

European stakeholders determined to advance the use of health data for the benefit of all

For the EU-wide use of health data to succeed and be sustainable, EU and national legislation need to be clarified to avert misinterpretation. To avoid losing valuable time, a political agreement on European health data should be reached before the European elections. These were the issues discussed at the final event of TEHDAS joint action.

The TEHDAS forum, held on 14 June 2023 in Helsinki and online, focused on the developments of the European health data space (EHDS), [the proposal/open in new window](#) published by the European Commission in May 2022, and the TEHDAS results that laid the groundwork for the proposal and implementation of the regulation. The discussion also touched upon how data plays a crucial role in shifting health systems around the world towards personalised healthcare. Nearly 600 European health data stakeholders took part, with speakers from the industry, public sector and research. The views of the forum participants were polled via an online tool.

Urgency for policy makers to act

In his opening remarks Sitra's President **Jyrki Katainen** stressed the need for policymakers to uphold the EHDS on the political agenda even after the European elections in 2024. "This is the right moment to influence all policymakers both in member states and on a European level that health data and the EHDS will be maintained on the next Commission's agenda." Member of the European Parliament **Sirpa Pietikäinen**, who participated the forum as a panelist, echoed Katainen's message: "If political agreement is not found before the elections, we might be looking at years of delay."

Ensuring secure data processing is crucial

The forum participants consider that the most critical element in the infrastructure of EHDS will be guaranteeing a secure environment for processing data and involving high security levels (figure

1).The EHDS proposal underlines the importance of having a secure processing environment (SPE), where data processing takes place after a data permit has been granted, as a key element of the EHDS architecture. [TEHDAS outlined the main elements](#) – known as the architecture – of the European health data space prior to the publication of the proposal.

Which do you think would be the most critical element in the infrastructure?

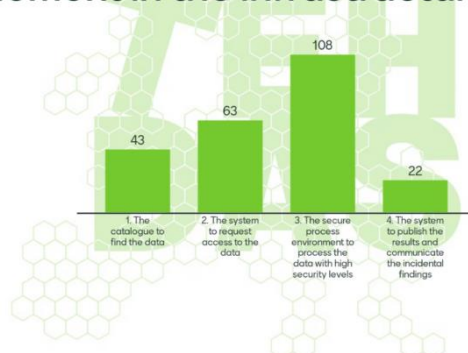


Fig. 1. TEHDAS forum participants think that the most critical element in the infrastructure of EHDS will be the secure processing environment.

In the discussion on data quality, the participants find that data management procedures will be a main hurdle to overcome in implementing the EHDS (figure 2). Data quality is a prerequisite for the reliable secondary use of data in research, regulation and policymaking. TEHDAS will publish a data quality framework in the summer.

EMA has built on the previous TEHDAS work on [data quality](#) to improve decision-making on the benefits and risks of medicines in the EU, explained **Fia Westerholm** of the European Medicines Agency.

Where do you envisage most difficulties for implementation? (pin on the box)

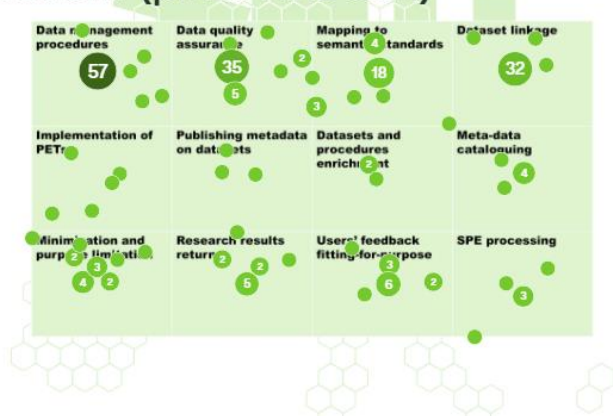


Figure 2. TEHDAS forum participants think that the most difficulties for implementation of EHDS concern the data management procedures.

Both EU and national legislation needs to be clarified

As differing legal interpretations of the law constitute the main obstacle to the cross-border access to health data both EU and national legislation needs to be clarified. Member states will also need to adjust their national legislation to ensure harmonised practices across Europe. These observations were included in latest [TEHDAS recommendations](#), shared by **Michel**

Silvestri, Head of Unit at Swedish eHealth Agency and **Louise Mathieu**, Researcher at Sciensano.

Member states should avoid the same kind of fragmentation with the EHDS as happened with the General Data Protection Regulation (GDPR), which hindered the secondary use of health data, stressed **Susanna Flaherty** of the consultancy IQVIA.

Most of the forum participants were fairly optimistic that the EHDS regulation will contribute to public trust for the cross-border exchange of health data, for both primary and secondary use (figure 3).

TEHDAS's findings indicate that European [citizens support greater transparency](#) and guidance on how their health data is used. The better informed they are, the more likely they are to favour its use.

The EHDS Regulation will contribute to public trust for cross-border exchange of health data, for both primary and secondary use. Do you agree?

