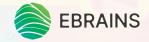
Challenges for Achieving Responsible Data Governance in European Health Data Space









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Challenges for Achieving Responsible Data Governance in European Health Data Space

The European Commission has proposed the creation of the European Health Data Space (EHDS) — a data sharing system that will improve both primary and secondary use of health data across EU member states. The EHDS will be established with two ambitious goals: to empower individuals through increased access to and control of their electronic health data, and to provide a consistent, trustworthy, and efficient set-up for the use of health data for research, innovation, policy making and regulatory activities.

This new initiative will require greater access to health data and health records, and a governance framework that can ensure responsible use. The use of sensitive health data for healthcare, research or commercial purposes is a contested topic, hence it is necessary to carefully consider different aspects of data utilisation to ensure that a responsible data governance structure can be implemented. However, safeguarding data in a complex socio-technical system like the EHDS makes it necessary to consider the challenges from an interdisciplinary point of view, and consider legal, societal/ethical, and technical aspects of these challenges.

The challenges presented in this brief were identified by a multidisciplinary group of experts during a workshop held in Brussels in June 2023. Using a three-step collaborative process, the experts were divided in three groups to brainstorm with peers on topics in their field, focusing on either the legal, ethical/societal, or technical challenges for responsible data governance in EHDS. In a second step, each group of experts were asked to reach consensus and come up with a list of the three most important challenges to address. In a third step, the groups were joined in a plenary session and asked to vote for one challenge from each group, to be addressed in new, interdisciplinary, groups. The three challenges do therefore not form a complete list in themselves, but they were identified as the most important and necessary to consider for achieving responsible data governance. Adequately addressing these challenges is pivotal to ensure that EHDS handles health data responsibly, is societally accepted and is considered a trustworthy solution to health data sharing in the EU, namely: 1) Engagement with and participation of stakeholders, 2) Rights, legitimate interests, and responsibilities, and 3) System security.

While the three challenges are presented separately, they are intertwined, as are all other challenges related to EHDS, resulting in overlaps in their description. This brief does not provide solutions to these challenges. Nonetheless, it is important to note that efforts to address these challenges will most likely also have reciprocal consequences and effects.

Call for Action

This brief provides one group of experts' views on challenges for achieving responsible data governance in EHDS, calling the EHDS to action to invite further and continuous dialogue and thorough consideration of the results presented in this brief by politicians, experts, policymakers, and other EHDS stakeholders. Without proper attention, these challenges will not be solved and achieving responsible data governance in EHDS is at stake. Ensuring engagement with and participation of stakeholders, protection of rights, legitimate interests, and responsibilities, system security and other challenges will require commitment and a sincere effort from the EHDS.

Challenge 1: Engagement with and Participation of Stakeholders

Why is this a challenge for responsible data governance in EHDS?

Responsible data governance could be a challenging objective for the EHDS because of the number of different stakeholders either directly involved or affected by its establishment. Stakeholders include citizens, patients, healthcare professionals, researchers, industry, governments, and others. All with different interests and concerns regarding data governance in the EHDS, that must be considered to ensure a responsible data governance framework. It is important that the EHDS clearly communicates to stakeholders what the mandate of their engagement and participation entails is if anything is to be achieved by engaging with them throughout the entire process: from conceptualising to operationalizing the ambition of EHDS. It is imperative to involve all these stakeholders throughout the entire lifecycle of EHDS, from its development, design, implementation, into operation. Given the broad spectrum of stakeholders with distinct interests, cultural backgrounds, and countries with different legal frameworks concerning data governance in the healthcare domain, it is pivotal for the success of EHDS to engage as many as possible.

What are the challenges?

There are multiple and diverse challenges associated with engagement with, and participation of, different stakeholder groups, but the advantages of engagement and participation should not be underestimated. Approaching the EHDS from their own unique perspectives, stakeholders can predict and anticipate potential concerns.

Engagement is equally important with respect to the two main goals of EHDS, namely empowering individuals' access to their health data, and allowing greater utilisation of that data for research, policy making and innovation. Whether that is data governance with respect to primary or secondary use, the engagement and participation of stakeholders is necessary.

