EUROPEAN HEALTH DATA SPACE

SECONDARY USE OF DATA AND DATA SUBJECT RIGHTS

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CONFERENCE ONLINE

“FROM CONSENT TO HEALTH DATA GOVERNANCE: SECONDARY USE AND ACCOUNTABILITY IN THE EHDS BETWEEN THE EU AND ITALY”

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The European Health Data Space as a Structural Transformation

The European Health Data Space should not be understood merely as a framework facilitating the cross-border circulation of electronic health data. Rather, it represents a deeper transformation in the legal conditions governing the legitimacy of secondary use.

This transformation signals a shift from a paradigm centred primarily on individual consent toward a procedurally structured model of data governance, in which legitimacy increasingly depends on institutional design, accountability mechanisms and the allocation of responsibilities within the health data ecosystem.

FRAGMENTATION OF EUROPEAN HEALTH DATA SYSTEMS

The European Health Data Space is often presented as an interoperability initiative. However, the European healthcare sector still suffers from significant normative and technological fragmentation.

Each Member State has historically developed its own infrastructures for collecting and managing clinical information, frequently built on non-communicating architectures.

This heterogeneity affects accessibility, interoperability and usability of health data across the European Union.

FROM MEDICAL RECORD TO DATA INFRASTRUCTURE

In this context, the European Health Data Space seeks to transform health data from a "document" of the care relationship into an **infrastructural resource** governed by common standards and procedures.

Health data are therefore no longer merely records of individual medical treatment, but elements of a broader **digital infrastructure** designed to support research, innovation and public health governance.

THE PROCEDURALISATION OF ACCESS

However, the central issue is not access in itself.
The real legal question concerns the proceduralisation of access.

Who authorises access?
Under what conditions?
With which controls?
With which remedies in case of malfunction or misuse?

SECONDARY USE OF HEALTH DATA

This procedural dimension becomes particularly relevant when we consider secondary use for research, innovation, public health monitoring and policy-making.

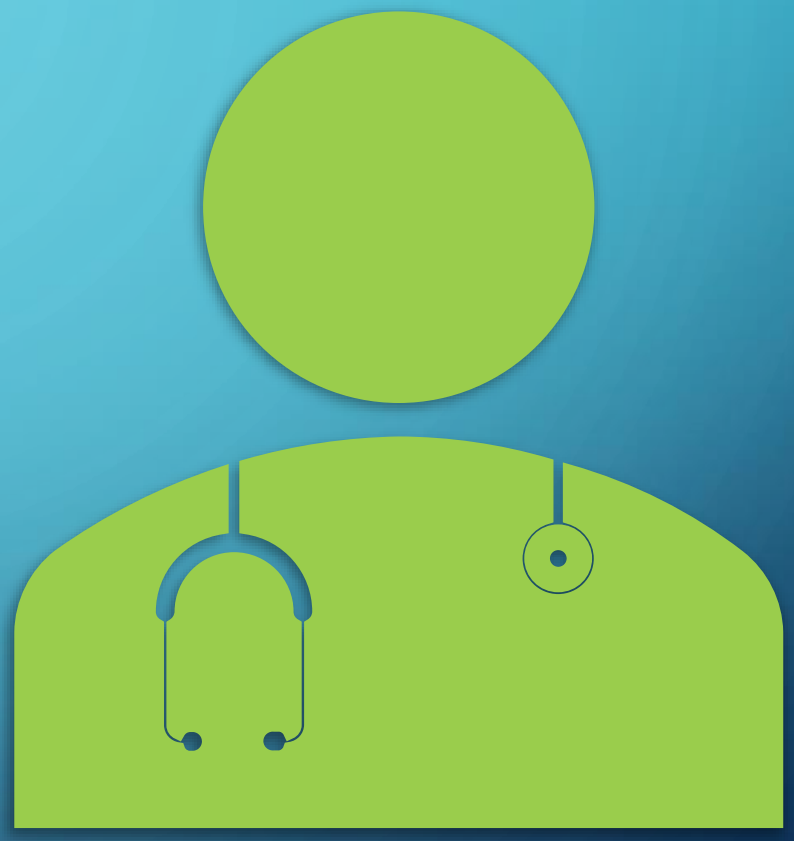
The pandemic has shown how crucial aggregated and reliable data can be for effective health responses.

The European Health Data Space aims to establish a homogeneous regulatory and technological framework that enables the use of anonymised or pseudonymized data for biomedical research and therapeutic innovation.

