EU

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ScanBalt Declaration 2022 - Potentials and risks of the European Health Data Space

ScanBalt - an international association of research clusters from the Baltic Sea Region and Scandinavia - has been accompanying the digitalisation and digitisation of healthcare and health research in Europe for many years. In 2020, during the German EU Presidency and the first wave of the SARS-CoV-2 pandemic, we initiated the ScanBalt Declaration together with research regions from all over Europe. In this follow-up document, we recommend concrete steps to digitise healthcare across the EU, based on a new European Commission proposal of 3 May 2022.

The European Commission has published the first proposal for its European Health Data Space (EHDS).1 **We as Scan Balt would therefore like to take advantage of the French Presidency of the Council of the EU and evaluate the current proposals of the European Commission together with our French partner Genopole.** We would like to comment on this proposal from a cluster perspective and with a special focus on patient-centred care: Will this proposal for an EHDS have the potential to improve patient care across Europe? What are the key issues that need to be considered in the design of the EHDS?

This document aims to help improve the quality of healthcare for patients across Europe. Our recommendations for the further development of the EHDS can be found below. Please get involved in this initiative and send us your ideas for a common European Health Data Space (EHDS) that will use digitalisation to improve the lives of patients and citizens across Europe.

General

Explanatory Memorandum, (1): "The European Health Data Space ('EHDS') is the first proposal of such domain-specific common European data spaces. It will address health-specific challenges to electronic health data access and sharing, is one of the priorities of the European Commission in the area of health2 and will be an integral part of building a European Health Union. EHDS will create a common space where natural persons can easily control their electronic health data. It will also make it possible for researchers, innovators and policy makers to use this electronic health data in a trusted and secure way that preserves privacy."

We strongly agree and would like to emphasise that this proposal is a fundamental and essential step forward in shaping a unified and safe EHDS. **It holds enormous potential if we work together to ensure that the concerns of patients and of research and innovation are sufficiently addressed.**

[1] https://ec.europa.eu/commission/presscorner/detail/en/ip_22_2711 (accessed 8 June 2022)

Although we do not aim for absolute completeness, we would **like to highlight the following points** as we consider them essential for a successful implementation of a concrete law.

Patient centricity and data protection

Introduction, §7: "In order to facilitate the free movement of personal health data across the Union and avoid negative consequences for patients when receiving healthcare in cross-border context, Union action is needed in order to ensure individuals have improved access to their own personal electronic health data and are empowered to share it."

Article 40: "When processing personal electronic health data, data altruism organisations shall comply with the rules set out in Chapter IV of Regulation […] [Data Governance Act COM/2020/767 final]. Where data altruism organisations process personal electronic health data using a secure processing environment, such environments shall also comply with the requirements set out in Article 50 of this Regulation."

Article 50: "The health data access bodies shall provide access to electronic health data only through a secure processing environment, with technical and organisational measures and security and interoperability requirements."

Article 10: "facilitate for persons with disabilities to exercise their rights listed in Article 3 of this Regulation in accordance with Directive (EU) 2019/882 of the European Parliament and of the Council"

In developing digital solutions to support the WHO's goal of creating integrated health systems, patient-centricity is critical. **As patients own their own data, altruism and informed decision-making become increasingly important. Accessibility for all citizens and *"health digital literacy"* are also important points.**

Although this point is already addressed in the proposal, we would like to take this opportunity to underline its importance.[2] **This fundamental right must be protected at all costs to ensure public trust. Furthermore, we believe it is extremely important to educate and empower citizens to be the owners of their data and to know what power they have.** Being the owner of one's data also always means prohibiting the storage and use of health data - there are also reservations from citizens in the EU about sharing their health data with public authorities.

The protection of health data and public trust is of paramount importance. We would like to emphasise the importance of data altruism and data donation and welcome the inclusion of these concepts in the draft. We also agree that security requirements are an important prerequisite for citizen acceptance. At the same time, we are convinced that educational offers are necessary to make people realise the potential of their data donations for improving public health and local European research. Only when the positive impact of data donations is demonstrated will individual citizens understand the fundamental impact they can have, and this is urgently needed.

Greater integration is needed to apply consent management in practice. When digital health solutions support a patient's journey through the healthcare system, consent can be obtained at each data collection point and from multiple different actors, as each must demonstrate that they have legitimate reasons for processing user data. **Without control over data provenance and access rights, it is impossible to manage**

[2] Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on accessibility requirements for products and services (Text with EEA relevance) (OJ L 151, 7.6.2019, p. 70).

consent or process data requests across multiple service providers. Control can be achieved through the consistent provision of metadata.

