Paris, June 8th, 2022

ScanBalt Declaration 2022 – Potentials and Risks of the European Health Data Space

[D R A F T]

ScanBalt - an international association originating from research clusters in the Baltic Sea Region and Scandinavia - has been accompanying the digitisation and digitalization of healthcare and healthcare 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 toward the digitalisation of health care across the EU, based on a new proposal issued by the European Commission on May 3rd, 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 benefit from the French presidency of the European Council and, together with our French partner Genopole, evaluate the current proposals made by the European Commission. We want 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? Which are major points to be considered while shaping the EHDS?

The focus of this document is to potentially help improving the quality of health care for patients throughout Europe. Our consensus opinions and advices can be found in the following. Please join us in this initiative and send us your ideas for a common European Health Data Space (EHDS) that will utilize 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."*

ScnaBalt community: We strongly agree and want to emphasise that this proposal is a fundamental and essential step forward in shaping a united and secure EHDS. Congratulations on this leap forward. It holds enormous potential if all crucial points will be accounted for. While we do not seek for absolute comprehensiveness, we want to stress the following points as we found them to be indispensable for a successful implementation of a concrete law.

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

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"

ScnaBalt community: While creating digital solutions which are supposed to help the goal of the WHO to create integrated health care systems, patient-centricity is crucial. As patients own their data altruism and informed decisions become more important and individuals can only contribute to their full potential, if considered right away and put in the centre of all future ventures. Important points also include the accessibility for all citizens and *'Health Digital Literacy'*. While this point is already addressed in the proposal, we would like to take the chance to emphasize its importance.[2] This fundamental right needs to be protected by any cost to ensure the trust of the public. Furthermore, we find it to be of highest importance to educate and therefore empower individuals who should own their data and know about the power it holds.

The protection of health data and public's trust is of highest importance. We want to emphasize the importance of data altruism and data donations as well as appreciate the appearance of these concepts in the draft. Additionally, we agree, that security requirements, are an important prerequisite for the acceptance of citizens. At the same time, we are convinced that educational offers are needed to enable people to recognise the potential of their data donations for improving public health and local European research. Only by demonstrating the positive impact of data donations and altruism on the European society, individual citizens will understand the fundamental impact they can have and that is desperately needed.

More integration is needed to apply consent management in practice. When digital health solutions support a patient pathway through the health system, consent may be requested at each data collection point and by several different actors, as each may be required to demonstrate that they have legitimate grounds to handle data from users. Due to the lack of association of data policies to the actual data stored on the patient, it is difficult to trace data provenance. Without the control over data provenance and access rights, it becomes impossible to manage consent or handle data requests across multiple service providers. The control can be achieved by consistent deploying of metadata. Interoperability depends on standardized metadata descriptions such as developed by standardization associations and industry networks. The EHDS could address the coherent methodology of metadata maintenance by all data processors.

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

Subsequently, communication and training activities are necessary to promote the common methodology to be deployed by stakeholders.

Use and misuse of date

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."

ScanBalt community: We appreciate the exclusion of certain fields of use for data included within the EHDS. Only by limiting the use of data to necessary, ethically correct, and beneficial reasons, the societies trust will be ensured. The consequence listed for applicants who indicate one or more of these purposes in their application – denying the access – is good and reasonable. Additionally, fees and consequences in case of misdeclaration or misuse must be implemented.

It must be made clear, where individuals can turn to in case, they experience misuse or any other kind of misconduct. Additionally, timelines on how long it can take to classify and prosecute misconduct need to be in place to protect trust with society and ensure deterrence from such unlawful conduct.

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."

ScanBalt community: The standardisation of electronic health records is an absolute prerequisite for any use of the EHDS and therefore for any potentials it may bring. We agree that the standardization according to predefined standards is key.[3] However, harmonizing the different national systems brings major technological and organisational challenges. Additionally, the individual countries within the EU have different depths of digitalisation within their respective health systems. Therefore, the practical implication

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

should not only include harmonising the technologies, but also set a common status quo for the varying performances of the electronic health records in different states. The organisational interoperability will benefit from the regulation - but still needs to consider the cultural approach in EU Member states and possibly further countries in Europe.

