Biomedical Alliance in Europe

Implementing EHDS: medical societies advise on how to bring health data sharing to the next level

The Biomedical Alliance in Europe (BioMed Alliance), representing 34 medical and research societies, welcomes the European Health Data Space (EHDS) provisional political agreement on the regulation concluded on 15 March 2024, and all the work that has been done towards it. We are glad to see a more developed text, with increased mentioning of training and stakeholder involvement as key users and implementers of EHDS. **Nonetheless, policy makers must address the remaining issues that challenge the functionality and purpose of the EHDS. Additional guidance and agreement are necessary to ensure the EHDS will be implemented in a harmonised way that concretely and positively impacts research and healthcare.**

Key issues that need to be addressed include:

- the **need for more structural stakeholder engagement,**
- **ensuring a harmonised implementation of the opt-out mechanism, and the additional safeguards that can be implemented at national level**
- **streamlining remaining definitions and enhancing legal clarity,**
- **support for healthcare professionals and researchers to fulfil their future roles.**

The purpose of the EHDS is to facilitate health research and innovation within the EU, while empowering patients by providing them more access to their health data, and overall improving healthcare and patient safety. If the EHDS will not be implemented in a manner that matches the reality in healthcare and research, the regulation risks falling short of its promises and goals.

Work with healthcare professionals & researchers as key partners

The active and regular inclusion of various stakeholders not only ensures diverse perspectives and expertise are taken into account in evidence-based decision making, but it also promotes trust and transparency. As we move to the implementation and operation phases of the EHDS, it is essential to ensure the EHDS is adapted to the situation that healthcare professionals and researchers face in their daily work. Close cooperation and incorporation of the feedback of stakeholders throughout the implementation and operation phases must happen in a systemic way and would benefit from formal working methods such as in the Medical Device Coordination Group MDCG. Such engagement would provide an opportunity for close cooperation between stakeholders and policy makers, enabling stakeholders to share their input and recommendations on the development of guidance and the overall coordination of the implementation of EHDS.

Ensure a well-implemented opt-out system

The current proposal for the EHDS needs to be accompanied with further guidance as well as an appropriately implemented and harmonised approach to the opt-out mechanism for the primary and secondary use of data. Clear and detailed implementation guidance is necessary to support member states in their interpretation and implementation, and it needs to have the necessary elements

included in order to not hinder cross border care and research, ensure a harmonised implementation, and prevent fragmentation and data bias due to exclusion of certain patient groups[1].

Streamlined communication materials are also needed in order to accurately inform patients on the impact of the sharing of their data on medical research and the safeguards in place to protect their privacy. This will help them to make an informed choice on how they choose to share their data. The information provided should be clear concise and shared equally among all Member States, and healthcare professionals must receive support and guidance to prevent that supporting their patients in this decisions will place an additional burden on their already high workloads.

Harmonise safeguards across Europe

Safeguards implemented at national level for the secondary use of certain types of data deemed 'sensitive', must be harmonised to prevent a patchwork of approaches across Europe. Under article 33.1, Member States may introduce certain additional security measures at a national level for data categories 'e, ea, fa, and m'[1]. This precondition may allow for the implementation of opt-in systems, which can lead to different approaches across member states.

In the past, BioMed Alliance has shared its concerns about a potential opt-in system and how it could significantly hinder health research. In a statement published in November 2023[1], healthcare professionals and researchers highlighted the risk of data bias, and that certain patient groups are less represented in data sets, in the case that a partial opt-in were to be adopted. Additionally, the risk for legal uncertainty for the use of secondary health data increases which can detrimentally impact life-saving research at an EU level.

It is essential that any opt-in systems need to be accompanied with clear guidance to ensure harmonised approaches across all Member States to reduce the impact on cross-border and collaborative health research.

Strengthen definitions and enhance legal clarity

Additional guidance and legal clarity are needed to clarify the practical application of the different definitions, and the interplay of the EHDS with other legislations. To enhance legal clarity, the interplay with e.g., the General Data Protection Regulation (GDPR), the Medical Devices Regulation (MDR), the Artificial Intelligence Act, In vitro Diagnostics Regulation (IVDR) and the Clinical Trials Regulation (CTR) must be clarified to ensure compatibility and consistency across the different regulatory frameworks. In addition, by strengthening definitions of concepts such as data holders, data users and trusted data holders, can have a better understanding of their tasks and rights to fulfil their roles in the implementation of EHDS.

Support for healthcare professionals and researchers

In order to make EHDS a success, we must ensure a broad inclusion of the key actors in the healthcare and research ecosystems throughout the implementation and operation phases. This depends on training and support for patients, healthcare professionals and (academic) researchers as well as not-for-profit organisations and SMEs. Article 42, on fees for data users requesting access to data for

[1] See e.g. our statement from November 2023 'Medical community calls on MEPs and Member States to act now to avoid putting an emergency brake on life-saving health research through EHDS': https://www.biomedeurope.org/images/news/2023/BioMed_Alliance_statement_EHDS_11.23.pdf

secondary use, fails to accommodate the differences between non-profits and other entities, overlooking the distinctive challenges and capacities of these organizations. It is essential for the European Commission and the Health Data Access Bodies to recognize the nuanced nature of non-profit organizations and SMEs, and academic researchers, and provide provisions such as reduced fees and additional guidance and support.

We look forward to continuing our contribution by providing essential recommendations towards building a safe and effective EHDS that improves healthcare and research in a concrete way to ultimately advances health for European patients. Additional work needs to be done to ensure adequate funding is committed to building the EHDS, as well as adoption of the necessary measures for the implementation and governance in cooperation with patients, healthcare professionals and other stakeholders