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Recommendations for Further Action when Implementing the European Health Data Space in Germany

Vol. 2: Think Globally, Act Locally

THINK TANK

Cuvillier Verlag Göttingen
Internationaler wissenschaftlicher Fachverlag

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Bibliographical information held by the German National Library

The German National Library has listed this book in the Deutsche Nationalbibliografie (German national bibliography); detailed bibliographic information is available online at http://dnb.d-nb.de.

1st edition - Göttingen: Cuvillier, 2024

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www.cuvillier.de

1st edition, 2024

This publication is printed on acid-free paper.

ISBN 978-3-68952-096-0

eISBN 978-3-68952-097-7

Co-funded by the European Union

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Collaborative Workshop “Global Denken. Lokal Handeln”

co-organized by Amgen, Siemens Healthineers, Medical Valley, EIT Health

Erlangen, April 29th, 2024

Outcome Report v2.0

Forewords

Dr. Kurt Höller

We need to fundamentally change the healthcare system in Europe, especially how we use data in health. This applies not only to the primary use of data, for the patient and the doctor, but also to secondary use, particularly for training algorithms, conducting research, making informed government decisions, and developing targeted products and devices. It is important to work cross-border and interoperably, so that citizens can access their data abroad and datasets can be used not only locally but also on a European level. This cross-border data use is crucial for achieving comprehensive and efficient healthcare solutions that benefit from a wide range of data sources and diverse patient information.

In a long process concluded in April 2024, the European Commission, Parliament, and Member States created a framework with the European Health Data Space, which aims to enable a seamless flow of health data across Europe, fostering innovation and improving public health outcomes. In Germany, this regulation is supported through the implementation of the Health Data Usage Act (Gesundheitsdatennutzungsgesetz, GDNG), which sets national standards for data sharing and utilization in the healthcare sector. Now, the focus is on the practical implementation at the local level, ensuring that healthcare providers and institutions, researchers, and patients can effectively collaborate and utilize these data resources to enhance healthcare delivery and improve patient outcomes. Achieving this goal in the best possible manner, it is important to note that as new developments arise the GDNG will require further legal updates to maintain its effectiveness and relevance.

The EHDS will impact everyone's lives, as well as our economic future. Therefore, this joint event on April 29th with Amgen, Siemens Healthineers, Medical Valley, and EIT Health was not only highly relevant but also extraordinarily insightful, especially due to the involvement of parliament and ministry representatives. Perspectives from healthcare providers, patient organisations, and industry complemented these insights.

With this report of the workshop conclusions, we will show how relevant the EHDS is for better health in Europe. In addition, we will outline the importance of positive communication and tangible pilots for broad acceptance, especially in Germany. These efforts will involve significant resources and investment, but they promise substantial benefits for the future of healthcare.

Dr. Kurt Höller,
Managing Director,
EIT Health Germany-Switzerland

Anna Goldsworthy

Germany's fragmented health data infrastructure has been hindering efficient data exchange and innovation, and therefore the current introduction of many new legislations, initiatives and products to counteract this situation is of great importance.

Particularly at the Bavarian level, healthcare providers, technology companies and research institutions are joining forces to enable the infrastructure for efficient data exchange. For most activities, aligning with the European Health Data Space (EHDS) initiative is key to making significant strides in enhancing digital health infrastructure and data interoperability. Looking ahead, the EHDS aims to create a seamless, interoperable health data ecosystem across Europe, improving patient care and accelerating medical research. This fosters and supports all activities within Bavaria and offers a great potential to leverage our position as a digital health leader.

Within this context and beyond, initiatives like TEAM-X also play a crucial role. TEAM-X focuses on fostering collaboration among key stakeholders, including healthcare providers, technology companies, and academic institutions, to develop innovative solutions for health data management. It's set up in the framework of Gaia-X that aims to establish a secure and transparent digital ecosystem where data can be shared across borders in a compliant and efficient manner. Further, the developments of TEAM-X lead the way for a practical implementation of the EHDS on a national level. By supporting these initiatives, Germany can address the fragmentation of its health data infrastructure and pave the way for a more integrated and efficient healthcare system. These efforts not only enhance data interoperability but also ensure that patient privacy and data security are maintained, ultimately leading to better health outcomes and more rapid medical advancements.

Anna Goldsworthy,
CEO,
Medical Valley EMN e.V.

Stefanie Polat

We all aspire the European Health Data Space (EHDS) become a catalyst for groundbreaking health innovations and a milestone for patients across the EU. If we succeed, the EHDS will be recognized as a tool for enhancing healthcare access, driving the digitalization of healthcare delivery throughout Europe, and empowering citizens and patients. Imagine a connected and interoperable EHDS revolutionizing healthcare innovation in the EU. To unlock this potential, we need a harmonized and clear regulatory environment across all EU member states, with straightforward and feasible requirements, especially regarding product compliance, the secondary use of health data for research and innovation, and the protection of intellectual property and trade secrets.