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

Subsequently, the EHDS has great potential to firstly harmonise and secondly increase the overall quality of healthcare in Europe. It is imperative that this fundamental necessity is also reflected in its funding. Especially in the current economically challenging times, it must be ensured that sufficient funds will be available for the development and implementation of a sustainably interoperable EHDS to impede irreversible shortcomings.

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."

ScanBalt community: The exchange of data among professionals and across national borders is legitimate and important to improve patient-centred health care. Like in all categories and as mentioned before, patient consent and interoperability are essential for this type of data. As this data is meant for direct use, one should provide a steady running infrastructure that ensures that the data is available and interoperable at all time. We agree that concrete cross-border care services are to be developed to exploit the full potential of digitalisation. Here it is crucial that both processes are started in parallel, the implementation of the infrastructure as well as the planning for concrete pilot projects. Only by considering concrete care projects, the requirements for the new technologies become clearly visible. Thereby, funding is important, and it is essential to avoid creating cross-border data systems that cannot keep pace with the constantly evolving requirements of modern care systems. The early investment of sufficient funding will prevent shortcomings later in the project phase and therefore have enormous potential to save money and help to treat patients more sustainable and reliable 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."

ScanBalt community: In our opinion, a holistic system which integrates primary and secondary use of data is of highest interest. The use of these existing health data will rapidly improve the guidance of future patient journeys, lower health care spending due to more efficiency, and drive the development of new treatments and technologies. While the ageing population is a major challenge for the European social systems, these modern measures hold our best hope to substantially reduce the constantly rising health care spending. This use of data will also help our health care systems and our technology developments to stay up to date and competitive. The separation of data use into two different silos must be prevented at all costs.

We highly appreciate the fact that the prohibited areas of data use include "taking decisions detrimental to a natural person based on their electronic health data" and "advertising or marketing activities towards health professionals, organisations in health or natural persons" (both Article 35). This will substantially profit to trust which has to be built with the public.

Additionally, at the same time we want to agree with the benefits of secondary data use by a wide range of stake holders including health care start-ups. This will potentially create incentives for young professionals to help improve patient care through innovative and data driven approaches. By not only holding, but also sharing these data with qualified stakeholders, enormous benefits can be created. However, as mentioned before, data security and the rights of individuals must be protected and considered at any possible time point.

Also, the implementation of the use of synthetic data, might accelerate and sustainably improve any developments based on the collected and carefully distributed data. However, when working with synthetic data, the anonymization of individuals must be ensured at any time and this technically challenging approach must be made sure to run smoothly before its first implementation to avoid any potential source of data leaks. This especially is important for citizens living with orphan disease.

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 Member States. The EHDS Board shall be composed of 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."

ScanBalt community: The establishment of democratically legitimised monitoring groups certainly makes sense to oversee the process. However, it has to be made sure that the expert groups are staffed with people who cover the full spectrum of experts available, which was failed to be achieved in previous attempts. While those delegates are considered to be 'high level', we demand that Technical expertise is essential and to be regularly verified by external stake holders.

Therefore, we suggest that not only all states should be represented but also two professional experts for the respective fields are to be included, originating from the panel of Member State representatives. Additionally, a close connection to civil society is necessary in order not to create technocratic bodies and therefore we suggest the inclusion of patient representatives in the panel. Regular, at least biannual, conferences and consultations with Europe's cluster organisations should be implemented to secure the civil perspective and again transform citizens from subjects to actors.

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."

ScanBalt community: This regulation and labelling is desirable to include the full potential of different data sources and develop a second health market. A constantly increasing proportion of individuals 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 use in everyday life, future patient care and research through high and certified interoperability. Especially, regarding the quality of data delivered by such tools, it is important to set common ground rules to avoid an enormous heterogeneity in data which would result in unserviceability for wide-ranging big data approaches and cross-comparisons.

In cases where the infrastructure for digital health services includes the use of tools (hardware and software) held by several parties, guidelines on data quality should be established along with ensuring data security.