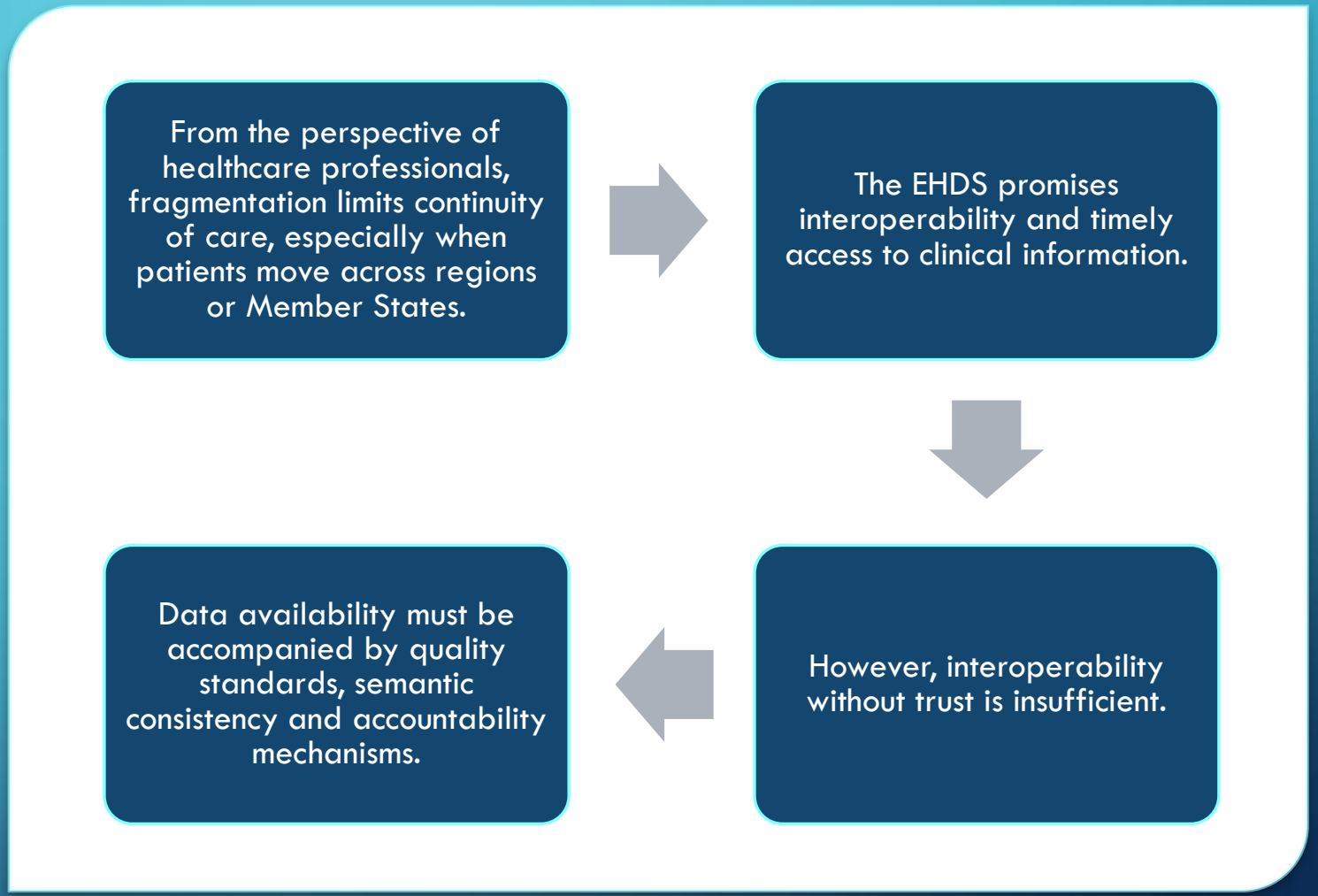
THE SYSTEMIC TENSION OF DATA OPENNESS

Yet this openness generates a **systemic tension**. The opening of health data for collective purposes requires **safeguards** that go beyond formal lawfulness.

Effective governance therefore requires **traceability**, monitoring and **responsibility** along the entire processing chain.



INTEROPERABILITY AND TRUST



CYBERSECURITY AND THE LEGITIMACY OF DATA CIRCULATION

Cybersecurity further complicates the picture. The health sector is among the most exposed to **cyberattacks**. As cross-border exchanges increase, the surface of risk expands.

