Position Paper

European Health Data Space - Roadmap/inception impact assessment

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Bitkom strongly welcomes the European Commission's efforts to create a European Health Data Space (EHDS) to unlock the potential of health data for sustainable and resilient healthcare systems. Access and (re)use of health data are preconditions to a digital transformation of healthcare systems and set the cornerstones for patient-oriented and data-driven health ecosystems for the future. The current Covid-19 crisis has already demonstrated that data sharing has been beneficial for expedited research, strengthening EU-wide public health surveillance systems with the intention of saving human lives. Fragmented implementation of regulations, and the lack thereof, is seen as the most significant hurdle that continues to limit effective data sharing within the Member States. Bitkom therefore encourages the necessary steps proposed by the European Commission to establish a robust and interoperable infrastructure for safe exchange and secondary use of data for all stakeholders in the health sector with a clearly defined governance framework.

Interoperability & Standardisation:

A strong and secure infrastructure is the basis needed to facilitate consistent access and use of health data. To allow data portability between different systems, **technical and semantical interoperability** should be defined by standardisation organisations and industry experts. Bitkom supports the formation of a **central health data authority** to establish the legal grounds by which it will operate and govern data sharing and access with the support of national health entities. Guidelines, standards, and profiles of standards are to be strictly adhered to by both parties and devised according to the FAIR (Findable, Accessible, Interoperable and Reusable) principles.

Data governance

Standards and protocols of interoperability, as defined on an EU-level, should be uphold and applied by the respective health data entity in each Member State. The assumed responsibility of each Member State's central health data authority should include the implementation of standards, as well as the provision of controlled data services, such as analysis and the distribution thereof.

A central health data entity at the EU level, which serves as a reference centre in a **public-private partnership**, will enable the secure facilitation of health data between national and regional data trust centres. On the one hand, the proposed dynamic demands that national and regional data trust centres ensure that health data is collected, anonymised, and aggregated in a form that is suitable for innovation, research, and development

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purposes. On the other hand, the health data entity on the EU level acts as a mediator between the health data trust centres of Member States, researchers and industry experts, and retains information about the breadth and depth of available data, while the raw data remains with the respective trust centres.

Aligning national strategies through an EU-wide governance framework will enable Europe to harness the power of health data in a resource- and cost-effective way. Such a framework should include:

1. To focus on health/patient data to safely store and manage their health data; to enable healthcare provides to store, administer, assess, exchange data; to foster precision medicine and to promote scientific research
2. A constant update and extension of the health data resource to constantly improve solutions and data quality
3. To provide data storage and computing power for efficient and secure data analysis
4. To encourage extensive use by the healthcare providers, doctors, researchers, and the industry. This will enable all players of the health sector to develop and deploy new digital services and innovations to significantly improve public healthcare and healthcare delivery.
5. To follow a federated approach, so that data can be stored either in a central cloud or in local, distributed databases (e.g. at healthcare providers). Smart technical solutions that allow an integrated view and centralised access to all data need to be implemented.
6. To create use cases to get the practical experience on how the EHDS could work.

Digital Health

The prevailing status quo, characterised by a diverse range of national legislative frameworks that embody certification, authorisation, and reimbursement regulations, challenges the collaborative efforts across the European digital health landscape and has resulted in significant incompatibility issues.

In order to overcome the lack of mutual recognition and successfully organise, finance and execute an approach that would enable the free movement and provision of digital health products and services, Bitkom advocates the initiative to build a common single market to make high-quality healthcare available, accessible and affordable across the EU. For value-driven and outcome-based healthcare, an interoperable data infrastructure with common standards, streamlined national laws and reimbursement schemes for digital health applications are essential. Existing barriers impeding the cross-border availability of health services and products should be addressed. An **EU wide system of authentication for health care provider should be established** to access patients' electronic health

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record and e-prescriptions. The creation of an EHDS certification process for products and services will provide guidance, promote trust, and incentivise the development of digital health applications.

European Electronic Health Record & E-Prescription
The **cross-border exchange of health data** should be improved, especially with regard to e-prescriptions and the European Health Record. In the light of the establishment of a European Health Union, EU-wide e-prescriptions should become a binding principle to improve medication therapy safety for patients throughout the EU. Achieving the initiatives proposed in the Recommendation on a European Electronic Health Record Exchange Format should be a precedent for the Commission. The primary concern should be to complete the exchange of electronic patient summaries and e-prescriptions between various Member States by 2022. In addition, the baseline domains presented in the Recommendation require profiles that outline specifications for interoperability and the guidance to achieve successful practical implementation. Furthermore, mutually agreed-upon standards and specifications for sharing health data, such as Fast Healthcare Interoperability Resources (FHIR) standards, would foster greater legal certainty and accessibility between Member States.

Finally, since the development and introduction of new therapies and forms of care is driven by the innovative power of companies and start-ups, the EHDS should ensure reasonable access to pseudonymised health record data for private research in a trustworthy and secure environment while preserving data autonomy of the patients.

Complementation with proposed Data Governance Act (DGA):
The DGA seeks to create a common EU regulatory framework for data-sharing ecosystems. The EHDS legislation should therefore support the shared goal of exchanging health data across borders and provide legal certainty on data processing and anonymsation, the right to withdraw consent, the medical device regulation (MDR) for AI as well as the application of the GDPR. Furthermore, the definition of data altruism should encompass specifically the possibility of research and development of commercial products and services in medical technology and the healthcare industry.

Moreover, data intermediaries that will play a crucial role in providing trust between data holders and data users within the EHDS should be subject to uniform data security and data protection requirements but not be restricted in terms of their legal nature.

Lastly, to preserve and strengthen Europe's participation in international research cooperation while pursuing a strict risk-based approach, anonymised datasets should explicitly not be considered as highly sensitive health data.

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Code of Conduct (CoC) for secondary use of health data:

The Code of Conduct (CoC) that defines the secondary use of health data should provide a well-defined understanding of what is considered to be "public interest" as well as a joint practice in providing access to health data for private-funded research as described in Recital 159 GDPR by national authorities across the EU to further foster innovation by national authorities across the EU. Furthermore, it should include an outline of industry initiatives and its participants, while preserving Intellectual Property Rights. In addition, the CoC should incorporate standards and tools that support the convergence of means by which health data is shared (e.g. data aggregation, pseudonymisation & anonymisation) in the EU and provide guidance on research cooperation with entities based in third countries. Lastly, cases of increased patient identification sensitivity require the creation of an opt-out model for secondary use of data and should be addressed in the CoC.

Bitkom represents more than 2,700 companies of the digital economy, including 2,000 direct members. Through IT- and communication services alone, our members generate a domestic annual turnover of 190 billion Euros, including 50 billion Euros in exports. The members of Bitkom employ more than 2 million people in Germany. Among these members are 1,000 small and medium-sized businesses, over 500 startups and almost all global players. They offer a wide range of software technologies, IT-services, and telecommunications or internet services, produce hardware and consumer electronics, operate in the digital media sector or are in other ways affiliated with the digital economy. 80 percent of the members' headquarters are located in Germany with an additional 8 percent both in the EU and the USA, as well as 4 percent in other regions of the world. Bitkom promotes the digital transformation of the German economy, as well as of German society at large, enabling citizens to benefit from digitalisation. A strong European digital policy and a fully integrated digital single market are at the heart of Bitkom's concerns, as well as establishing Germany as a key driver of digital change in Europe and globally.