European Health Data Space: The EU's Digital Health Framework

Experts in health

The European Health Data Space (EHDS) Regulation was officially published in the Official Journal of the European Union on 5 March 2025: it entered into force 20 days after publication, on the 25 March 2025.

It is a binding EU regulation that creates a unified legal, technical, and governance structure for accessing and using electronic health data across the 27 EU member states.

Approximately **450 million people**, and their data, will be included in this regulation.

Key logistics of the regulation

- Data will be accessed through a **cross-border digital infrastructure**: MyHealth@EU
- **EU-wide standards** for data sets, security, interoperability, and identification will be set
- **Governance bodies** for oversight, issue-resolution and coordination will be set up
- All health-data collecting bodies will adopt a **standardised, interoperable format for EHRs**
- All EHR systems should integrate **certified components** for data compatibility and logging
- **Non-compliant systems will face penalties**

Outlined timeline 2025-2035

- 2025: Regulation enters into force; start of annual progress reports
- 2027: Full applicability begins (legal obligations of EHDS become enforceable)
- 2029: Implementation of first data categories (allergies, vaccines, and imaging data)
- 2031: Implementation of remaining data categories (lab results, discharge summaries)
- 2033: Targeted evaluation
- 2035: Overall evaluation

Benefits

For individuals

- Healthcare professionals across borders can access a patient's electronic health data to support continuity and quality of care.
- Individuals have the power to access, rectify and restrict their health data—including the option to opt-out of sharing data beyond the provider who originally provided treatment
- Vulnerable groups have proxy access and support
- Digital health literacy and support services for citizens must be developed

For research

- Access to large, diverse, and population-level datasets, improving the statistical power and generalisability of research.
- Comparative analysis of healthcare utilisation, clinical effectiveness and care pathway optimisation.
- Real-time monitoring of drug reactions and long-term medication safety using population-scale health data.
- Enhances trial efficiency and diversity by identifying eligible populations more easily.
- Multi-state data pool enables faster discovery of patterns and treatment options for small patient populations
- High-quality, structured health data to train and validate clinical decision-support tools and diagnostic algorithms.

For policy makers

- High-quality, aggregated data for evidence-based policymaking, evaluation of public health interventions, and cost efficiency of health-related public services
- Enables early detection tracking and response to health threats or environmental health risks.
- Supports research into health inequalities and access gaps
- Improves cross-border coordination and data-driven collaboration
- Strengthens digital governance through EU-wide standards and oversight
- Enhances transparency and accountability in data use

Challenges

- **Data trust and privacy**: Ensuring patient confidence in sharing sensitive data.
- **Interoperability and infrastructure**: Outdated systems and uneven digital maturity across EU.
- **Data quality and cybersecurity risks**: Inconsistent records and heightened exposure to cyber threats.
- **Compliance and rollout pressures**: Heavy burdens on providers and tight implementation timelines.
- **Funding demands**: Long-term investment needed for systems, training, and support.
- **Stakeholder engagement**: Requires digital literacy, clinician training, and careful balancing of interests.