Looking ahead, digitalization and data/AI-supported applications have the power not only to revolutionize healthcare delivery but also to save costs, address the shortage of healthcare professionals, and, most importantly, enable more precise, individualized, and targeted diagnoses, treatments, and prevention. Precision diagnostics will be the key to ensuring that each patient receives the right treatment at the right time. To reach the goal of personalized and precise individual healthcare, we must ensure the availability of high-quality, structured health data and provide equal access to data pools for both the research-based industry and academic researchers. By building on existing interoperability efforts and developed standards, we can foster collaborations between the public and private sectors, driving data-driven innovations in healthcare in the EU, Germany, and Bavaria for the benefit of all patients – because, ultimately, data saves lives.

Stefanie Polat,
Senior Vice President, Head of Strategy & Customer Engagement Europe, Middle East & Africa,
Siemens Healthineers

Dr. Georg Münzenrieder

After the successful conclusion of the trilogue negotiations at EU level on March 15, 2024, we now have a future-oriented legal framework for the use of health data (primary and secondary use) in Europe. From the point of view of the Free State of Bavaria, this is an important success. The EHDS is now the basis for better care, more research and more innovation in the EU. Everyone involved will benefit from this: patients, service providers, research institutions, research industry and the healthcare industry alike. When implementing the EHDS, the acceptance of the legal framework by all those involved will be a decisive prerequisite for its success. What we all have to be clear about is that digital innovations can only unfold their benefits if society accepts them. But this is not a sure-fire success: the key to success is communication and the imparting of digital competence. This applies first and foremost to the patients, whom we want to win over as self-determined users and data donors for the project. But it also applies to service providers and the research community.

The decisive factor is that the introduction of the EHDS will enable better healthcare for European citizens. At the same time, patient sovereignty will be strengthened: citizens will have electronic access to their complete health data. They can pass on their data to healthcare professionals - but they do not have to. They can add information, correct errors, restrict access and receive information about how their data is used. It goes without saying that data sovereignty will be guaranteed for users. In Germany, the opt-out ePA can therefore come into effect as planned and patients can remain masters of their data. The Bavarian State Ministry of Health, Care and Prevention has also been working towards this for a long time.

Dr. Georg Münzenrieder,
Head of Department - Fundamental Issues of Digital Transformation & New Technologies,
Bavarian State Ministry of Health, Care and Prevention

Manfred Heinzer

The medicine of the future needs health data - for an innovative, sustainable and robust pharmaceutical research location in Germany. After all, health data is the basis for the development of better medical treatments. Digitalization offers enormous opportunities to efficiently collect, share and use health data. It is already possible to make predictions about disease progression in some cases by collecting and linking existing health data ("big data" method). Clinical studies could be accelerated through the use of high-quality data, for example by using control groups consisting of data sets (digital twins) instead of human probands.

In the last couple of years, Germany has initiated a remarkable race to catch up in the field of digital health: The Health Data Use Act and the Digital Act are milestones that have taken the collection, sharing and use of health data to a higher level. In Europe, the European Health Data Space opens up unprecedented opportunities for data exchange within Europe. In the future, this will not only make the research and development of medicines and healthcare more efficient, but also more patient- focused.

Now is the time to effectively put into practice the legislative starting signal for a "Zeitenwende" in health data policy. We need high-quality and structured healthcare data - "data for action". On the one hand, this requires improvements to the telematics infrastructure as a powerful tool for data exchange and the establishment of a sustainable register landscape for data collection. On the other hand, pragmatic guidelines and straightforward application channels are needed for the research data center. Finland and the UK are shining examples from which we can learn.

In the pursuit of efficient and innovative ways of data usage, we as a research-based pharmaceutical company can also make our contribution, e.g. by establishing dialog platforms such as "Think globally, act locally". In this way, we bring together stakeholders from the various areas of the healthcare system who are willing to act, with the aim of moving from talking to action. Together, we want to overcome the existing challenges and take concrete measures step by step. Be it to establish the positive "European Health Data Space Mindset" among stakeholders in the healthcare sector or to point out necessary investments in a robust health data infrastructure. One thing is clear: the ability to respond quickly to new health challenges - pandemics and the consequences of demographic change - will depend to a significant extent on the availability and quality of existing health data in the future.

Manfred Heinzer,
Vice President & General Manager,
Amgen GmbH

Content

Who is EIT Health?

EIT Health is one of nine Knowledge and Innovation Communities (KICs) of the European Institute of Innovation and Technology (EIT), an EU body. EIT Health is an Institutionalised Partnership under Horizon Europe's Pillar III – Innovative Europe. Established in 2015 to tackle the societal challenges of 'health, demographic change and well-being' within the EU, its mission is to help overcome the well-known EU paradox whereby state-of-the-art education, excellent research and a dynamic industry are challenged to turn breakthrough ideas into new transformative products and services.

Within the EIT Health network, over 130 partner organisations and institutions from academia, business, research and health care delivery collaborate across disciplines, borders and sectors to reinforce excellence, create knowledge and innovation and encourage greater investment in innovation that delivers the outcomes that matter to citizens and patients. As a result, EIT Health represents a unique match between a sustainable innovation ecosystem model gathering and leveraging different partners and funding sources, and a change agent with extensive capacity to generate real-world data for evidence-based policymaking and the transformation of health care.

