Opportunities for the European Health Data Space to change clinical trial recruitment

ACT EU Multi-stakeholder Platform Annual Meeting,
European Medicines Agency

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29 October 2025

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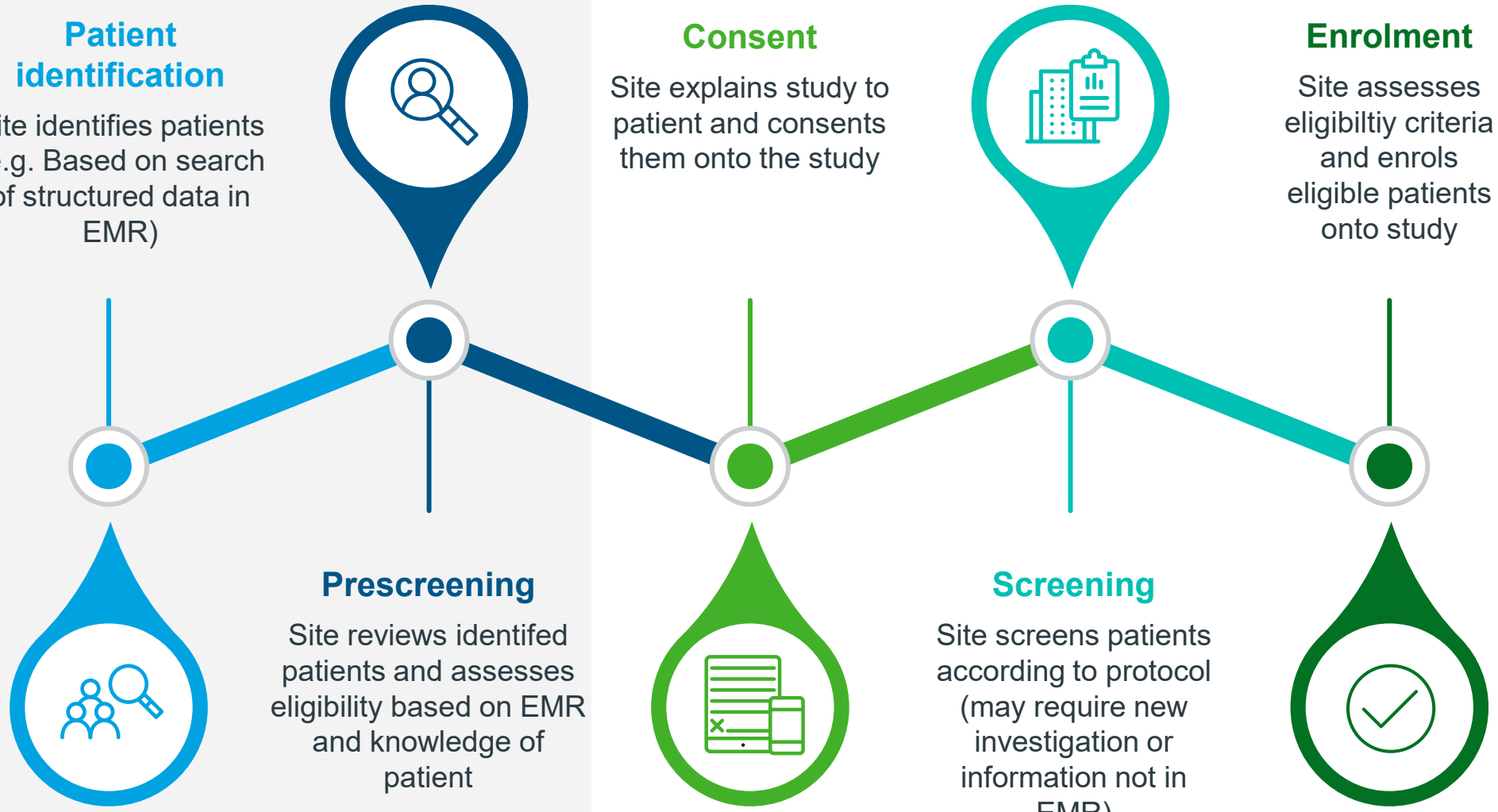
As with any attempt to estimate future events, the forecasts, projections, conclusions, and other information included herein are subject to certain risks and uncertainties, and are not to be considered guarantees of any particular outcome.

