

Implementing the European Health Data Space to enable health research

We want to thank all the members of The Guild's Health Data Task Force and the Deans of Health working group.

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Introduction

The European Health Data Space (EHDS) Regulation aims to empower citizens by giving them greater control and access to their health data, while bringing crucial benefits for groundbreaking health research and public health.

On the first anniversary of the EHDS's adoption on 26 March 2026, The Guild highlights the critical importance of successful national-level implementation to optimise cross-border health research. We call for particular attention to how secondary legislation will affect data-sharing procedures, including practical steps for researchers and universities, to prepare them for compliance and operational adjustments.

Data sharing and consent

Currently, researchers and universities, together with their research partners, often control access to their research data. Sharing this data with external stakeholders such as non-academic actors is tightly regulated and based on consent.

The Guild emphasises the importance and benefits of collaborating with non-academic research actors, as exemplified by collaborative research projects funded under the EU Horizon Europe Framework Programme, bringing together academic and private actors to address major current and future societal challenges. Given the EHDS's goal to enhance health data reuse, including for R&I, the basic principles of collaboration for the societal good must be maintained. While the work of the research community requires a high level of trust in the researcher from study participants, as demonstrated through consent and ethical review, secondary use of data must safeguard scientific integrity and trust, preventing potential misuse by health data users.¹

With the implementation of the EHDS Regulation, a new level of complexity in data sharing becomes particularly evident when applied to researchers generating data from health research cohorts, questionnaires, and surveys (Article 51(1)(p)). As of 26 March 2031, once a researcher publishes their first scientific results from a cohort or

¹ – Preliminary note from CRESS UMR 1153 Points of vigilance regarding the impact of the EHDS Regulation on research cohorts (2025)

survey, the associated dataset becomes subject to Article 51, making the university the data holder and, therefore, responsible for making the dataset available upon request to the national Health Data Access Body (HDAB) either in accordance with an issued data permit or approved health data request (Article 60(1)(2)). At that point, access for other health data users such as researchers and for-profit organisations is centrally regulated in line with the provisions outlined in Articles 53 and 54.

The above raises concerns about pre-existing consent for research cohorts, particularly when consent was given on the condition that data would not be shared with third parties such as industry stakeholders. Even if the consent states that no data can be shared with industry, it could be argued that when a researcher is publishing scientific results based on data collected before the EHDS Regulation was implemented, the university as a health data holder is obliged to make the data available upon request to the national HDAB.

Member States should establish an engagement framework with health data holders and HDABs to ensure that the new sharing and consent model is implemented in a manner that actively strengthens the European research ecosystem. This should go beyond communication and include structured engagement with the broader research community, including research managers, to prevent inadvertent impacts on scientific progress or on the trust placed in researchers by research cohorts. As such, the added value of integrating researchers' data into the HealthData@EU infrastructure should be understood as increased visibility and reuse of their work, while mitigating concerns about sharing data with unknown actors and for unknown purposes. Operational guidance on the management of existing consent frameworks and ethical approval should be issued by the HDAB and, where necessary, by Data Protection Authorities, addressed towards researchers and health data holders. This includes best practices for engaging with health data holders and the kind of data they hold to ensure a constructive, trustworthy and transparent data sharing mechanism. Guidance should be developed through comprehensive stakeholder consultation, drawing on expertise from health data holders, users, and patient representatives.

On a practical level, consent forms need to be revised to reflect the requirements of the EHDS Regulation, and, for research cohorts, participants who have already consented need to be informed. In addition, with respect to the above-mentioned provisions, it is necessary to monitor developments to determine whether the framework may (unintentionally) influence researchers' behaviour. This includes researchers' publication and data-sharing strategies, as the dataset must be made available only after the first publication. It also involves monitoring potential changes to the willingness to initiate investigator-driven cohorts, as well as shifts in number of participants in research cohorts e.g. because of concerns regarding data sharing with commercial actors.

Opt-out mechanisms

One of the most ambitious endeavours of the EHDS is to empower European citizens to exercise their rights over their health data. While implementing the EHDS Regulation, it is of utmost importance to strike a fair balance between protecting citizens' rights and trust and at the same time enable robust, unbiased research that benefits from data that represent the entire population.

Article 71 gives natural persons the right to opt out of the secondary use of their personal electronic health data and instructs Member States to provide an accessible, easily understandable opt-out mechanism to exercise that right. The Guild emphasises that the HDAB must provide public information on the benefits and drawbacks of the opt-out (Recital 51) and advise with whom health data can be shared. Ultimately, health research that relies on comprehensive population datasets may be compromised by sampling bias if opt-out rates differ significantly across countries or within a population.

Furthermore, it is important to clearly communicate that exceptions to the right to opt out under Article 71(4) are within the discretion of the Member States. This discretion could lead to divergent implementation of exceptions to the national opt-out mechanism. It should also be communicated that exceptions to the right to opt out may apply to universities that are classified as public sector bodies with a mandate to perform public health tasks, provided that processing the data is necessary for scientific research in the public interest. Recent studies note that "public perceptions of topics such as opt out and the communication of results require continuous attention and exploration. [...] Support relies on data being used for purposes that citizens see as aligning with their values"².

Ethical approval process

As ethical assessment is an integral part of health research, particularly when studying personal health data, Member States' specificities in ethical review processes might become a bottleneck when applying for multi-country health research under the EHDS framework.