The EIT Health Think Tank

The EIT Health Think Tank is EIT Health's thought leadership forum. It brings health care leaders together to prepare the ground for life-changing innovation and to identify the next opportunity for a step-change in how health care is delivered. Research participants collaborate across disciplines and borders to explore and assess the most pressing topics impacting health and the uptake and adoption of innovation. This allows for continual assessments of the environmental needs of EIT Health's portfolio of projects and programmes. To facilitate this dialogue and its findings, EIT Health drives a range of activities to generate knowledge and insight, including research, expert Round Tables and interviews, publications, and dissemination of key information.

Previous EIT Health Think Tank projects have focused on determining how to overcome the barriers to, and capitalise on the opportunities of, the adoption of innovation and new technologies in health care, including the harmonisation of digital medical devices, use of Big Data, future-proofing Europe's digital health innovation pathway, the role artificial intelligence (AI) can play in health care workforce and organisational transformation, and the impact of the new Medical Device Regulation (MDR). In 2021, the EIT Health Think Tank produced a report entitled "Learning from health data use cases: Real-world challenges and enablers to the creation of the EHDS" that served as an initial step towards EIT Health's focus on the EHDS regulation, producing an overview of challenges in roles, regulations, and policies and practices. The latest EIT Health Think Tank report focuses on digital medical devices and explores pathways to regulatory harmonisation across Europe.

Introduction

Digitalisation in healthcare: Germany on its way to implementation

Health data is a crucial driver of innovation and progress in medical research, diagnostics and treatment. The European Health Data Space (EHDS[1]) and the German Health Data Use Act (GDNG[2]) provide a legal framework for the collection, sharing and use of health data. The current focus is on successful local implementation.

Key stakeholders from medical research and practice, industry and entrepreneurship, state and federal government, patient advocacy and data security convened in Erlangen on April 29th, 2024, at the invitation of EIT Health Germany-Switzerland, Amgen Germany, Medical Valley EMN e.V. and Siemens Healthineers. The goal was to discuss the current state of healthcare digitization in Bavaria and Germany, to identify concrete solutions for further advancement, to talk about the next to do's of certain stakeholders and also share insights about what is already working well in order to make the German healthcare- and hospital systems more digital as well as sustainable, moderated by Marina Leonie Moskvina.

This report summarizes the results of the event and provides an overview of the current status and opportunities for constructive development. Improvements across all areas – technical infrastructure, financial and human resources, education, and communication – are needed to overcome existing hurdles and accelerate successful implementation.

'Think globally, act locally' continues the expert dialogue on healthcare digitization in Germany, initiated in autumn 2022. Initial findings from a German-Swiss Roundtable were published by EIT Health Germany-Switzerland in 2023.[3] Additionally, a Europe-wide report on the implementation status of the EHDS was published by EIT Health e.V. in 2024.[4]

Key participants of the event

Speaker	
Marina Leonie Moskvina	Healthcare & Innovation Consultant and Lecturer
Dr. Kurt Höller	Managing Director, EIT Health Germany-Switzerland CLC GmbH
Anna Goldsworthy	CEO, Medical Valley EMN e.V.
Dr. med. Stefan Kropff	Executive Medical Director, Amgen GmbH
Stefanie Polat	Senior Vice President, Head of Strategy & Customer Engagement Europe, Middle East & Africa, Siemens Healthineers
Bernhard Seidenath, MdL	Chairman of the Committee on Health, Care and Prevention, Bavarian State Parliament
Nick Schneider	Head of Division 511 - New Technologies and Data Use, German Federal Ministry of Health
Dr. Georg Münzenrieder	Head of Department - Fundamental Issues of Digital Transformation & New Technologies, Bavarian State Ministry of Health, Care and Prevention
Birgit Bauer	Founder, Data Saves Lives Germany
Dr. med. Eimo Martens	Senior Physician, Head of Device Therapy and Telemedicine Center, Klinikum Rechts der Isar, TU Munich
Dr. Thomas Poeppe	Head of Digitalization, IT and Processes, AOK Bayern
Anna Wierzchowski	General Counsel, Wellster Healthtech Group
Dr. Anne Sophie Geier	Managing Director, German Digital Health Association
Markus C. Müller	Board Member and Treasurer, German Digital Health Association
Workshop Captains	
Dr. Johannes von Büren	Wellster Health Group
Oliver Ullrich	JustHealth
Dr. Yoni Goldwasser	Springboard Health Angels
Christian Hieronimi	Oncare
Sebastian Hilke	Bavaria Innovative Health
Joerg Traub	Bavaria Innovative Health
Birgit Bauer	Founder, Data Saves Lives Germany

