

# HEALTH DATA REPORT #1

European Strategy for Data  
and its Implementation in the  
German Health Data Legislation



## **A. Introduction**

For medical research today, a comprehensive stock of structured and longitudinal data with good data quality is essential.<sup>1</sup> Despite the increasing digitalization of the health care process and thus the growing number of health data collected by different institutions (hospitals, databases, etc.), an effective use of health data in research is still not achieved. Data is a key enabler for digital transformation.<sup>2</sup> Because of the different data management systems in the different EU Member States the availability of health data to the patients themselves or to public authorities, medical professionals or researchers differs immensely. Even where the availability of health data is guaranteed, health data often depends on technologies that are not interoperable, thus hindering its wide use.<sup>3</sup> Because of this, health systems lack key information to optimize their services, and providers find it hard to build economies of scale to offer efficient digital health care solutions and to support cross-border use of health services.<sup>4</sup>

In the effort to battle these problems the European Commission published a Communication Paper on the EU-Data-Strategy on February 19<sup>th</sup>, 2020. The regulatory framework concerning the health data, the access to it, its implementation and portability are all big topics in this Paper.

A similar situation can be observed in Germany in recent years. There has been a lot of effort from the legislator to enable a more effective and secure use of the health data. Digitale-Versorgung-Gesetz (DVG) and Patienten-Datenschutz-Gesetz (PDSG) are some examples of laws, which try to push the digitalization ahead.

This paper will present the key points of the EU-Data-Strategy concerning the use of health data. It will compare those points with the current developments in Germany and investigate, if the developments in Germany are sufficient to reach the goals of the EU-Data-Strategy.

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<sup>1</sup> See: Decision recommendation of the Health Committee (14th Committee), BT-Drs. 19/14867, 85.

<sup>2</sup> Communication from The Commission on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, 25<sup>th</sup> April 2018, 1.

<sup>3</sup> Communication from The Commission on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, 25<sup>th</sup> April 2018, 1.

<sup>4</sup> Communication from The Commission on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, 25<sup>th</sup> April 2018, 2.

## **B. A cross-sectoral governance framework for data access and use**

### **I. EU-Data-Strategy<sup>5</sup>**

The first of the four priorities in the EU-Data-Strategy is a cross-sectoral governance framework for data access and use, which should be used in the implementation of the common European data spaces. The regulation will not be overarching and overly detailed. It will focus on the specificities of individual sectors and of the Member States. For the sector of health care this means a framework, which focuses on the possibilities for access and use of health data. This framework will build on recent initiatives in the Member States (e.g. Finnish Health and Social Data Permit Authority (Findata) for the governance of the secondary use of health data for research purposes). EU-Data-Strategy also focusses on standardization activities and on the work towards a more harmonized description and overview of datasets, data objects and identifiers to foster data interoperability between sectors and, where relevant, within sectors. Very important for the EU-Data-Strategy is also to facilitate decisions on how and by whom which data can be used for scientific research purposes in a way, that is compliant with the GDPR. The framework should also make it easier for individuals to allow the use of the data they generate for the public good, if they wish to do so (“data altruism”). All these issues are crucial for the effective and safe use of health data in the future. There are other priorities of the EU-Data-Strategy, like implementing acts on high-value data sets under the Open Data Directive and the need for legislative action on issues that affect relations between actors in the data-agile economy. These are also included under the EU-Data-Strategy key points on cross-sectoral governance framework, but do not play a huge role for the health data sector and are therefore not a part of the EU-Data-Strategy for the healthcare sector.

To encourage better implementation of the framework as well as a more effective data access and use the Commission itself will also strive for excellence in the way it organizes its own data, uses the data for better policy making, and makes the data it produces and funds available to others, including through the EU Open Data Portal.

### **II. Situation in the German healthcare sector and need for future developments**

The first key point in the EU-Data-Strategy so far has a broad implementation in the healthcare sector in Germany.

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<sup>5</sup> This section is based on the Communication from The Commission on the European Strategy for data, 19<sup>th</sup> February 2020, 12 ff.

