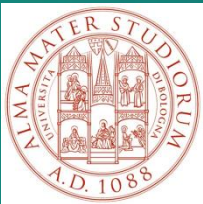


Health Data Reuse

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What you need to know - Relevant Regulations

1. General Data Protection Regulation
2. Data Governance Act
3. European Health Data Space

General Data Protection Regulation (GDPR)

Personal Data

«means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;»

Personal Data for Scientific Research

art. 9 «Processing of special categories of personal data»

«processing is necessary for [...] scientific research purposes [...] in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.»

Data Governance Act

Recital n. 11

«Personal data should only be transmitted for re-use to a third party where a **legal basis** allows such transmission. [...] The public sector bodies, where relevant, should facilitate the re-use of data on the basis of consent of data subjects or permissions of legal persons on the re-use of data pertaining to them through adequate technical means. In this respect, the public sector body should support potential re-users in seeking such consent by establishing technical mechanisms that permit transmitting requests for consent from re-users, where practically feasible.»

Art. 5 «Conditions for Re-use»

«Public sector bodies which are competent under national law to grant or refuse access for the re-use of one or more of the categories of data referred to in Article 3 (1) shall make publicly available the conditions for allowing such re-use. In that task, they may be assisted by the competent bodies referred to in Article 7»

European Health Data Space



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Recital n. 37

In the case where the user has access to electronic health data (for secondary use of data for one of the purposes defined in this Regulation), the data user should demonstrate its legal basis pursuant to Articles 6(1), points (e) or (f), of Regulation (EU) 2016/679 and explain the specific legal basis on which it relies as part of the application for access to electronic health data pursuant to this Regulation: on the basis of the applicable legislation, where the legal basis under Regulation (EU) 2016/679 is Article 6(1), point (e), or on Article 6(1), point (f), of Regulation (EU) 2016/679.

Art. 2 «Definitions»

'electronic health data' means personal or non-personal electronic health data

'secondary use of electronic health data' means the processing of electronic health data for purposes set out in Chapter IV of this Regulation. The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of the secondary use;

Secondary Use (EHDS) ≠ Further Processing (GDPR)

Art. 34 « Purposes for which Electronic Health Data Can Be Processed for Secondary Use »

Health data access bodies shall only provide access to electronic health data referred to in Article 33 where the intended purpose of processing pursued by the applicant complies with: [...]

- (e) scientific research related to health or care sectors;
- (f) development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;
- (g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;

Article 45 «Data access application»

The data access application shall include:

- (a) a detailed explanation of the intended use of the electronic health data, including for which of the purposes referred to in Article 34(1) access is sought;
- (b) a description of the requested electronic health data, their format and data sources, where possible, including geographical coverage where data is requested from several Member States;
- (c) an indication whether electronic health data should be made available in an anonymised format; [...]

Article 45 «Data access application»

Where the applicant intends to access the personal electronic health data in a pseudonymised format, the following additional information shall be provided together with the data access application:

- (a) a description of how the processing would comply with Article 6(1) of Regulation (EU) 2016/679;
- (b) information on the assessment of ethical aspects of the processing, where applicable and in line with national law.

Article 36 «Health data access bodies»

Member States shall designate one or more health data access bodies responsible for granting access to electronic health data for secondary use.

Article 46 «Data permit»

Health data access bodies shall assess if the application fulfils one of the purposes listed in Article 34(1) of this Regulation, if the requested data is necessary for the purpose listed in the application and if the requirements in this Chapter are fulfilled by the applicant. If that is the case, the health data access body shall issue a data permit.

Article 46 «Data permit»

Data users shall make public the results or output of the secondary use of electronic health data, including information relevant for the provision of healthcare, no later than 18 months after the completion of the electronic health data processing or after having received the answer to the data request referred to in Article 47.


Those results or output shall only contain anonymised data. The data user shall inform the health data access bodies from which a data permit was obtained and support them to make the information public on health data access bodies' websites. Whenever the data users have used electronic health data in accordance with this Chapter, they shall acknowledge the electronic health data sources and the fact that electronic health data has been obtained in the context of the EHDS

What to expect in the future

State of the Art

Procedure 2022/0140/COD

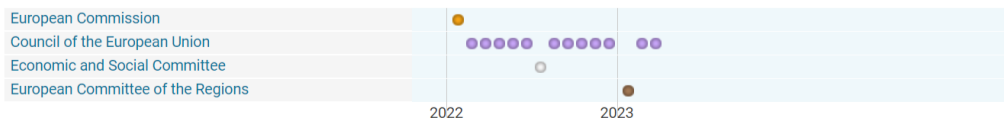
COM (2022) 197: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space

 Ongoing

Type: Ordinary legislative procedure (COD)

[More information about this procedure](#)

[What is an Ordinary legislative procedure](#)



Follow the steps of procedure 2022/0140/COD

[Reverse Order](#)



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FIRST READING

European Parliament



+ Council of the European Union



OPINIONS

+ European Committee of the Regions



+ Economic and Social Committee



PROPOSAL

+ European Commission

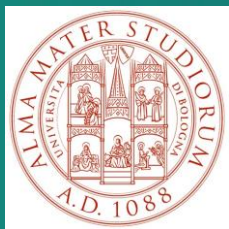


Thank you!

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