Clinical trial recruitment today

Patient identification and Prescreening can be augmented by other channels



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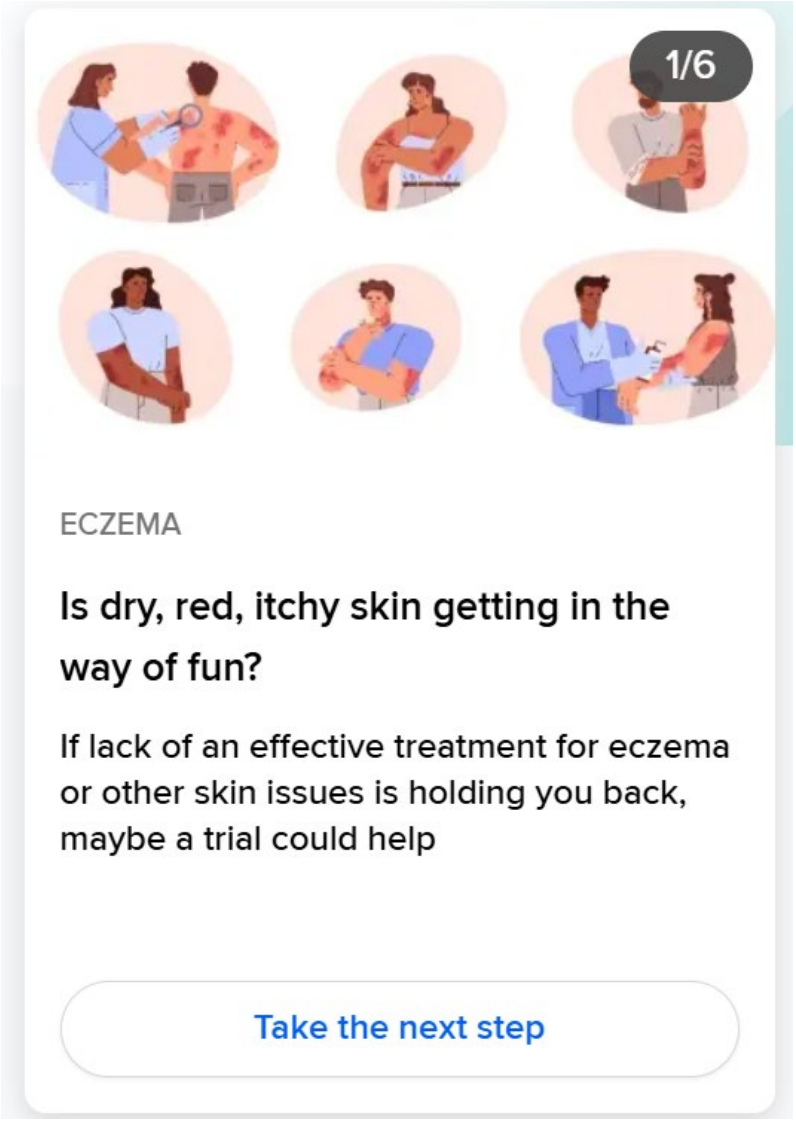
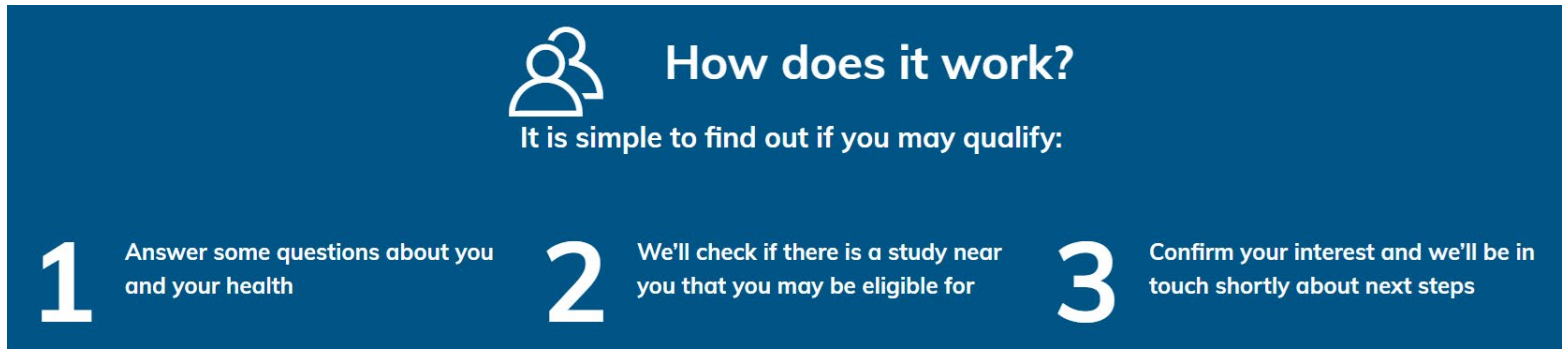