From discussion to action

1. General assessment

Satisfaction with the legal situation

The legal basis has been created, and now the focus turns to implementation

First steps towards creating a functioning European Health Data Space were laid with the Council conclusions on COVID-19 lessons learned in health[5] during the German EU Presidency in 2020 and a first draft presented by the European Commission in May 2022. Although the final ratification is still pending, a political agreement on the legal act was reached in March 2024. In April 2024, the German Parliament already adopted the Health Data Use Act (GDNG), paving the way towards the implementation of the EHDS in Germany. Representatives of the Federal Ministry (Nick Schneider) and the Bavarian State Ministry (Dr. Georg Münzenrieder) expressed their satisfaction with this development. They emphasized that with regard to Article 1 of the General Data Protection Regulation (GDPR) the rights of the individual should be protected without unnecessarily restricting the free movement of personal data. As Nick Schneider stated in their joint opening keynote, “We must approach the GDPR in an enabling manner. It’s important to understand that the regulation is not just about data protection; it’s about protecting people while making use of data.” To derive greater benefits from health data for research, diagnosis, and treatment, progress in implementation is crucial. All players in the healthcare system are called upon to contribute to this effort.

The legal framework requires continuous adaptation and further development. The Health Data Use Act (GDNG) was established alongside developments at the European level (EHDS) to prepare the German health care system at an early stage for changes introduced by the EHDS. Trust and ongoing exchange between federal and state levels, as well as between practice and legislation, are essential for continued improvement.

While some voices have warned of over-regulation, those involved agreed in principle that all stakeholders in the health sector must now work together to overcome the challenges of implementing legal principles and support implementation through effective communication. "We have enough laws; we are slowly losing track. We need to get all players on board and build trust, then something will come of it," said Anna Wierzchowski, a lawyer from Wellster Health Group, summarizing the current situation.

> We're moving beyond bulky file folders to seamlessly access to data across EU borders. EHDS is a game-changer, though full implementation will take time.
>
> Nick Schneider, German Federal Ministry of Health

Obstacles to further development

Barriers to further development are well known

The major obstacles to collecting and using health data are well known. These include technical, financial, and personnel-related issues, such as poor system interoperability, in consequence insufficient resources for medical staff to transfer data from healthcare provider-based documentation systems to electronic patient records (ePA), and a general lack of knowledge and information, leading to reservations about handling health data. Effective change management that involves everyone would help to ensure the acceptance of digitization and to overcome the still prevalent practice of analogue data exchange, as noted by Dr. med. Eimo Martens from the university hospital Rechts der Isar at the Technical University of Munich.

Some recent changes, such as the transition from an opt-in solution to an opt-out solution for electronic data transfers to and from the electronic patient record, have been viewed positively. However, compared to the progress made by some European countries (such as Sweden, Denmark, Spain, and Portugal) and non-European countries (such as Israel), Germany still lags in many aspects. This is partly due to the complexity and decentralized structure of the German healthcare system, as well as the ongoing focus on the risks associated with digital developments. Advocates for healthcare digitization argue that the greatest risk is failing to exploit health data, thereby preventing its positive use for primary patient care and secondary use for research and economic development.

Potential for improvement and positive communication

Information, training and success stories must accompany implementation

The discussants highlighted several compelling arguments for the benefits of utilizing health data: it improves medical care across Europe and across borders, helps bridge increasing supply bottlenecks in a rapidly growing and aging population, and opens up new opportunities for research, making it an important economic factor for Germany.

Health data and AI-based solutions are already being used extensively in various areas. The flagship projects from Bavaria include digiOnko[6], which focuses on the prevention, early detection, therapy, and relapse prevention of breast cancer, and Digi Med Bayern[7], which contributes to P4 medicine (predictive, preventive, personalized, participatory). Stefanie Polat from Siemens Healthineers discussed the possibilities that arise in precision medicine with data twins and AI-based auto-contouring solutions in radiation therapy, although these developments often rely on American data sets.

Despite these advantages, they are not yet well-known enough to silence critics and convince sceptics. "If there is a small system error, the whole system is called into question," noted Dr. Thomas Poeppe of AOK Bayern. Blockages are removed and change processes work when all actors are informed, supported, and included. Therefore, significant investment in effective communication and training is necessary, as emphasised by Bernhard Seidenath, Chairman of the Committee on Health, Care and Prevention in the Bavarian State Parliament. Without this, developments like the electronic patient record risk causing more resentment than support. Key elements for progress include building health data skills among medical personnel, caregivers, and patients, and relying on expert advice rather than stirring up fears in the field of data protection. Clear communication about positive examples and successes is essential, not only from political decision-makers, but also from successful practice, to make the concrete improvements visible.

In thematic workshop groups with diverse expertise, individual aspects of the potential for improvement were examined in more detail. Specific results from the four areas of discussion - innovation and entrepreneurship, industry, patient perspective, and data protection and security - are summarised below.

