

EEHRxF Regulators Forum



Letter of entry

Dear Prospective Member,

The xShare Project Consortium is writing to formally invite you to participate in its EEHRxF (European Electronic Health Record Exchange Format) Regulators Forum, an essential initiative within the xShare project. Your involvement as a government agency and/or regulatory authority is crucial for aligning and shaping the future of electronic health data exchange across Europe under the emerging European Health Data Space (EHDS) regulations and the related European Electronic Health Record Exchange Format. The Forum's kick-off meeting will be held under the auspices of the XpanDH project in continuity of ongoing efforts to activate, expand and mature the EEHRxF ecosystem.

Kick-off meeting: **October 28th, 14-15 CET (ONLINE)**

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EHDS, EEHRxF, xShare Standards and Policy Hub, MyHealth@EU, and HealthData@EU

The **European Health Data Space (EHDS)** represents a key development in the European Union's efforts to establish a unified framework for the secure and interoperable exchange of health data across member states. Introduced by the European Commission in 2022 and provisionally adopted in 2024, the EHDS aims to facilitate both the primary and secondary use of electronic health data for healthcare delivery and research, respectively. This regulatory framework complements and builds upon existing data protection laws such as the General Data Protection Regulation (GDPR) by mandating new rights and obligations related to the portability and security of personal health data across Europe. It is designed to improve healthcare services, support research, and foster innovation across the digital health sector, enhancing both citizen engagement and healthcare system efficiency.

Central to the implementation of the EHDS is the **European Electronic Health Record Exchange Format (EEHRxF)**, introduced by the European Commission in 2019. The EEHRxF provides the technical foundation for secure cross-border access to electronic health records (EHRs), facilitating the flow of personal health data between member states and enabling better continuity of care. The format supports six priority categories of health



data—patient summaries, electronic prescriptions and dispensations, medical imaging and reports, laboratory test results, and discharge summaries—that are crucial for primary healthcare. Moreover, the EEHRxF enables the secondary use of health data for research and policy development, further supporting the European Union’s strategic goals for digital health transformation.

Building on the success of the EEHRxF, the **xShare Standards and Policy Hub** is being established under the xShare project to provide a scene for stakeholders to align on technical standards, policy frameworks, and best practices related to the EHDS and health data interoperability. The Hub convenes government agencies and/or regulatory authorities, industry leaders, and researchers to ensure that health data exchange is conducted in a manner that supports innovation while adhering to legal and ethical standards.

Two key infrastructures connected to the EHDS are **MyHealth@EU** and **HealthData@EU**. MyHealth@EU serves as the digital backbone for cross-border healthcare services, allowing EU citizens to access healthcare in other member states with the same ease and security as they would in their home countries. This infrastructure supports the seamless exchange of ePrescriptions, patient summaries, and other essential health information, fostering greater mobility and patient autonomy within Europe.

HealthData@EU, on the other hand, is focused on the secondary use of health data. It supports large-scale research projects, public health monitoring, and evidence-based policymaking by providing secure access to anonymised and pseudonymised health data. By enabling researchers and policymakers to tap into a rich pool of health data, HealthData@EU accelerates the development of new therapies, improves public health interventions, and informs health policies that are responsive to real-world needs.

What is the EEHRxF Regulators Forum?

The EEHRxF Regulators Forum will be a collaborative platform bringing together government agencies and/or regulatory authorities from across Europe to engage in dialogue, share insights, and contribute to the development and implementation of standards, governance frameworks, and operational guidelines for the secure exchange of electronic health data. This Forum will be launched under the XpanDH project, before operating under the xShare project, which is particularly dedicated to supporting industry and regulatory bodies in navigating and implementing the EHDS regulations. The EEHRxF Regulators Forum will provide government agency and/or regulatory authorities with a direct influence on the

development of standards and guidelines, ensuring they are practical and aligned with national and European expectations.

What are the focus areas of the EEHRxF Regulators Forum?

The priority areas of attention of the Forum include:

- Input and feedback on project proposals and initiatives that could impact regulators' activity in the area of the EEHRxF.
- Develop shared understanding on regulatory requirements and challenges related with the EEHRxF.
- The establishment of strong working relationships between regulators and the xShare project, facilitating adoption and implementation of the Standards and Policy Hub.

How Will the Forum Benefit Regulators?

Participation in the EEHRxF Regulators Forum offers several benefits, including:

- **Influence:** You will have a direct impact on the development of standards and frameworks that will shape the future of electronic health data exchange in Europe.
- **Collaboration:** The Forum provides a unique opportunity to collaborate with peers, industry leaders, and European institutions, fostering mutual understanding and alignment.
- **Knowledge Sharing:** Engage in knowledge exchange on best practices, challenges, and solutions, enhancing your ability to navigate and implement EHDS and related regulations.
- **Capacity Building:** Through participation, you will gain insights and tools that will support the effective regulation and oversight of emerging technologies and standards in health data exchange.

Your expertise and insights are invaluable to the success of the xShare project, and we are confident that your involvement in the EEHRxF Regulators Forum will contribute significantly to shaping the future of healthcare in Europe.

Thank you for considering this invitation.

Sincerely,

The xShare Project Consortium

