

Manifesto for the Ethical and Responsible Reuse of Health Data from Research

Foreword

The European Health Data Space (EHDS) is a new European framework intended, in particular, to facilitate the reuse of health data for research, public health, and health policymaking. The EHDS Regulation provides for the gradual implementation of the rules governing this reuse starting in 2029.

Accordingly, this manifesto was drafted at the initiative of researchers working in the field of public health, who seek to ensure that the reuse of health data within the EHDS framework complies with a number of essential principles, ensuring scientific integrity, transparency, stakeholder trust (patients, researchers, healthcare professionals, etc.), and the sustainability of the research infrastructures that generate these data.

This manifesto is endorsed by its signatories in their individual capacities. It does not in any way bind the institutions, organisations, or governing bodies with which they are affiliated. Each signature constitutes a personal commitment and binds only the signatory.

With the entry into force of the European Health Data Space (EHDS) Regulation, the large-scale reuse of health data becomes possible for a **diverse range** of academic, public, non-profit, and private actors. This represents an **opportunity** to expand knowledge, accelerate innovation, strengthen transparency, and promote reproducibility of research – provided, however, that it is **governed by strong principles**.

Indeed, health data – sociodemographic, clinical, biological, genetic, imaging, environmental, or behavioural – are not an ordinary resource.

They originate from individuals who entrust them to research teams within a relationship of trust, as part of research projects (clinical trials) or research infrastructures (cohorts, registries, and platforms), in order to **generate knowledge for the public good**.

They are the result of a **considerable human, scientific, and financial investment**: that of **participants**, who voluntarily give their time and experience – sometimes by completing questionnaires on multiple occasions, undergoing medical examinations, sample collection, imaging, or long-term follow-up – and that **of the research teams** who design, collect, document, audit, secure, and maintain these data over time.

Thus, we – patients, participants, researchers, healthcare professionals, and committed citizens – **support the sharing of health data for responsible reuse**. To this end, we call for compliance with **ten essential principles**:

1. Serve only the public interest and public health

Health data must be reused solely to generate knowledge that benefits society and public health: understanding health determinants, improving quality of care, strengthening public health, and informing public policies. Opening up access to data must never come at the expense of participants, scientific quality, or public health. Furthermore, it must not become a mechanism for value capture or undue influence without a fair return to society. Therefore, when reuse of health data is likely to generate significant economic benefits, access conditions must ensure a fair return to both society and research.

Every request for access should therefore be **assessed independently and thoroughly to ensure that the intended purpose, the scientific quality of the project, the guarantees of independence and transparency, and the expected outcomes serve the public interest and public health.**

2. Respect the relationship of trust established between participants and research teams

Health data are entrusted within a **relationship of trust** established between participants and research teams. This trust must be respected.

Participants must be informed and be able to object to **certain categories of reuse of their data**, particularly where such uses may **conflict** with the research, public health, or public-interest purposes that formed the basis of their participation.

This relationship of trust also implies reciprocity: participants must be able to receive, within reasonable timeframes and in accessible formats, the key findings generated through their contribution. **Preserving this trust is an essential condition for maintaining and developing research based on the voluntary engagement of patients and citizens in the service of the public interest and public health.**

3. Safeguard scientific integrity in the presence of conflicts of interest

Science based on health data must be rigorous: a clear question, robust methodology, consideration of bias, transparent analyses, and contextualised interpretation.

Applicants' own interests may influence the choice of questions asked, the conduct of analyses, the interpretation of results, and their dissemination. This therefore calls for particular vigilance in order to preserve scientific independence and alignment with the public interest.

The risks of conflicts of interest must therefore be rigorously assessed. **Whenever significant conflicts of interest are identified, access must be subject to strict safeguards, potentially including refusal if the guarantees of independence and transparency are insufficient.**

4. Make scientific transparency a condition for access to health data

The reuse of health data can contribute to scientific progress and public trust only if the work conducted using these data is **accessible, transparent, verifiable, and reproducible**. Before any access to data is granted, each project must be **registered** on a **public** transparency portal, including a plain-language summary, a protocol, a statistical analysis plan (where relevant) and a declaration of interests to prevent potential conflicts.

