acatech IMPULSE

Secure, Controlled Use of Health Data

Olaf Dössel, Thomas Lenarz (Eds.)

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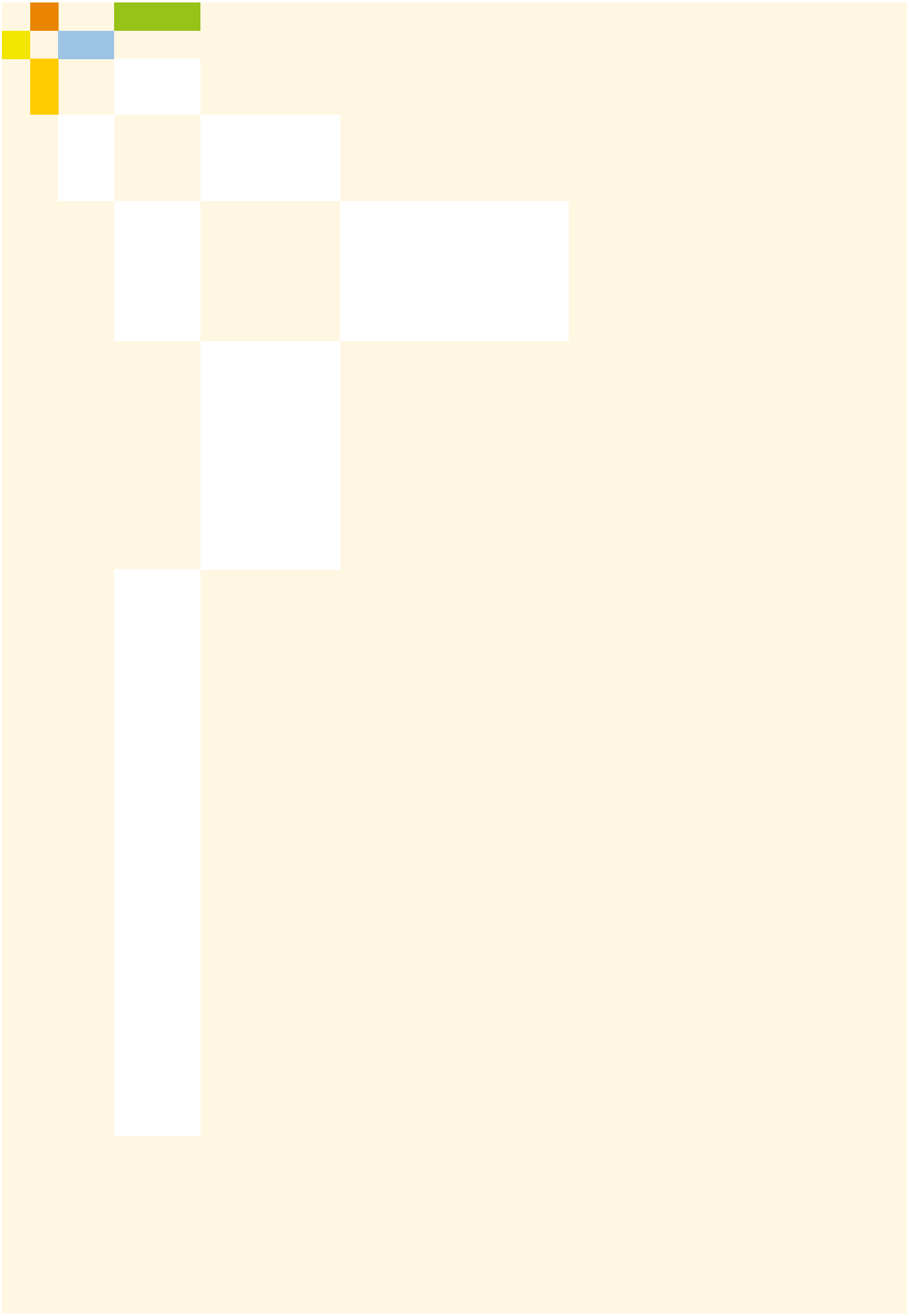
NATIONAL ACADEMY OF SCIENCE AND ENGINEERING



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The acatech IMPULSE series

This series comprises contributions to debates and thought-provoking papers on strategic engineering and technology policy issues. IMPULSE publications discuss policy options and are aimed at decision-makers in government, science and industry, as well as interested members of the general public. Responsibility for the contents of IMPULSE publications lies with their authors.

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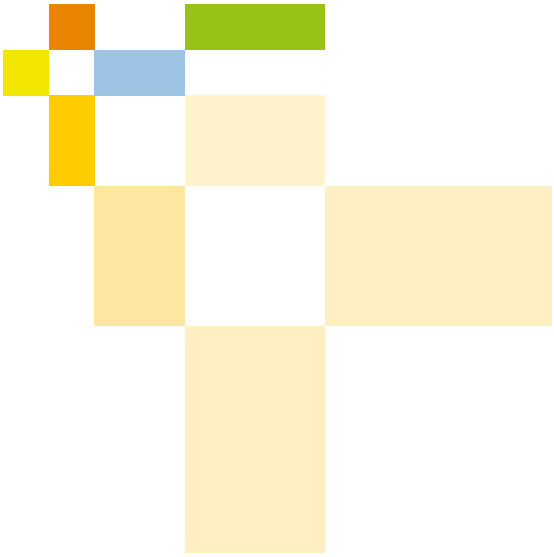


Foreword

Digitalisation in the German healthcare sector remains far short of the possibilities. There are numerous opportunities to improve the provision of healthcare in Germany and avoid unnecessary costs. Even today, how often is medical information that is already stored digitally printed out and passed from one doctor to the next? That information then has to be input into another computer system by qualified professionals – which results in a lot of lost time and may cause errors that could have an impact on diagnosis and treatment. Furthermore, although high numbers of people in Germany are treated for multiple conditions in parallel, all too often the doctors treating them are not aware of their full medical history. This leads to incorrect diagnoses and prescriptions for medications with problematic interactions. Improving the exchange of information and data would therefore enhance the quality of care and make the overall process more efficient. There is another key aspect to this picture: with vast amounts of health data available in digital form, there is an opportunity to use this data to gain new research insights. This, in turn, can lead to better prevention, diagnosis, treatment and care. In relation to prevention in particular, more effective data aggregation and analysis has the potential to yield insights that, in the case of certain diseases, could prevent people from becoming severely ill altogether.

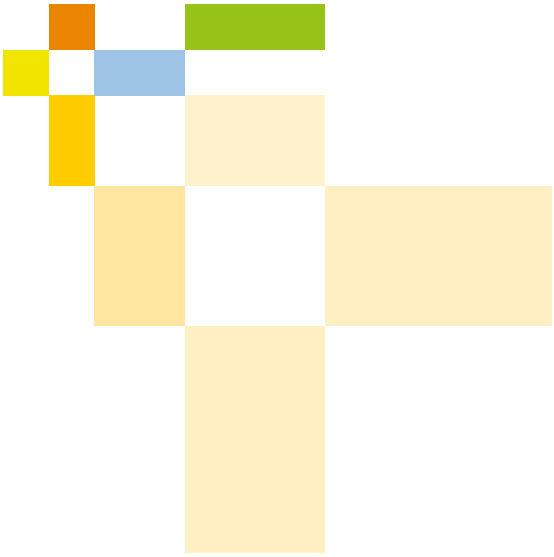
So, what is preventing us from pressing swiftly ahead with extensively digitalised healthcare? There reasons are wide-ranging, but let us introduce a handful. Our healthcare system is heavily segmented: into inpatient and outpatient care, health-related powers are reserved to the 16 federal states (Länder) and to "island kingdoms" beyond that, such as the division of responsibilities in municipalities. Successful digitalisation will require better coordination between these areas. Even when we set digitalisation aside, such coordination is long overdue. Moreover, the significance of the collected data is unrecognised in many quarters, which means that data quality to date has often been insufficient because datasets are incomplete or have not been documented in a standardised form. Health data is also very personal data in most cases that must be protected against unauthorised access as effectively as possible. The importance of the terms "anonymisation" and "pseudonymisation" has, however, not been defined with sufficient stridency for the healthcare sector.

