Knowledge Ecology International

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Registration for Secondary Use Data Access under the European Health Data Space Regulation

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Decision-Making Prior to Health Data Access Application or Health Data Request

Who can apply?

Under the EHDS Regulation, any natural or legal person may apply for access to electronic health data for secondary use, provided they meet the territorial eligibility requirements set out in Article 67(1).

Eligible applicants include:

- Persons established in the European Economic Area (EEA); and
- Persons established in a third country that:
    - Has been recognised, via an implementing act under Article 91(2), as providing reciprocal access to EU-based applicants; or
    - Has become an authorised participant in HealthData@EU pursuant to Article 75(5).

Lawful purposes and societal benefit

Before submitting a permit application, applicants must assess whether their intended use falls within the lawful purposes for secondary use defined in Article 53.

Lawful purposes for processing electronic health data for secondary use under the EHDS regulation (Article 53) include the following:

a. Public interest
b. Policymaking and regulatory activities

c. (official) statistics
d. Education
e. Scientific research related to health
f. Personalized healthcare

Secondary use data should benefit society, such as through the research and development of new medicines, medical devices, and healthcare products and services, at fair prices for Union citizens (Article 53). Use outside the scope of the approved purposes set out in the EHDS is prohibited. Some prohibited purposes are expressly laid out in Art. 54. For example, insurance discrimination and advertising.

Choosing correct application pathway

There are two different application paths based on the type of secondary use needed by the applicant. The EHDS define each of these application types.

Article 67 (Health data access application) of the EHDS Regulation sets out the terms by which a natural or legal person may submit a health data access application to a health data access body (HDAB) for secondary use data. This article is related to individual-level personal electronic health data.

Data made available under this pathway:

- Is provided only after anonymisation or pseudonymisation;
- Is accessible within a secure processing environment (SPE); and
- Requires a clear argumentation where pseudonymised data is required.

This application path under Art. 67 applies to two types of data sets:

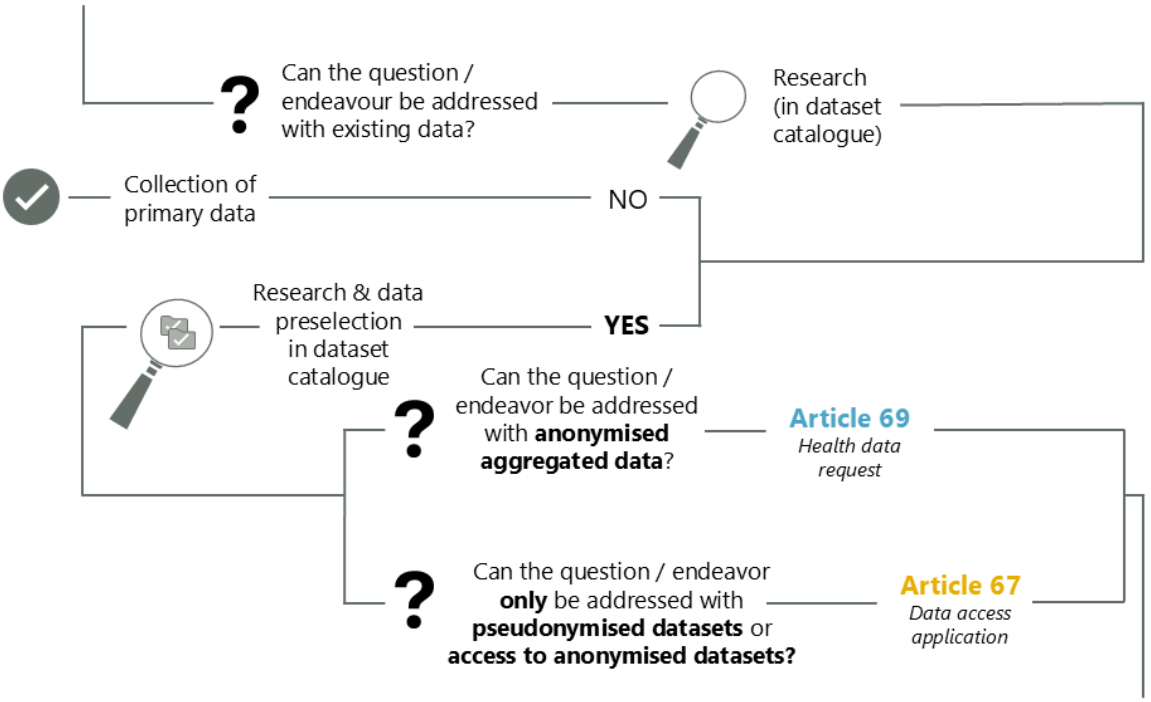
1. Pseudonymised dataset: when anonymised data is insufficient to achieve the objective of the processing, and a clear justification is provided.
2. Anonymised datasets: when direct access to anonymised datasets is sufficient for the intended analysis and/or pseudonymised data is not considered by HDAB to be needed for the described purpose.

