



BDVA POSITION PAPER ON THE EUROPEAN HEALTH DATA SPACE

Task Forces Healthcare, Data Spaces & Policy, Societal and Regulation
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Introduction

BDVA is an actor that plays at the interface of research, innovation, and regulation. As an industry-driven association focused on data-driven research and innovation and fully committed to European values, BDVA stresses the importance of providing feedback to the regulators on specific matters of concern to the industry and research areas.

The main objective of European Health Data Space is to provide a framework that guarantees personal health data protection, while ensuring that those data are made available to improve research and innovation in the health domain. This objective imposes a delicate balance, so that all parties benefit from the potential of the EHDS while individual rights are respected.

The association welcomes this ambitious two-fold objective and through this position paper, it aims to highlight some of the issues that were identified in the EHDS regulation proposal and suggest improvements. The overall objective is to address the debate of opt-in and opt-out for patients in the secondary use of healthcare data, to suggest further improvements on the balance between regulation and innovation, as well as recommending for legal interoperability and clear terminology. The paper has been co-authored by members of BDVA, experts in healthcare research and innovation, policy and data spaces. By combining input from academics, researchers, entrepreneurs and representatives of large enterprises, our recommendations aim to balance scientific goals with commercial goals and in respect of European values in support of citizens.

Towards adequate secondary use of health data: debate on opt-in and opt-out mechanisms

BDVA highlights the value of health data and its potential for data-driven policy, research, and innovation. To leverage this potential in a way that fully respects European values, BDVA acknowledges the importance of the discussion on a potential opt-out mechanism in the EHDS.

Being a diverse community, BDVA guides and facilitates evaluation of different approaches and their respective strengths and shortcomings both from the citizens' perspective and for the research community. This community stresses the importance of research and innovation in the health domain and at the same time aims to consider patient empowerment and how it should be guaranteed in research and more broadly, within the practice of secondary use of health data.

The potential introduction of an opt-in or opt-out mechanism passes through the assessment of the interplay between people's autonomy and the public good. Several BDVA members believe that the European Commission found in the initial proposal a satisfactory balance between protecting the interests of patients, ensuring that data is kept safe and secure to build trust, while enabling health research & innovation. However, ***to ensure that natural persons in the EU have increased control in practice over their electronic health data, the discussion should rather be about the governance supporting the control over data and for what purpose those are used.*** Therefore, ***BDVA suggests that no opt-in nor opt-out mechanisms should be foreseen.***

Firstly, the introduction of a consent mechanism for the secondary use of data could generate a disproportionate burden on data subjects and undermine the availability for research oriented at public good. Instead, ***BDVA supports the development of robust transparency and reporting requirements for data users,*** in order to ensure their accountability and liability for the use of data. The obligation to comply with additional safeguards should preferably fall under the responsibility of data users rather than being imposed on data holders or subjects.

Secondly, the quality and representativeness of data is of utmost importance for the research community. Such mechanisms would create imbalances in the data quality and poor representativity of the data sets. ***BDVA voices the concern of the risk of data and algorithmic bias resulting in unreliable research results due to the introduction of any opt-in or opt-out mechanisms for secondary use of data.***

Finally, ***BDVA suggests the condition that clarifications regarding the definition and delineation of different purposes for secondary use are provided.*** Nonetheless, scientific research should be allowed to re-use the data,

within reasonable boundaries, without opt-mechanisms. Thus, in case an opt-in or opt-out mechanisms shall be employed, BDVA suggests applying it only to the commercial re-use while other purposes shall require an impact assessment to evaluate the clear implications of those mechanisms for the research and innovation community.

Towards a healthy balance between Regulation vs. Innovation

BDVA welcomes the concrete and on-the-ground approach of the 2 initiatives supporting the European Health Data Space: the MyHealth@EU infrastructure (for the primary use of health data) and the HealthData@EU pilot project (for the secondary use of health data).

BDVA encourages moreover the possibility to explore multiple initiatives that may enable the practicalities of the EHDS Proposal by considering the versatile range of stakeholders that could be involved in activities implicating secondary use of health data. ***It is of utmost importance to achieve stakeholder alignment by letting these initiatives be adjusted and coordinated according to the needs of the community associated to the secondary use of health data*** (innovators, researchers, policy makers, etc.). Therefore, the different actors within the broad R&I community would benefit from having the possibility to test and assess proposed solutions with the European Health Data Space and use the latter also for generating innovative ideas.

