



Health data holder obligations under the EHDS

Do you hold health data? Get ready for the EHDS.

The European Health Data Space (EHDS) establishes a common framework to facilitate the secure secondary use of electronic health data for the purposes of research, innovation, public health, policymaking and education.

As a health data holder, you play a key role in this system.

Find out whether you are in scope by consulting the page:

[*Are you a health data holder?*](#)

Your main obligations

Identify and describe the data held

Provide a description of your health datasets using the [HealthDCAT-AP](#) to the national datasets catalogue, accessible on LetzData.lu. Only the description is published in the catalogue, not individual-level health data.

Keep dataset descriptions up to date

Check that the descriptions in the national datasets catalogue are accurate and up to date, at least on a yearly basis, and, where necessary, provide an updated description.

Make the data available to the CGSD

When [the CGSD authorises the re-use of electronic health data](#), make the data covered by the decision available to CGSD within a reasonable time and, in principle, no later than 3 months after its request.

Additionally, provide the CGSD with an estimate of the costs incurred for compiling and preparing the electronic health data.

Health data are only made available to the CGSD after it has adopted a decision authorising their re-use. The EHDS therefore does not provide for the permanent centralisation of all health databases.

Protect intellectual property rights and trade secrets

Identify which datasets are protected by intellectual property rights and trade secrets, establish and keep the documentation justifying the need to protect them up to date, and provide it to the CGSD.

Contribute to data quality

Where a dataset carries a data quality and utility label (in particular where national or EU funding is involved), you must provide the documentation needed to verify its accuracy.





Provide access to non-personal electronic health data

If you hold open non-personal electronic health data, make them available through trusted open databases in line with the EHDS requirements.

Respect the rights of natural persons

Inform the natural persons concerned of any significant finding made by re-users in the course of their research, in accordance with the conditions laid down in national law.

Guarantee the right to opt out in accordance with national law: any natural person may opt out of the secondary use of their health data.

When will these obligations apply?

26 March 2029

First phase of secondary use of certain categories of health data (Art. 51)

26 March 2031

Second phase of secondary use of health data (other categories: genomic data)

Overall timeline based on the transitional provisions of the Regulation. The exact dates depend on the categories of data and the provisions concerned.

How can you prepare today?

As the obligations will apply gradually, start preparing for their implementation now.

Your preparation checklist:

- ☐ Assess the impact of the EHDS on your entity's current infrastructure and work processes;
- ☐ Identify the electronic health datasets held by your entity;
- ☐ Identify the related rights (personal data protection, intellectual property, trade secrets, ...);
- ☐ Identify the persons responsible for keeping an inventory of your datasets and for making them available to the CGSD;
- ☐ Start compiling the metadata of a dataset using HealthDCAT-AP;
- ☐ Assess the technical options for extracting health data and making them available to the CGSD;
- ☐ Prepare internal procedures for responding to EHDS-related requests.

Need support?

Prepare your entity for the EHDS

As Luxembourg's future health data access body (HDAB), the CGSD will support health data holders in understanding their obligations and in preparing for the implementation of the EHDS.

Practical resources and information for health data holders are available on [LetzData.lu](https://letzdata.lu)