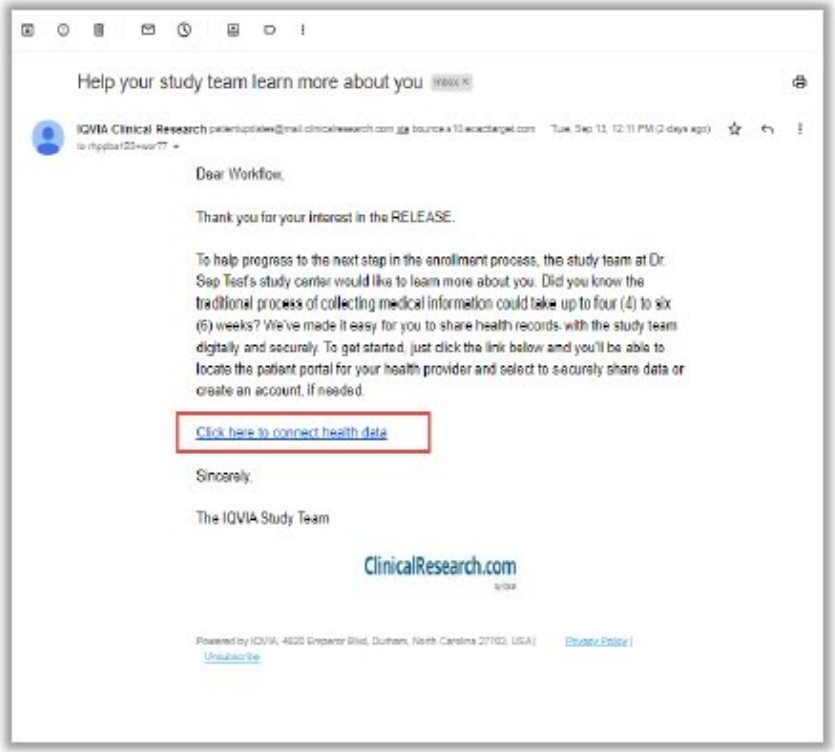
Prescreening questionnaire

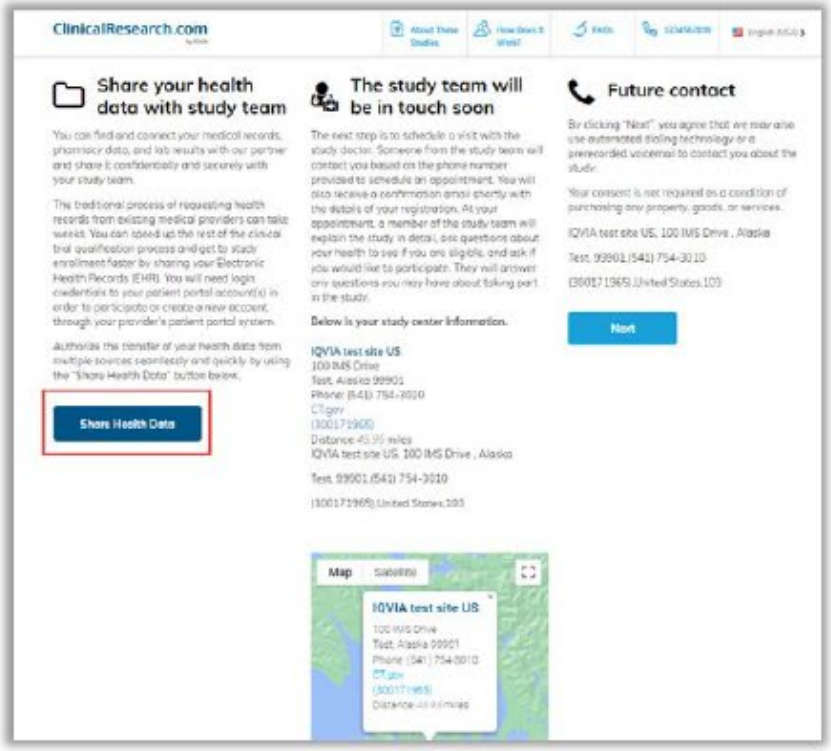
Patient allocated to a site

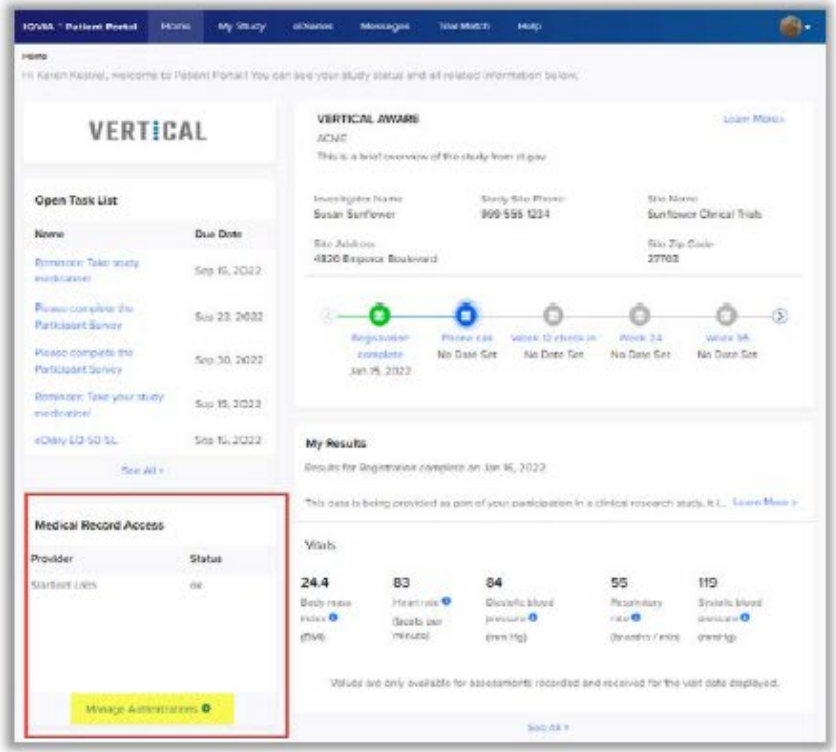
Site screening process begins

Source: clinicalresearch.com

For patients from alternative recruitment channels, the qualification process is faster when patients share their medical records







US legislation enabling this approach

- Patient data access rights enshrined in **HIPAA** and interoperability mandated in the **21st Century Cures Act**
- FHIR APIs enable automatic health data transfers to researchers via health data portals
- In the case of non-interoperability, signed medical records release forms are used to manually request medical records

Enabling easier and faster clinical trial qualification with patients not connected to clinical trial sites has a number of benefits:

- ✓ Increases access for patients
- ✓ Accelerates clinical trial recruitment
- ✓ Increases trial diversity

HIPAA: Health Insurance Portability and Accountability Act

But wait!

