastructures or third countries).

Source: Regulation (EU) 2025/327 and European Commission FAQ (March 2026).

Published implementing regulations — current snapshot

Four EHDS implementing regulations are identifiable in EUR-Lex as of 22 September 2026.

2026/771	7 Apr 2026	**Art. 92(11)**	EHDS Board — establishment and operation
2026/2083	18 Sep 2026	**Art. 23(4),(8)**	MyHealth@EU — technical development, security, compliance and processor rules
2026/2098	18 Sep 2026	**Art. 77(4)**	Dataset descriptions — minimum metadata / HealthDCAT-AP
2026/2099	21 Sep 2026	**Art. 16(2)**	Cross-border identification & authentication

Important: 2026/2099 was published in the Official Journal on 22 September 2026 — this is a very recent addition to the implementation landscape.

Official Journal / EUR-Lex: 2026/771, 2026/2083, 2026/2098, 2026/2099.

When does the EHDS Board become operational?

- Regulation (EU) 2025/327 generally applies from 26 March 2027; this includes the EHDS Board governance provisions in Articles 92–94.
- Commission Implementing Regulation (EU) 2026/771 already lays down the Board's establishment, management and functioning and is in force.
- Member States must nominate two representatives: one for primary use and one for secondary use; each Member State has one vote.
- The Board will gradually take over relevant cooperation from the eHealth Network. The eHealth Network remains during the transition and ceases on 26 March 2031.
- Therefore: 2026 = organisational preparation; 26 March 2027 = EHDS Board governance becomes applicable; 2027–2031 = staged transition/overlap with existing structures.

What moves into the new EHDS governance?

Area	Before / transition	New EHDS body	Nature of decision
Consistent primary-use implementation	eHealth Network / eHMSEG cooperation	EHDS Board + primary-use subgroup	Coordination, opinions, implementation guidance, best practices
Consistent secondary-use implementation	EHDS2 Community of Practice / project structures	EHDS Board + secondary-use subgroup	Coordination of HDAB practice, guidance, best practices
MyHealth@EU day-to-day operation	eHealth Network / eHDSI governance	MyHealth@EU Steering Group	Operational decisions on development and operation
HealthData@EU day-to-day operation	EHDS2 preparatory governance	HealthData@EU Steering Group	Operational decisions on development and operation
Binding implementing acts	Commission + existing comitology preparations	Commission + Article 98 Committee	Binding EU implementing acts — NOT an EHDS Board decision

The nine key implementing-act topics due by 26 March 2027

Commission FAQ identifies the core legal/technical blueprints needed before build, test and deployment.

13(4)	Data quality requirements	Pending
15(1)	EEHRxF technical specifications	Pending
23(4)	MyHealth@EU	PUBLISHED
36(1)	Common specifications for EHR systems	Pending
70	Templates: applications, permits, requests	Pending
73(5)	Secure processing environments	Pending
75(12)	HealthData@EU	Pending
77(4)	Dataset descriptions / metadata	PUBLISHED
78(6)	Data quality & utility label	Pending

2 / 9 published • 7 / 9 remaining

Source: European Commission "Frequently Asked Questions on the European Health Data Space", published 26 March 2026. Status cross-checked against EUR-Lex on 22 September 2026.

What the newly published acts change now

They turn parts of EHDS from architecture into implementable requirements.

MyHealth@EU • 2026/2083

Defines operational rules for the cross-border infrastructure, including technical development, security/confidentiality, compliance checks and Commission processor responsibilities.

Road-map impact: NCPeH architecture, conformance, service management and security planning can be aligned to binding rules.

Metadata • 2026/2098

Sets the minimum metadata elements and characteristics for dataset descriptions and anchors them to HealthDCAT-AP. Applies from 26 March 2029.

Road-map impact: HDAB/data-holder catalogues should design metadata pipelines and governance against this model now.

Identity • 2026/2099

Defines interoperable cross-border identification/authentication for natural persons, health professionals and healthcare providers. Applies from 26 March 2027, with specified provisions from 2029.

Road-map impact: identity, attributes and NCPeH integration become immediate design work.

Sources: Commission Implementing Regulations (EU) 2026/2083, 2026/2098 and 2026/2099.

