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Explainer: What the European Health Data Space means for trans people

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Introduction to this resource

This is a brief resource introducing the European Health Data Space (EHDS) adopted by the European Union. The EHDS was adopted in 2025 and details of how it will be implemented are still developing. Nevertheless, its key features already demonstrate the advantages and risks of processing trans people's electronic health data in a shared network. This resource tries to answer some basic questions about the EHDS and identify why it is a relevant development for trans people.

What is the European Health Data Space?

The ***Regulation on the European Health Data Space (EHDS)*** is a new governance framework adopted by the European Union in 2025 to regulate the integration of the health data spaces of different EU Member States. A health data space is a secure, common infrastructure of rules, standards, and governance for sharing electronic health data. It aims to strengthen the region's healthcare systems by improving access to electronic health data both inside individual EU Member States and across the region for various purposes, such as the provision of healthcare, research, policymaking and regulation. The EHDS sits within a broader set of patient-centred health initiatives at the EU level, including e-prescriptions, electronic patient records, and access to cross-border healthcare[1] within the EU.

Once it is implemented, the EHDS is expected to:

1. Give individuals better access to and control over their electronic health data,
2. Improve access to health data for healthcare providers and biomedical research, and
3. Boost innovation and competition in the health sector.

The implementation of the EHDS, which will involve the development of a range of regulations, technical standards and guidance by the European Commission, is expected to take until at least 2028. The long and complex process of harmonisation of health data systems across EU Member States is essential for the successful operation of the EHDS.

What does 'electronic health data' mean?

The EHDS Regulation considers all data on the health and genetic information of a person that is stored and processed in an electronic form to be 'personal electronic health data'. This includes all sensitive personal information on a person's physical and mental health status such as patient summaries, prescriptions, results of scans and tests, and discharge reports. All information on general healthcare and sexual and reproductive healthcare, including trans-specific healthcare[2], is personal health data.

Personal health data also includes demographic data that is relevant to health. This means that information on gender identity and sexual orientation would be considered as personal health data.

1 For more information on cross-border healthcare in the EU, see: *https://health.ec.europa.eu/document/download/d20a2351-0ff1-4317-9dfa-df35a0c51dd0_en?filename=cbch_navigating_factsheet_en.pdf*.

2 For example, the diagnosis, medications used, and all medical interventions.

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Non-personal electronic health data is defined as all health data that is not personal and is mainly relevant for specific purposes like research. This includes data that (a) has been anonymised or partially anonymised so that it cannot be traced back to any individual person and (b) data that was never related to any person. Personal electronic health data that is anonymised or partially anonymised becomes non-personal electronic health data. Where data has only been partially anonymised (known as 'pseudoanonymisation'), Article 66 of the EHDS states that only certain mandated bodies can hold the information necessary to reverse the partial anonymisation.

How will electronic health data be used in the EHDS?

The EHDS envisages two uses of electronic health data: primary use and secondary use.

Primary use refers to processing of data for the purpose it was originally collected. This means, it refers to data that relates to the provision of healthcare. Primary use covers healthcare delivery, the prescription and dispensation of medication, provision of medicinal products and medical devices, and social and administrative reimbursement purposes. For example, trans people's health data about specific diagnosis or medications used could be relevant information in cancer screening, prevention and treatment. Primary use of your health data means a cancer-care specialist can access information on trans-specific healthcare (as long as you allow it) to inform their care provision.

Secondary use of data refers to uses for all purposes other than which it was originally collected (see Article 51 of the Regulation[3]). This could be for scientific research, innovation, or regulatory purposes. For example, a researcher who wishes to study the cancer-care provision to trans people in the EU can make a request to access relevant data via the appropriate authority established under the EHDS. Only researchers and other users of health data who are located within the EU or in countries with whom the EU has appropriate arrangements can apply to access electronic health data for secondary use. Health data access bodies must publish transparent information about the requests they have received and the outcome of the research (Article 58).

It is important to note that secondary use that results in detrimental decisions against a group of people is not permitted under the EHDS. For example, an insurance company cannot process electronic health data for secondary use to increase premiums for trans people.