GDPR *should* allow patients to access a copy of their own health data in the EU and allow them to share it for clinical trial qualification, but in practice, **this is not happening**.

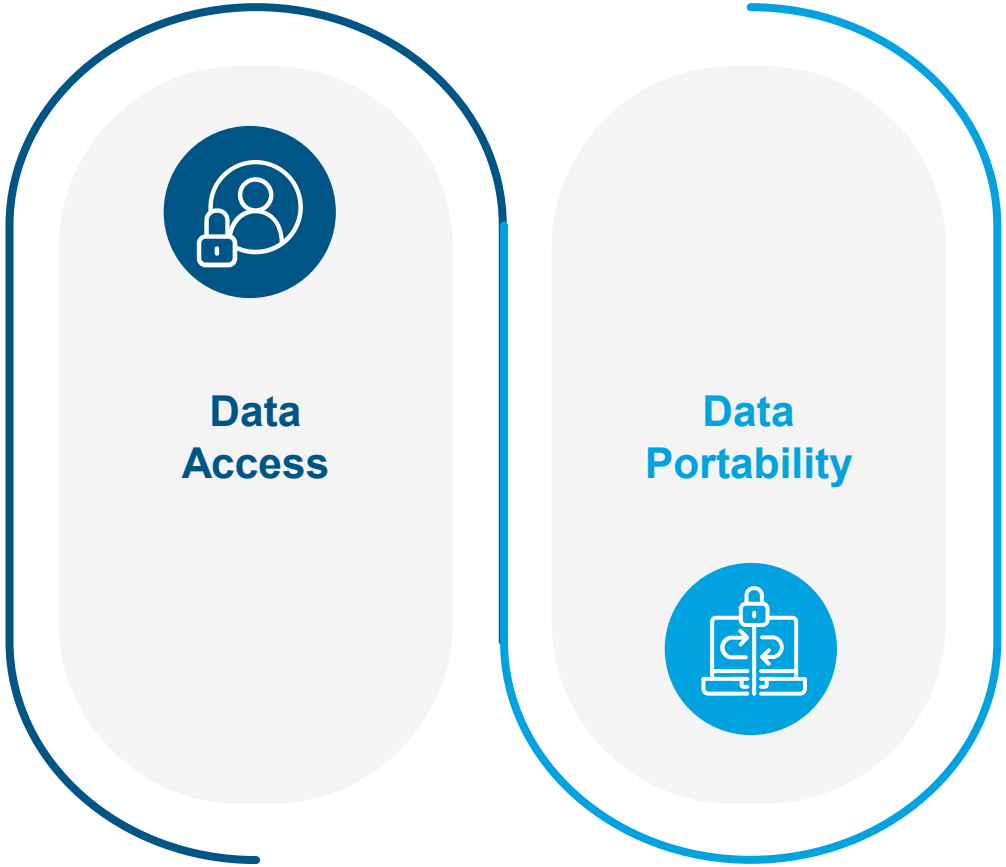
GDPR gives patients the right of access and to health data portability

Right of Access

Article 15

What is it?

- Data subjects have a right to **receive a copy of personal data undergoing processing**
- Where the data subject makes the request by electronic means, and unless otherwise requested by the data subject, the **information shall be provided in a commonly used electronic format**
- Requests are made using a **Data Subject Access Request**, and can be made by authorized third parties on behalf of the subject
- Data controllers have **up to 90 days to comply**



Right to Data Portability

Article 20

What is it?