While the tasks before us are difficult and multi-faceted, we are convinced that they can be accomplished. Alena Buyx, Chair of the German Ethics Council, recently emphasised how innovation in medical care could be accelerated: "In Germany, we have spent decades addressing the risks of data use and, unfortunately, have not spoken so much about the opportunities it presents. It is time for us to focus on how, while ensuring a responsible level of data protection, we can turn our attention to the opportunities and successes achieved by using data.[1]

This IMPULSE report was initiated by the acatech Healthcare Technologies topic network. It also includes input from experts in other fields and projects, from within acatech and beyond. It aims to analyse the advantages, opportunities and obstacles on the path to a digital healthcare sector, outline a vision for the future and propose measures to pave the way for this imagined future. This IMPULSE report is published at a time when the German federal government has announced legislative proposals with the aim of advancing the digitalisation of the healthcare sector – most notably the German Health Data Use Act (Gesundheitsdatennutzungsgesetz – GNDG) and an opt-out system for electronic patient records (elektronische Patientenakte – ePA) – and the European Union (EU) has published proposals for a European Health Data Space (EHDS). We hope to contribute to the objectification of this often emotionally charged discussion and highlight fields of action along with options for balancing the interests of different stakeholders. We want to leverage this wealth of data – for the good of everyone in society.

Prof. Dr. Olaf Dössel
Karlsruhe Institute of Technology, deputy spokesperson for the acatech Health Technologies topic network

1 | See bvitg 2023.



Summary and core messages

The advantages of data use in the healthcare sector are now so obvious that it would be negligent not to seize them. This IMPULSE report aims to drive progress towards the secure, controlled use of health data. It highlights opportunities, obstacles, points for discussion and fields of action, including the context of current legislative proposals in this area. This paper is primarily addressed to political decision-makers and aims to illustrate ways to leverage the wealth of data for the good of all patients.

Building on a review of the current healthcare system and an analysis of the existing hurdles and obstacles, we have identified fields of action in which the relevant stakeholders must play an active role:

Data sharing is of vital, fundamental importance for data use. In a system as complex as the healthcare sector, a binary either-or choice is insufficient. Instead, a graded, differentiated consent process is required to facilitate a system in which each individual's health data is handled in a controlled manner. Today, methods of obtaining highly granular consent on data use can be structured in ways that inform people relatively swiftly and effectively, such as using mobile telephones.

For data to be useful in medical care and in the context of research and development, ensuring sufficient **data quality** is essential. There is therefore an urgent need for uniform standards and formats.

All public and private stakeholders that collect health data should engage in the **provision of data** to shared health data spaces. Besides ensuring that data is published as extensively as possible, this also requires clear regulations to protect the intellectual property and thus the competitiveness of those involved. Furthermore, in addition to public research institutions such as university hospitals, companies in the pharmaceutical and medical technology industries should also be given access to this data in order to ensure that the results of research actually reach millions of patients.

In the interests of security, **data transfer** should take place in anonymised and aggregated form wherever possible. At the same time, in light of the data's potential medical value, it should also be possible to use pseudonymised and personalised data in certain circumstances. Institutions and companies that provide health data for general use should also be given better access to such data. The publication of data-based research results should be the rule.

In relation to **infrastructure and data security**, is it important to ensure that the collection, provision and sharing of data are systematically separated, i. e. based in different institutions, to prevent the misuse of data as far as possible. A basic requirement for this is faster, robust and secure infrastructure for health data; all stakeholders must be systematically integrated in development of this infrastructure, including in relation to high-quality user interfaces.

Data use should be in the interest of value-based healthcare, with a focus on preventive services and the expansion of telemedicine services. Additionally, there is a need for new metrics to facilitate comprehensive health assessments and integrate new services into healthcare provision..

Digital health literacy must be improved through **training and development** at all levels – from patients to medical and nursing staff to the press and other media. We urgently need additional, highly qualified IT experts for the healthcare sector, such as medical data scientists.

In addition to legitimate data protection concerns, **work to shape public opinion** on the topic of data use in the healthcare sector should also account for the potential benefits and stimulate public discourse on potential data protection measures and the added value of data use.

Innovation promotion on the basis of data use will require the implementation of uniform framework conditions at national and European levels to provide legal certainty. At the same time, data-driven approaches and potential new diagnostic and treatment methods, integrating AI for example, should be given equal weighting with conventional methods in approval processes.

Through automation and personalisation, digitalisation and data use are making it possible to create a sustainable, future-ready healthcare sector that puts patients front and centre and has a holistic view of health.

Project

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1 Current status of the healthcare system

The German healthcare system currently faces widespread problems that can be traced back to unavoidable external factors as well as regulatory shortcomings and negative effects of the existing incentive system. While German healthcare is still above average internationally, these factors could lead to a deterioration in care quality in future – in relation to individual services, including in international comparisons, and in terms of the fair distribution of these services.

The external factors fuelling this development in Germany are the results of demographic change: the German population is growing older and there is an increasing shortage of skilled workers. People increasingly require healthcare services as they grow older. Given the solidarity principle and the accumulation of age-related diseases, the increasing imbalance in the insurance pool's age structure is ultimately exerting growing financial pressure on the system.[2] In the future, this pressure will negatively impact treatment quality, either directly or indirectly, as service providers will have less time and/or financial resources to provide treatment and care. The problem is exacerbated by the shortage of skilled workers, which continues to worsen. The German healthcare and nursing sectors have experienced the most pronounced fall in the number of skilled workers – in terms of the absolute number of vacancies as well as vacancy rates for which no qualified, currently unemployed professionals are available.[3] Consequently, professionals currently in employment are overworked and forced to contend with ever-rising documentation requirements, which significantly reduces the effective time available to care for patients. A survey has shown that almost two-thirds of doctors expect the quality of care to deteriorate in coming years as a result of the shortage of skilled workers.[4]

The current incentive structure in the healthcare sector places a focus on curative treatment and the treatment of acute symptoms, rather than on prevention. However, this model lags behind both demographic and medical developments because our reality is increasingly influenced by diseases that, on the one hand, have complex pathogenesis and development, but on the other hand are increasingly well understood and manageable. Various external and personal factors affect pathogenesis over the course of years or even decades before diseases and disorders can be diagnosed or have an adverse effect on a person's life. This pertains in particular to cancer but also to cardiovascular diseases, which collectively accounted for around 56 per cent of registered deaths in Germany in 2021.[5] The same applies to neurodegenerative disorders, such as Alzheimer's disease, which is becoming increasingly prevalent as a result of population ageing while also creating high demand for nursing care. At the same time, given the often individual combination of etiopathogenic factors, it is increasingly clear that only personalised treatments have a realistic change of curing or preventing diseases. Supplementing evidence-based medicine on the basis of additional patient characteristics could provide considerable added value for the treatment – and thereby the quality of life – of the people affected, as small-scale studies have already demonstrated.[6]

Besides the dominant diseases and disorders, environmental conditions are also changing at present, due to climate change as well as lifestyle changes, such as increased urbanisation. The impacts of climate change include increased transmission of infectious diseases,[7] while the increase in environmental noise leads to an elevated risk of heart attacks.[8] Dynamic factors such as these therefore create additional complexity in determining pathogenesis and assessing etiopathogenic relationships.

Data use in the healthcare sector offers potential means of solving these problems. It can support service providers, such as the medical profession and nursing staff, with both medical and administrative tasks and reducing their workload in their day-to-day work; it can simplify administrative processes and thereby make them more cost-effective; big data technologies and artificial intelligence (AI) applications have the potential to deliver improved and newly developed diagnosis and treatment methods for all diseases and disorders, especially those with various, diffusely linked influencing factors. Viewed as a stress test, above all for the healthcare sector, the coronavirus pandemic highlighted problems in digitalisation, specifically in data provision and data use. For example, when it came to conducting scientific analyses of vaccine efficiency, Germany was reliant on case data from other countries. This ignorance about the current system weakens resilience in the healthcare sector

2 | See RKI 2015.
3 | See IW 2022.
4 | See MLP 2022.
5 | See Destatis 2017.
6 | See AOK 2023.
7 | See Mora 2022.
8 | See UBA 2016.

because then assumptions delay or interfere with responses in crisis situations.[9] However, even apart from that example, the problems are evident: in an international comparison, Germany is trailing considerably behind in the digitalisation of its healthcare sector.[10] This is reflected, for example, in the problems with integrating healthcare, which remains limited due to the lack of data continuity between outpatient and inpatient care.