3 The categories of health data to be made available for secondary use include electronic health data from electronic health records; data on factors impacting on health, including socioeconomic, environmental and behavioural determinants of health; aggregated data on healthcare needs, resources allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing; data on pathogens that impact human health; healthcare-related administrative data, including on dispensations, reimbursement claims and reimbursements; human genetic, epigenomic and genomic data; other human molecular data; personal electronic health data automatically generated through medical devices; data from wellness applications; data from population-based health data registries such as public health registries; data from medical registries and mortality registries; data from clinical trials, clinical studies, clinical investigations and performance studies; data from registries for medicinal products and medical devices; data from research cohorts, questionnaires and surveys related to health, after the first publication of the related results; health data from biobanks and associated databases.

> *Health data access bodies must publish transparent information about the requests they have received and the outcome of the research (Article 58).*

The EHDS makes sharing of electronic health data for primary and secondary uses possible because the EHDS is **interoperable**. This means that the data is recorded and stored in a common format, which makes it shareable between different healthcare providers and other users of health data, located in different EU Member States or even in different parts of the same Member State. For example, if a person is seeking healthcare at different specialist clinics, all of the clinics will be able to access the person's healthcare data and update it electronically, and will be fully informed about the individual's medical status. Similarly, electronic health data can be processed and shared easily for reimbursement of claims.

At the same time, when sensitive personal data is collected, stored and processed under the EHDS, there are justified concerns around data security. Particularly for trans people, breaches of data on gender identity and trans-specific healthcare can be life-threatening. The EHDS tries to address this by operating on a **decentralised** basis. In other words, all the electronic health data will not be stored in a single location, repository, or server that creates the conditions for large-scale data breaches. Instead, electronic health data will be stored across interconnected systems that are able to share and communicate with each other because they are interoperable.

Why is the EHDS relevant for trans people in the EU? How can it benefit trans people and what are the risks?

The EHDS will help healthcare providers and related services have complete information on a person's health conditions and treatments. This ensures that the healthcare provider can have a full picture of a person's health status before recommending certain treatment. This can be particularly helpful in cross-border situations. The EU has already started establishing the infrastructure needed for e-prescriptions and patient summaries, particularly for situations where an individual has to access healthcare in another EU Member State while travelling. For example, a trans person from France is on holiday in Italy and realises that they have run out of prescription hormones. The EHDS infrastructure will enable the trans person to use the e-prescription facility to top up their medication. In another situation, a trans person who is travelling experiences an allergic reaction they had previously not experienced. A doctor who has access to their complete patient summary can better investigate what may have set off the reaction.

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picture of a person's health status before recommending certain treatment.

Notwithstanding the advantages of the EHDS, there are several areas where its benefits are still not completely clear for trans people. For example, it is not clear whether a diagnosis for gender dysphoria or transsexualism obtained in one Member State will be considered by healthcare providers in another Member State. Already under the EU's Cross-border Healthcare Directive 2011/24/EU and in situations where trans people have migrated between EU Member States, we observe that trans people may face issues precisely because EU Member States are under no obligation to recognise a diagnosis obtained in another country and can require person to undergo the assessment from the beginning.

In addition, as the EHDS places the burden of 'opting out' of sharing electronic health data for primary and secondary uses on the individual, it requires trans people to be vigilant about their health data, which in turn requires a reasonable level of digital health literacy. However, trans people are among the most vulnerable groups in the EU.[4] Although Article 84 of the EHDS Regulation requires Member States to promote digital health literacy and support patients in developing the skills needed to use the EHDS infrastructure through awareness-raising programs, this may not be sufficient in comparison to the pace at which digital health technologies are being deployed. It will be crucial for trans organisations to connect and work closely with patient advocacy organisations at the national level, to support the community in building relevant digital health literacy skills.[5]

Another important concern is the data of trans people who are under 18-years-old. The EHDS does not specifically refer to the data of minors in any provision and it can be assumed that parents or guardians will be responsible for providing or revoking access to minors' electronic health data. However, when it comes to young trans people, providing access to data on trans-specific healthcare is a particularly relevant concern from a policymaking perspective as some EU Member States are considering the provision of puberty blockers solely through a research study. As such data can be accessed by researchers across the EU despite not being involved in the clinical team that provided the care, there are significant concerns around how the data may be politicised to restrict access to care for young trans people. It is essential that Member States clarify under national laws, how access to health data of minors will be regulated. They must safeguard the autonomy of minors over their personal health data and decision-making on health, in line with international human rights law. This can be an important advocacy priority for national-level advocacy for organisations working with trans people and children, as well as patient advocacy organisations.