> Significant investment in effective communication and training is necessary to ensure that all stakeholders are fully informed, engaged, and equipped to handle new processes.
>
> Bernhard Seidenath, Bavarian State Parliament

2. Innovation and entrepreneurship in digital health

Germany is an attractive marketplace for ideas

Germany offers several advantages for international entrepreneurs

Germany, as Europe's largest healthcare market alongside France, is an attractive location for startups in digital health. The nascent state of healthcare digitization provides ample opportunities for innovation and new business models. Entrepreneurs appreciate Germany's stable and predictable legal framework, the availability of highly trained specialists from its universities, and access to research funding. Additionally, factors that affect the quality of life, such as a good work-life balance, further enhance Germany's appeal.

Wish list for improvement

Better data access, supportive policies, and a startup-friendly climate

Entrepreneurs have several concrete suggestions for enhancing Germany as a hub for innovators. They observe challenges such as lack of interoperability and the associated difficulties in accessing large data sets, which hinder the digitization of the healthcare system in Germany. More solidarity in data sharing based on an awareness of its advantages, an improved data architecture, and more startup-friendly public tenders are other items on interested entrepreneurs' wish list.

Soft factors also play a role: international stakeholders would like to see greater openness and a 'hunger for innovation' in Germany. Finally, as a small but important detail that can open or close doors for foreign innovators and entrepreneurs, the English language was mentioned. The structure of the event itself was characteristic of the language barriers encountered: while this workshop was held in English, the rest of the event was conducted in German.

Recommendations

- *Standardized contracts for easier and faster data access*
- *Coordination and cooperation between federal states to avoid duplication and enhance competition*
- *More collaboration, including (government-supported) innovation hubs, e. g. in rural areas*
- *Attracting talent and investment through broad collaboration, never by individual players hub*

3. Health data as a booster for industry

On the way to becoming a 'Research Nation', again

Germany as a business location continues to strive for even greater progress

Health data is crucial for developing more effective and tailored products in the healthcare sector. It not only advances healthcare but is also a key economic driver. Access to high-quality data is also a decisive factor for economic development. As in the area of startups and entrepreneurial innovations in biotech, medtech and digital health, there is also considerable room for improvement when it comes to making health data usable for industry and thus for Germany as a business location. According to a study that examined access to health data as a location factor for companies in the field of biotechnology, medical technology and digital health, access is "not possible or only insufficiently possible" in Germany.[8]

Prior to the adoption of the GDNG, the difficulty of accessing health data compared to other countries was a hindrance and cost factor, and thus a decisive competitive disadvantage for German companies. The conclusion of industry today is therefore often to buy data from other regions of the world rather than work with German data. According to companies, this data is more structured and access is more predictable and therefore more cost-effective. However, this has the disadvantage that algorithms are trained with data that does not accurately reflect the reality of healthcare in Germany and potentially harming patients in Germany. There is also a risk that industry will relocate to regions with better data access, thus making Germany even less attractive as a location for innovation and business, instead of catching up internationally. Thus, the GDNG introduced the option to grant access to health data for specified purposes in the public interest in accordance with national law, including research and development, especially the training of AI algorithms used in the health sector.

Improvements are needed to fully exploit the benefits of health data

Addressing hurdles to data sharing

The workshop identified several issues that industry currently sees as limiting access to high-quality data. Overregulation and excessive caution in assessing the legal situation are cited as obstacles that currently impede data sharing. The quality of the available data also plays a role. If data is not collected and processed in a uniform manner, its use for research purposes is severely limited. Different standards and parameters for data collection, coupled with a variety of data providers, make it difficult to aggregate and evaluate health data for research purposes.

In contrast to the more centralized, state-controlled health systems in other European countries, Germany's healthcare system is decentralized and used by numerous health insurance companies and providers. Although a lot of patient data is available digitally, sharing and exchange is blocked by the fact that the respective systems cannot communicate directly with each other and use different data formats. As a result, digital data such as patient files are often analogized again, i.e. printed out, filed, and passed on manually instead of being communicated digitally.

Agreement on uniform data standards and easier access to data are suggested as necessary solutions. At the same time, improved cooperation is also needed on the part of patients and doctors, who ultimately must give their consent to the use of data and feed the data into the system in an appropriate quality and uniformity. Some even suggest that data protection concerns are sometimes used as a protective claim to postpone investments in infrastructure, changes to processes, and employee training. Good data collection is expensive. Reducing the costs of data access and providing appropriate resources for transforming business operations are essential steps forward.

Streamlining processes and responsibilities to be conducive to use

Lengthy processes make data use difficult

There are also obstacles in terms of regulating data use. The processes for enabling data use in Germany are still lengthy (6-9 months) and comparatively complicated, and contract negotiations are complex. Data requests frequently need to be submitted completely anew, even if they involve related data sets and the responsible authorities have already signalled openness and given their consent.

In this regard, Germany should "make a leap of faith and learn from abroad," as Dr. med. Stefan Kropff of Amgen GmbH emphasized. The United States in particular, but also countries such as Israel, Denmark, Finland, and Great Britain, have models that Germany should learn from for its future development.