EHDS regulation— beyond the “nine key acts”

PRIMARY USE
Arts 13, 15, 17, 23, 24

EHR INDUSTRY
Arts 36, 40, 47, 49*

SECONDARY USE
Arts 62, 63, 70, 73, 74, 75, 77, 78, 80

GOVERNANCE / EXTERNAL
Arts 91, 92 + case-specific acts

26 Mar 2027
Deadline-critical implementing acts

→

2027–2029
Testing, infrastructure, vendor engineering

→

2029 / 2031
Phased market & data obligations

* Article 49 contains a delegated-act empowerment for the EU EHR-system database.
For industry planning, delegated acts must be tracked alongside implementing acts.

EHDS acts with industry relevance

Provision	Instrument / subject	Timing	Who is affected	Industry relevance
13(4)	IA — data quality requirements for primary-use registration	By 26 Mar 2027	EHR vendors, HCPs, MS	HIGH
15(1)	IA — EEHRxF technical specifications	By 26 Mar 2027	EHR vendors, MS, HCPs	CRITICAL
15(2)	IA — updates to EEHRxF coding systems/nomenclatures	Recurring	EHR vendors, terminology services	CRITICAL lifecycle
15(3)	IA — extension of EEHRxF to additional categories	Conditional	EHR vendors, MS	HIGH if activated
17	IA — technical implementation of primary-use rights	Future	Access services / EHR ecosystem	HIGH
36(1)	IA — common specifications for harmonised EHR components	By 26 Mar 2027	EHR manufacturers	CRITICAL
40(4)	IA — common specifications for digital testing environment	Future; Art.40 no explicit 2027 date	Commission, MS, EHR manufacturers	CRITICAL
47(3)	IA — interoperability label for wellness applications	Future	Wellness-app industry	HIGH
49(4)*	Delegated act — data to enter in EU EHR/wellness database	Future	EHR/wellness manufacturers	HIGH

The critical path to 2029

Legal acts are only the blueprint; Member States need two years for implementation, testing and deployment.

NOW → MAR 2027 **LEGAL & DESIGN**	Track final acts; national gap analysis; governance; architecture; procurement preparation
2027 → 2028 **BUILD & CONFORM**	Implement access services, NCPeH, HDAB/SPE, catalogues, EEHRxF, EHR testing and conformity processes
2028 → MAR 2029 **TEST & GO-LIVE**	End-to-end testing; security; semantic validation; operational readiness; onboarding providers/data holders
FROM MAR 2029 **OPERATE**	Primary-use Group 1 + most secondary-use obligations become applicable

Interpretation based on EHDS milestones and the Commission explanation of the 2027 → 2029 build/test window.

National implementation workstreams

A practical roadmap should run legal, governance, infrastructure and market-readiness work in parallel.

1	**Governance & law**	Digital Health Authority; HDAB; national contact points; national legal adaptations
2	**Primary-use services**	Patient/professional access; rights; logging; data quality; priority datasets
3	**Interoperability**	EEHRxF; terminology; identity; APIs; national interoperability framework
4	**MyHealth@EU**	NCPeH; Group 1 readiness by 2029; Group 2 by 2031
5	**EHR market**	Common specs; technical documentation; self-assessment; CE marking; digital testing environments
6	**Secondary use**	HDAB processes; dataset catalogue; HealthData@EU; SPE; permits; fees; labels

Programme principle: do not wait for every implementing act before starting “no-regret” architecture, governance, data-quality and testing preparation.

Hot topics of Q4/2026

Act / Article	Status	Expected / adopted	National dependency	Owner
Art. 15 EEHRxF	Drafting	≤ Mar 2027	National data models, terminology, API profiles, conformance	DHA
Art. 36 EHR specs	Drafting	≤ Mar 2027	Vendor readiness, testing environment, procurement clauses	DHA/MSA
Art. 73(5) SPE	Drafting	≤ Mar 2027	SPE architecture, security controls, procurement	HDAB
Art. 40 DTE specs	Drafting	≤ Mar 2027	DTE test tools for self declaration of EHR Systems	DHA/MSA

Member States — what must be legally and organisationally established

Requirement	Legal basis	By / applicability	Member State action
Digital Health Authority/Authorities + coordinator if multiple	Art. 19	Notify by 26 Mar 2027	Designation, mandate, powers, resources, task allocation
National Contact Point for Digital Health	Art. 23(2)	Notify by 26 Mar 2027	Legal/organisational designation + MyHealth@EU gateway
Health Data Access Body/Bodies + coordinator if multiple	Art. 55	Notify by 26 Mar 2027	Designation; independence/conflict safeguards; resources
National Contact Point for secondary use	Art. 75	Notify by 26 Mar 2027	Designation + HealthData@EU connection responsibility
Market Surveillance Authority for EHR systems	Art. 43	Before Chapter III enforcement	Designation, powers, resources; may be DHA with safeguards
Penalties for EHDS infringements	Art. 99	Notify by 26 Mar 2027	National rules: effective, proportionate, dissuasive
National EHR requirements outside harmonised components	Art. 42	If adopted	Ensure no adverse effect on harmonised components; notify Commission