Given the current data availability and data use situation, it is vital to adopt a more differentiated view of existing structures. Many hospitals already have structured, standardised datasets that could, for example, be analysed using AI. However, there are also healthcare institutions in which data is not standardised and, in some cases, is not even stored digitally. Consequently, some data is not accessible at all. The means of linking data within an institution's digital infrastructure are also lacking to date. While standardised interfaces for data transfer between different institutions exist, they are rarely used in practice, which has led to a segmented landscape of data silos within service providers as a group but also between other stakeholders in the healthcare structure. Data is generally only stored where it is collected, so the systematic retrieval and machine-based read-out of this data is only possible in certain circumstances.

Although data-intensive research questions can sometimes be explored using "federated learning", there is still considerable potential for expansion. Initiatives to promote standardised data collection have been launched, such as the 356 different health registers currently compiled in Germany (for example cancer register, implant register, etc.).[11] However, such initiatives are compartmentalized, not interconnected and only place a limited focus on ensuring the general usability of data. The use of individual and proprietary data formats and organisational structures impedes general interoperability and the flexible exchange of data.

The aspects of interoperability and standardisation currently are the subjects of several parallel initiatives in Germany, the most prominent being the *Medical Informatics Initiative (Medizin-information-Initiative – MII)*, the *Network of University Medicine (Netzwerk Universitätsmedizin – NUM)* and the *HEALTH-X dataLOFT* and *TEAM-X* projects led by Gaia-X. Other programmes, such as the *German National Research Data Infrastructure (NFDI)* for Personal Health Data (*NFDI4health*), also pursue similar objectives. Furthermore, private sector initiatives are already implementing decentralised, interoperable networking of large quantities of clinical data, pursuing a practical approach parallel to the initiatives named above. At the same time, all of these projects are based on the standardisation of health data in one form or another, with data use planned in line with the FAIR (findable, accessible, interoperable, reusable) principles. The data formats used in these systems needs to be interoperable and machine-readable by medical information objects (MIOs) – which is not the case for the commonly used PDF format. While MIOs are supposed to be established by the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung – KBV), so far the pace of implementation has been slow.

Since 2005, gematik GmbH has been implementing telematics infrastructure as the basis for networking actors in the healthcare sector. It is currently developing Telematics Infrastructure 2.0, a revised architecture to network all stakeholders in the healthcare sector. This includes end-to-end encryption – without physical connectors – and digital identities to improve the accessibility and user-friendliness of services. Also part of gematik is the Interop Council, an interdisciplinary expert committee tasked with advancing the integration of standards in the healthcare sector. While it is possible to point to significant progress, technical and structural problems persist – for example, in the use of electronic incapacity for work certificates (elektronische Arbeitsunfähigkeitsbescheinigung – eAU) and the electronic prescription (elektronisches Rezept).[12] Quite apart from the infrastructure, there is sometimes a lack of specialist expertise in the implementation of digitalisation measures in the healthcare sector, so that medical and IT/digital expertise are rarely interconnected. Furthermore, there is a shortage of training and development opportunities to obtain qualifications that are urgently needed (for example as a medical data scientist).

In addition to the technical and organisational barriers to data use in the healthcare sector and the utilisation of patient data, a further obstacle lies in the reluctance expressed by many patients. While a majority of the population (82 per cent) express a willingness to permit the use of anonymised health data on the basis of an ethical responsibility to ill people, this willingness is subject to individual consent.[13] Although patients have a positive opinion in principle of data sharing between hospitals and academic institutions, they are sceptical about the use of such data by the private

9 | See acatech 2021.
10 | See SVR 2021.
11 | See Wissenschaftsrat 2022.
12 | See Haserück 2022a.
13 | See TMF 2022.

sector. This is despite the fact that the private sector conducts the majority (two-thirds) of research and development work in the German healthcare sector and, given the tremendously costly licensing and approval procedures involved, is essential for the use of new medications and technical solutions.[14]

In 2021, the electronic patient record (ePA) was introduced in Germany as the basis for collating personal data and facilitating its utilisation (see info box). To date, however, less than one per cent of people with health insurance in Germany have begun to use the ePA. Studies of patients' attitudes towards the ePA show that a large proportion of the population has been insufficiently or incorrectly informed about it; there is also widespread doubt regarding the digitalisation of the healthcare sector in the near future.[15] In some cases, this leads to anxiety, which will require factual explanation and considerable persuasion to overcome.

Electronic patient record (ePA)

What is the ePA?
The ePA (elektronische Patientenakte) creates a database for each patient in which their medical history and treatment data, information about medications and other health-related data and documents, such as a maternity record and vaccine certificates, are stored across sectors and cases. This gives insured people access to all their health data. The fundamental availability of data for service providers also facilitates faster and better care when needed.

How is data collected and processed?
In principle, patients themselves determine which existing data is stored in the ePA and which data from their current treatment context should be input or deleted. Service providers therefore only have access to data where permitted by the patient. And, although they provide the ePA, health insurance providers do not have access to ePA data because it can only be accessed with an electronic medical data card (elektronische Gesundheitskarte – eGK).

What are the advantages of the ePA?
The ePA makes health-related information – such as details of a person's allergies, blood group, past treatments, pre-existing conditions and medical plans – more easily accessible for both patients and service providers. This promotes patient data sovereignty and, in many cases, also enhances treatment quality. It also makes it possible to improve the flow of information between different stakeholders in the healthcare sector, which in turn reduces the number of repeated examinations, lightens the administrative burden and avoids unnecessary costs in the healthcare sector. And, ultimately, a research-compatible ePA also facilitates the utilisation of this data for research and development.

What is the current situation with the ePA?
The ePA has been offered by health insurance providers since 01/01/2021. So far, insured people have had to actively apply to use the ePA and have it filled out. Less than one per cent of insured people use the ePA at present. There are various reasons for this lack of adoption, in particular the lack of knowledge about the ePA and ways to access it, and the currently complex set-up process. The decision to scrap the video identification method in the ePA set-up process has further hampered its accessibility. In the future, every insured people will automatically receive an ePA unless they actively object (opt-out system). This aims to ensure the ePA is rolled out across Germany by the end of 2024.

14 | See Destatis 2019.
15 | See acatech 2022.

Current legislative proposals for the European Health Data Space at the European level and the German Health Data Use Act (GDNG) and the German Digital Act (Digitalgesetz) at the national level represent important steps forward in promoting the usability of health data. On the one hand, these proposals must underpin patient sovereignty by providing clear regulations on the provision of data. On the other hand, they should create clear incentives for all stakeholders, i.e. the general public, service providers, scientific institutions and both public and private parts of the healthcare sector. Implementing nationwide regulations to ensure legal certainty should be a particular priority, while the substantive focus should be on generating and sharing high-quality health data.

The European Health Data Space aims to consolidate the use and sharing of health data in the European Union. This includes expanding and harmonising infrastructures and technologies to improve data quality and interoperability. Data could then by used across EU member states once appropriate administration structures have been defined. This data should be available to patients as well as to research, politics and business when subject to certain conditions. The European Commission's draft regulation therefore provides for primary use in the context of medical care as well as broadly defined secondary use of this data. All stakeholders, with the exception of micro-enterprises, will also be obligated to share health-related data. The Commission's draft relies on a very broad definition of health-related data. It includes real-world data from wellness apps on conventional smartphones and other portal devices (smartwatches, fitness trackers, etc.) that do not require certification as medical devices as well as information about factors known to influence health, such as homelessness, minimum income and employment status. The current version does not provide for patients to object to the transfer of their data.[16]

The Federal Ministry of Health (BMG) proposed a Health Data Use Act (GDNG) intended to regulate this issue at the national level in Germany as part of its Digitalisation Strategy for the healthcare sector. It includes establishing a central data access and coordination body to regulate access to research data based on the Health Data Lab (Forschungsdatenzentrum Gesundheit – FDZ Gesundheit) at the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte – BfArM). In the proposed legislation, for the first time the data would remain decentrally stored and made available through the use of research pseudonyms and accessible to industry. A decisive criterion in such applications would be the intended use of this data, not the identity of the applicant. As part of the proposed Digital Act also introduced by the BMG, the electronic patient records (ePA) system would also operate on an opt-out basis – with ePA data set to be made available for research purposes automatically via the Health Data Lab in the future. The proposed Health Data Use Act (GDNG) aims to establish the legal framework in Germany for the data-sharing opportunities opened up by the European Commission's proposed European Health Data Space – including the ability to conduct entirely virtual, decentralised clinical studies.[17]

These legislative proposals are based on a will and desire to share and use data while putting extensive safeguards in place to protect personal privacy. They clearly identify the value of data use for all stakeholders in the healthcare sector, as well as the opportunity to create scaling effects through EU-wide data sharing. Nevertheless, numerous areas of ambiguity remain in relation to the precise nature of data sharing arrangements and potential conflicts with existing laws.