The interplay between regulation and innovation should also be looked at from an IPR perspective. Data spaces, including the European Health Data Space, could serve as environments that support generation and testing of innovative ideas. However, a challenge arises in determining how earnings from public-private, collaborative data-driven innovations should be redistributed. To address this, mechanisms must be established to grant transparency for the involvement of all stakeholders and a fair allocation of the benefits of a certain innovation.

Therefore, clear guidelines and references to regulations are necessary to define distribution of IPR for innovations resulting from the re-use of electronic health data, ensuring transparency, encouraging participation, and safeguard equitable sharing of the benefits derived from these innovations.

Interaction EHDS with other frameworks and clarity of terminology

The BDVA community has identified other important points of concern that require further attention by the legislators. It is important that the Regulation will be aligned as much as possible with the already existing laws concerning personal and non-personal data.

The definition of personal electronic health data under the EHDS proposal might be broader than “data concerning health” in the GDPR. The EHDS refers also to “determinants related to health” and it could broaden the scope to other categories of data such as socio-demographic categories of data (e.g. nutrition, income, etc.).

Furthermore, the European Health Data Space paves the way to multiple ways of sharing health data for secondary purposes, by undergoing an anonymisation process. However, data anonymisation could pose restrictions in the aggregation of data-sets for secondary use. Other alternative techniques to overcome these restrictions can be, for example, pseudonymisation or other Privacy Enhancing Technologies. ***The Regulation proposal should however make clear reference to specific GDPR articles or other legislation and address the risk of potential re-identification with a delineation of the weaknesses of those techniques by providing additional safeguards to mitigate them.***

If the EHDS regulation fails to specify specific criteria for responsibly using Privacy Enhancing Technologies and other techniques, regardless of the data type (ranging from genomic data over medical images to sensory data of wearables) then researchers and innovators may fail to deliver the openness that is at the core of the EHDS objectives.

Therefore, BDVA stresses the importance of further work on delineation and definition of the terms "anonymisation" and "pseudonymisation" in order to allow future health data access bodies to safely disclose data to researchers and innovators without risking future liabilities.

BDVA furthermore sees specific opportunities in approving the public release of data of fully synthetic patients/citizens, even if such data was generated by models of highly sensitive patient data. Synthetic healthcare data corresponds to artificially manufactured data that, by using AI methods, statistically reproduces patterns from actual patient/citizen groups, without corresponding to any single person. As such, synthetic data intrinsically circumvents in its entirety any potential breach of personal data protection, while being valid for research and innovation purposes that are required to improve healthcare services in the future.

Editorial team:

Main editors in alphabetical order (surname):

Natalie Bertels (KU Leuven)

Hortense Dumont de Chassart (BDVA)

Mattia Trino (BDVA)

Contributors:

This paper is the result of cooperative work that gathered input from BDVA members that participated in several meetings and surveys throughout the period June – July 2023.

The main contributors are in alphabetical order (surname):

Daniel Alonso (BDVA)

Håkan Burden (RISE)

Gorka Epelde (Vicomtech)

Iñaki Fernández (Fundación Cartif)

Flavio Fuart (GZS - Chamber of Commerce and Industry of Slovenia)

Ana García Robles (BDVA)

Axel Loewe (Karlsruhe Institute of Technology)

Rob Smeets (Philips)

Susanne Stenberg (RISE)

Pieter van Gorp (Eindhoven University of Technology)

Robin van Stokkum (TNO)

Tuomo Tuikka (VTT)

About BDVA

The Big Data Value Association – BDVA, (from 2021, DAIRO - Data, AI and Robotics aisbl), is an industry-driven international not-for-profit organisation with more than 240 members all over Europe and a well-balanced composition of large, small, and medium-sized industries as well as research and user organizations. BDVA focuses on enabling the digital transformation of the economy and society through Data and Artificial Intelligence by advancing in areas such as big data and AI technologies and services, data platforms and data spaces, Industrial AI, data-driven value creation, standardisation, and skills. BDVA has been the private side of the H2020 partnership Big Data Value PPP, it is a private member of the EuroHPC JU, it is also one of the founding members of the AI, Data and Robotics Partnership and a partner in the Data Spaces Business Alliance. BDVA is an open and inclusive community and is always eager to accept new members who share these ambitious objectives.

Contact for information: info@bdva.eu



www.bdva.eu