It is fundamental that citizens have trust in how their data is handled across borders. In order to ensure trust, it is necessary to engage with citizens from diverse backgrounds, cultures, ages, digital competencies. Member states' governments, health care sectors and health care professionals are also key stakeholders in ensuring the function of the primary use of health data. The current state of digitization of each member state's health data and health records is not equal. Therefore, it is crucial that each member states' health care sector and healthcare professionals are equipped to handle digital health data and health records in a responsible manner, in order to obtain citizens' trust. To achieve this, engagement and participation will be pivotal. Additionally, it is important that the EHDS does not become a burden for health care professionals in their daily work. To ensure this, it is necessary to have engagement and participation of healthcare professionals in the development, design, implementation, and operationalization of EHDS for primary purposes.

One challenge associated with the use of health data and records for secondary purposes is related to ensuring trust between citizens and the scientific community. It is fundamental that citizens have trust in how their data is handled if the EHDS is to succeed with the ambition of giving the scientific community greater access to health data and healthcare records for secondary purposes, whilst ensuring those data are used responsibly. Therefore, it is crucial that citizens are engaged in the development of responsible data governance structures for secondary purposes. Furthermore, the engagement and participation of the scientific community is pivotal to ensure that the procedures for accessing health data are manageable for researchers. Within the frame of concerns related to data governance are also a need to engage with stakeholders such as industry representatives, governments, data holders and others to align and respect already established rights and concepts such as IP-rights, data processing, procedural clarity, and innovation.

Across all groups of stakeholders, whether involved with primary and secondary use, it is important to ensure they are properly informed about the challenges related to their specific stakeholder position, thereby giving them the knowledge, they need to take informed decisions. This is particularly important when dealing with vulnerable stakeholder groups.

What will be gained from solving this challenge?

Engagement with, and participation of, stakeholders throughout the entire lifecycle of the EHDS is pivotal to ensuring it can unfold its potential. Though timely and thorough engagement with, and participation of, a wide range of relevant stakeholders, EHDS will be able to achieve its ambition of having responsible data governance structures in place. Furthermore, EHDS can achieve societal acceptance, trust and accountability through engagement with and participation of stakeholders which will all help support the realization of the EHDS.

Challenge 2: Rights, Legitimate Interests, and Responsibilities

Why is this a challenge for responsible data governance in EHDS?

Uncertainties emerge also for well-established concepts such as rights, legitimate interests and responsibilities when a new sociotechnical system such as EHDS is under development. These uncertainties need to be considered and dealt with before launching the EHDS. These uncertainties include challenges for achieving responsible data governance because of how they are understood will impact the design, function and operationalizing of EHDS. Challenges related to rights, legitimate interests and responsibilities are numerous and affect all stakeholders within both primary and secondary use of health data. The challenges impact different stakeholders and their roles in different ways. Managing these challenges is complex, as the EHDS embodies conflicting interests due to the ambition of allowing greater access to data (for both citizens and third parties) and governing that data responsibly, ethically, and legally.

What are the challenges?

Among the key challenges related to rights, it is necessary to consider how to balance of the rights and obligations of stakeholders. For instance, how the autonomy of Member States to define their own health policy can be balanced against the necessity for harmonization at the EU-level to fulfil EHDS's potential and aspirations. Another challenge that will affect all member states is how to harmonize the EHDS with existing EU-legislation such as the GDPR. Furthermore, how EHDS interplays with other established data spaces also needs to be defined. The rights of other data spaces could be at stake if EHDS aims to become the predominant data space for the use of health data for primary and secondary purposes.

Defining responsibilities related to data protection is also a challenge in establishing responsible data governance in EHDS. There is a challenge related to determining the appropriate "data controller" as dictated by GDPR due to misalignment with the concepts of "data holder" and "data user" suggested in the EHDS proposal. Additionally, the responsibility related to who should be responsible for data minimization should also be defined, as well as who should be tasked with the responsibility for ensuring effective data preparation for secondary purposes, which also poses a significant challenge. This is further complicated by the fact that there will be a wide range of different data types that differ in their ways of being handled.