In the face of demographic changes, and in a globalised world characterised by systemic competition, in future the healthcare system and the medical profession can and must rely more on technology-assisted medicine to better serve patient welfare. This applies above all to the use of health data, with technological solutions now capable of improving the efficiency of the existing system and making new approaches a reality. The advantages of data use in the healthcare sector are now so evident that it would be negligent not to utilise them. In this context, this IMPULSE report adds impetus to the movement towards the secure, controlled use of health data. The following sections highlight the opportunities, obstacles and fields of action in relation to these legislative proposals. This paper primarily is primarily addressed to political actors and aims to illustrate ways to utilise the existing wealth of data for the good of all patients.

1.1 Opportunities for the use of health data

Significant opportunities for data use in the health care sector are based on the vast quantity of data that is already available, and which continues to increase, as well as new and increasingly mature technologies to structure and standardise this data, thereby making it useful for AI and big data approaches. Using data thus opens the door to new diagnostic and treatment methods

16 | See European Commission 2022a.
17 | See BMG 2023.

and, in turn, to transform the healthcare system, shifting from its current focus on curative treatments to the intelligent prevention of disease, early intervention and individually targeted, precise medicine. All this would be a huge benefit for society. At the same time, significant cost savings could be achieved for society – and the collective body of people with statutory health insurance – if, instead of prescribing prolonged courses of treatment (which entails the costs of medication, medical staff and absence from work, etc.), the sector invested in early detection and prompt intervention. This vision foresees, for example, a system in which early detection in cancer diagnostics is improved to such an extent that patients can avoid highly debilitating chemotherapy.

The specific added value of preventive measures can already be identified in current examples, such as the mammography screening programme for early detection of breast cancer,[18] lung cancer screening for current and former smokers using low-dose computed tomography (LDCT) scans[19] and multiparametric magnetic resonance imaging (mpMRI) scans in prostate cancer screening.[20]; These early detection procedures increase the patients' chances of recovery and avoid the potential treatment costs for operations and protracted follow-up treatments. Data use can also eliminate the need for multiple examinations and unnecessary treatments in normal methods by more efficiently networking all parties involved in providing healthcare. This reduces the stress on patients and can accelerate the provision of healthcare services.

Great strides forward have been made in diagnostic and treatment methods in recent decades. These include new imaging technologies, such as molecular imaging, which are significantly improving our understanding of physiology and pathophysiology compared to morphological imaging technologies. A further example is personalised cancer treatment: two decades ago, systemic cancer treatments were mainly limited to chemotherapeutics. Today, immunological treatments are increasingly used to enable a patient's own natural defences to fight the cancer, while anti-angiogenic therapies block the blood supply to the tumour. Furthermore, in the field of adaptive radiotherapy, the algorithmic application of large quantities of data can now relieve the pressure on service providers when producing radiation treatment plans, to the extent that radiotherapy treatments can now be adjusted in response to physical changes or tumour regression as treatment progresses. A combination of minimally invasive surgery, precise radiotherapy and individualised chemotherapy can ultimately improve the precision of cancer treatments and alleviate their side effects.

Regardless of the type of disease, digitalisation lays the foundations for personalised medicine by facilitating the collection, collation, storage and analysis of large volumes of data. Patients therefore benefit from evidence-based treatment decisions that take all aspects of the affected person into account – from obvious intolerances to genetic predisposition to a higher chance of success with certain types of treatments. In addition to improving existing treatments through personalisation, extensive data availability presents considerable added value for research and development of new treatment methods.

It also facilitates new forms of (remote) diagnosis and communication. In the case of telemedicine, for example, this integrates the patient as an active participant in the treatment process: if, say, a person notices symptoms, they can use common technological devices (such as a laptop or smartphone with a microphone and camera) to facilitate a remote appointment in which the doctor either provides a diagnosis and prescribes treatment or refers the patient to a specialist practice or hospital. This method saves time and travel, which improves access to medical care for people in structurally weak areas or who have limited mobility while also reducing influxes into specialist practices and hospitals in line with infection protection rules, as occurred during the Covid-19 pandemic. In many cases, this type of care facilitates faster diagnosis and thereby enables more targeted, efficient interventions with better recovery prospects. Furthermore, the networked use of data by means of increased automation and decentralised studies also allows for the effective, economically viable development of diagnostic and treatment methods for rare diseases. In general, this creates further opportunities to record treatment results through data-driven analysis, leading to a broader evidence basis and increased availability to patients.

Digitalisation and data use offer significant opportunities to introduce automation and thereby relieve pressure on day-to-day operations for all stakeholders in the healthcare system, first and foremost for service providers. This relates to all aspects of healthcare, from conducting laboratory tests to preparing diagnoses, producing documentation and completing administrative tasks. Data-based and networked systems can perform or provide support with routine tasks, enabling staff to devote their time – which is often at a premium – to patient contact once again, purposefully applying their specialist knowledge in providing treatment. The networked use of data in medicine also enables more effective dissemination of specialist knowledge by making it directly accessible to all stakeholders for specific applications.

18 | See KOG Mammographie 2020.
19 | See EUnetHTA 2020.
20 | See European Commission 2022b.

Example: Dementia diseases

According to figures from the Federal Statistical Office (Statistisches Bundesamt), almost 1.8 million people in Germany had dementia at the end of 2021, the most common form being Alzheimer's. This figure is also rising sharply. If there is no breakthrough in prevention or treatment, current estimates suggest that up to 2.8 million people in Germany could be affected by the illness by 2050. Dementia involves a progressive deterioration in a person's mental, emotional and physical capabilities. It places an enormous strain on patients, as well as on the relatives caring for them, care institutions, health systems and economies. The German Centre for Neurodegenerative Diseases (Deutsches Zentrum für Neurodegenerative Erkrankungen – DZNE), puts the total costs of dementia to society as a whole in Germany in 2020 at 83 billion euro – more than 2 per cent of the country's gross domestic product. The costs could rise to roughly 141 billion euro by 2040 and around 195 billion euro by 2060.[21]

Despite intensive research, the cause of the illness is still not understood in detail. Advances in digital technologies offer significant potential to advance research into dementias – in terms of prevention, ways to manage the illness and new treatment methods. Many research activities are focused on early-detection tests. Biomarkers in particular could be an important component in tests to diagnose dementia at an earlier staff and thereby positively influence the often decades-long course of the illness. The identification of such biomarkers and relevant lifestyle factors to improve the course of the illness requires analysis of large amounts of data. Using new analysis methods (such as big data analysis and artificial intelligence) and making health data available across the board could be a substantial help to scientists in their search.

The current lack of effective treatments for dementia means that prevention of such illnesses plays a major role. In a study by the International Commission on Dementia Prevention, analysis of large volumes of data showed that, in addition to genetic factors and unavoidable causes, there are also risk factors for dementia that can be influenced.[22] The study identified twelve lifestyle-related factors that can increase the risk of developing dementia. The example of dementia shows the scale of the challenges posed by diffuse syndromes, but also the huge potential that data use offers in the healthcare sector, specifically for such syndromes. Even today, using large volumes of data makes it possible to detect illnesses earlier and facilitates improved, personalised prevention.

The data-based automation of numerous processes in the healthcare sector is helping to secure broad medical care and establish a health economy that is socially appropriate and efficient in equal measure. In particular, this will only be possible if we can implement the concept of personalised medicine through comprehensive digitalisation and automation. At the political level, a broader and more up-to-date data base can also improve the collection and planning of healthcare provision in society as a whole. Expanding the healthcare sector with digital technologies also opens up an avenue for economic growth, primarily in relation to the medical technology industry, which is already strong in Germany.

