Biomedical Alliance in Europe

Biomed Alliance Position on the trilogue discussions on the European Health Data Space proposal

Need for legal clarity and a harmonised approach

The Biomedical Alliance in Europe (BioMed Alliance), representing 34 medical and research societies calls on representatives of the European Commission, European Parliament and the Council that are part of the trilogue negotiations on the European Health Data Space proposal to follow the advice of the scientific community and create an EHDS that is fit for purpose, provides legal clarity, enhances harmonisation and has a concrete positive impact on health data sharing for research. We reaffirm support for the ambitions laid down by the European Commission proposal for a European Health Data Space Regulation. The efficient and effective use of electronic data for healthcare purposes as well as for research, policy making, and regulatory decisions is extremely important to enable better health outcomes both at population and individual level.

As the future users of the EHDS (both for primary and secondary use), and in the light of current final negotiations, our community of healthcare professionals and researchers calls on legislators to address the main challenges that remain open and that were already mentioned in our previous statements.

Main elements:

- There is a lack of legal clarity regarding key definitions, their scope and the interaction with other legal frameworks;
- The current provisions that are being discussed risk implementing opt-out/opt-in systems in a way that could affect the harmonisation and usefulness of health data sharing for both health care and research and innovation activities;
- It is necessary to clearly define the role of experts from stakeholder organisations in the implementation of the EHDS at both the EU and national levels (including health professionals, researchers and patients)
- There is a need to consider the specific needs of non-commercial actors as users and data holders (including the academic sector, healthcare professionals and research groups in medical societies).

Legal clarity and harmonised approach

We are concerned that a number of key definitions remain unclarified. The current level of legal uncertainty could lead to risks for patients and for researchers alike. To mitigate this risk, the EHDS should clarify certain key definitions and their scope, including its interaction with other legal frameworks. To ensure legal certainty and consistency under EU law, it is important to address critical points in the interaction of the EHDS with the GDPR, AI Act, Medical Devices Regulation, In Vitro Diagnostics Regulation, Clinical Trials Regulation, and other relevant legal acts and legislative proposals. In addition, data categories in Art 33 should also be clarified and currently leave much room for interpretation.

Opt-out

If an opt-out system is adopted, 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. We are concerned that if too much discretion is left to the national level to implement an opt out system, this would create a patchwork of approaches and would mean that some countries are underrepresented in European datasets compared to counterparts that have not implemented an opt-out system. In addition, it is important to exclude retrospective datasets from the scope and to prevent unnecessary bureaucracy.

Opt-in

The health research community is also 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 or not 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[1].

Stakeholder representation

The active engagement of a broad range of stakeholders would facilitate responsible, trustworthy, and impactful implementation of the EHDS. The co-legislative procedure has highlighted the complexity of creating the EHDS. Therefore, it is useful to leverage the expertise of stakeholders from across the healthcare ecosystem in the implementation of the EHDS at both EU and national level. Healthcare professionals, researchers and patients will be some of the main users of the EHDS and they must be able to support the implementation and operation of the EHDS by feeding in their experiences and expertise through a formal framework for cooperation. The functioning of the EHDS Board could be based on a combination of top-down and multi-stakeholder governance approaches. The EHDS Board could offer a forum to facilitate cooperation and exchange of information among Member States and the Commission, while also involving the European Data Protection Board and health technology assessment bodies. The performance of its tasks could be supported by steering subgroups, established by the EHDS, with specific expertise, involving health professionals & health researchers at every level.

We also welcome the suggestion of the European Parliament to establish an Advisory Forum where stakeholders can share their expertise. We believe such a forum should be established along the lines of the Commission's Medical Device Coordination group by connecting the national and European level with stakeholder groups and providing a formal route for integrating stakeholder input into guidance and other relevant instruments guiding the implementation of the EHDS.

Specific recognition of the needs of non-commercial actors

A large number of non-commercial entities will have to adhere to obligations established in the current negotiations. The academic sector, healthcare professionals, small research groups and

[1] For more information see, also our previous statement on opt-in/opt-out here: https://www.biomedeurope.org/images/news/2023/BioMed_Alliance_statement_EHDS_11.23.pdf

medical societies will be future data holders and users and they may need additional guidance, support, training, or funding. Non-commercial actors will need specific provisions, and the specific interests of academic and non-commercial entities must be taken into account when setting the fees for data users (in line with EP amendment 397).

In addition, there is a need for investment in capacity building and training for patients, healthcare professionals, academics, and other non-commercial entities to make effective use of the EHDS and comply to its obligations.