



Are you a “health data holder” within the meaning of the EHDS?

Regulation (EU) 2025/327 on the European Health Data Space (EHDS) imposes certain obligations on “health data holders”. To find out whether your entity is in scope, you need to answer three main questions:



1. Does your entity operate in the healthcare or care sectors?

To qualify as a health data holder, an entity must carry out an activity in “*the healthcare or care sectors*”, including reimbursement services where necessary. Entities that perform research in relation to the healthcare or care sectors, act as mortality registries, develop products or services intended for the health, healthcare or care sectors, or develop or manufacture wellness applications are also covered.

It is therefore necessary to examine whether the entity falls within one of these categories, having regard to the tasks entrusted to it or the activities it carries out.

The legal nature of the entity is irrelevant: it may be a public or private entity, or any other form of body.

Examples of entities generally concerned:

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| – healthcare providers and care providers (e.g. hospitals); | – entities providing services to persons with disabilities; |
| – nursing homes; | – research institutes in the field of health or care; |
| – day-care centres; | – professional associations in the field of health; |
| – insurers offering health insurance; | – developers of wellness applications; |
| – developers of products or services intended for the health, healthcare or care sectors; | |
| – entities carrying out business and technological activities related to care (e.g. orthopaedics). | |

Excluded: courts and other entities of the justice system.

2. Does your entity hold data covered by the EHDS?

The EHDS lists the categories of electronic health data that health data holders must make available for secondary use. These include in particular:

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| – data from electronic health records (EHRs); | – aggregated data on healthcare needs, resources, provision and expenditure; |
| – healthcare-related administrative data; | – data on health professionals; |
| – data from medical devices; | – data from wellness applications; |
| – data from population-based health data registries, medical registries and mortality registries; | – data from research cohorts, clinical trials and clinical studies; |





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| – data on factors impacting health, including social, environmental and behavioural determinants of health; | – human genetic, epigenomic and genomic data and other human molecular (“-omic”) data. |
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This data may be personal (a), or non-personal (anonymised data or data that never related to natural persons) (b). Depending on the nature of the data, additional conditions may apply.

a. Personal electronic health data

To qualify as a health data holder, an entity must also have the obligation or the right, in its capacity as a (joint) controller, to process personal electronic health data for one or more of the purposes listed in the EHDS, i.e. the provision of healthcare or care, public health, reimbursement, research, innovation, policymaking, official statistics or patient safety, or regulatory purposes.

The entity must be entitled to process this data for its own purposes among those mentioned above, and to determine the main means of processing.

b. Non-personal electronic health data

To qualify as a health data holder with regard to non-personal electronic health data, your entity must have the ability to make such data available through the control of the technical design of a product and related services. This ability may result, in particular, from the possibility of registering or providing the data, restricting access to it or exchanging it.

3. Is your entity among the excluded entities?

Category	Status
<i>Natural persons, including individual researchers</i>	Exempt from the obligations
<i>Micro-enterprises (economic activity, <10 persons and annual turnover and/or balance sheet ≤ EUR 2M)</i>	Exempt from the obligations
<i>Courts / other entities of the justice system</i>	Not applicable (recital 63)

Reference texts:

* Chapter IV of the [Regulation \(EU\) 2025/327 of 11 February 2025 on the European Health Data Space](#)

* [Regulation \(EU\) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data \(GDPR\)](#)