1.2 Obstacles and challenges to data use

The political will to use health data clearly exists, as digitalisation strategy, initiatives and various regulatory proposals at the European and German level demonstrate. At the same time, there are still several obstacles that, given the complexity of the healthcare sector and the numerous stakeholders involved, relate to many different dimensions. It is therefore vital to give due consideration to practical, technical, ethical, societal, cultural and economic aspects. We will outline these aspects briefly here and discuss them with reference to different stakeholders' interests in Chapter 3.

The technical infrastructure required to ensure secure and stable networking of all stakeholders in the healthcare sector and, by extension, inter-institutional data availability, is still fundamentally

21 | See DAlzG 2022.
22 | See Livingston 2020.

lacking at present. This is due, at least in part, to the lack of incentives to digitalise the German healthcare sector, which is a precondition for the extensive infrastructural investments needed. Existing data processing systems experience recurrent faults (connection problems, transmission errors, etc.), connectors are missing in some places and often have limited transmission capacity. Furthermore, there are still no national guidelines on standardised security protocols or transmission formats, despite these being fundamental to interoperability. In this context, the Health Data Lab (FDZ Gesundheit) at the Federal Institute for Drugs and Medical Devices (BfArM) should draw up an information technology security concept, although no such concept has been produced to date.

Although stakeholders in the healthcare sector have already found some structured and interoperable applications that facilitate data use, they often still rely on heterogeneous software solutions and incompatible operating structures. There is also a lack of open interfaces in information systems as well as a shortage of data formats that can be processed across federal states and institutions. With regard to the standardisation of data formats in a medical context, concepts and practical examples of interoperable solutions have already been produced. They include the DICOM format for medical images, the Clinical Document Architecture (CDA) for text-based clinical documents and the Anatomical Therapeutic Chemical (ATC) classification system for medicines. The Systematised Nomenclature of Medicine Clinical Terms (SNOMED) has also been developed for medical terminology, while Health Level 7 has produced models for medical laboratory observations (Logical Observation Identifiers Names and Codes – LOINC) and administrative classification.[23] Nevertheless, there are still various areas in which data exists in non-standardised, non-interoperable form, such as electrocardiography and electroencephalography data, which are often still transmitted in PDF format. Although, as noted previously, there are efforts to establish medical information objects (MIOs), this process must move faster and adopt an international focus in the future. Data sharing between institutions and across federal states in Germany is problematic from a legal perspective due to the fragmented interpretation of the EU General Data Protection Regulation (GDPR) in different states. Although European data protection regulations are supposed to be standardised, different federal states still rely on different interpretations and somewhat restrictive handling of data under the supervision of data protection officers. Data protection regulations at the European and national level – which are progressive compared to other such regulations internationally – potentially represent a good foundation for data use in the healthcare sector. The GDPR and the German Federal Data Protection Act (Bundesdatenschutzgesetz – BDSG) define explicit exceptions that permit the processing of health data, including the use of personalised data for research purposes without consent. Pursuant to Section 27 BDSG, the research interests must substantially outweigh those of the data subject and appropriate technical and organisational measures must be taken to safeguard the data.[24]

Although, from a technical perspective, the sharing and use of data presents an opportunity to improve efficiency in almost all medical care processes, among service providers there remains widespread scepticism as to whether technical optimisations will actually provide relief in their day-to-day operations. This is primarily due to experiences with existing systems, some of which are cumbersome in practice, and the prospect of additional tasks that cannot be refinanced. Doctors often complain about the significant amount of time they spend documenting their activities. They fear that this will increase even further as a result of digitalisation. However, good documentation is an essential requirement for high-quality, data-based medicine. Training staff to use new digital applications also takes time. And, ultimately, critical voices also point to the already conceivable shortage of skilled professionals for the interface between medicine and informatics, who will be needed to implement and maintain interoperable systems for using data in the healthcare sector.[25]

Data quality must be ensured for digitalisation to actually deliver added value. Structured, high-quality data is a precondition for effective data use. Although this exists in the current system, this high quality standard is not consistently and does not apply to all data types. A lot of data has to be thoroughly prepared and structured before it is utilised in order to achieve the requisite data quality. Above all, data quality must be ensured so that AI-based analysis can achieve improvements in treatment and diagnostic methods. Otherwise, if the data is not of sufficient quality, machine analysis will propagate misconceptions. Insufficient source data quality cannot be offset by using large quantities of data. There is also the risk that, despite the large quantities of data available, the number of people who are actually available for specific research questions remains small, meaning that the added value remains relatively small.[26]

23 | See TAB 2022.
24 | See Dierks 2019.
25 | See WHO 2023.
26 | See Bundesärztekammer 2023.

The completeness and quality of data depends above all on the willingness of patients to share their data, which balances individual data sovereignty against the data's value to the collective body of the insured. At the same time, the complete provision of personal data – ideally on a voluntary basis in the interest of patient sovereignty – can only work if the security of this data is guaranteed. As yet, it is not clear to what extent this provision of data would be implemented with pseudonymisation or anonymisation using existing technological methods.[27]

Due to its sensitive nature, health data is a tempting target for hackers, which has led to attacks on IT structures at German university hospitals – even though, as part of the country's critical infrastructure, their data's security is supported by the Federal Office for Data Security (Bundesamt für Sicherheit in der Informationstechnik – BSI).[28] Data is stored in encrypted form, making it potentially unusable to hackers. It is important to note, however, that the aim of cyberattacks is to extort money from the data owner/administrator. Decrypting the original data – to invade the affected patients' privacy, for example – is almost never the aim of such attacks.

In addition to the problem of insufficiently secured access to data, in terms of the pseudonymisation and (partial) anonymisation of data, the problem of re-identification and de-anonymisation has not yet been solved. Due to the wide-ranging data available in other sources, it is possible re-identify a person – not only for very specific, rare diseases but also for very general clinical patterns, as examples from research projects have demonstrated.[29, 30] In this context, it is also unclear at what point health data is considered anonymous from a legal perspective. No legal definition has been produced to date to determine the conditions under which minimised health datasets would be considered anonymised. At present, the possibility of using synthetic datasets for research purposes is also being explored as an alternative to anonymised datasets, though it is not currently possible to ascertain whether this would provide comparable added value.

Due to existing concerns, data security in Germany is often achieved by implementing restrictive access across the board, which inherently inhibits effective data use. Despite the public's willingness in principle to share data, a culture of wariness remains prevalent in Germany when it comes to people making their data available for use. The discussion focuses more on the potential dangers than on the achievable benefits and opportunities. The dangers and disadvantages of not using this data are also afforded little consideration in public discourse. There are also fears that the digitalisation and technologisation of healthcare could lead to a feeling of alienation between service providers and patients, to the effect that, in future, a consultation appointment might revolve around data-related content more than the patient's actual state of health. Against this backdrop, scepticism towards data-driven and even evidence-based medicine persists in parts of the population. This is due on the one hand to insufficient acceptance of technology and, on the other hand, to the desire for trust in personal treatment instead of being subjected to an objective, technocratic decision. Consequently, patients often remain unclear as to the personal benefits of sharing their data.

It is also important not to underestimate economic obstacles to digitalisation projects. Today, stakeholders work with different target systems that impede the simple, multilateral opening of access routes to data and databases. The desire to protect vested rights in outpatient and inpatient medicine has therefore blocked the introduction of electronic patient records in Germany for many years, as the potential loss of earnings and absorption of costs arising from the creation and management of these records had not been clearly defined.

Our analysis to this point has highlighted current problems in the German healthcare sector and illustrated how data use can help to solve them. It has also pinpointed central challenges in relation to data use. Building on this, Chapter 2 sketches out a vision for a future, digital healthcare system that has the patient at its heart and uses data to facilitate the best possible healthcare. Based on this vision, and on the basis of the aforementioned legislative proposals at the European and national level, fundamental fields of action will become clear in relation to data use. Chapter 3 compares these fields of action in relation to the interests of all relevant stakeholders. These include, above all, patients as well as scientific institutions, private and public stakeholders in the health economy, service providers and the collective body of the insured.

27 | See Die Zeit 2023.
28 | See BSI 2020.
29 | See Sweeney 2015.
30 | See Schröder 2022.