Interoperability depends on standardised metadata descriptions, such as those being developed by standardisation associations and industry networks. **The EHDS could address the coherent methodology of metadata maintenance by all data processors.** Subsequently, communication and training activities are needed to promote the common methodology to be used by stakeholders.

Use and misuse of data

Article 35: "Seeking access to and processing electronic health data [...]for the following purposes shall be prohibited:
[1] taking decisions detrimental to a natural person based on their electronic health data; in order to qualify as "decisions", they must produce legal effects or similarly significantly affect those natural persons; […]
[2] advertising or marketing activities towards health professionals, organisations in health or natural persons;."

Article 45: "Health data access bodies shall refuse all applications including one or more purposes listed in Article 35 or where requirements in this Chapter are not met."

We welcome the exclusion of certain uses for the data contained in the EHDS. **Only by limiting the use of data to necessary, ethical and beneficial reasons will the trust of society be secured**. The listed consequence for applicants who specify one or more of these purposes in their application - denial of access - is good and appropriate. In addition, fees and consequences for misrepresentation or misuse must be introduced.

It must be made clear who individuals can turn to if they experience abuse or any other kind of misconduct. There is also a need to set time limits on how long it can take for misconduct to be classified and prosecuted in order to protect trust in society and ensure a deterrent to such unlawful behaviour.

Semantic and technical interoperability

Explanatory Memorandum, (5): "[Chapter II] includes provisions related to the interoperability of certain health related datasets. Member States will also have to designate national contact point tasked with enforcing the obligations and requirement of this Chapter. Finally, a common infrastructure MyHealth@EU is designed to provide the infrastructure to facilitate cross-border exchange of electronic health data."

Article 10: "build national capacity for implementing interoperability and security of the primary use of electronic health data and participate in information exchanges and capacity building activities at Union level"

Article 13: "Member States and the Commission shall seek to ensure interoperability of MyHealth@EU with technological systems established at international level for the exchange of electronic health data."

Standardisation of electronic health records is an indispensable prerequisite for the use of the EHDS and thus for the associated potentials. We agree that standardisation according to predefined standards is the key.[3] **However, harmonising the different national systems poses major technical and organisational challenges.** In addition, the individual countries within the EU are at different stages in the digitisation of their health systems.

Therefore, the practical implementation should not only include the harmonisation of technologies but also create a common status quo for the different services of electronic health records in the different states. Organisational interoperability will benefit from the regulation but still needs to take into account the cultural approach in the EU Member States and possibly other countries in Europe.

When standards are used, they should be available in an open format, i.e., allow integration. **Open technical specifications should be tailored to the specific context in which they are used.** An example of such an open system is OpenEHR (Open electronic health record), which consists of open specifications, clinical models and software that can be used to create standards and build healthcare information and interoperability solutions using the commonly known FAIR principles.

Consequently, the EHDS has great potential, firstly, to harmonise healthcare in Europe and, secondly, to improve overall quality. It is imperative that this fundamental need is also reflected in the funding. Especially in the current difficult economic times, it must be ensured that sufficient funds are available for the development and implementation of a sustainable interoperable EHDS in order to prevent irreversible deficits.

Cross-border use of primary data

Introduction, §17: "Categories of electronic health data such as patient summary, electronic prescription and dispensation, laboratory results and reports, hospital discharge reports, medical images and reports have been selected by the eHealth Network as most relevant for the majority of healthcare situations and should be considered as priority categories for Member States to implement access to them and their transmission."

Article 1: "[This Regulation] establishes a mandatory cross-border infrastructure enabling the primary use of electronic health data across the Union"

Article 5: "Access to and exchange of electronic health data for primary use may be enabled for other categories of personal electronic health data available in the EHR [Electronic Health Record] of natural persons."

Article 12: "The Commission shall establish a central platform for digital health to provide services to support and facilitate the exchange of electronic health data between national contact points for digital health of the Member States."

Sharing data between professionals and across national borders is legitimate and important to improve patient-centred healthcare. As in all categories and as mentioned earlier, patient consent and interoperability are essential for this type of data. **As this data is for immediate use, one should provide a stable running infrastructure to ensure that the data is always available and interoperable.**

We agree that concrete cross-border care services need to be developed to realise the full potential of digitalisation. It is crucial that both processes are started in parallel, both the implementation of the

[3] The European Interoperability Framework in detail | Joinup (europa.eu) (accessed 8 June 2022)

infrastructure and the planning for concrete pilot projects. Only by looking at concrete care projects will the requirements for the new technologies become clearly visible.

