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Unlocking Health Data for Innovation: The Promise and Risks of the European Health Data Space

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Introduction

Europe is on the cusp of a new era in health data governance. With the proposal and progressive development of the European Health Data Space (EHDS), the European Union is charting an ambitious course toward unlocking the full potential of health data for better healthcare delivery, research, and innovation while upholding the foundational values of privacy, trust, and fundamental rights.

As the legal partner of LUCIA, we are deeply engaged in navigating the complex legal terrain that underpins this transformation. In this post, we explore the opportunities and legal challenges presented by the EHDS and what it means for stakeholders across the health data ecosystem.

What is the EHDS?

The EHDS is part of the EU's broader Data Strategy, designed to create common "data spaces" across different sectors. For healthcare, the EHDS has two key pillars:

1. **Primary use of health data:** ensuring patients have better access to their electronic health records across Member States, so they can receive care anywhere in the EU.
2. **Secondary use of health data:** enabling researchers, innovators, and policymakers to access pseudonymised and anonymised health datasets under strict conditions, through national health data access bodies.

The EHDS is not just a technical infrastructure-it's a legal and governance framework aiming to harmonize divergent national rules, empower individuals, and foster a data-driven health economy. For EU projects like LUCIA, the secondary use framework is the most relevant. It means that, in principle, projects will be able to access high-quality, cross-border datasets for research without facing the current patchwork of national rules.

Opportunities for Innovation

The EHDS could unlock significant opportunities for projects dealing with health data:

- **Access to Rich, Diverse Datasets:** Researchers and developers can benefit from broader access to high-quality, real-world health data from across the EU fuelling breakthroughs in personalized medicine, AI diagnostics, and population health analytics.
- **Cross-Border Collaboration:** The EHDS facilitates cross-border data sharing, removing legal and administrative hurdles that have traditionally hampered multi-country clinical trials and joint innovation projects.
- **Trust by Design:** With its emphasis on data protection, patient consent, and ethical use, the EHDS provides a governance model that can enhance public trust and promote responsible data use.

In the context of LUCIA's mission i.e. to harness data for smarter, more inclusive healthcare solutions the EHDS is a foundational step toward scalable, interoperable, and ethically aligned innovation.

Legal and Ethical Challenges

The EHDS introduces several legal and ethical challenges that projects will need to address carefully:

1. Relationship with GDPR

The EHDS must operate within the strict boundaries of the General Data Protection Regulation (GDPR). Questions remain about how secondary use of data, particularly pseudonymised datasets, will align with existing legal bases under GDPR, especially in the absence of explicit consent.

As legal advisors, we must assess how the EHDS creates new legal bases for secondary use while ensuring alignment with individual rights, transparency, and accountability.

2. Governance and Oversight

The EHDS proposes the creation of Health Data Access Bodies at the national level, responsible for authorizing secondary data use. These bodies will play a pivotal role, but their interpretation of “public interest,” data minimisation, and access rights may vary, potentially leading to fragmentation in implementation.

Robust oversight mechanisms, clear guidance, and harmonization will be essential to prevent legal uncertainty.

3. Intellectual Property and Commercial Use

One contentious issue is how data access under the EHDS intersects with intellectual property rights, trade secrets, and commercial interests. While the EHDS promotes innovation, it must also protect the legitimate rights of data holders and avoid disincentivizing private sector participation.

Striking a balance between openness and protection is a legal tightrope that must be walked carefully.

4. Ethical and Social Considerations

Beyond the law, the ethical implications of data reuse, especially for AI and algorithmic decision-making, must be addressed. Fairness, bias mitigation, and explainability of data-driven tools are not yet fully codified in EU law but are essential for trust.

As partners in LUCIA, we advocate for a legal-ethical by design approach to every stage of health data innovation.

Preparing for Compliance: What Projects Like LUCIA Should Do

For EU-funded initiatives, early preparation is key. LUCIA and similar projects should start aligning with EHDS principles even before the legislation is fully in force. Recommended steps include:

- **Mapping Data Flows:** Understand what health data is collected, how it is processed, and whether it may fall under EHDS secondary use rules.
- **Reviewing Legal Bases:** Ensure compliance with GDPR legal bases for processing sensitive health data, particularly for cross-border transfers.

- **Strengthening Data Governance:** Develop internal policies for access control, pseudonymisation, and accountability.
- **Engaging Patients and Stakeholders:** Foster trust through transparent communication about how health data is used in research.

Why This Matters for LUCIA

As a health data–focused project, LUCIA stands at the intersection of innovation and regulation. The EHDS will shape the way we collect, manage, and re-use health data. By anticipating these changes now, we can ensure that LUCIA not only remains compliant but also leads by example in responsible and ethical data use.

Moreover, positioning ourselves as early adopters of EHDS principles can enhance LUCIA’s credibility with policymakers, partners, and patients. It signals that we are not only advancing health innovation but also respecting the rights and values at the heart of EU law.

Conclusion

The European Health Data Space represents a bold experiment in data solidarity, public trust, and technological leadership. Its success will depend not only on laws and infrastructure, but on the values that guide their application.

At LUCIA, we believe that the responsible use of health data can deliver tangible benefits to patients, researchers, and society at large—provided that privacy, equity, and transparency remain at the core of innovation.

As legal stewards of this vision, we remain committed to ensuring that data unlocks progress not problems.



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