Recommendations:

- *Create model contract clauses and templates for data usage and develop data protection guidelines to avoid reassessing each individual case*
- *More standardization in data anonymization processes*
- *Implement a central point for the allocation of usage rights and complete a 'data map' showing available data*
- *Enable data usage for multiple studies simultaneously*
- *Financial support for high-quality data collection*

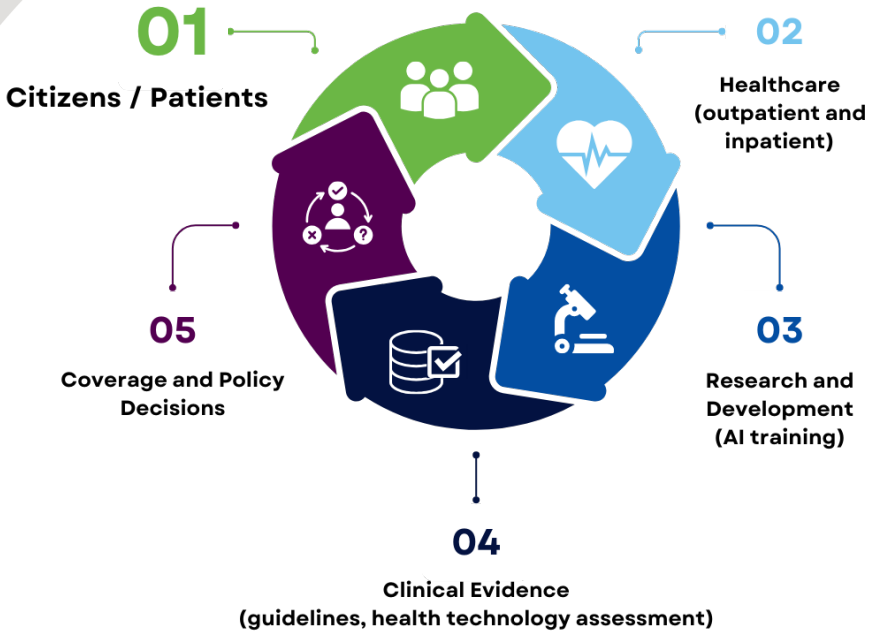

Figure 1: Data integrity – from collection to reimbursement

(adapted from Lennerz, Schneider & Lauterbach, 2024[9])

4. Digitalisation from the patient's perspective

Barriers hindering data sharing

Many patients have reservations about sharing their health data

In Germany, the unwillingness of many patients to share their health data is causing difficulties for the overall project of 'digitalization of the healthcare system'. While private data is published and distributed relatively freely, for instance in areas like sports, lifestyle, and wellness (including via social media), many people still have considerable reservations about health data, even in protected environments. This scepticism is fuelled by regular negative headlines and loud criticism, while serious information sharing, education, and skills development lag behind.

During the discussion, three key barriers that currently prevent patients from sharing their health data were identified:

- *Lack of knowledge:* Consumers have insufficient knowledge about which data is shared and how, and what happens to the data. Many do not even realize that a lot of private data from the area of sports or wellness is de facto health data that is readily shared with profit-oriented companies. There is insufficient knowledge about data security and the risks of conventional, analogue data processing, as well as the disadvantages of refusing to share and use data.
- *No tangible added value:* Improved treatment decisions based on data are often understandable advantages for seriously ill patients and those with chronic diseases, but very abstract for the broad mass of the population who currently enjoy good health. There is a lack of understanding that shared health data benefits other people and therefore ultimately everyone, and not just increases the profits of the healthcare sector.
- *Fears and loss of control:* Questions such as "What happens to my data? Can I revoke a data sharing consent? What will the pharmaceutical industry do with my data?" often remain unanswered or are associated with negative ideas.

Requirements for patients to provide their health data

Building trust through communication

For each of the three barriers, several approaches were identified that could help increase patients' willingness to share their health data. The lack of knowledge and resulting fears can be addressed with information and awareness campaigns. Overall, more educational work is needed, including educated and experienced 'ambassadors' who share positive examples from their own experiences. Various incentives could be created to increase the immediate added value of data sharing for patients. Awareness of the longer-term benefits, such as better treatment methods, can also be achieved through education, public relations, and effective storytelling.

The question was also raised as to who is best placed to communicate this information. Since there are major reservations in relation to politicians, health insurance companies, and industry, doctors as the primary sources of trust, along with NGOs and organisations such as patient representatives, are the most promising messengers of information and educational work. In this context, as Birgit Bauer from 'Data Saves Lives' in particular repeatedly emphasised, it is important not only to talk about patients and citizens, but above all to talk to them. Participatory formats such as public hackathons or public days at conferences or trade fairs and communication materials prepared by experts for laypeople in a targeted group-oriented manner and in understandable language are important tools.