Preserving the rights and legitimate interests of data holders in the EHDS present further challenges. These include protecting legal and economic incentives, safeguarding intellectual property rights, trade secrets, regulatory data, commercial property rights, and establishing a level playing field for both private and public data holders.

EHDS poses challenges for data subjects' rights, including ensuring alignment between the rights of individuals regarding the primary use of electronic health records, and their rights concerning secondary use as data subjects under the GDPR. Striking a balance between granting access to health data and health records for secondary use and providing choice mechanisms (e.g. opt-in or opt-out) for data subjects is another concern. Additionally, safeguarding data subject rights during data transfers to third countries or international organizations are vital challenges. Furthermore, it is important to consider how emerging technologies can affect data subjects' rights and how to put safeguards in place that can mitigate these potential challenges.

Many of these challenges have a legal nature, yet legislators cannot anticipate all unintended consequences and risks inherent in a complex socio-technical system like the EHDS. Therefore, tackling the challenge of rights, legitimate interests, and responsibilities is closely aligned with the challenge of engaging with stakeholders as discussed in relation to engagement with and participation of stakeholders.

What will be gained from solving this challenge?

Addressing challenges related to rights, legitimate interests, and responsibilities is vital for establishing responsible data governance in the EHDS. Developing an ethically, legally-harmonized, integrated, multilevel data governance framework for EHDS would protect the individual rights of EU citizens and enable responsible use and access to health data for clinical care provision, innovation, and biomedical research throughout the EU. Such a framework would offer transparency to all stakeholders across the EU regarding responsibilities, structures, activities, and the use of data.

Challenge 3: System Security

Why is this a challenge for responsible data governance in EHDS?

Solid system security is a prerequisite for responsible data governance. However, obtaining this security presents several challenges. System and network security are vital for any data management system, as the failure of these measures jeopardizes the trust placed in the system and its intended purpose by data holders, data users and data subjects alike. The challenge of ensuring system and network security within the EHDS is of utmost importance due to the sensitive nature of health data. Security measures can never be not absolute, and it appears as if there is a general lack of awareness regarding the potential impact of failed security measures.

What are the challenges?

One challenge that presents itself to the EHDS is to specify what risks EHDS is willing to accept and what risks should be eliminated at all costs. It must be noted that security always has to be evaluated against the evolving technology landscape. While system and network security should always adhere to state-of-the-art cyber security standards, more specific baselines need to be established for individual access control of data, secure data transfer, traceability of data, and prevention and detection of attacks. Human errors can occur at any point throughout EHDS; therefore, it is necessary to consider safeguards that can mitigate their effects. It is a challenge to responsible data governance that human errors are unavoidable and considerations for efforts on how to minimize human errors should be made.

Another challenge is how to have coordinated and harmonized security across multiple systems. It is crucial that the EHDS is manageable for all users, whether that be data controllers, data users, data holders or others. Another challenge is related to how data users can be motivated to be cautious and vigilant when using data provided by EHDS. Incentives could be provided to data users to encourage compliance with high security standards. These should not be limited to financial benefits, but extended access to the system could be considered as an incentive. Additionally, organizational commitment to providing the necessary security controls is crucial and poses a challenge for EHDS, and how to offer management support should be given consideration.

It is crucial that EHDS succeeds in raising awareness about the risks involved with its use. It should also be made clear that complete prevention of errors may likely not be achievable. Therefore, the development of emergency plans to handle unforeseen security incidents must be considered. While EHDS is groundbreaking in its ambition, there are several examples from which lessons can be learned, for example within industries such as food security, pharmaceuticals (pharmacovigilance), and aviation. All these examples can provide valuable insights into how complex sociotechnical systems can be implemented across member states.

What will be gained from solving this challenge?

Addressing the system security challenges within the EHDS is imperative for safeguarding data and maintaining trust. Assuring system security will positively impact citizens' and stakeholders' trust and support in the EHDS. Implementing security measures to mitigate potential failures will be pivotal for having continuous support from all stakeholders. If EHDS is successful in the transparency about potential failures and the mitigating measures implemented, societal acceptance will increase if citizens and other stakeholders have trust in those mitigating measures.