2 Vision

Against the backdrop of these problems in the healthcare sector, and in view of the technological development relating to the sharing and use of data, the healthcare system requires a new direction, a paradigm shift – moving away from the principle of curative treatment of manifested disease and towards prevention within the framework of value-based healthcare. This involves using digital tools to redefine prevention, diagnosis and treatment success, based on a person's individual profile. Rather than continuing to divide people into two categories, healthy and ill, it means ensuring and improving their well-being. In the future, therefore, medical care should be made up of connected components of outpatient, digital and inpatient care.

It will require more comprehensive evaluation of a person's state of health and closer networking of service providers and health insurance providers, with patients in control at the centre of the new structure. This will be possible in a digital health ecosystem that facilitates the exchange and use of relevant health information. Creating a European framework for data collection, data evaluation and data protection should be the aspiration. Networking health data across international borders presents opportunities for better treatment and prevention services on a broader data basis while also strengthening Europe both as a location for business and in terms of the resilience of its healthcare system. Building on this data basis, the German healthcare system should evolve into a learning system that not only creates an enhanced structure of healthcare provision but also promotes the development of new strategies, specifically in relation to prevention and follow-up care. At the same time, this data can support control and research activities in shaping health policy, thereby facilitating a forward-looking, evidence-based legislative approach guided by current, actual needs rather than being forced to adopt a cautious, reactive approach. This concerns aspects such as planning treatment capacities and the targeted promotion of preventive measures based on measurable treatment successes.

Digitalisation lays the foundations for process automation in service providers' everyday operations, including in relation to data collection and data transfer. For example, doctors in hospitals currently spend 44 per cent of their working hours working on documentation.[31] Digital systems – including AI-assisted systems – can help doctors to produce documentation faster, more comprehensively and without errors. Digitalisation and automation help to reduce bureaucracy and simplify processes in order to relieve the pressure on service providers and enable them to create more time for patient-related work, which ultimately has a positive impact on the quality of care. In fact, the lack of time for patients is currently one of the leading criticisms levelled at medical care.[32] Digital systems and AI-based technologies can therefore also help to counter the aforementioned shortage of skilled professionals in the healthcare sector and mitigate the expected increase in patient numbers due to demographic change.

However, in addition to becoming more digital, medical care also needs to become more personalised. For instance, individual circumstances must be given more consideration in diagnosis and treatment in order to achieve maximum added value for each patient in the interest of value-based healthcare. On the basis of genome profiles, preventive measures can also be increasingly integrated into healthcare provision, with treatments such as mRNA-based cancer treatments and immunotherapy tailored to the patient's individual profile.

In this context, it is important to consider potential conflicts between technologisation and the core aspect of healthcare: the relationship between the service provider and the patient. The use of technologies is not intended to render the provision of medical care by a doctor superfluous, nor should machine-assisted decisions deprive patients of their right to choose. On the contrary, technologisation creates more space for this relationship and thereby facilitates better care. Indeed, data-based medicine should help specialists to make the right decisions faster. However, doctors and, where appropriate, patients retain responsibility for the medical treatment itself and all medical decisions, while constant quality controls should be carried out in the form of scientific monitoring. The expanded use of data in the healthcare sector entails new roles for service providers and data subjects. Patients will take on a more active role as controllers of their data; easy access to their own health data will be decisive for patients who wish to make informed, autonomous decisions. At the same time, in addition to their medical role, doctors will also have a technological role to play in future, as they will be required to assess novel digital or digitally assisted treatment methods and integrate them sensibly into a patient's course of treatment. This concerns, for example, AI-based support in diagnostic decision-making, for which doctors must understand the basics of how AI models operate. As in the case of patients, this will also require improved health and technology competencies in the medical professional in order to make meaningful use of the additional technological opportunities.

31 | See ÄrzteZeitung 2015.
32 | See PWC 2023.

Furthermore, enhanced administrative structures could also accelerate the spread of innovative technologies in an increasingly digitalised healthcare ecosystem. If applied across the board, new services, such as telemedicine, would level out the currently prevalent inequality in medical care provision between urban and rural areas. While the disconnect between outpatient and inpatient care currently leads to problems, consistent data structures could also create integrated medical care pathways. Furthermore, a healthcare sector based on high-quality personal data would allow for faster, more suitable service provision with a consistent quality of care across the board. It could also help to reduce premature mortality in Germany and, with the help of the prevention paradigm, improve quality of life by identifying complications and risk factors at an earlier stage and minimising radiation exposure in corresponding treatments. This would lead to lower costs for the collective body of the insured, as early interventions could avoid the need for cost-intensive treatments. As for service providers, it would reduce their documentation-related workload and lower the risk of malpractice, while giving them more time to actually care for the patient. This would also relieve the burden on caregivers and family members.[33]

Thanks to a range of examples, we are already able to identify the benefits of a digitalised healthcare system that makes extensive use of data, while existing digitalisation and data use initiatives demonstrate the feasibility of this vision. The German Portal for Medical Research Data (Deutsche Forschungsdatenportal für Gesundheit – FDPG) established by the *Medical Informatics Initiative* (MII) currently contains basic data on more than 7.6 million patient hospital stays and making this data available for the MII's medical research. This data is already structured in line with the international HL7 FHIR standard and the research projects underway using this data are accessible to patients.[34] Today, vast quantities of data already exist in hospitals and health registers, with some of this data also in use as part of data-based healthcare. In addition, the German Institute for Drug Use Evaluation (Deutsche Arzneiprüfungsinstitut – DAPI) collects 600 million datasets made up of individual prescriptions each year. All these examples demonstrate the wealth of available data that can be made usable with existing technologies.

The introduction and integration of digital health applications (German: digitale Gesundheitsanwendungen – DiGA) into the healthcare system since 2019 also shows that such services can be incorporated into the existing healthcare landscape because, just like conventional medical devices, they offer medical benefits. The Martini-Klinik in Hamburg, for example, has demonstrated the added value of using large-scale medical datasets. It maintains the world's most extensive database for patients with prostate cancer – and stays in contact with patients for several years after their operation in order to gain insights into patients' quality of life. By pursuing this value based, data-based approach, the clinic achieves significantly better outcomes in comparison to other German clinics in terms of the long-term effects of surgery, and thereby achieves enhanced quality of life for its patients.[35] This example therefore also shows that digitalising the healthcare sector is possible and creates tangible added value.

33 | See BMG 2023.
34 | See TMF 2023.
35 | See Martini-Klinik 2023.

3 Fields of action

Based on the vision presented above, this next step considers the central fields of action in the use of health data, with reference to both necessary measures and potential dilemmas. We will first define the data and its usages that are relevant in this context by looking at three dimensions: purpose of collection, personalisation and usage type. In terms of the purpose of collection, we distinguish between two types of data in the healthcare sector, namely medical and administrative data. Medical data, also referred to as primary data, is generated by treatments, in diagnoses by resident and clinically active doctors, in clinical studies and in the use of health applications, such as wellness apps. This data contains specific information about patients' state of health. By contrast, administrative data relates to billing for medical services, quality assurance, the planning and progression of medical care and epidemiological observations. It can be personal or non-personalised data. Personalised data is explicitly associated with a data subject and makes it possible to identify them. Non-personalised data does not provide any indication of the data subject's identity and is generated by processing originally personalised data by means of pseudonymisation, anonymisation and aggregation.[36] This relates above all to data on healthcare provision, which is typically transmitted in aggregated form or only pertains to specific characteristics – and, in both cases, does not make it possible to identify individual patients. In addition to these types of health data, there is a further distinction in relation to data usage, namely between primary and secondary use (see Figure 1).[37]

