



# Medical community calls on MEPs and Member States to act now to avoid putting an emergency brake on life-saving health research through EHDS

Researchers and clinicians represented within the Biomedical Alliance in Europe (BioMed Alliance), a unique initiative of 36 medical and research societies, urgently call on policy makers to take action to ensure the European Health Data Space (EHDS) will not severely jeopardise health research.

The medical community initially welcomed the European Commission proposal for an EHDS and the intention to facilitate health data sharing for health care (primary use) and research and policy making (secondary use). Nonetheless, political discussions in the European Parliament and the Council have moved away from provisions in the Commission proposal in the direction of an opt-out system for the secondary use data, with some even suggesting an opt-in for certain types of data (particularly genomic data) and for certain research purposes. While we welcome the concern to protect data privacy and to ensure citizen trust in the EHDS, the risks must be balanced against EU citizen's right to health and the need for EU health systems to access data to better perform their duties and to deliver more efficient and more personalised care.

If an opt-out system is adopted as a compromise solution in the European Parliament and the Council, then we urge MEPS and Member State representatives in the Council to make sure there is provision in the Regulation to implement this decision in a pragmatic, efficient and harmonised manner, with a clearly defined scope. Otherwise, EHDS risks creating fragmentation between regions and countries across Europe and will increase obstacles to access health data currently used for research. For example, it will be important to exclude retrospective datasets from the scope of the provisions. This promising initiative risks becoming unnecessarily bureaucratic, which will be difficult to implement and will further burden struggling health care systems and will slow down research and innovation in the EU.

The health research community is extremely concerned about a partial opt-in system. Opt-in approaches significantly impinge on the availability of datasets for researchers to gain new insights into human health and understanding of disease, or for developing new diagnostics and treatments for patients. In addition, it could lead to certain patient groups being less represented in data sets used by researchers, resulting in healthcare treatments and screening that have inherent biases and are less adapted to their specific needs. The facilitation of secondary use of healthcare data for research, and inclusive data sets, will be essential for the future evolution of science and healthcare in general towards more data-based approaches.

### Practical impact on health research<sup>1</sup>

In the cancer field, researchers need to access pseudonymised data to be able to understand more about which groups of people have the highest risk of developing certain types of cancer in order to develop risk-based screening guidelines. This cannot be accomplished with anonymised data – researchers need to know age, background, genetic information, ethnicity, etc., and also need to link screening data with patient registries to monitor outcomes, which all help to guide better decision making. Any option which could introduce a bias to population data means that clinical guidelines do not accurately reflect the needs of people who are not captured in the data, thus screening and care for these groups is sub-optimal.

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<sup>1</sup> See also additional BioMed Alliance case-studies here:

[https://www.biomedeurope.org/images/news/2023/Case\\_Studies\\_from\\_medical\\_societies\\_on\\_the\\_European\\_Health\\_Data\\_Space.pdf](https://www.biomedeurope.org/images/news/2023/Case_Studies_from_medical_societies_on_the_European_Health_Data_Space.pdf)



The current focus of radiological research on artificial intelligence (AI) has also highlighted the need for large datasets including imaging data alongside detailed clinical, pathological, immunological and genomic data. Facilitating access to large datasets – as potentially included in the EHDS – would not only be economically beneficial as it would allow for easier development, validation, and monitoring of AI solutions in radiology but would also benefit patients through higher-quality research and updating of imaging biomarkers in shorter timeframes. Especially in the context of AI it is imperative to include diverse datasets (including minorities and borderline cases) to ensure comparable performance across different patient characteristics. It has recently been shown that e.g., AI models for detection of pathology on chest X-rays show varying performance depending on patients' reported ethnicity<sup>2</sup>.

### Key considerations to preserve life-saving health research

- A partial opt-in increases legal uncertainty for the secondary use of health data for certain types of data or research purposes. This is expected to hinder life-saving research in the EU and goes against ongoing EU-wide efforts to create a genomic infrastructure facilitating genomic data flows across the EU.
- A partial opt-in is expected to lead to data bias and puts additional pressure on healthcare professionals to help their patients make informed decisions regarding their data.
- If an opt-out mechanism is approved, and considering it was not foreseen in the original Commission proposal, trilogue should be informed by an impact assessment. The concrete and practical impact of the provisions that are being discussed are potentially far-reaching for patients, research and innovation in the EU. It is important to ensure as much alignment of approach across the EU as possible to avoid additional barriers to cross-border research.
- Citizens need to be appropriately informed on the benefits and impact of sharing their health data, and on the safeguards that are put in place to protect their privacy so they can make an informed decision about the use of their data.
- At a time when the EU healthcare workforce crisis is well documented, an opt-out model must not contribute excessively to the, often heavy, workload that healthcare professionals already face, and they must be well resourced and receive the necessary guidance to assist their patients in making an informed decision.
- Not all research projects, clinical trials and patient registries only include data within EU borders, and EHDS must take this into account to make sure that international health research activities are not put to a halt.
- Ethical principles may need further elaboration for the specific purposes of secondary use. This ethical oversight could be performed by the Health Data Access Bodies (in collaboration with ethical bodies and the European Data Protection Board) but they will need time to develop that competency and it will not come overnight.
- Governance mechanisms are also a possible way to manage EU citizen trust. A governance framework that involves citizens, patients and patient representatives and healthcare professionals can help shape the implementation of the EHDS.
- EHDS needs to provide sufficient resources to academic researchers, SMEs and not-for-profit entities to help in the transition and responsibilities as users and data holders in the new system.

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<sup>2</sup> Algorithmic encoding of protected characteristics in chest X-ray disease detection models (<https://www.sciencedirect.com/science/article/pii/S2352396423000324>)