Upon completion of the project, results, scientific publications, and the methodological information necessary to understand and verify those results must be made **freely accessible** within a **reasonable timeframe**. Findings must also be **reported back to participants and the public in accessible formats and in clear language** within the same timeframe.

5. Limit access to data to what is strictly necessary (data minimisation principle)

Access to data must be guided by the intended purpose, such that **only data that are necessary and proportionate to the intended purpose are made available**. This necessity must be **justified** in the protocol, particularly with regard to the research question, the analysis plan, the requested variables, and the required level of detail. This assessment must also consider the risk of re-identification through the combination of variables.

6. Evaluate data use to ensure that data sharing serves the public interest and public health

The EHDS creates a new framework for the reuse of health data, the implementation of which will need **to be evaluated over time**. Responsible sharing does not end once access has been authorised: the actual use of the data must be traceable, verifiable, and subject to evaluation. This evaluation must assess the **alignment** between the authorised purpose, the approved protocol, the analyses conducted, the results produced, and the final publications, in order to ensure that the data have not been used for other purposes and that any deviations from the protocol are justified and transparent.

The evaluation must also help **identify** any deviations, **prevent** misuse, and progressively **improve** the rules governing access, the safeguards required, and the support provided to applicants, so that data sharing effectively contributes to **high-quality research serving the public interest and public health**.

7. Recognise the scientific role of research teams that produce data, and support research infrastructures

Data sharing **cannot exist** without data production, nor without the rigorous work of research infrastructures that make data reliable, interpretable, and reusable.

Cohorts, registries, and platforms are not static data repositories: they are living, continuously enriched, costly, and fragile infrastructures. They rely on **research**

teams whose work – methodological design, participant recruitment, longitudinal follow-up, quality control, documentation, data security, and ethical governance – constitutes a major scientific contribution.

Open access to data must **neither undermine planned or ongoing work** by the research teams that produce the data, **nor discourage their long-term scientific investment, nor destabilise** the infrastructures necessary to **produce reliable data**. **These research teams must therefore be recognised as scientific actors in their own right, rather than merely as data producers.**

Their expertise in interpreting data, identifying the limitations of the data, preventing misuse, and supporting rigorous reuse, as well as the costs associated with preparing, documenting, and making data available, must be **fully taken into account in the conditions governing reuse**. Otherwise, data sharing risks weakening the very infrastructures on which it depends.

8. Ensure pluralistic governance of decisions on access to health data

The decision to grant access to health data must not be reduced to an administrative process: it must incorporate substantive legal, ethical, scientific, and methodological assessment, considering the sensitivity of the data, the quality of the analyses, and public trust. It must therefore be embedded within a pluralistic governance framework involving patients or research participants and their representatives, data producers, and independent experts in methodology, ethics, law, and data protection. **This governance must ensure that decisions are transparent, reasoned, and traceable, allowing access to be granted, made subject to conditions, or refused when scientific or ethical safeguards are insufficient.**

9. Provide the necessary resources to assess access requests and make data responsibly available

Assessing requests for access to data requires sufficient human and material **resources, time, scientific, methodological, and ethical expertise**, as well as **in-depth knowledge of the data, their limitations, and the conditions under which they were produced**. The research teams responsible for the data must therefore be involved in this assessment: they are best positioned to assess the relevance of the data requested, the risks of misuse, the conditions for interpreting results, and the safeguards necessary for scientifically rigorous and ethically acceptable reuse.

Making data available through research infrastructures also entails specific costs that must be properly evaluated, recognised, and funded. These costs must not be hidden or passed on to infrastructures that produce the data, which are often under-resourced.

10. Guarantee a right of appeal and sanctions in cases of non-compliant use

Any decision regarding access, refusal, restriction, or conditional approval must be reasoned, traceable, and subject to appeal. Any individual or organisation must also be able to report uses for purposes other than those authorised or a failures to comply with the required safeguards through an accessible and independent

reporting mechanism that allows appropriate follow-up. Effective, proportionate, and dissuasive penalties must ultimately be established and implemented in cases of unlawful use or failure to comply with the established conditions.

The European Health Data Space is being built now. The rules that will be adopted will permanently shape the trust of patients and participants, the production of scientific knowledge, and the sustainability of research infrastructures.

We call on all those who agree with these ten essential principles to sign this manifesto and disseminate it.

Signature: