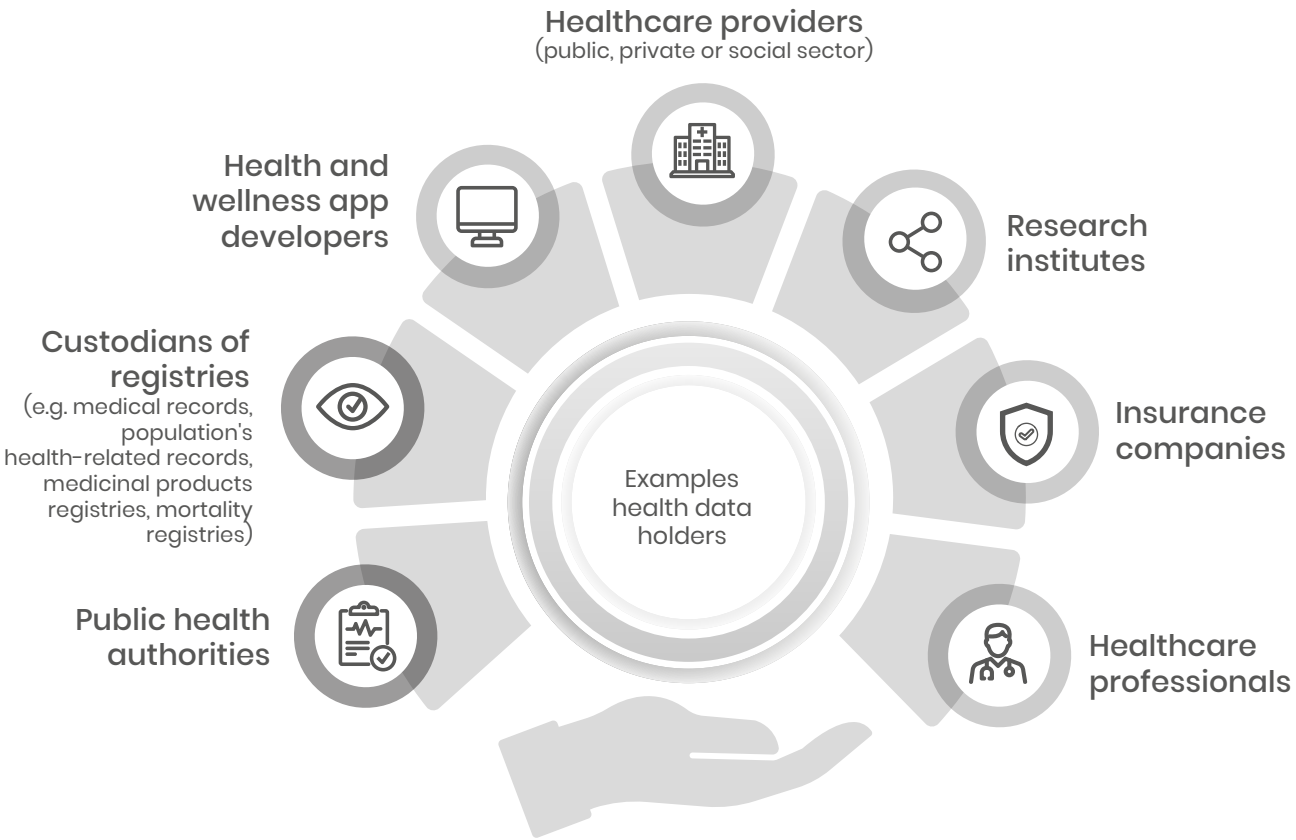
Health data holders and the European Health Data Space (EHDS) regulation

Health data holder under the EHDS regulation

Natural or legal person, public authority, or **public or private entity** that processes **personal electronic health data** or that **may make available non-personal electronic health data** in the context of the provision of care or activities in the health sector.

Article 2.º (19)



Trusted data holders (Article 72.º): Data holders that have the capacity to support the Health Data Access Body (HDAB) in certain tasks pertaining to health data access or request processes, that hold a secure processing environment.

The **EHDS Regulation** (UE 2025/327) for the **secondary use of health data** comes into application on **26th March 2029**

REPÚBLICA PORTUGUESA SAÚDE
SNS SERVIÇO NACIONAL DE SAÚDE
SPMS EPE Serviços Partilhados do Ministério da Saúde
Co-funded by the European Union
HEALTHDATA@PT Setting Up Services by Health Data Access Bodies

Duties of health data holders

Making health data available for secondary use (Articles 60 and 68)

- Upon request from the HDAB
- Within a period, normally no longer than three months after the HDAB request

Accurately communicate the held datasets (Article 60)

- Provide a description of the held datasets according to European Commission´s set criteria (Article 77), towards datasets' description in the national datasets catalogue
- At least once a year, check/update the provided descriptions on the held datasets

Inform about intellectual property rights and confidential/protected content of the data they hold (Article 52)

- Inform the HDAB of content protected by intellectual property rights or trade secrets in the description of its datasets
- Identify which parts of the dataset are protected and justify the need for specific protection

Cooperation (Article 55)

- Actively cooperate with HDAB and other relevant stakeholders

Ensuring transparency (Article 60)

- Provide access to non-personal health data for all users through public, open and reliable databases

Setting fees for data access (Article 62)

- Provide the HDAB with an estimate of the fees to cover the costs incurred in compiling and preparing the health data to be made available in the course of a request approved by the HDAB

Data Quality and utility label[1] (Articles 60 and 78)

- Provide a data quality and utility label in the description of the datasets
- Provide sufficient documentation to the HDAB to verify the accuracy of the issued quality and utility label

[1] Only for data holders with national or European public funding

Natural persons or microenterprises are exempt from these duties (Article 50)

Categories of health data that need to be made available (Article 51) and when (Article 105)

March 26th, **2029**

Data:

- from Electronic Health Records (EHRs)
- on healthcare needs, allocated resources, and on the delivery, access, costs and financing of those healthcare services
- on pathogens that impact human health
- from dispensations, reimbursement claims and reimbursements in the healthcare sector
- generated by medical devices and wellness applications
- on healthcare professionals
- from registries such as i) medical, ii) population health, iii) medication and iv) mortality registries
- from biobanks and associated databases

March 26th, **2031**

Data:

- on socioeconomic, environmental and behavioural determinants that impact health
- on genetics, genomics, epigenomics and other -omics
- from clinical trials, studies and investigations, and clinical performance studies
- from research cohorts, questionnaires and health-related surveys, after the first publication of the results

The HealthData@PT action is co-funded by the European Union, EU4Health Program 2021-2027 under Grant Agreement Nr 101128332. The views and opinions expressed are those of the author(s) and do not necessarily reflect the position of the European Union or HaDEA. Neither the European Union nor the grant-awarding authority can be held responsible for these opinions.