A second application process for access to secondary data is set out in **Article 69 (Health Data Request)**. This article sets out the method to access anonymised (aggregated) statistical outputs. This request pathway is ideal where there is no need for direct access to personal electronic health data or for querying datasets to obtain further anonymised aggregated details on its contents and there is no need for the data user to access the datasets themselves. Overall, this request allows for insight into data without granting dataset-level access

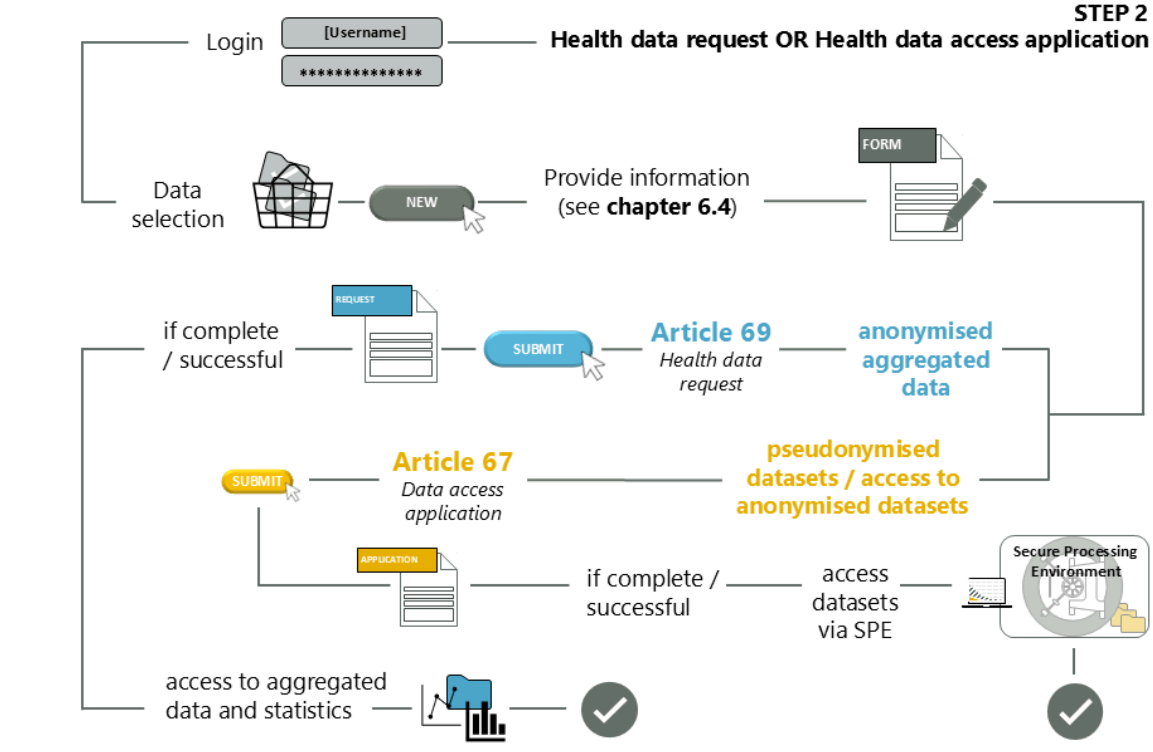
The European Commission funding project TEDHAS 2, which is charged with developing guidelines and technical specification for the implementation of secondary use data within the scope of the EHDS, has developed practical guidance and technical specifications for both data access applications (Article 67) and data requests (Article 69).

User Journey
Application process for data access and data requests

STEP 1
(Research) Question / Endeavour covered by the purposes listed in Article 54



STEP 2
Health data request OR Health data access application



Health Data Access Application and Health Data Request

Applicants will first need to decide which is the suitable HDAB portal for their application. This will depend on whether the application includes data from cross-border registries, data from multiple countries, or data from a single country.

Where an applicant seeks access to electronic health data from health data holders established in more than one Member State, the applicant must submit a single data access application to the HDAB of the main establishment of the applicant, which shall be automatically forwarded to other relevant HDABs.

The health data access application needs to include the following content. The minimum requirements are set out in Art. 69(2) and further elaborated by the TEDHAS2 Guideline for data users on good application and access practice.[1]

1. Selecting project sources
    a. Identification of data source
2. Public information on the project
    a. General overview of the project that is fit for public disclosure (project name, purpose for which data will be used, research objectives, description of the data used, etc.)
3. Applicant and contact person information
    a. Identify of applicant, professional functions and identification of any natural persons who would have access to the data if the permit were issued
4. Purposes of data use
    a. Which purposes the health data is to be used for, description of project aims, and expected benefit, including societal impact.
5. Description of the data needed (defining extraction criteria etc.)
    a. Description of the data for HDAB to better understand if it aligns with EHDS and GDPR (scope, time range, format etc). This includes the data extraction criteria, the groups of controls and relatives and other data to be combined.
    b. A description of whether the data needs to be made in a pseudonymised or anonymised format
6. (for Data Access Application only) Other data to be combined
    a. Details about the existing dataset(s) the applicant wants to have combined with the dataset(s) they are applying for.
7. (for Data Access Application only) Data processing, data protection and safeguards
    a. Details on the SPE (Secure Processing Environment) (computational needs, the SPE provider, time frame for processing, time frame for inactive data storage, how the applicant complies with the principle of data minimisation)
    b. A description of safeguards to prevent misuse of the data and to protect the rights and interests of the data holder or persons concerned

[1] https://tehdas.eu/results/new-tehdas2-guideline-supports-researchers-in-secure-use-of-health-data-2/

The application is sent to the relevant HDAB, which is thereby responsible for deciding on the application, authorizing and issuing data permits, providing access to electronic health data, and monitoring and supervising compliance with the requirements under the EHDS.

Implementing Acts and Timeline

Importantly, while the EHDS Regulation establishes the legal criteria and framework for secondary data access, many practical issues related to registration and access to the secondary data will be governed by the Commission's implementing acts expected in early 2027.

As set out in Article 67(6), the Commission, by means of implementing acts, may create templates for the data access application. The key implementing acts are expected by March 2027. The intention of this is to allow a two year period to set out the detailed implementation blueprints, and then two more years to build and deploy them before key parts of the EHDS regulation become applicable. The key implementing acts are as follows:

- Art. 13(4) on data quality requirements in primary use;
- Art. 15(1) on the technical specifications for the EEHRxF;
- Art. 23(4) on MyHealth@EU;
- Art. 36(1) on common specifications for the harmonised components of EHR systems;
- Art. 70(1) on templates for data access applications, permits, and requests;
- Art. 73(5) on requirements for secure processing environments;
- Art. 75(12) on HealthData@EU;
- Art. 77(4) on the requirements for dataset descriptions; and
- Art. 78(6) on the data quality and utility label.[2]

In this regard, the chapter on secondary use data of the EHDS regulation will only be applicable from 2029 (five years after entry into force of the regulation. As such, from 2029, the first applications can be submitted for most data categories. However, certain data categories (genomic data) will only be applicable from 2031. In particular, this genomic category of data relates to data on factors impacting on health, including socio-economic, environmental and behavioural determinants of health; human genetic, epigenomic and genomic data; other human molecular data such as proteomic, transcriptomic, metabolomic, lipidomic and other -omic data; data from clinical trials, studies and investigations; and research data.

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[2] https://health.ec.europa.eu/document/download/4dd47ec2-71dd-49fc-b036-ad7c14f6ed68_en?filename=ehealth_ehds_qa_de.pdf