Interoperability as Governance

Digital Health and the Transformation of EU Policy-Making

Policy brief

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Key messages

- Digital health is not only transforming healthcare systems; it is reshaping how health policies are **designed**, **negotiated**, and **implemented** at EU level.
- **Interoperability** has become a central governance mechanism for EU health coordination.
- **Private technology** companies increasingly shape policy outcomes through their control over digital infrastructures.
- **EU-funded projects** play a growing role in developing standards and coordinating implementation, but can obscure decision-making processes.
- Digital health debates are increasingly structured around **technical performance and efficiency**, raising new questions about democratic legitimacy and accountability.

1. Introduction: From interoperability to governance

Health data have become a **key resource** in the transformation of European healthcare systems. As the European Commission states, health data are essential to improve healthcare delivery, support research, and strengthen innovation.

At EU level, digital health policy has largely developed around **interoperability**: the ability of health data systems to exchange and use information across borders through shared technical and regulatory frameworks.

This brief examines how interoperability reshapes EU health governance and asks:

To what extent does acting on interoperability create new decision-making dynamics at EU level?

Rather than being purely technical, interoperability has become a **governance mechanism**. Decisions about standards and infrastructures increasingly shape who participates in policymaking, where authority lies, and how legitimacy is produced.

The analysis is based on two cases:

- **The EU-level harmonisation of COVID-19 contact-tracing apps**, illustrating crisis-driven soft coordination.

- The **European Health Data Space (EHDS)**, representing a shift towards institutionalised EU health data governance. The EHDS includes two elements: MyHealth@EU, which enables cross-border access to electronic health records for primary use, and HealthData@EU, which enables secondary use of health data for research and innovation.

The study is based on **qualitative methods**, combining analysis of EU policy documents with 24 semi-structured interviews with key policy actors.

2. Results

2.1 The growing role of private actors

Digital health introduces new actors into a highly institutionalised policy field, in particular **large US technology companies**.

Their influence varies depending on the **governance context**.

In soft coordination processes during the COVID-19 crisis, their power was highly **visible**. When EU Member States and the Commission had to choose between centralised and decentralised contact-tracing apps, Apple and Google effectively shaped the outcome by only supporting decentralised systems on their operating systems, which dominate the smartphone market. Their control over infrastructure gave them decisive influence over policy design.

In more formal legislative processes such as the EHDS, their influence is **less visible** but not absent. The EU is attempting to regain control over digital governance, for example by limiting the role of standardisation bodies where private actors are strongly represented. However, tech companies remain influential due to their **control over infrastructure** (cloud systems, platforms, connectivity), and are likely to play a major role again during implementation.

This suggests that the power of major tech companies is best understood as **infrastructural power**, which varies depending on the stage and context of the policy process.

2.2 Governance “by project”

Interoperability governance raises a key question: **where are digital health decisions actually made**?

Unlike traditional health policy, where decision-making is concentrated in formal regulatory bodies, interoperability governance has developed through more **fragmented arrangements**.

Many standards and infrastructures have been developed over the past two decades through **EU-funded projects**. The outputs of these projects are likely to be reused in Commission implementing acts. As a result, decisions on data infrastructures and standards—despite their major implications for health systems and inequalities—are difficult to trace, as they are shaped across **multiple governance arenas**.

In addition, under current comitology procedures, affected stakeholders, including citizens and some interest groups, are not systematically **included**. At the same time, **technical complexity** limits the ability of many actors to participate effectively in standard-setting debates.

This governance model, heavily based on projects, tends to **dilute decision-making centres** and reduce transparency over how interoperability choices are made. While it has enabled EU coordination despite limited formal competence in health, it raises challenges for **accountability** and **democratic oversight**.

2.3 Digital health politics and legitimacy

Digitalisation is reshaping how political debates in health policy are framed.

A key development is the rise of **performance-based legitimacy**. Digital health policies are increasingly justified through claims of efficiency, innovation, better healthcare outcomes, and crisis management. This shifts debates away from traditional political questions—such as power distribution and institutional responsibility—towards technical problem-solving.

At the same time, political debate has become more **technicised**. Participation increasingly requires familiarity with issues such as centralisation versus decentralisation, opt-in versus opt-out systems, and data access architectures. While these choices should be democratically debated, this trend creates two **risks**: exclusion of non-expert actors and reduced visibility of broader political and legal questions.

The EHDS opt-in/opt-out debate illustrates this dynamic. While it appears to enhance citizen control over data use, it does not replace legal consent frameworks and does not fully prevent data use under public interest provisions.

Finally, debates in the European Parliament suggest that traditional **left/right political cleavages are less effective** in explaining positions on digital health policy. Instead, divisions increasingly reflect attitudes toward innovation and regulation.

Overall, digitalisation is not politically neutral: it reshapes how **legitimacy** is constructed and how policy choices are justified.

3. Policy implications

Strengthen transparency and accountability: Interoperability governance should become more transparent, particularly regarding the role of EU-funded projects and technical standard-setting bodies.

Address infrastructural dependencies: The EU should monitor and manage dependencies on private digital infrastructures that may shape policy outcomes beyond democratic control.

Improve inclusiveness of technical governance: Standard-setting processes should include mechanisms to better involve non-technical stakeholders and citizens.

Prepare for future European data spaces: The EHDS will likely serve as a model for other EU data spaces. Lessons on governance, transparency, and accountability should be integrated into future policy design.