The EHDS Regulation therefore imposes reinforced security measures, including encryption, pseudonymization and strong authentication.

Security becomes not merely a technical requirement, but a **structural element** of legitimacy.

THE EHDS WITHIN THE *EUROPEAN DATA STRATEGY*

At the same time, the EHDS is embedded in the broader European Data Strategy. It seeks to strengthen strategic autonomy and to consolidate a European digital health market.

The harmonization of technical standards aims to remove barriers, stimulate innovation and attract investment, including in artificial intelligence and big data analytics.

This raises a crucial policy question: how can innovation incentives be reconciled with the protection of fundamental rights?

LEGAL FOUNDATIONS OF THE EHDS

The Regulation relies on Articles **16** and **114** of TFUE:

- **Article 16 TFUE** anchors the framework in the fundamental right to data protection.

- **Article 114 TFUE** provides the competence to remove obstacles deriving from legislative fragmentation within the internal market.

This dual legal basis reflects the hybrid nature of the EHDS: it is simultaneously a rights-based instrument and a market-integration measure.

THE TRANSFORMATION OF CONSENT

Within the EHDS architecture, the role of consent undergoes transformation.

Consent does not disappear, but it is re-articulated within a system of technical and procedural guarantees designed to render large-scale reuse sustainable at European level.

The protection of individuals is therefore increasingly embedded in institutional design, governance mechanisms and accountability structures.

SECONDARY USE GOVERNANCE UNDER THE EHDS

1. A decisive step in understanding the architecture of the EHDS lies in the discipline governing secondary use.
2. **Article 50 of Regulation (EU) 2025/327** introduces a differentiated regime concerning the obligations connected to the reuse of electronic health data.
3. The Regulation identifies specific categories of actors and modulates their obligations accordingly. Natural persons, including individual researchers, and micro-enterprises may benefit from certain exemptions.
4. At the same time, Member States may extend obligations through national law. This reflects an open regulatory model in which European uniformity coexists with national discretion.
5. The EHDS therefore constructs a **regime of risk allocation**, redistributing vigilance, security and accountability obligations among data holders, access bodies and users.

SECONDARY USE AND DATA GOVERNANCE: THE ITALIAN EXPERIENCE

These dynamics are also reflected in recent developments in Italian law.

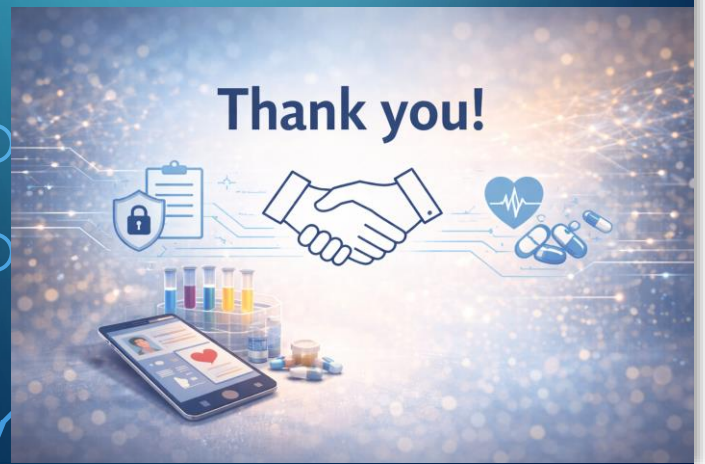
Law No. 132 of 23 September 2025, particularly Article 8, addresses the reuse of health data for research and governance purposes.

The provision qualifies such reuse as an activity of **significant public interest**, thereby integrating Article 9(2)(g) of the GDPR.

Reuse without renewed consent is permitted, provided that adequate safeguards are adopted, including **anonymization, pseudonymization and synthetic data techniques**.

Italian law therefore confirms the transition from a **consent-centred model** toward a **procedural model of governance**, in which legitimacy depends on risk-reduction measures, technical standards and institutional oversight.

CONCLUSION: FROM CONSENT TO GOVERNANCE



The EHDS should be understood not simply as an interoperability project, but as an attempt to construct a multilayered governance regime for the secondary use of health data.

The transformation from a consent-centred paradigm to a procedurally structured model does not diminish the protection of fundamental rights. Rather, it relocates that protection within institutional architecture, technical safeguards and distributed accountability.

The ultimate test of the EHDS will therefore lie not in the volume of data circulating within the system, but in its capacity to ensure coherent standards, traceable responsibility and credible oversight.

Thank you for your attention