> It is important to talk not just about patients and citizens, but with patients and citizens. Knowledge, information exchange and last, but not least, participation are the foundation of trust and are crucial for decisions to be understood and accepted.
>
> Birgit Bauer, Data Saves Lives Germany

Recommendations:

- *Improve and raise awareness about data security and the insecurity of traditional data storage systems*
- *Participatory formats and improved education and communication tailored to target groups*
- *Create incentive and reward systems for short-term added value and make long-term added value visible*
- *Train medical and care staff as trusted partners in implementation*

5. Data protection and patient safety viewed realistically

Perception and focus on risks to data protection and patient safety predominate in communication

Germany's traditional scepticism about data protection

When considering the topic of data protection and patient safety, the focus in the public discourse in Germany traditionally is on the risks rather than on opportunities and possibilities. Difficulties and setbacks in the development of the digital health system are immediately used as an opportunity to redirect communication and thus public perception to the risks. This was the case, for example, with the introduction of the electronic patient record (ePA), where the video authentication system was successfully hacked by the Chaos Computer Club (CCC), albeit in a 'friendly' way, to reveal security gaps.

To balance this discourse, the voices that emphasize the opportunities of digitalization must be strengthened. It is important to argue and explain things precisely. For example, the difference between data protection - i.e. the legal question of the conditions under which personal data may be collected, stored, and shared - and data security, i.e. the necessary technical measures to prevent unauthorized access to the data or misuse of data. Data security experts also pointed out in the discussion that a professional assessment is important when assessing the risk of data security, because centrally managed systems in particular need specific technical and organisational measures to avoid that attackers get access to large amounts of sensitive data at once.

It is also important in a discourse on data protection and patient safety to take different perspectives into account when evaluating, communicating, and developing approaches for further development, because the advantages and disadvantages are not equally distributed among all groups. The current (political) communication strategy is perceived as not sufficient to reach or convince all actors equally. It makes sense to talk about weaknesses and risks to encourage improvements, but the discussion is currently dominated by a few loud critics without listening to the patients profiting from better care. It would be more important to create awareness of the negative consequences if data is not shared and is therefore not available for patient care or for further developments in (especially healthcare related) research.

Priorities for implementation

Distinction between technical and legal solutions

Beyond the general perception, there are also concrete hurdles related to data protection and data security that stand in the way of further development. A distinction must be made between legal aspects, especially liability issues, and the technical dimension. Currently, liability questions are still debated. There are fears that doctors could be fully liable if data is intercepted or manipulated when being transferred to the ePA, even if all systems and processes comply with the valid specifications. It is also unclear what obligations doctors have when consulting well managed ePAs before treatment. Here electronic patient records could profit from technological developments, e. g. the use of large language models to extract relevant data from PDF files. Currently, patients are still urged not to blindly rely on the available data, but to actively exchange information with the treating doctors.

Inadequacies in the technical infrastructure also diminish the acceptance of digital solutions. This concerns the ease of filling and compatibility of technical systems for data exchange. Currently, there is no universal ePA system, but rather different storage systems that are managed by different statutory health insurance companies. The current legal situation allows a doctor to be sanctioned for not using interoperable systems. In contrast, however, the manufacturer and provider of software cannot be regulated in this regard. There are currently no incentives for business actors to substantially improve the situation. For example, providers of technical systems have no added value or market advantage from making their systems compatible and thus increasing the interoperability of the systems, because if data migration were easy, users could more easily switch to another provider. With the adoption of the Digital Act (DigiG) and the establishment of the Coordination Office for Interoperability in the Healthcare Sector (KOS), however, some important steps have been made in this area.

As long as the technical systems do not facilitate data sharing and ideally make it more straightforward, it will be difficult to overcome the still prevalent practice of analogue data transmission by fax and paper-based data exchange. The fact that analogue processes also represent questionable solutions in terms of security (e.g. when files are open and visible to everyone on counters of medical practices) is often ignored. Although there are financial incentives or support for doctors to fill out electronic patient records, these are so low that many doctors shy away from the work involved and do not invest in new systems or the time which is needed to fill in the data. Trust in an improved technical infrastructure for the ePA that offers more security than the previous one, as well as interoperability of the systems, would encourage users to use them consistently.

Recommendations:

- *Clarify liability and create incentives, including liability relief for doctors during the transition period*
- *Improve the technical infrastructure to ensure efficient data sharing and use*
- *Develop positive, consistent, target group-oriented communication to educate and inform*
- *Focus less on risks and more on the opportunities and positive experiences of digital health*

6. Case studies on digital health and care applications (DiGA and DiPA)

Two perspectives from the German implementation reality

Progress and obstacles to innovation

Germany has created a pioneering achievement in the European context: digital health applications (DiGA) and digital care applications (DiPA). These are officially recognized digital health and care applications that can be prescribed by doctors and psychotherapists in Germany and whose costs can be covered by statutory health insurance companies. So far only one other country, France, has implemented similar applications.

There are official directories for the registration of applications in both the health and care sectors. While the managing director of the umbrella association for digital health care (SVGDV), Dr. Anne Sophie Geier, reported on an increasing number of officially registered digital health applications and activation codes for patients, the situation on the digital platform with solutions for caregivers is much more difficult, according to Markus C. Müller - board member of the SVDGV. Not a single application has been approved there yet.