- It is the right for data subjects to receive the personal data that they have provided to a controller, in a structured, commonly used and machine-readable format, and to **transmit those data to another data controller**
- The aim is to **empower data subjects regarding their own personal data**, as it facilitates their ability to move, copy or transmit personal data easily from one IT environment to another (whether to their own systems, the systems of trusted third parties or those of new data controllers)

GDPR: General Data Protection Regulation

The EHDS regulation in the EU aims to make patient access to their own health data faster

> The aim of this Regulation is to establish the EHDS in order to **improve natural persons' access to and control over their personal electronic health data** in the context of healthcare, as well as to better achieve other purposes involving the use of electronic health data in the healthcare and care sectors that would benefit society, such as **research, innovation**, …

Overall aim

> [Natural persons] should have the right to have **free-of-charge and immediate access**

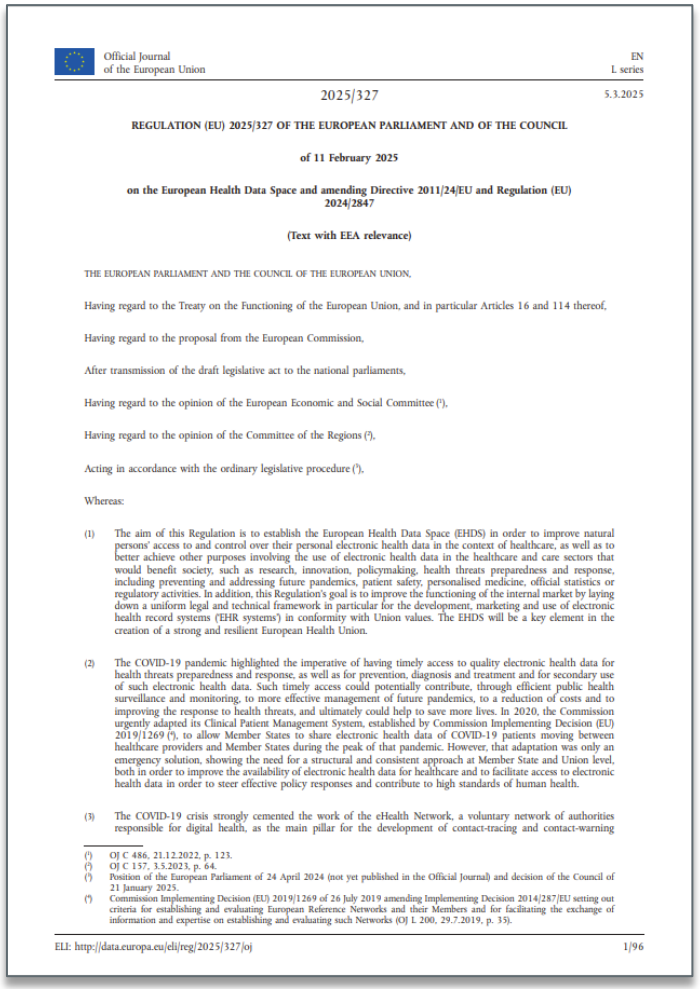
Faster access

> The EHDS should make it easier … to control better the access to and sharing of their personal electronic health data

Easier control

> … ensuring that natural persons as data subjects can transmit their personal electronic health data, including inferred data, in the EEHRxF, irrespective of the legal basis for processing the health data.

Data portability expansion and interoperability



Official Journal of the European Union — EN — L series

2025/327 — 5.3.2025

REGULATION (EU) 2025/327 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 February 2025

on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 16 and 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

Having regard to the opinion of the Committee of the Regions (2),

Acting in accordance with the ordinary legislative procedure (3),

Whereas:

(1) The aim of this Regulation is to establish the European Health Data Space (EHDS) in order to improve natural persons' access to and control over their personal electronic health data in the context of healthcare, as well as to better achieve other purposes involving the use of electronic health data in the healthcare and care sectors that would benefit society, such as research, innovation, policymaking, health threats preparedness and response, including preventing and addressing future pandemics, patient safety, personalised medicine, official statistics or regulatory activities. In addition, this Regulation's goal is to improve the functioning of the internal market by laying down a uniform legal and technical framework in particular for the development, marketing and use of electronic health record systems ('EHR systems') in conformity with Union values. The EHDS will be a key element in the creation of a strong and resilient European Health Union.