4 Trans experience significant challenges with accessing education, employment, digital literacy, and having a high household income, which are all key determinants of digital health literacy. For example, 43% of trans women and 35% trans men who responded to the FRA LGBTIQ Survey 2024 noted that they experienced discrimination when looking for employment or while being employed. Trans people are also more likely to experience *homelessness.*

5 Some tools that support the development of digital health literacy exist, which can serve as inspiration for trans organisations in developing capacity-building and training programmes. See for example: *https://datasaveslives.eu/*; *https://gdhp.health/wp-content/uploads/2025/05/00-GDHP-CHE-Digital-Health-Literacy-Toolkit-Full.pdf.* WHO-Europe also conducts webinars on building digital health literacy, available here: *https://www.who.int/europe/news-room/events/item/2024/11/21/default-calendar/strengthening-digital-health-literacy-to-empower-people-in-the-digital-age.*

> *The EHDS does not specifically refer to the data of minors in any provision and it can be assumed that parents or guardians will be responsible for providing or revoking access to minors' electronic health data.*

There are still many unknowns about how the EHDS will be implemented. By March 2027, the European Commission is expected to set various standards for the collection and registration of personal electronic health data as well as anonymisation of electronic health data. Due to the sensitive nature of the health data involved, it is important to take note of these developments and track them, and check with your healthcare providers when and how they process your health data.

Further, the extended period of implementation of the EHDS at the national level offers opportunities to trans organisations for engagement. The involvement of trans communities in the implementation of the EHDS at the national level and in addressing privacy and data protection risks specific to trans people will help address many of the concerns outlined in this paper. Trans health activists and organisations must work closely with patient advocacy organisations at the national level to ensure that concerns around trans people's experiences of barriers to healthcare access, especially in the digital sphere, are adequately reflected in civil society engagement with national governments.

How can you provide and withdraw consent for the use and transfer of your data to healthcare providers?

As the patient, trans people will have a certain amount of control over their personal electronic health data – you can add information, restrict access, see who has accessed your data, and request corrections. A notification system is also expected so that individuals can receive information when a third party has accessed their personal health data.

The EHDS envisages an 'opt-out' system ie a person can choose to opt-out of the infrastructure that enables sharing of their health data to healthcare providers. However, this is not a right under the EHDS, and it will depend on whether a Member State decides to provide this option. This means that trans people in some EU Member States may never have the option of restricting access to certain kinds of electronic health data, which could pose significant personal safety risks.

If a person opts-out, their data will not be accessible by healthcare providers besides those who have been expressly consulted for the specific medical issue.6 This can have disadvantages. For example, when a trans person travels to a different EU Member State or to another region of their home country and faces a medical issue, the medical professional will not be able to access complete information on their health status if they have opted out of sharing. Where Member States have provided the option to opt-out, the EHDS mandates that individuals should have the option to reverse their decision.

6 This too may be derogated from where it is necessary to protect the vital interests of the data subject.

In summary, the EHDS requires vigilance on the part of the individual. In situations or periods where sharing of personal health data may not be advisable or safe, the individual will need to monitor and withdraw permissions as needed. Where the person has opted-in, they can undertake regular monitoring of access requests and confirm the accuracy of information recorded.

How can you provide and withdraw consent for the use of your healthcare data for secondary purposes like research?

Requests for access to healthcare data for secondary use will be regulated by the Health Data Access Body established in each Member State. These bodies are empowered to evaluate 'reasonable requests' from health data users and pass it on to individuals for their consent to hand over their data. Individuals can challenge a request as being unlawful.

An opt-out mechanism is not mandatory and may be put in place by a Member State for secondary use of data as well. Where the option is available, individuals can opt-out of sharing of data for secondary use in a number of cases at any time, and on a reversible basis. However, EU Member States can still exceptionally override this and allow access in a limited number of situations and on a case-by-case basis, such as for scientific research of important public interest, where such data cannot be obtained by any other means, or where it is commissioned by a public authority or an entity entrusted with carrying out public tasks in the area of public health.

Is there an authority you can approach if you wish to file a complaint for data breaches?

The EHDS empowers digital health authorities (in relation to primary use) and health data access bodies (in relation to secondary use) to receive complaints of an individual's rights being negatively affected. They are required to assess the complaint and transfer it to the supervisory authority under the GDPR i.e. the data protection authority established in the EU Member State for further action in accordance with national law.

However, the digital health authority and the health data access bodies will remain the primary point of contact for the individual through the complaint process and is required to keep them informed of the progress.

If you would like to learn more about the EHDS or connect with patient advocacy organisations at the national level, please reach out to the Policy Team at TGEU (policy@tgeu.org).

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