



FORTIFY Launches to Strengthen Innovation Protection in Europe's Health Data Space

A new IHI-funded project aims to unlock health data for research while safeguarding intellectual property and trade secrets

Stockholm and Leeds, 1 May 2026 — The **FORTIFY project** (*Framework for Optimized Regulation, Trade Secrets, and Intellectual Property in a Federated European Health Data Space*) has officially launched to tackle one of the most pressing challenges in health innovation today: **how to enable broad, trusted secondary use of health data for research purposes without putting intellectual property, trade secrets, and commercially sensitive information at risk.**

Funded under the **Innovative Health Initiative (IHI)** and aligned with the implementation of the **European Health Data Space (EHDS)**, FORTIFY brings together **33 public and private partners** from academia, industry, healthcare, policy, and patient organisations. Over the next **three years**, the project will develop, test, and validate **legal, governance and technical solutions** that allow health data to be reused safely, fairly, and efficiently—without undermining Europe's capacity for innovation.

Addressing a critical gap in the European Health Data Space

The EHDS is designed to accelerate research, innovation, and better health outcomes by enabling the secondary use of health data across Europe. However, many data holders—particularly hospitals, research infrastructures, and industry—remain concerned about **loss of control over sensitive data, trade secrets, and intellectual property once data is shared.** Without clear safeguards, these concerns risk slowing adoption and limiting the availability of high value datasets.

FORTIFY aims to break this deadlock by proving that **data sharing and innovation protection do not have to be a trade-off.**

“Europe's health data has enormous potential to drive medical breakthroughs, but that potential will only be realised if health data holders trust the system,” said **Pedro Ramos**, Department of Learning, Informatics, Management and Ethics at **Karolinska Institutet (KI)** and FORTIFY scientific coordination. *“FORTIFY is about turning trust into practical tools—so data can flow without compromising innovation.”*

Clear objectives with practical, real-world validation

FORTIFY combines **law, technology, and real-world testing.** The project will develop clear **legal guidance, model contracts, and practical governance** tools that clarify



how intellectual property, trade secrets, and regulatory data can be protected at every step of the EHDS data sharing process.

On the technical side, FORTIFY will create and test **traceability and watermarking solutions** that allow data owners to track how their data is used and protect it—even after it has been shared. It will also provide guidance on when **synthetic, anonymised or transformed data** can be used to reduce risk while preserving scientific value.

Crucially, all solutions will be **tested in real health data environments**, including clinical trials, medical imaging, biobanks, federated studies, genomics, real-world evidence, AI models or device generated data.

*“This is not a theoretical exercise,” explained **Simon Bates**, Director of Patent Law at **Johnson & Johnson** and project lead. “We are working with real data holders, real researchers, and real access bodies to show what works in practice.”*

After the three-year period, FORTIFY aims to deliver a unified, IP-sensitive data-sharing framework tailored for adoption by Health Data Access Bodies (HDABs) and data holders throughout Europe, alongside practical training and policy recommendations for EU and national authorities to ensure the EHDS supports broad data sharing and robust protection of intellectual property.

What this means for Europe—and for patients

FORTIFY’s mission is to unlock higher value health data across Europe by reducing uncertainty and administrative delays, while strengthening safeguards for innovators. That, in turn, could mean **faster research, better treatments, and stronger European competitiveness in health and life sciences**.

Through FORTIFY’s approach, health data holders can benefit from clearer rules, contractual templates, and technical safeguards, enabling them to share data without risking the loss of competitive assets. Researchers and innovators, in turn, can gain improved access to high-quality data along with greater legal certainty. Meanwhile, HDABs and public authorities will be equipped with practical tools and guidance to assess data access requests consistently and efficiently.

Patients and citizens also stand to benefit. By building clearer rules and stronger safeguards, the project aims to increase confidence that health data is reused **responsibly, securely, and in the public interest**.

“By combining law, technology, and governance, FORTIFY will provide future health data access bodies with practical tools supporting their tasks as independent bodies responsible for fair, consistent and efficient evaluation of data access procedures” added **Inge Franki**, EU Unit Manager, Health Data Agency, Belgium.

About FORTIFY

FORTIFY is a public-private partnership funded by the Innovative Health Initiative (IHI) with support from European Union's Horizon Europe research and innovation programme and COCIR, EFPIA, Europa Bio, MedTech Europe, Vaccines Europe and Clarivate as a contributing partner. It was launched on 1 April 2026 and will run for 36 months, through March 2029.

FORTIFY partners

The 33 partners include: Karolinska Institutet (**coordinator**), Johnson & Johnson (**project lead**), KU Leuven, OTTAWA UNIVERSITY, UNIVERSITA DI BOLOGNA, Teamit Research, Vaccine Monitoring Collaboration for Europe, FUNDACION PARA LA INVESTIGACION DEL HOSPITAL UNIVERSITARIO LA FE, Timelex BV, CHARITE - UNIVERSITAETSMEDIZIN BERLIN, Patvocates, Universidad Politécnica de Valencia, Health Data Agency Belgium, Agència de Qualitat i Avaluació Sanitàries de Catalunya, Imperial College, Rizzoli Orthopaedic Institute, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Health Data Hub France, Sanofi, AbbVie, AstraZeneca, Bayer, bioMérieux, Boehringer Ingelheim, GSK, Merck, Merck Sharp & Dohme Corporation, Novartis Pharma, Novo Nordisk, Pfizer Ltd, UCB Pharma and ResMed **as consortium members.**

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Website article: [FORTIFY launches to protect innovation while enabling health data reuse in Europe](#)

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