(2) The COVID-19 pandemic highlighted the imperative of having timely access to quality electronic health data for health threats preparedness and response, as well as for prevention, diagnosis and treatment and for secondary use of such electronic health data. Such timely access could potentially contribute, through efficient public health surveillance and monitoring, to more effective management of future pandemics, to a reduction of costs and to improving the response to health threats, and ultimately could help to save more lives. In 2020, the Commission urgently adapted its Clinical Patient Management System, established by Commission Implementing Decision (EU) 2019/1269 (4), to allow Member States to share electronic health data of COVID-19 patients moving between healthcare providers and Member States during the peak of that pandemic. However, that adaptation was only an emergency solution, showing the need for a structural and consistent approach at Member State and Union level, both in order to improve the availability of electronic health data for healthcare and to facilitate access to electronic health data in order to steer effective policy responses and contribute to high standards of human health.

(3) The COVID-19 crisis strongly cemented the work of the eHealth Network, a voluntary network of authorities responsible for digital health, as the main pillar for the development of contact-tracing and contact-warning

(1) OJ C 486, 21.12.2022, p. 123.
(2) OJ C 157, 3.5.2023, p. 64.
(3) Position of the European Parliament of 24 April 2024 (not yet published in the Official Journal) and decision of the Council of 21 January 2025.
(4) Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 200, 29.7.2019, p. 35).

ELI: http://data.europa.eu/eli/reg/2025/327/oj — 1/96

EHDS: European Health Data Space

Source: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202500327

Under EHDS, patients will be able to access priority categories of their own health data *where it exists electronically*

Electronic dispensations
Information on the supply of a medicinal product to a natural person by a pharmacy based on an electronic prescription

Medical imaging and related reports
Electronic health data related to the use of or produced by technologies that are used to view the human body in order to prevent, diagnose, monitor or treat medical conditions.

Electronic prescriptions
Electronic health data constituting a prescription for a medicinal product

Medical test results
Including laboratory and other diagnostic results and related reports

Patient summaries
Electronic health data that include significant clinical facts related to an identified natural person and that are essential for the provision of safe and efficient healthcare to that person.

Discharge reports
Electronic health data related to a healthcare encounter or episode of care and including essential information about admission, treatment and discharge of a natural person.

EHDS: European Health Data Space

Source: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202500327

The Patient Summary category has a lot of useful information relevant for clinical trial qualification

Selected data elements from the Patient Summary Guidelines

- Current Problems
- History of Past Problems
- Results
- Allergies
- Pregnancy history
- Functional Status
- Vaccinations
- History of Procedures
- Social History
- Medication Summary
- Devices and Implants
- Plan of care

Gaps:

- Medication history (only past medicines that influence current health status or are relevant to a clinical decision)
  - Cannot validate past medicine exposure unless in the prescription category (important for trial eligibility)

Source: https://health.ec.europa.eu/system/files/2023-10/ehn_guidelines_patientsummary_en.pdf

Clinical trial recruitment in the EU post-EHDS

xShare envisions everyone sharing their health data in European Electronic Health Record Exchange Format (EEHRxF) with the click-of-a-button – the xShare Yellow Button – to be featured across health portals and patient apps, allowing people to exercise their data portability rights under GDPR.

Xshare Yellow Button*

- Patients will be able to upload their health data to secure **trial matching** websites to help them find relevant trials across the EU (AI enabled)
- Clinical trial **qualification process** can be expedited by patients being able to share their records instantly rather than waiting for clinical trial sites to source them.
- Generative AI will be able to help interpret health data and provide an initial **assessment of eligibility**

*Source: https://xshare-project.eu/ EHDS: European Health Data Space

Thank you