Member States — infrastructure and operational obligations

- Operate a national digital testing environment for harmonised EHR software components, compliant with the Commission's common specifications under Article 40.
- Ensure the national contact point for digital health is connected to MyHealth@EU and can exchange the applicable priority categories in EEHRxF.
- Establish the national secondary-use operating model: HDAB workflows, national dataset catalogue, secure processing environments and HealthData@EU connection.
- Implement the rights and access services required for natural persons and health professionals, including logging and access-control arrangements.
- Create enforcement and cooperation arrangements between Digital Health Authority, market surveillance, data protection, cybersecurity/eID and other competent authorities.
- Fund and staff these structures sufficiently — designation alone is not EHDS readiness.

End-to-end implementation chain

- REGULATION (EU) 2025/327 → defines the mandate, deadlines and essential requirements.
- COMMISSION DRAFT → converts legal empowerments into detailed implementing rules.
- ARTICLE 98 COMITOLOGY → Member States scrutinise and vote under the examination procedure.
- ADOPTED IMPLEMENTING ACT → binding technical/operational baseline published in the Official Journal.
- EHDS BOARD → coordinates consistent application, guidance and Member State practice from 26 March 2027.
- STEERING GROUPS → take operational decisions for MyHealth@EU and HealthData@EU.
- MEMBER STATES → designate authorities, legislate where needed, build infrastructure and enforce.
- VENDORS / PROVIDERS / DATA HOLDERS → implement, test, demonstrate, operate and maintain compliance.

EHDS vs Swiss HDS

EHDS implementation vs. Switzerland’s DigiSanté

Two routes toward interoperable health data spaces — regulatory harmonisation vs. federated national transformation

European Union — EHDS

Binding Regulation (EU) 2025/327 • common rights, infrastructures, EHR-system market rules and secondary-use framework

Switzerland — DigiSanté / SwissHDS

10-year transformation programme (2025–2034) • standards, common services, data-space infrastructure and enabling legislation

Core comparison

EHDS defines the legal destination first; DigiSanté is building the national architecture, standards and law in parallel.

Sources: Regulation (EU) 2025/327; European Commission EHDS; Swiss Federal Office of Public Health / DigiSanté (accessed 23 Sep 2026).

Same destination, different implementation logic

IHE CATALYST

EHDS: regulation-led

EU-wide obligations → implementing acts → national authorities/infrastructure → vendor compliance

Rights & governance

Patient rights • Digital Health Authorities • HDABs

Primary use

MyHealth@EU • EEHRxF • priority data categories

EHR market

Mandatory interoperability/security components • self-assessment/testing

Secondary use

HealthData@EU • permits • secure processing environments

DigiSanté: programme-led

Federal/cantonal transformation → standards & architecture → MVP/common services → enabling legislation

Digitalise & orchestrate

~50 projects across federal health-system functions

Standardise

FHIR as technical foundation • semantic standards • uniform identifiers

SwissHDS

Federated data mesh • common services • standard interfaces • Zero Trust

Anchor in law

New/updated federal & cantonal legal bases; Digital Health Data Space Act project