According to Article 55(2), if an assessment by ethics bodies is required under national law, they shall make expertise available to the HDAB to perform its task or enable Member States to provide that ethics bodies form part of the HDAB. As highlighted during a workshop organised by TEHDAS2 in June 2025, responsibilities need to be defined among national, regional and local ethics committees, the ethics bodies that will be part of HDABs, the HDAB itself, the health data holder and data users, to ensure accountability. This includes whether the ethical function in the

2 – Ganna, A., Carracedo, A., Christiansen, C. F., Di Angelantonio, E., Dykstra, P. A., Dzhambov, A. M., Eils, R., Green, S., Schneider, K. L., Varga, T. V., Vuorinen, A.-L., Zuccolo, L., Rod, N. H., & Hoeyer, K. (2024). The European Health Data Space can be a boost for research beyond borders. *Nature Medicine*, 30(11), 3053–3056. <https://doi.org/10.1038/s41591-024-03246-6>

HDAB should be advisory or decision-making and how HDABs are expected to act on ethical concerns. In line with Article 55(2), Member States need to ensure that each HDAB has the necessary expertise, resources, and timelines to conduct ethical assessments in a workable and efficient manner. This should also consider cross-country exchange and coordination, particularly if a health data access application was denied by one HDAB in country A but accepted by a different project partner in country B.

Third-country participation

Cross-border health research is already conducted between researchers and institutions located within and outside the EU, such as those associated with Pillar II of Horizon Europe or the European & Developing Countries Clinical Trials Partnership (EDCTP). The EHDS Regulation needs to support existing and upcoming R&I collaborations without creating additional bureaucracy in an already complex environment.

Given that upcoming implementing acts will specify how, when, and under what conditions health data users and health data holders outside the EU can interact with EHDS mechanisms, it should be noted that, for EEA-EFTA countries, the EHDS Regulation will be incorporated into the EEA Agreement. Once incorporated into the EEA Agreement and the secondary use provisions become operational on 26 March 2029, applicants from EEA EFTA countries will be treated as equivalent to EU-based applicants for secondary use, subject to the same procedures and safeguards. This timeline will allow universities and researchers to plan with regulatory continuity in mind.

By contrast, Switzerland, the United Kingdom, and other non-EU, non-EEA countries will be treated as third countries under the EHDS, irrespective of their association with Horizon Europe or EDCTP. For these countries, two legal pathways exist: Access depends on reciprocity decisions under Article 91, assessed through implementing acts that evaluate third-country frameworks, governance, safeguards, and procedures. Once approved, applicants from these countries can apply via EU-based HDABs from 2029, provided the third country allows access to EU-based data users. In the long term, Article 75(5) allows authorised participation in the HealthData@EU infrastructure, including dataset catalogues and cooperation, starting in 2035.

To maximise the strategic value of the EHDS beyond the European Union, the implementation phase should prioritise the proactive use of Article 91 as a policy instrument to enable structured cooperation with trusted research partners. Early dialogues should be launched with associated countries of Europe's Framework Programme for Research and Innovation to advance cross-border health research. Finally, reaching a decision on reciprocity may aid the transition to joining HealthData@EU in 2035.

Secondary legislation will be critical in translating these legal pathways into operational clarity. Clear guidance and timelines for Article 91 assessments should be established to provide predictability for data holders and researchers based in or collaborating with third countries on how third-country applications are processed in practice, which documentation and metadata must be provided, and how responsibilities are allocated, as well as how partners can prepare for the participation in the HealthData@EU infrastructure under Article 75(5). It needs to be clarified how the EHDS Regulation aligns with and impacts the principles of the TRUST Code, which EDCTP-3 JU and the European Commission have presented as a global standard for ethical conduct in dealing with data subjects.

Fees and costs

For health data holders and users, The Guild acknowledges that the technical and financial responsibilities involved in making data available, applying for a data permit, or submitting a health data access request can be demanding. Providing clear guidance on data preparation and budgeting will help stakeholders feel supported and confident in their ability to comply, as TEHDAS2 already foresees.

As researchers (data users) draft their research project proposals and the anticipated budget well in advance of a project's start, invoices issued by the HDAB at the beginning of a project may not match the costs estimated in the proposal, leading to disputes. Guidance should clarify cost eligibility for research projects funded by European funding programmes, such as Horizon Europe. It should also inform the HDAB to avoid changes to costs between the initial cost estimate at the project proposal stage and the actual project, unless significant changes were made since relying on broad cost estimates may discourage researchers, while actual costs could impact project success. In addition, the future implementing act (Article 62(6)) should elaborate on a homogeneous fee structure at the national level and a common understanding at the EU level regarding the categorisation of public-private partnerships, and on the distribution of fees incurred by the health data holder and the HDAB to the health data user.

Compliance and enforcement

Under the EHDS Regulation, health data holders, such as universities, are responsible for ensuring compliance, meaning they must make health data, as outlined in Article 51, available in a standardised, secure, and lawful manner and provide the required technical infrastructure. It should be noted that this responsibility is agnostic to the health data holders' financial or human resources.

However, under Article 63(4), the regulation permits transparent and proportionate enforcement, allowing authorities to provide support. Universities must be provided with sustained institutional capacity, technical infrastructure and resources to comply with the requirements, without affecting their research and publishing activities.

In this context, the imposition of administrative fines under Article 64 should take into account the demonstrable efforts, structural constraints, and public-interest mission of health data holders. In turn, health data holders are expected to take reasonable steps and engage with national or regional support structures. During the implementation phase, it will be crucial for Member States to establish national, regional and local support frameworks, including dedicated funding streams and technical assistance to enable data holders to develop sustainable compliance capacity aligned with the objectives of the EHDS. The above is important to consider when drafting the implementing act, as outlined in Article 63(7) and issuing guidelines on the enforcement measures to be taken by the HDAB (Article 63(8)), with clear emphasis on capacity building and enabling the responsible reuse of health data for R&I across the European Union.