Firstly, with the Digitale-Versorgung-Gesetz (DVG) the German Parliament established a Forschungsdatenzentrum (research data center), which is responsible for collecting the pseudonymized health data of the patients in the statutory health insurance and governing the access to it by authorized bodies. Even in the EU-Data-Strategy paper the Forschungsdatenzentrum is mentioned as an example for the governance structure under the first key point. The Forschungsdatenzentrum is a step in the right direction, but is still insufficient to enable Germany's innovation and competitiveness in an international comparison.<sup>6</sup> For example, access is only granted to a very limited number of authorized bodies within the meaning of § 303e para. 1 SGB V, which does not include, for example, research companies that make a major contribution to medical research. Opening up government-held information is a long-standing EU policy.<sup>7</sup> These data have been produced with public money and should therefore benefit society.<sup>8</sup> Society will not be able to benefit from an effective healthcare research, if a key player in research, the research companies, will not have an opportunity to use the health data for research purposes. **The limitation of the access to the Forschungsdatenzentrum in § 303e I SGB V does therefore not align with the EU-Data-Strategy and should be changed in the future.**

Secondly with the Patientendaten-Schutz-Gesetz (PDSG) the German legislator created a framework which partly allows data altruism (also referred to as data donation) for scientific purposes in § 363 SGB V-new. This should generate a solid data basis for scientific research. According to § 363 para. 1 SGB V-new, the admissible purposes of data donation are:

- Improvement of the quality of care
- Research, especially for longitudinal analyses over longer periods of time, analyses of treatment processes or analyses of care provision
- Support of political decision-making processes for the further development of the statutory health insurance system
- Performance of health reporting tasks

According to § 363 para. 2 SGB V-new, the insured persons would declare their data donation via the user interface of the electronic patient file. The donated data is collected in the Forschungsdatenzentrum. Its scope should be freely definable. The ability to consent to data sharing is based on the ability to consent to the respective treatment itself. However, the release could only take place with regard to electronic patient files that do not contain any

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<sup>6</sup> See: Decision recommendation of the Health Committee (14th Committee), BT-Drs. 19/14867, 85.

<sup>7</sup> This section is based on the Communication from The Commission on the European Strategy for data, 19<sup>th</sup> February 2020, 7.

<sup>8</sup> This section is based on the Communication from The Commission on the European Strategy for data, 19<sup>th</sup> February 2020, 7.

personal reference. Notwithstanding the donation of data for research purposes to the Forschungsdatenzentrum pursuant to § 363, para. 1-7 SGB V-new, § 363 para. 8 SGB V-new allows the possibility for insured persons to make their "electronic patient record available for a specific research project or for specific areas of scientific research also on the sole basis of informed consent". This clarifies that consent according to Art. 6 para. 1 lit. a) in conjunction with Art. 9 para. 2 lit. a) GDPR does not fall under the prohibition of discrimination as a result of § 335 para. 2 SGB V-new (also introduced under the PDSG), which fundamentally prohibits an agreement with the insured person aimed at permitting access to health data. The facilitation of the data altruism through PDSG in Germany is an important step towards the free disposability of ones own health data in the future. **The restrictions to the type of health data which can be donated and the purposes it could be donated for are however holding back various possibilities for the use of health data for research purposes with the consent of the person concerned.**

The recent developments concerning the use of health data for scientific purposes in Germany are taking a direction which is on par with the EU-Data-Strategy. However, there are still a lot of adjustments that will have to be made. Most important for the effective use of health data for scientific purposes is the implementation of the long-standing EU-Policy to open up government held information for (research) companies. This could be done in accordance with the EU-Data-Strategy though extension of the circle of authorized bodies under § 303e para. 1 SGB V. This would allow the research companies to use the data produced with public money to improve the healthcare standards and develop new medication possibilities, which would have a positive effect on the public health and therefore would be implemented for the public good.

## **C. Investments in data and strengthening Europe's capabilities and infrastructures for hosting, processing and using data, interoperability**

### **I. EU-Data-Strategy<sup>9</sup>**

The second key point of the EU-Data-Strategy is investing in European data spaces, data sharing architectures (including standards for data sharing, best practices, tools), governance mechanisms and energy efficient and trustworthy cloud infrastructures and related services. The Commission wants to launch a high impact project to support the implementation of these developments. An effective European data space cannot function without innovative and high-quality cloud-based structures enabling the data use, processing and access.

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<sup>9</sup> This section is based on the Communication from The Commission on the European Strategy for data, 19<sup>th</sup> February 2020, 15 ff.

## **II. Situation in German healthcare sector and need for future developments**

A cross-sector German project which is also mentioned in the EU-Data-Strategy Paper as being aligned with the second key point of the EU-Data-Strategy is GAIA-X. GAIA-X is a project to build an efficient and competitive, secure and trustworthy data infrastructure for Europe, which is supported by representatives of the German Federal Government, industry and science. The goals of the project are the preservation of a European "data sovereignty" against "oligopolistic tendencies in the platform economy", reduction of the "dependence" on "international providers", making "cloud services on a broad scale" more attractive through more trustworthy service offers and the creation of an "ecosystem for innovation" so that "those who drive innovation are also those who benefit economically from it".<sup>10</sup> **The German healthcare sector however, does not have any specific developments that are on par with the second key point of the EU-Data-Strategy.**

### **D. Empowering individuals, investing in skills and in SMEs**

#### **I. EU-Data-Strategy<sup>11</sup>**

The third key point in the EU-Data-Strategy focuses on empowering individuals with respect to their data, investments in skills and general data literacy. Individuals should be given more control over who can access and use machine generated data, which could be done through enhancing the portability right under Article 20 of the GDPR. Furthermore, there should be a bigger investment in specialists, who are able to deploy the latest technologies in businesses throughout the EU.

