A Call for Effective Stakeholder Engagement and Capacity Building during the Implementation of the European Health Data Space

39 representatives of the EU health community welcome the publication of the EHDS in the Official Journal of the EU. We take the opportunity to call on policymakers to guarantee **an actionable process for involvement in this new health data ecosystem**.

As outlined in previous statements over the past two years[1][2][3], the **formal engagement and best practice sharing of experiences** by health stakeholders will be critical to ensure the success and longevity of this new health data ecosystem. A collaborative approach that includes citizens, civil society, healthcare professionals, scientists, academia, healthcare providers, payers, industry stakeholders, and patient representatives will foster trust and contribute to the acceptance, effectiveness, and rapid adoption of EHDS initiatives. By involving **a diverse range of voices**, the EHDS can enhance its credibility, interoperability, usability, and reach across the healthcare landscape. It is critical that the EHDS implementation avoids additional unnecessary bureaucracy and workload for health care providers and professionals and prevents a fragmented interpretation of the law.

We appreciate the efforts made in the regulation to enhance stakeholder engagement, particularly through the establishment of the **Stakeholder Forum**. We offer the following **three main recommendations** to further strengthen collaboration, optimize co-creation, and facilitate the smooth and effective implementation of the EHDS. These recommendations relate to the functioning of the Stakeholder Forum, and Capacity Building and Funding and Transparency of the EHDS Board.

This group of stakeholders from the health community stands ready to be **an active and engaged partner** in implementing the EHDS. We believe that by fostering meaningful collaboration and ensuring the provision of resources and support to multiple stakeholders, the **EHDS will be well-positioned to become a cornerstone of Europe's digital health landscape**, enhancing healthcare outcomes across the Union.

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[1] October 2022**:** 7 recommendations for the European Health Data Space to improve patient outcomes, empower EU citizens, and strengthen health systems

[2] February 2024: European Health Data Space in trilogues sparks deep concerns in the European healthcare ecosystem

[3] April 2024: Charting the path forward: Joint stakeholder statement on the implementation of the EHDS

Recommendations:

Functioning of the Stakeholder Forum
The Stakeholder Forum serves as the formal platform representing all stakeholders and its operational methods must ensure the meaningful contribution to the building and functioning of the EHDS. We, therefore, recommend to:

- **Set up the Stakeholder Forum in a timely manner** to ensure early preparedness and involvement of all stakeholders in the implementation of the regulation. Allocate **sufficient resources** to ensure the Forum's effective operation, including the means to gather meaningful input from a diverse range of stakeholders.
- Ensure that the Forum represents **a broad spectrum of stakeholders**, encompassing patients, frontline healthcare professionals, researchers, industry representatives and a balanced regional and demographic diversity across the European Union. This diversity is essential for ensuring that all perspectives are incorporated in a way that fosters trust and credibility in the EHDS.
- Manage the Forum so that it meets **at least four to six times a year** either online or in person to enable continuous dialogue, the exchange of best practices, and feedback on the EHDS implementation.
- Ensure that the Stakeholder Forum **operates under principles of transparency** and that its key recommendations are published online.
- **Prioritise use cases and development of Key Performance Indicators (KPIs) as an initial priority for the Stakeholder Forum, ensuring clear** provision for monitoring, evaluation and accountability.**.**
- **Establish effective channels and protocols to ensure timely cross-dissemination of information, feedback and recommendations** between the EHDS Board and the Stakeholder Forum. This is needed to foster an iterative, transparent process that improves the EHDS's impact and supports its acceptance.
- **Provide sufficient time and explanation to members** of the Stakeholder Forum to respond to consultations and questions in a constructive way.
- Acknowledge that each stakeholder group —such as healthcare professionals, patients, researchers, and industry partners—has unique perspectives and needs. **Develop specific engagement strategies for each group** to ensure their insights are fully captured, as a 'one-size-fits-all' approaches risk missing valuable input.
- Complement the Stakeholder Forum with an overall policy of **regular open public consultation** on key matters and decisions. This approach will promote transparency, build broader public trust, and ensure a wider range of input on EHDS developments.

Capacity building and Funding

The EHDS will only reach its full potential if all stakeholders have the capacity and knowledge to engage with its processes. To ensure it reaches that potential, we recommend to:

- Invest in **capacity building activities** that support cross-border knowledge exchange, drawing on best practices and lessons learned from successful data integration projects. Structured **training and education** in data governance, digital literacy for the transformation of healthcare, and information sharing will equip all stakeholders, including smaller and less well-resourced organizations, to align with EHDS-compatible new standards and regulations.
- Ensure sustainable and adequate **EU-level funding to support training and education, capacity building, and compliance** across Member States - enabling researchers and healthcare professionals to maximise the opportunities presented by the EHDS. Equitable funding will prevent disparities in the implementation of the EHDS and promote equitable access to health data.
- **Maintain, and where possible, increase ongoing funding** through initiatives like EU4Health[4] to support the EHDS and its related health initiatives.

Transparency of the EHDS Board

According to the final text of the Regulation, the EHDS Board will draw up its rules of procedure, including how it will cooperate with the Stakeholder Forum. We believe that, drawing on lessons learned from previous experience, the EHDS Board should:

- Publicly consult and agree on the **EHDS Board's principles and approach to transparency.**
- Commit to **open publication of EHDS Board agendas and papers** in advance of meetings, rapid and open publication of Board meeting minutes, and consideration of webcasts. Good practices from EU agencies such as the European Medicines Agency[5], the European Food Safety Agency[6] and elsewhere should be actively drawn from.
- Define rules of procedure which should clearly encompass **regular and meaningful exchanges and consultations with the Stakeholder Forum**. The response of the EHDS Board to the suggestions and recommendations of the Stakeholder Forum should be made public. This would ensure that stakeholders' perspectives and feedback are integrated and reflected in the efforts to implement the Regulation.

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[4] https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/eu4health_en
[5] https://www.ema.europa.eu/en/about-us/who-we-are/management-board
[6] https://www.efsa.europa.eu/en/events/event/47th-management-board-meeting-webcast-available

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