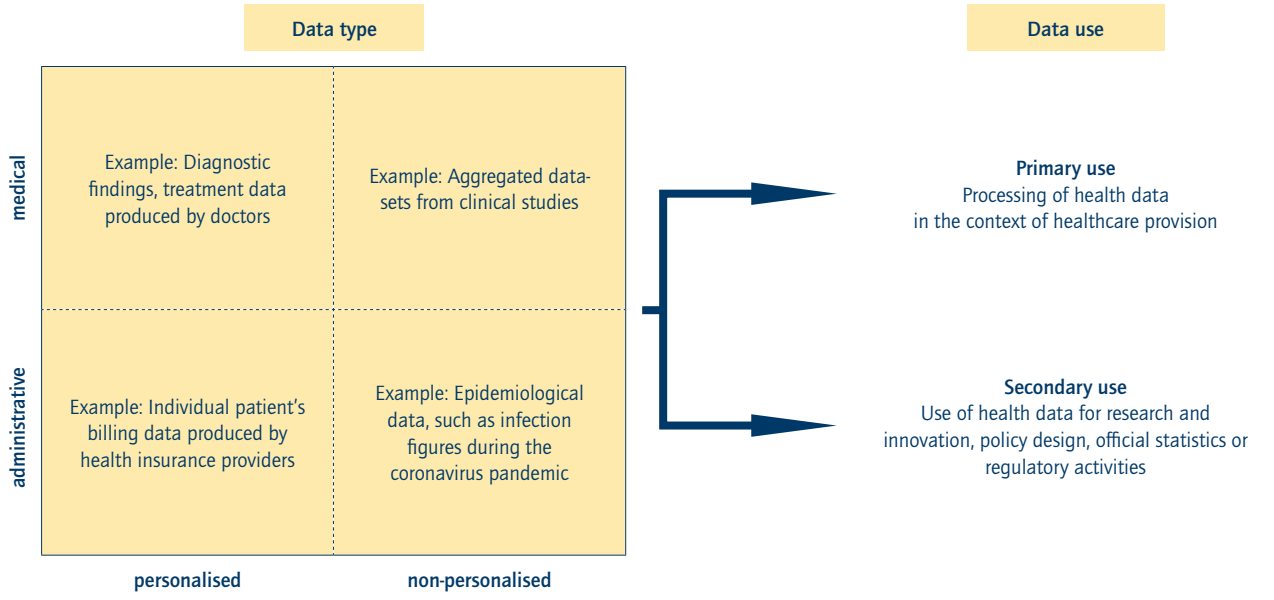

Figure 1: Schematic categorisation of different health data and usage types (source: own presentation)

36 | See Initiative D21 2022.
37 | See TAB 2022.

The collection of personalised data and its primary use is the core of data use in the healthcare sector. However, non-personalised data is also already in use under existing legislation, such as secondary use in health authorities to assess healthcare quality or as the basis for epidemiological controls. Non-personalised datasets in anonymised and aggregated form are sufficient for these purposes. The use of non-personalised data as a secondary use in research and innovation is already possible theoretically within current legal frameworks, provided that anonymity within a dataset is ensured. However, the infrastructure required to facilitate this is not yet in place. This form of data usage typically only occurs in university hospitals where the hospitals themselves already collect this data in the course of primary use, meaning that this data is already within their digital infrastructure. This silo usage is also associated with the fact that legal opinions have stated that it is practically impossible to anonymise the health data of living people because, due to the ongoing nature of healthcare, there will always be a key to their re-identification somewhere. Consequently, the notion of anonymisation has not yet been legally clarified. The current legal situation does not allow for the secondary use of personalised data. The discussion points in the following and in Chapter 3 primarily focus on questions concerning the secondary use of health data. How can these secondary uses be implemented? What framework should be established to facilitate them?

The starting point for the following deliberations on creation of a legal framework/organisation of data used in the healthcare sector is a differentiated balancing of interests between patient well-being, the collective body of the insured, science and business. In an effort to provide guidelines for the political decision-making process, this IMPULSE report primarily aims to highlight relevant issues of data use and discuss them from a technological perspective. It strives to focus on the benefits for all stakeholders in order to shift the public discourse, which currently concentrates above all on data protection, limitations and concerns, towards the wealth of available data and different ways to use it. This serves to find a secure, controlled, pan-European approach to data use. The complexity in the question of the correct way to handle health data lies in the fact it must always deal with the inherent conflict between the personal nature of this data and the overall societal interest in improving general health. In this context, an individual's fundamental right to informational self-determination (German: informationelle Selbstbestimmung) is in opposition to their entitlement to health protection and the state's duty to protect and keep citizens safe; neither has priority, so it is vital to find an optimal balance between these interests in support of the greater good.[38]

Figure 2 provides a schematic depiction of the flow of data, from creation through to usage. Starting with the patient, the first question that arises is the form in which data should be shared to assert the principles of patient sovereignty and informational self-determination while also ensuring the requisite level of data availability for general health protection. A similarly tricky balancing act relates to the scope of data collection and the corresponding quality assurance measures required to create added value in healthcare provision. The services providers in Figure 2 represent all stakeholders and institutions that collect health data, though it remains unclear exactly who would be required to provide data and under what conditions. The same applies to the form of data transfer, i.e. the question of whether the use of aggregated, anonymised datasets should be restricted in the interest of data security, and whether the use of pseudonymised and even personalised data should be permitted in view of the associated medical value. And, finally, there is the issue of the underlying infrastructure, i.e. whether the bodies involved in the data sharing and provision process (data pseudonymisation, collection and sharing as well as information platforms), should be privately and/or publicly organised, and centralised or decentralised. Data use may also give rise to potentially competition-relevant and publication-relevant intellectual property that must be protected depending on the nature of the user (for example public research institution or industrial healthcare industry). As yet, it remains unclear how such protection can be ensured in a system that facilitates mutual data sharing.

38 | See Haserück 2022b.

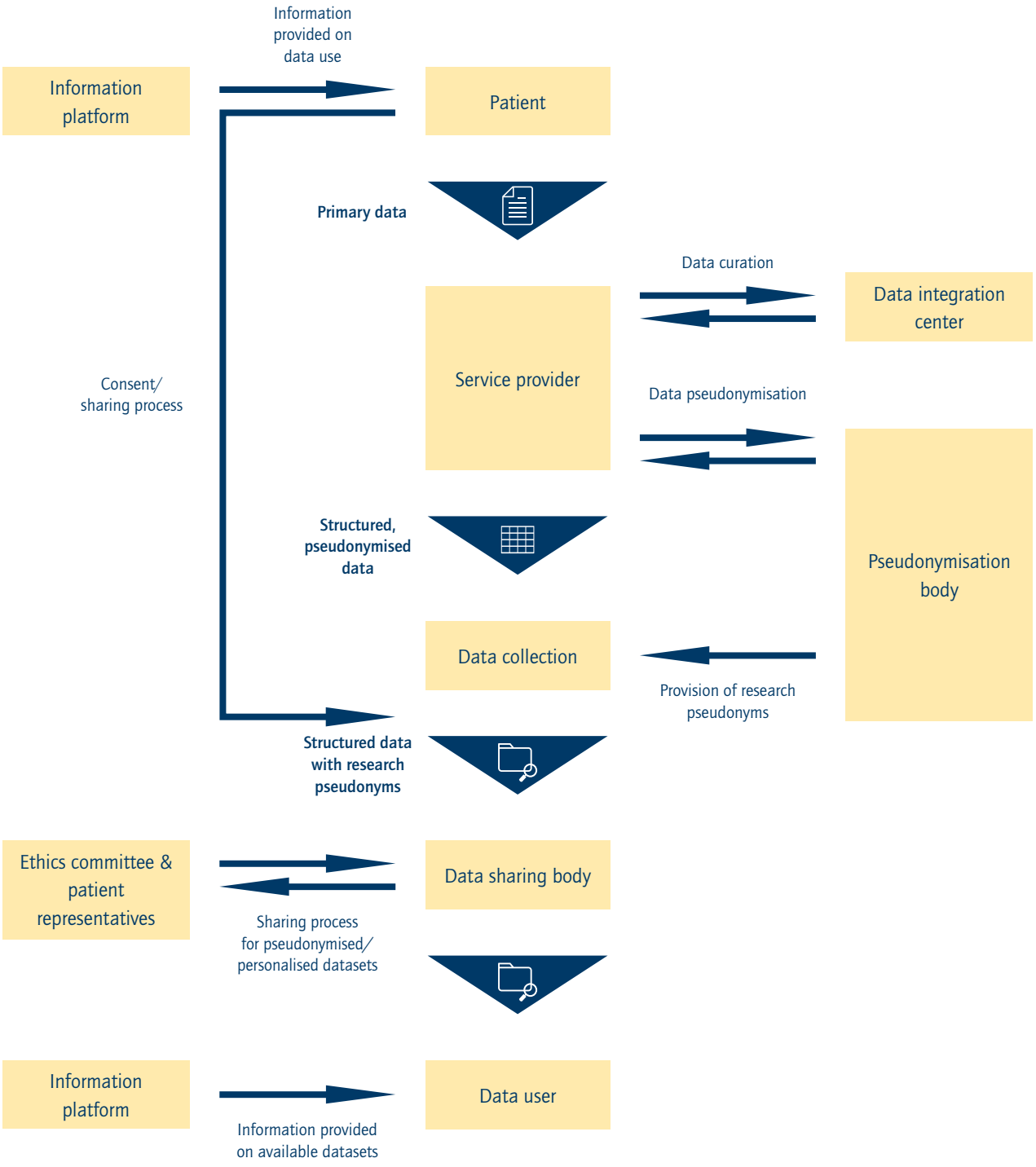

Figure 2: Schematic overview of the data provision and data sharing process in the context of a data sharing architecture. The flow of data runs from the patient to the data user; there are different approaches to data sharing, as compared in Chapter 3.1. This process involves curating, standardising and pseudonymising data for use. At the same time, patients receive information about data use, while the user receives information about the available datasets (source: own presentation).