In this context, funding is important, and it must be avoided to create cross-border data systems that cannot keep up with the constantly evolving requirements of modern care systems. **Investing sufficient funding at an early stage prevents later deficits in the project phase and thus holds enormous savings potential and helps to treat patients more sustainably and reliably across borders.**

The power of secondary data

Article 33: The electronic health data referred to in paragraph 1 shall cover data processed for the provision of health or care or for public health, research, innovation, policy making, official statistics, patient safety or regulatory purposes, collected by entities and bodies in the health or care sectors, including public and private providers of health or care, entities or bodies performing research in relation to these sectors, and Union institutions, bodies, offices and agencies."

In our opinion, a holistic system that integrates the primary and secondary use of data is of utmost interest. **The use of this existing health data will rapidly improve the advice given to future patients, reduce healthcare expenditure through greater efficiency and drive the development of new treatments and technologies.**

While the ageing population is a major challenge for European social systems, these modern measures are our best hope to significantly reduce the ever-increasing healthcare expenditure. The use of data will also help to keep our health systems and our technological developments up to date and competitive. It is imperative to prevent the separation of data use into two different silos.

We very much welcome that the prohibited areas of data use include "making decisions to the detriment of a natural person on the basis of his or her electronic health data" and "advertising or marketing activities to health professionals, health care organisations or natural persons" (both Article 35). **This will greatly benefit the trust that needs to be built in the public. In addition, however, it is crucial that citizens retain the right to object to any storage of their health data.**

At the same time, we want to recognise the benefits of using secondary data by a wide range of actors, including healthcare start-ups. This will potentially incentivise young professionals to improve patient care through innovative and data-driven approaches. By not only storing this data but also sharing it with skilled actors, huge benefits can be created. **However, as mentioned above, data security and the rights of individuals must be protected and considered at every possible stage.**

The use of synthetic data could also accelerate and sustainably improve developments based on the collected and carefully distributed data. However, when working with synthetic data, the anonymisation of individuals must be guaranteed at all times and it must be ensured that this technically demanding approach works smoothly before its initial implementation to avoid possible data leaks. This is particularly important for citizens living with a rare disease.

HEALTH AND LIFE SCIENCES

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The institutionalisation of a European Digital and Health Data Board

Article 64: "A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among the Member States. The EHDS Board shall comprise the high-level representatives of digital health authorities and health data access bodies of all the Member States. [...] Depending on the functions related to the use of electronic health data, the EHDS Board may work in subgroups, where digital health authorities or health data access bodies for a certain area shall be represented."

The establishment of democratically legitimised monitoring groups is certainly useful to oversee the process. However, it is important to ensure that the expert groups are staffed with people who cover the full range of available experts, which has not been achieved in previous attempts. Even if these delegates are considered "high-level", we demand that technical expertise is essential and must be regularly reviewed by external stakeholders.

Therefore, we propose that not only should all states be represented, but two professional experts in the respective fields, drawn from the panel of Member State representatives, should be included. In addition, a close link with civil society is necessary in order not to create technocratic bodies and we therefore propose the inclusion of patient representatives in the body. Regular conferences and consultations with the European cluster organisations, at least every six months, should be held to ensure the civil perspective and to turn citizens from subjects to actors again.

Wellness data as more than a "nice-to-have" addon

Article 31: "Where a manufacturer of a wellness application claims interoperability with an EHR system and therefore compliance with the essential requirements laid down in Annex II and common specifications in Article 23, such wellness application may be accompanied by a label, clearly indicating its compliance with those requirements."

This regulation and labelling is desirable to include the full potential of the different data sources and to develop a second health market. A steadily growing proportion of people are using wellness services for their personal fitness tracking and well-being. **The future certainly lies in the sustainable development of digital applications that can be of great benefit for everyday life, future patient care and research through high and certified interoperability**.

Especially with regard to the quality of the data provided by such tools, **it is important to establish common ground rules in order to avoid enormous heterogeneity of data**, which would lead to uselessness for far-reaching Big Data approaches and cross-comparisons.

In cases where the digital health infrastructure involves the use of tools (hardware and software) owned by multiple parties, guidelines should be established for data quality and ensuring data security.