Skadden

Cybersecurity and Data Privacy Update

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EU and Germany Lay Groundwork for the Use of Medical Data for Research and AI Training

Executive Summary

- Both the EU and Germany are taking significant steps to accelerate digitalization in the health sector and facilitate the exchange and use of health data for research and innovation purposes.
- They aim to improve individuals' access to and control over their personal electronic health data, while also enabling the use of data for public interest, policy support and scientific research.
- The measures would lay the groundwork for a unified market for digital health services and products.
- For life sciences and health care companies, these laws create both opportunities and challenges, as they will have implications for data protection, data sharing, data analysis and data-driven innovation.
- The expanded secondary use of medical data will open up opportunities for AI companies and tech companies to develop tools for medtech, and pharma companies will gain access to new sets of data to further their research programs.
- Health insurers should carefully consider how the new opportunities created by these laws can benefit their customers and amend their processes accordingly.

The Future of Medical Data Analysis and Usage

On March 15, 2024, the Council of the European Union and the European Parliament reached a provisional agreement on new legislation that will facilitate the exchange of and access to health data at EU level. The proposed European Health Data Space Regulation (EHDS) seeks to enhance individuals' access to and control over their personal electronic health data while facilitating its reuse for purposes such as public interest, policy support and scientific research. The law would help establish a health-specific data environment to foster a unified market for digital health services and products.

Meanwhile, Germany is advancing a series of new laws with overlapping goals, and the German government has made data-based medical research a priority, reflecting the new National Pharma Strategy, unveiled on December 13, 2023.

Both governments recognize that medical data analysis has the potential to produce invaluable insights, reshaping the landscape of health care by harnessing the potential in patient information. From optimizing treatment strategies to predicting disease trends, the utilization of advanced analytics not only enhances clinical decision-making but also paves the way for personalized medicine, ultimately fostering improved health outcomes and greater efficiency across entire health care systems.

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Artificial intelligence (AI) has demonstrated effectiveness in risk stratification, precise diagnosis, treatment allocation and mitigating health disparities. But reliable AI models must train on large, diverse datasets that accurately represent the population. This necessitates collaboration among multidisciplinary, multinational teams to mitigate developer, statistical and social biases.

First, we will discuss the coordinated measures that Germany is taking.

Health Data Initiatives in Germany

Current Legal Obstacles

Current data protection requirements often hinder the provision and use of health data for scientific research purposes and AI training. Health data are subject to the strict and sometimes unclear requirements of both the EU's General Data Protection Regulation (GDPR) and German regulations.

In Germany, where individual state laws have to be observed, researchers can be faced with nearly 20 different sets of legal regulations. These can complicate data sharing and analysis, as they often include stringent anonymization standards and strict informed consent requirements that must be satisfied before personal data, including health care information, can be processed or shared for research or analysis purposes. Patients must be fully aware of how their data will be used, by whom, and for what specific narrow purposes, before giving consent and before any processing occurs. However, potential future research purposes are often not foreseeable at the time consent is obtained.

To facilitate the consent process, a template form was developed by the Medical Informatics Initiative but it is very extensive and therefore not easily understandable for patients. As a consequence, the proportion of people whose data can be used in studies is relatively low. Another challenge is that potential study participants and research leaders often do not find each other due to a lack of registered data.

Center for Medical Data Usability and Translation: An Important Development

An important step forward was taken on February 29, 2024, with the establishment of the Center for Medical Data Usability and Translation (*Zentrum für Medizinische Datennutzbarkeit und Translation,* or ZMDT) at the University of Bonn. The center was founded to enable an interdisciplinary exchange between law, medicine and computer science and aims to address legal and medical challenges related to the access and use of medical data in the public interest.

The research focus of the ZMDT is on data-based therapies and technical innovations in the fields of diagnosis, treatment and prognosis. The center will also promote spin-offs in the field of medical data usage to help translate innovative academic research into advances in clinical practice.

As an indication of both state and federal government support, the ZMDT's opening ceremony was attended by the North Rhine-Westphalia Minister for Culture and Science Ina Brandes, as well as Federal Minister of Health Prof. Dr. Karl Lauterbach, who said that "the initiative is one that we urgently need in this time. The topic of data use in medicine is gaining enormous momentum and we will pursue this path together consistently." Other senior federal officials also spoke at the event.

All stakeholders interested in the use of medical data should consider participating in an open dialogue facilitated by the ZMDT to further opportunities.