## **II. Situation in German healthcare sector and need for future developments**

The German healthcare sector is not lagging behind when it comes to empowering individuals and investing in data literacy. In December 2019, the German Parliament introduced the new § 20k SGB V, which focuses on promotion of digital health literacy. According to § 20k SGB V the participants in the statutory health insurance have a claim, to receive services which promote the self-determined health-oriented use of digital or telemedical applications and procedures. This development does not target the data literacy as a whole but focusses on digital and data literacy in the healthcare system. The already mentioned PDSG with the possibility of data donation and introduction of electronic health record also opens opportunities to empower the data literacy of individuals.

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<sup>10</sup> <https://de.wikipedia.org/wiki/GAIA-X#BMWIGAIA-X2019>.

<sup>11</sup> This section is based on the Communication from The Commission on the European Strategy for data, 19<sup>th</sup> February 2020, 20 f.

## **E. Common European data spaces in strategic sectors and domains of public interest**

### **I. EU-Data-Strategy<sup>12</sup>**

The last key point in the EU-Data-Strategy is the promotion of the development of common European data spaces in strategic economic sectors and domains of public interest. The governmental framework, sectoral legislation and ensured interoperability from the first key point will play a huge role in setting up the data spaces. These will be developed in full compliance with data protection rules and according to the highest available cyber-security standards. Data spaces need to be complemented by policies that stimulate the use of data and demand for services enriched with data. One of the nine Common European data spaces to be established is the Common European health data space, which is essential for advances in preventing, detecting and curing diseases as well as for informed, evidence-based decisions to improve the accessibility, effectiveness and sustainability of the healthcare systems.

In the effort to establish the Common European health data space the Commission will firstly develop sector-specific legislative or non-legislative measures for the European health data space, complementing the horizontal framework of the common data space. The main form of regulation to be implemented is a Code of Conduct for processing of personal data in health sector, which must be established in accordance with Article 40 GDPR. With the help of these regulatory instruments the Commission will take measures to strengthen citizens' access to health data and portability of these data and tackle barriers to cross-border provision of digital health services and products.

The Commission will secondly deploy the data infrastructures, tools and computing capacity for the European health data space, more specifically support the development of national electronic health records (EHRs) and interoperability of health data. The Commission will also scale up cross-border exchange of health data; link and use, through secure, federated repositories, specific kinds of health information, such as EHRs, genomic information (for at least 10 million people by 2025), and digital health images, in compliance with the GDPR. These actions will support prevention, diagnosis and treatment (in particular for cancer, rare diseases and common and complex diseases), research and innovation, policy-making and regulatory activities of Member States in the area of public health.

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<sup>12</sup> This section is based on the Communication from The Commission on the European Strategy for data, 19<sup>th</sup> February 2020, 21 ff.

## **II. Situation in German healthcare sector and need for future developments**

The fourth key point of the EU-Data-Strategy, which builds upon the first three points, has already received some attention from the German legislator and government. The establishment of the Forschungsdatenzentrum, the possibility of data donation and the introduction of the electronic health record are the first steps to implement the EU-Data-Strategy successfully. The idea of the implementation of a Code of Conduct has also been supported by the German Minister of Health Jens Spahn.<sup>13</sup> However, there are still a lot of areas, where German legislation and government have a lot to work on. Especially the possibility for private research companies to get access to pseudonymized data for scientific purposes must be put in place. In addition, the quality of the collected data has to be improved, so that it could be used more effectively and have a higher impact on the research.

## **F. Conclusion**

The EU-Data-Strategy of the European Commission published in the Communication Paper on February 19<sup>th</sup>, 2020 consists of four key points. The Commission wants to:

- Establish a cross-sectoral governance framework for data access and use
- Invest in the infrastructures for hosting, processing and using data as well as fostering interoperability
- Empower individuals and ensure data literacy
- Use these structures to establish Common European data spaces, including a Common European health data space

The developments in Germany are moving into the direction, which is prescribed by the EU-Data-Strategy. In some areas however, the healthcare system in Germany is lagging behind, especially concerning the quality of collected data and the access possibilities for private research companies.

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<sup>13</sup> <https://www.aerztezeitung.de/Politik/Spahn-fordert-Code-of-Conduct-fuer-Gesundheitsdaten-in-Europa-402563.html>.