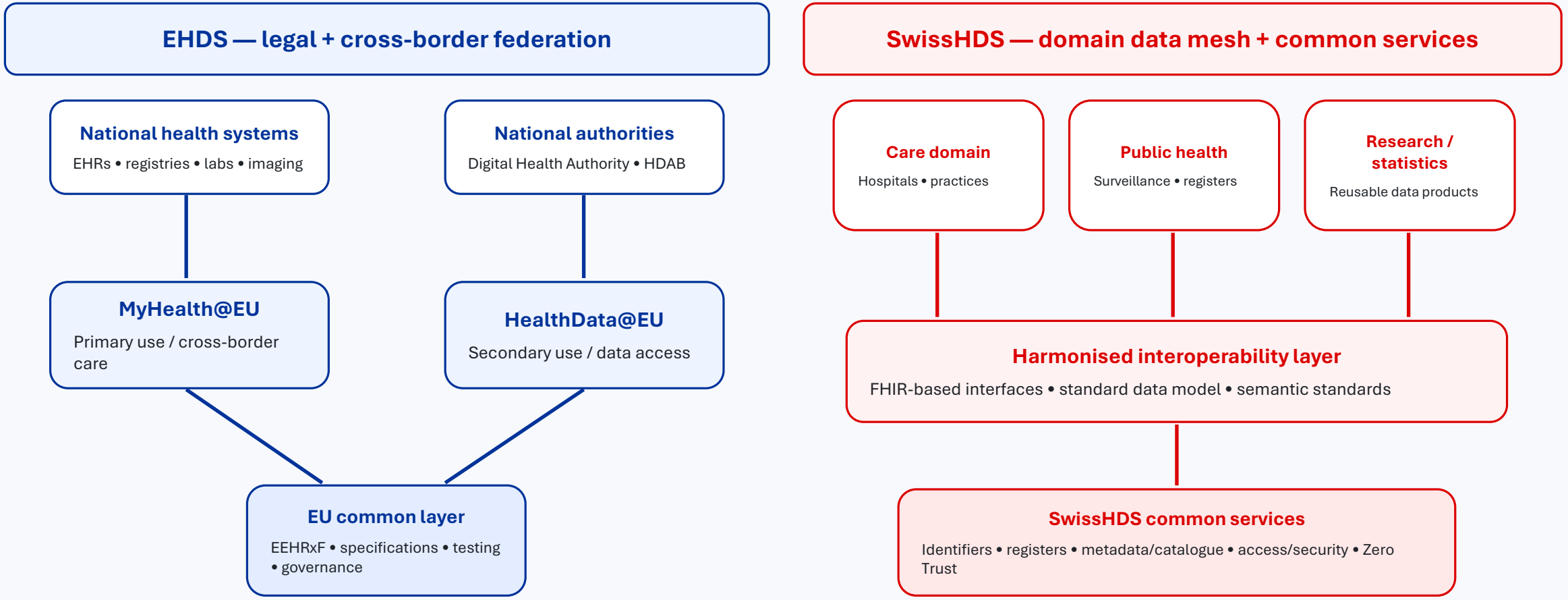
EHDS–DigiSanté comparison matrix

IHE CATALYST

DigiSanté is not a Swiss copy of EHDS; it is a broader national digital-health transformation programme.

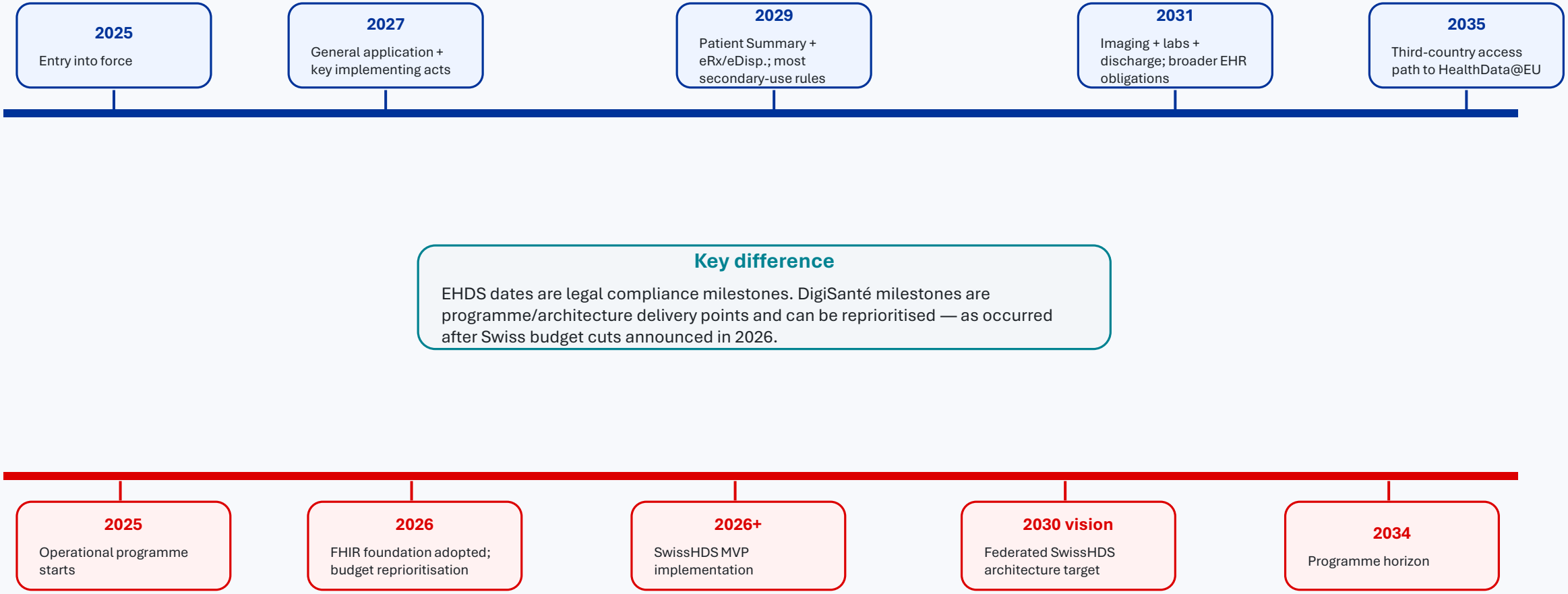
Dimension	EHDS (EU)	DigiSanté / SwissHDS (CH)
Legal nature	EU Regulation: directly applicable; detailed by implementing/delegated acts	Programme + projects; legal foundations created/updated through Swiss federal/cantonal legislation
Time horizon	2025 entry into force; 2027 general application; major obligations 2029/2031	Operational programme 2025–2034; SwissHDS now proceeding through an MVP phase
Architecture	Federated EU infrastructures: MyHealth@EU + HealthData@EU + EHR testing/registration services	Federated SwissHDS data mesh; data remain with domains; common services and standard interfaces
Interoperability	EEHRxF + common EHR-system specifications; harmonised priority datasets	FHIR selected as technical foundation; technical + semantic standards and implementation guides
Industry impact	Explicit EHR-system conformity regime, testing, technical documentation and market obligations	Primary-system providers must implement SwissHDS interoperability layer/interfaces; bindingness depends on standards/legal framework
Secondary use	Dedicated HDAB access-permit model and secure processing environments	Secondary use is a programme pillar; Microdata Center and legal access framework under development
Governance	EHDS Board + national Digital Health Authorities/HDABs + EC infrastructure governance	Shared federal/cantonal/sector governance; specialist groups including GGDS; programme steering

