

Enabling effective secondary use of health data in Europe: specific recommendations for a potential opt-out mechanism for the EHDS

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In October 2022, a large group of European stakeholders joined forces to welcome the European Commission's proposal on the European Health Data Space (EHDS), and to highlight [common recommendations](#).

We share the view that health data are precious and renewable resources that can power decision-making for clinical care, deliver life-saving innovations, and strengthen health systems in the 21st century. In light of the current political discussions in the European Parliament and the Council, stakeholders are now sharing publicly their vision and six specific recommendations for a potential opt-out mechanism in the future EHDS.

Health data sharing for secondary use under EHDS (see HealthData@EU – Chapter IV)

Discussions in the policy-making process now include proposals for an opt-out mechanism for citizens to withdraw their data from secondary use purposes.

The Commission's EHDS proposal makes no provision for a consent mechanism for HealthData@EU (secondary use) beyond referring to national law (Art 33 (5)). This approach has been justified because (a) data for secondary use are either anonymised or pseudonymised¹ and (b) there are strong mechanisms in place to safeguard against abuse, including lists of permitted uses (Art 34) and prohibited uses (Art. 35) and rules for governance and practical mechanisms.

We support the approach taken in the [Commission's original legislative proposal from May 2022](#) as it strikes a sensible balance between protection of personal data while enabling the use of data for research and innovation to create tangible benefits for patients and citizens.

Where a research aim cannot be fulfilled using anonymised data, the Commission's EHDS proposal foresees the possibility for pseudonymised (personal) data use, if the justification for this is approved and provided that appropriate safeguards are applied. For the sharing of pseudonymised data, the General Data Protection Regulation (GDPR) sets the legal governance framework across the European Union. However, the GDPR leaves significant scope for EU Member States to derogate on the specifics of health and research. These variations in implementation have led to a current 'patchwork' of

¹ **Anonymisation** permanently removes personal data so that data subjects can no longer be identified.

Pseudonymisation is defined in GDPR as "the processing of personal data in such a way that the data can no longer be attributed to a specific data subject with the use of additional information, as long as such additional information is kept separately and organisational measures are taken to ensure non-attribution to an identified or identifiable individual".

approaches across the European Union (EU), such as the variable grounds that are considered suitable for pseudonymised data use and what safeguards are appropriate. This lack of harmonisation on the use of health data for research across the EU is a barrier to the re-use of data for research[i].

The EHDS regulation brings an opportunity to provide for European alignment regarding access to pseudonymised data in the EHDS, through a harmonised approach to the permissions, procedures, and safeguards which could be applied consistently in all Member States.

Currently, the collection and storage of health data in an electronic health record in EU Member States is performed in accordance with national regulations. It is fundamental to the success of the EHDS that multiple, complete datasets are included, and that the data are truly representative of European citizens and their demographic, ethnic or socio-economic backgrounds. Any form of opt-in or opt out mechanism would introduce the real risk that data bias will form part of the EHDS from its inception and thus undermine its principal value for secondary use research purposes. We believe this risk to be substantial because there is much evidence available about a) the complexities of including certain populations, including ethnic and deprived groups in Member States' data, as well as b) many healthy citizens having little interest in actively providing their information. As a result of this risk, data from these groups may not in the future be adequately represented in the EHDS. These are the reasons why we support the original Commission proposal not to include an opt out. If, however, an opt-out is ultimately proposed in a future EHDS Regulation, because its potential effect would be so fundamental, we believe that a full impact assessment of this specific mechanism should be undertaken as soon as possible in order to understand its implications and to inform implementation.

Our recommendations for an effective opt-out mechanism

If the proposals including in the EHDS a **European** opt-out mechanism for secondary use do move forward in the negotiations, we believe the opt-out mechanism should:

- be **applicable across all Health Data Access Bodies in EU Member States**, limiting the scope of national derogation and ensuring that the technical specifications are aligned.
- **consider the impact on health and care professionals and for other data holders**. The EHDS cannot contribute to the 'ticking time bomb' threatening health and care workforce as described in a 2022 World Health Organization Europe report[ii]. If an opt-out mechanism is pursued, then it is critical that its application is as light touch as practical in terms of any additional responsibilities and tasks it imposes upon frontline healthcare professionals. Opt-out mechanisms will need significant infrastructure to be in place to ensure they become implementable in health and care systems and will require investment in trusted professionals who are able to explain and communicate the opt-out to patients and the broader population.
- be **capable of implementation across the EU, without limiting lawful and ethical data sharing** for secondary purposes. Until the opt-out is evenly and consistently in place in all 27 EU Member States, existing safeguards will need to be recognised, especially for retrospective data.
- be **routinely monitored** as part of a regularly updated HealthData@EU data governance framework in terms of the general implementation across EU Member States and uptake of the opt-out, including among certain groups of populations to ensure justice and equity and

to avoid bias. This routine monitoring is crucial to ensure inclusion and consideration of all demographics, for example, in evidence-based public health policy, health system planning, and when developing digital health tools.

- have a **limited, but well-defined, consistent and transparent scope** for categories of data where the opt-out would create disproportionate effort such as medical registries and clinical trials data, render the research impossible, or seriously impair the objectives of the research, the opt-out should not be possible.
- have necessary investment, infrastructure and budget to **ensure sufficient transparency** so that **citizens are well informed** of the opt-out, what it means for them and for society, when it may not apply, and how to enable the opt-out.

Finally, the current debate on enabling secondary use of health data in Europe highlights the need to achieve **stakeholder alignment** where possible on the implementation journey ahead for the EHDS. It also speaks to the need for implementation decisions to be highly informed by those with experience and responsibilities for **on-the-ground implementation**. This reiterates a need for strong, balanced and inclusive stakeholder representation within the governance model of the EHDS such as its Board of Directors.

[i] DG Health and Food Safety. (n.d.). *Assessment of the EU Member States' rules on health data in the light of GDPR*. <https://doi.org/10.2818/546193>

[ii] World Health Organization. Regional Office for Europe. (2022). Health and care workforce in Europe: time to act. World Health Organization. Regional Office for Europe. <https://apps.who.int/iris/handle/10665/362379>. License: CC BY-NC-SA 3.0 IGO. See also: [WHO/Europe regional meeting on health and care workforce: Time to act](#)