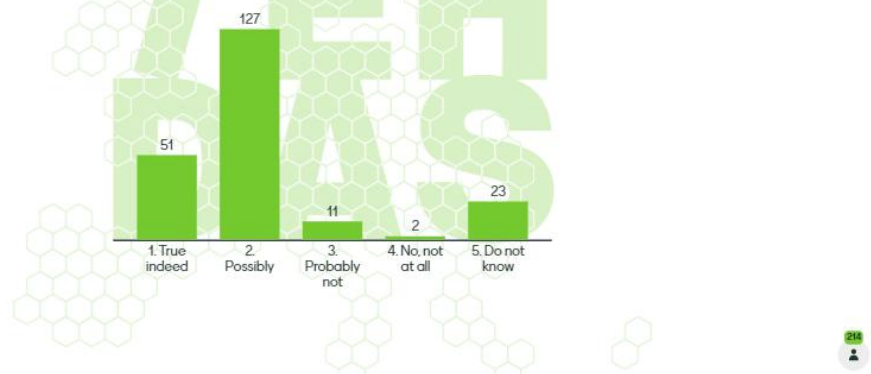


Figure 3. The most of TEHDAS forum participants believe that the EHDS regulation will potentially contribute to public trust concerning the cross-border exchange of health data for primary and secondary purposes.

Wide collaboration is needed to solve sustainability challenges

Sustainability has several dimensions in addition to funding and financing. They include a legal basis and governance, access to quality data, capacity and competence and trust. The debate on the sustainability of the EHDS was led by **Tapani Piha**, Senior Advisor at Sitra and **Henrique Martins**, Associate Professor at ISCTE – Lisbon University Institute.

The forum participants think that trust among all organisations working with health data and forming a clear legal basis and governance are the most challenging dimensions of sustainability to implement (figure 4). Governance refers to the rules and legislative framework created to protect health data.

Which dimension of sustainability do you think is the most challenging to implement?

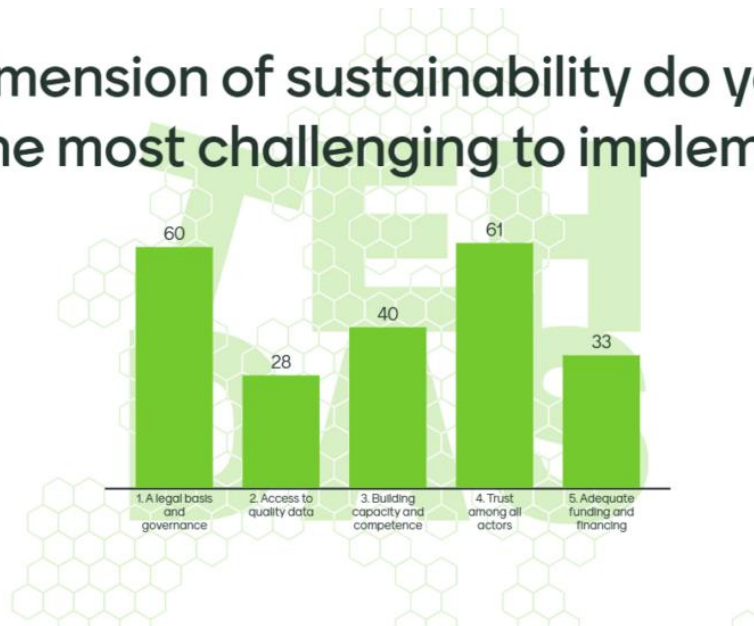


Figure 4. TEHDAS forum participants think that the most challenging dimensions of sustainability to be realised concern trust among organisations and the legal basis and governance.

For the EHDS to be sustainable individuals, tech and data platform providers and health service providers all need to be included in solving the challenges, said **Hille Hinsberg** of Proud Engineers. “We will need heavy capacity building, support to adopt technology and we know it will take time.”

Health for all with smart data use

“With data, quality and accessibility and building trust we can help all EU member states to move to personalised health”, said **Antonio Estrella**, Author & Strategic Futurist. He linked the forum’s discussions about health data to a wider context of the future of health systems, which are moving to the provision of more personalised health services instead of basic health services only or costly chronic disease management. However, providing personalised health services is currently not possible in all countries. For instance, just two of the many trial sites used for a highly impactful clinical study on Parkinson’s Disease are outside of Europe and the United States. “It’s not a single disease that causes us to have bad health, it’s lack of access”, said Estrella.

Way forward – in collaboration

Alongside the negotiation process on the EHDS proposal at the Council of the EU and the European Parliament there are ongoing initiatives on the secondary use of health data. The [HealthData@EU\(open in new window\)](#) pilot project is testing the technical infrastructure for the secondary use of health data as presented in the EHDS proposal. At the forum, the Commission disseminated information about the grants for member states. Under the Commission’s proposal, each member state will create one or more health data access bodies to enable access to health data for secondary purposes.

This forum was the third and last organised by TEHDAS, the joint action Towards the European Health Data Space, carried out by 25 European countries since 2021.

A follow-up joint action is planned to begin in 2024.