This discrepancy has been attributed to the stringent requirements in place for proving the benefits of care applications. In contrast to the medical sector, there are significantly fewer measurement instruments available, and studies that prove the connection between symptoms, interventions, and benefits are much more difficult to produce in the complex care situation. Unlike with digital health applications, there is not yet the option of a one-year trial period for the care applications. Proof of use must be fully provided at the moment of approval, which means that the risk lies entirely with the manufacturer of the application.

The way forward

Acceleration of processes and relaxation of requirements

The demand for digital therapy solutions is growing. With the improved options provided by approved apps and browser products, medical staff can be supported and relieved. However, further improvements are needed for the positive trend to continue. Patients turn away from digital solutions if access to them is not made more user-friendly, e.g. by reducing the long waiting times for the application to be activated by health insurance companies. At the same time, some service providers in the healthcare sector are still hesitant to use digital products because they see them as competition to their own work. According to Markus C. Müller, the approval of digital products by the Federal Institute for Drugs and Medical Devices (BfArM) is still too slow and limited, particularly in the care sector: "In care, it is not a matter of life or death, but of whether the situation will improve. And currently the situation in the care sector is so catastrophic that it can hardly get any worse."

Recommendations:

- *Approval of hybrid application models in healthcare to reduce the reservations of service providers and expand their treatment toolboxes*
- *Rethink exclusion criteria and high admission requirements, especially in the care sector*
- *More agile methods for assessing and approving software solutions*
- *Introduce a one-year trial period for care applications*

Conclusion of the event

Germany has laid a solid foundation in many respects, especially regarding the legal framework. This is continually being adapted and developed to support the collection, sharing, and use of health data within Germany, as well as in Europe and beyond. However, participants agreed that compared to other countries there is still a lot of catching up to do when it comes to the concrete implementation of the creation of a digitalized health system.

There is also a high degree of agreement regarding the analysis of current hurdles and necessary improvements. Key areas needing development are access to and the quality of structured health data, interoperability of systems, technical skills, and financial and human resources. Numerous solutions were identified in specialist discussions, and concrete strategies for improvement were formulated.

A central role in these efforts is assigned to communication and transparent information sharing. All actors – from policy makers to researchers, industry professionals, data protection experts, practitioners, and patient representatives – are called upon to further reduce reservations and fears, thereby achieving progress.

The aim of the event series "Think globally, act locally" is to provide a platform to highlight positive examples, exchange information and solutions, articulate and channel wishes, and provide support. Partners willing to act should be brought together to gain momentum for constructive further development. This approach aims not to ignore existing resistance, but to integrate it sensibly.

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2. Conflict of interest: There is no conflict of interest. EIT Health listens and respects all the opinions expressed during this roundtable session.

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Acknowledgements

On behalf of EIT Health, Medical Valley and Amgen, we thank all the event participants and team members for their contributions, without which this activity would not have been possible. Special thanks to our speakers: Bernhard Seidenath, MdL (Bavarian State Parliament), Nick Schneider (Federal Ministry of Health), Dr. Georg Münzenrieder (Bavarian State Ministry of Health, Care and Prevention), Anna Goldsworthy (Medical Valley), Stefanie Polat (Siemens Healthineers), Dr. med. Stefan Kropff (Amgen), Birgit Bauer (Data Saves Lives), Dr. med. Eimo Martens (Klinikum Rechts der Isar, TU Munich), Dr. Thomas Poeppe (AOK Bayern), Anna Wierzchowski (Wellster Healthtech Group), Dr. Anne Sophie Geier (German Digital Health Association) and Markus C. Müller (German Digital Health Association). Thank you also to our workshop captains for their enthusiasm, expertise and preparation: Dr. Johannes von Büren (Wellster Health Group), Oliver Ullrich (JustHealth), Dr. Yoni Goldwasser (Springboard Health Angels), Christian Hieronimi (Oncare), Sebastian Hilke & Joerg Traub (Bavaria Innovative Health) and Birgit Bauer (Data Saves Lives).

We would like to extend our gratitude to the incredible team of organisers that made this event possible: Marina Leonie Moskvina as our key organizer and moderator, Anna Goldsworthy, Dr. Bojan Ljepoja, Jakob Defer, and Dr. Kurt Höller as the core team of curators, Yvonne Dauer, Jona Schmitz, Kerstin Beres, Julian Geißendörfer as our Medical Valley onsite team and last but not least Stefanie Polat and Marie-Alix Ebner von Eschenbach as our hosts at Siemens Healthineers. Their exceptional coordination, hard work and passion brought this vision to life.

Big thanks also to Kathrin Hoeckel for collecting and consolidating the information to generate the present report.

We are also grateful for the support of the wider EIT Health community, especially Jean-Marc Bourez (CEO EIT Health e.V.), Cristina Chiotan (Head of Public Affairs and Stakeholder Relations EIT Health e.V.) and my contributing colleagues at EIT Health Germany-Switzerland, especially Dr. Lisa Walter, Elisa Bott, Regina Bach, Jiskia Reis, Marina Alzner and all other colleagues.

Munich, July 9, 2024

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Co-funded by the
European Union

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