Recent German Legislation Regarding Health Care Data

Today, health data in Germany is fragmented and stored in decentralized silos, rather than being consolidated in a central repository. The German government aims to address this and to boost digitalization in the health sector with two new laws.

On February 2, 2024 the Federal Council *(Bundesrat),* the national legislative body representing Germany's 16 states, approved the Law to Accelerate Digitalization in the Health Sector (known by its German shorthand *Digital Gesetz* or DigiG) – and the Law to Improve the Use of Health Data (Health Data Use Act or GDNG in the German shorthand). Both laws will come into force on January 1, 2025.

Digital Act (DigiG)

The DigiG is intended to simplify day-to-day treatment with digital solutions. The cornerstone of this legislation is the implementation of the electronic patient record (*elektronische Patientenakte* or ePA), slated for inauguration in mid-January 2025, which will promote the exchange and use of health data and provide targeted support for health care.

Its primary objective is to facilitate the seamless exchange and utilization of health data, thereby enhancing targeted health care delivery. At the ZMDT opening ceremony, Minister Lauterbach emphasized that the ePA is designed to be user-friendly and serve as "more than just a storage place," ensuring, for instance, that patient medications and possible allergies and comparable information are stored directly in the electronic health record. In addition, digital health applications are to be integrated deeper into the care processes and their use made transparent.

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This law will affect all health care system participants, such as pharmacies, doctors and health insurance companies.

Health Data Use Act (GDNG)

The GDNG aims to facilitate the use of health data for research purposes. It will establish a central data repository and coordination point to enable access to research data from various sources, *e.g.*, existing silos, such as the cancer registry or health insurance data. The new Health Research Data Center of the Federal Institute for Drugs and Medical Devices (German shorthand: *BfArM*) will act as the intermediary between data users and data holders.

At the ZMDT opening ceremony, Nick Schneider, a senior official in the Federal Ministry of Health, said that it is vital to open up secondary use of medical data for the training of AI models in the EU, noting that there can be significant differences between data sets of, for example, German patients and Chinese patients. The German legislation aims to promote innovation, in part by allowing AI to train using regulated and secure data repositories. The GDNG also aims to prepare Germany for the EHDS, the EU's new law, as currently Germany would not be able to comply with the intended EHDS requirements. Making health data available for secondary use, setting up data access points and providing data via secure processing environments are among the core elements of the GDNG. These are also essential elements of the EHDS.

The GDNG will open up new opportunities for companies relying on secondary use of medical, including pharma and research companies, and tech companies developing medtech. Health facilities are strengthened in their own research and health insurance and long-term care insurance funds will be able to provide personalized advice to their policyholders based on billing data.

More Health-Care-Related Legislation Planned in Germany

At the ZMDT event, Minister Lauterbach also discussed two other legislative proposals that are in the works: the Digital Agency Act and the Medical Research Act. Together with the DigiG and GDNG, these would create a comprehensive framework to bolster innovation, streamline data exchange and propel medical research.

In addition, two other possible pieces of related legislation are under discussion: the Research Data Act and the Register Act.

Digital Agency Act (*Digitalagentur-Gesetz*)

The Federal Ministry of Health intends to further develop the Society for Telematics, a research institute devoted to digitalization of health data, into a digital agency wholly owned by the federal government. This transformation would give the institution more autonomy and decision-making authority and augment its capabilities to oversee processes from inception to completion.

Medical Research Act (*Medizinforschungsgesetz* or MFG)

In January 2024, the Federal Ministry of Health introduced a draft Medical Research Act to amend the regulation of clinical trials as a crucial component of a new National Pharma Strategy. The goal is to enhance Germany's appeal for pharmaceutical research and development as well as manufacturing.

The proposed legislation would alter the law across multiple domains, primarily focusing on national laws and procedures governing clinical drug trials, medical devices and in-vitro diagnostics, as well as German drug pricing and reimbursement laws pertinent to market access. It would also restructure regulatory agencies and ethics committees while delineating their competencies.

A public hearing on the proposal was held on February 24, 2024. When the Medical Research Act will be submitted to Parliament (*Bundestag*) is uncertain. However, considering the advanced stage of drafting and the hearings on the draft, it is anticipated that an official draft bill will be presented to the *Bundestag* in the coming months. The legislative process must be concluded within this year to adhere to the timeline outlined in the current draft, with certain provisions slated to take effect on January 1, 2025.