Architecture: both are federated — but the organising layers differ



SwissHDS explicitly uses a federated Data Mesh approach and standardised interfaces; GGDS adopted HL7 FHIR as the technical foundation in 2026.

Implementation timelines: fixed regulatory milestones vs. staged programme delivery



What this means for EHR / health-IT vendors

EHDS vendor compliance cycle

1 Scope
Does the product qualify as an EHR system / harmonised component?

2 Build
Implement EEHRxF + common interoperability/security requirements

3 Test
Use European / Member State digital testing environments

4 Document
Technical documentation + assessment results + EU database obligations

5 Market & monitor
Place compliant product on market; post-market obligations

DigiSanté / SwissHDS vendor readiness cycle

1 Align
Track SwissHDS architecture, legal project and national standardisation

2 FHIR-enable
Implement standard APIs / exchange formats and selected implementation guides

3 Interoperability layer
Map local/domain data to the harmonised SwissHDS model

4 Trust & access
Support identifiers, metadata, access rules and Zero-Trust security

5 Join use cases
Validate through MVP / domain-specific services as requirements mature

Strategic convergence — and where Switzerland can leverage EHDS

Convergence

Both models prioritise structured reusable data, international standards, federated infrastructure, secure access, primary + secondary use.

Distinctive EHDS feature

A single-market regulatory layer: common EHR-system requirements, testing and defined legal milestones across EU/EEA.

Distinctive Swiss feature

Data-mesh architecture explicitly connects autonomous domains while preserving Swiss federal/cantonal responsibilities.

Potential interoperability bridge

International standards

FHIR + common terminologies and profiles

Dataset alignment

Map Swiss exchange formats to EEHRxF priority categories

Testing

Reuse conformance-testing concepts and machine-testable rules

Cross-border readiness

Design Swiss interfaces so future EU/Swiss exchange requires less translation

EHDS can be viewed as a regulatory reference architecture; DigiSanté/SwissHDS is a national implementation architecture that can deliberately remain compatible with European specifications without replicating EU governance.

References

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Official Regulation Text: https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng

Reference links

EHDS Regulation (EU) 2025/327	https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng
European Commission — EHDS Regulation	https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en
Commission Implementing Regulation (EU) 2026/771	https://eur-lex.europa.eu/eli/reg_impl/2026/771/oj
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EHDS Regulation Explorer — non-official tracker	https://ehdsexplorer.eu/implementing-acts

Thank you