The MFG will particularly affect companies that are involved in pharmaceutical research projects, as well as development and manufacturing.

Research Data Act (*Forschungsdatengesetz* or FDG)

Another proposed law, the Research Data Act, would aim to create the basis for a micro data center to simplify and expand access to public data and to create linking possibilities. Another goal is to make data protection more accessible and research-friendly and to take better account of the special needs of research.

To facilitate the use of personal data by researchers, it will be necessary that any new law is consistent with both the data protection and research privilege provisions of the EU's GDPR.

At the same time, there needs to be more uniform national data protection supervision when research projects take place across different German states. The aim is for the federal cabinet to discuss the draft Research Data Act in the last quarter of 2024 and for the law to come into effect during the current legislative term, which runs through fall 2025.

Like the MFG, the FDG is primarily relevant for companies that conduct research.

Register Act (*Registergesetz*)

Medical registries are gaining increasing attention. There, standardized data from patients, organ donors or medical devices can be stored and analyzed. These are intended to improve care transparency, or to monitor and evaluate certain processes, and to further help answer specific research questions and identify risks — all by means of complex data evaluations. However, due to a lack of infrastructure and legal regulations, this data is not available in Germany in the form required for optimal patient care. The Register Act is intended to lay the foundations for a sustainable registry landscape in Germany.

The data for a health registry are collected proactively over a long period of time. This means that data is collected from a certain point in time to be evaluated for a specific purpose. The plan is to set up a central office for medical registries with a directory that provides an overview of the data inventory as well as data quality and availability.

At this stage, no draft law has been published, but the key points as outlined by a senior Ministry of Health official have already received approval.

Internationalization of Digitization in the Health Sector

Various international initiatives such as the recent agreement in Brussels on the EHDS are currently in development to tackle global health data challenges and foster collaboration among nations in the sharing and utilization of health care information. These efforts signify a growing recognition of the importance of cross-border cooperation in advancing health care innovation and improving health outcomes globally.

EU Health Data Space

The agreement between the European Parliament and the EU Council on the EHDS reflects a larger European data policy, and it is the first agreement on a common EU data space in a specific area.

The legislative proposal introduced by the European Commission aims to facilitate cross-border health care for patients and doctors while advancing health policy research and innovation. One example: Establishing a common health data space is seen as crucial for better monitoring and combating future pandemics.

One objective of the regulation for the EHDS is to enhance individuals' access to and control over their personal electronic health data. Concurrently, it seeks to enable the reuse of certain data for purposes of public interest, policy support and scientific research. The regulation outlines a health-specific data environment that will help promote aims at empowering individuals through increased digital access to and control of their electronic personal health data, at national level and EU-wide.

It further aims to support their free movement, as well as fostering a genuine single market for electronic health record systems, relevant medical devices and high-risk AI systems (primary use of data) and providing a consistent, trustworthy and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities (secondary use of data). Patient privacy is protected by ensuring individuals have the right to object to the sharing of their sensitive health data for research purposes.

The fragmentation of health data in different locations will create challenges for the implementation of the EHDS, because the law does not require a centralized data infrastructure. The current system has the advantage that it reduces the risk of large data leakages, but it can create problems of interoperability and interconnectedness.

The provisional agreement on EHDS must now be approved by the Council and Parliament.

Hope for Transatlantic Data Space

In expanding the current plans for the creation of the EHDS, German Health Minister Lauterbach also outlined his vision of creating a transatlantic data space in cooperation with the U.S., building a framework for secure data exchange between the EU and U.S.

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This would involve agreements, standards and technologies to facilitate seamless data flow while ensuring privacy and security. It has the potential to foster collaboration, drive innovation, improve health care outcomes, and strengthen public health responses on both sides of the Atlantic. However, it is essential to address privacy concerns, data security issues and regulatory challenges to realize these benefits fully.

Outlook: Opportunities, Benefits and Future Developments

Recent investments, in the field of research and manufacturing, from pharmaceutical giants like Eli Lilly and Roche, which Minister Lauterbach emphasized during his ZMDT speech, underscore the growing confidence in Germany's potential as a hub for research and innovation, further highlighting the importance of leveraging data analytics to enhance the research environment.

To fully capitalize on this momentum, stakeholders should prioritize preparation of new access and usage options for medical data to facilitate the integration and analysis of treatment data, study data and information from various registers. This approach is crucial for fueling the development and training of AI systems, ultimately driving innovation, improving patient outcomes and advancing the frontiers of health care and technology.

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