3.1 Data sharing

A system for sharing health data has patients at its heart. Digitalisation measures are intended to enhance patient well-being and thereby improve public health. This requirement is the core of data use and thereby decouples the intended use of data from the party requesting it, which should also make it possible to integrate the private sector into this use of data. Citizens should be able to handle their data in an informed, controlled way, which requires a transparent system and clear communication so that each individual can access their data and be informed of how their data is used and by whom. The EHDS aims to achieve this through the MyHealth@EU portal. There is also a need for low-threshold methods of sourcing information about how to withdraw consent and restrict the use of data, for example once studies have been completed. In this context, electronic health records (elektronische Patientenakte – ePA) and the information portal could be linked to avoid duplicated structures and give the public standardised access to their health data as well as information about its use. It is also important to note that the decision to share data, or to withdraw this data, must be detached from the provision of treatment to avoid influencing patients' decisions. Specifically, patients must not be given the impression that the quality of the treatment they receive is dependent on their willingness to provide data.

In terms of data sharing, there are different models already in use in different contexts. In terms of the solutions currently under discussion, a distinction is drawn between: an opt-in solution with specific consent; an opt-in solution with different, granular degrees of consent in the form of meta consent; broad consent, and an opt-out solution. Starting from the vision of a sovereign individual who manages their data in an informed, autonomous manner, individual use-related consent to the sharing of individual data packets would be the preferred option. Such a solution would also comply with current data protection regulations. It means that data can generally only be disclosed and used by others with the informed consent of the data subject (specific consent), unless permitted for reasons of public interest; the GDPR specifically provides that health data may ordinarily only be processed for reasons to which the individual has given their explicit consent.[39]

In this context, a survey has found that a majority of the population (82 per cent) would be fundamentally willing to share their data based on a sense of ethical responsibility to ill people, which suggests that this consent model would achieve a high participation rate. The electronic health records system has operated in Germany using an opt-in model to date, but has made few inroads. This is also due in large part to a lack of awareness, as the ePA was not actively advertised and remains under development; it also still fundamentally requires the patient to fill in and use their record, while the utilisation of ePA data for research remains uncertain. Nevertheless, the example of organ donation shows that a fundamental willingness among the general public does not necessary translate into active participation, even with high awareness. Although the majority of people (84 per cent) are in favour, only 43 per cent have actually given written consent to donate their organs.[40] Low data availability therefore raises concerns about a solution based on specific consent. In terms of the degree to which the public is informed or has access to information about data provision, consideration must be given to providing such information via general portals, as it is not practically feasible for patients to receive individual training on this, such as from doctor's practices or pharmacies.[41]

39 | See BDI 2022.
40 | See BZgA 2022.
41 | See BMG 2020.

Consent solutions for data sharing

Specific consent (opt-in): The patient consents to their data being used for a specific purpose. The patient also has the necessary information about their type of data usage and potential risks.

Meta consent: Data is divided into different categories including the type of data, its intended use and the user. This allows the patient to select instances in which they consent to data sharing. Theoretically, this model can also facilitate general consent to data sharing.

Broad consent: The patient consents to use of their data for a broadly defined purpose. This also includes further research projects which were not known at the time they gave consent. However, the patient always retains the right to withdraw their consent.

Opt-out: Data is used without consent unless a patient actively objects. At the same time, the patient has the opportunity to see how their data is used and by whom.

A graduated version of the opt-in process is the idea behind meta consent with granular consent options, such as in the form of an electronic data sharing passport. This would allow patients to share specific findings and corresponding data for certain purposes and users. In practice, this means that a patient could limit the degree to which their data is shared in different clinical fields of application. Users could be divided into hospitals, scientific organisations and technology providers, with a more granular breakdown within each of these user groups. A similar structure could be used for data type, with a general classification into data from social security offices and health insurance providers, data from electronic health records, image data, sensor data and data from biomaterials, with corresponding sub-groups for each type. This three-dimensional consent matrix (type of data, user group, intended use) would therefore ensure patient sovereignty and, by enabling patients to make autonomous decisions, potentially even support health literacy, i. e. the ability to find, understand and evaluate health information and apply it when making health-related decisions. Furthermore, patient organisations could publish data protection recommendations as guidelines, outlining different combinations of consent options (for example general sharing of data on physical diseases + selective sharing of data on psychological diseases) that patients could then directly import, to increase data availability. In addition to selecting the type(s) of data they wish to share, patients could also choose to share their data with specific users. Surveys show that the German population is very willing to share data with scientific institutions but is sceptical of the use of data by industry.[42] However, the private sector conducts the majority of research and development in the German healthcare sector and, in order to develop innovative digital methods, also requires access to health data from a healthcare context – though compliance with applicable data protection legislation and safeguarding patient well-being must still be a focus. Above all, innovative medical devices are subject to exacting approval processes that can only be negotiated by a research-based healthcare industry. Additionally, data provision by the public is accompanied by an expectation of new, improved and data-based treatments and for industry to develop such treatments, access to data is essential.

As in the case of specific consent, depending on the complexity of the data sharing passport for and the resulting barriers to its use, there is a danger of low participation from certain user groups and the risk that the data base would be affected by consent bias. This is when the data resource does not correspond to the actual distribution of sociodemographic characteristics such as age, sex or educational background in the population, in this case because it would primarily be health-conscious people familiar with digital applications who registered for data sharing. Consent bias can be corrected to a certain degree by using consent statistics during data collection, although this model still risks creating a database that is not representative of the population.

A broad consent solution could constitute a simplified form of data provision. Although it requires individuals to actively consent to the use of their data, this form of consent has a general effect and does not focus on individual research projects or users. This makes anonymised patient data usable on a broad scale. This type of consent also covers future issues that were not known at the time the patient gave consent.[43] A permanent option to withdraw this consent ensures the data sovereignty of the data subject. This solution is currently being implemented by the *Medical Informatics Initiative* (MII) using a consent form that has already been confirmed as compliant with data protection

42 | See PWC 2023.
43 | See BMG 2020.

requirements by the Committee of Independent German Federal and State Data Protection Supervisory Authorities (Konferenz der unabhängigen Datenschutzbeauftragten des Bundes und der Länder – DSK). In addition to the legal basis, likely participation also depends above all on the public's trust in the data security measures and the conceivable added value to the individual and to society. As with other opt-in solutions, consent bias also presents a risk depending on the complexity of the declaration of consent.

In addition to the question of future data use, the existing wealth of data in the German healthcare system must be considered in relation to all opt-in-based solutions. This data is already partially usable and, through data curation and standardisation, can be made usable as part of the European Health Data Space. Consent would also be required for this existing data, though this would significantly delay the utilisation of this data, even if the necessary infrastructure were already in place. It would also require existing applications based on this data to be paused until consent is given.

Another way to utilise patient data is the opt-out model, in which data is made available without explicit consent unless the patient actively objects. This restricts patient sovereignty but ensures broad availability of data in the interest of the greater good. The opt-out procedure is currently planned for the electronic health record (elektronische Patientenakte - ePA) system, as use of the opt-in procedure has only led to adoption by less than one per cent of citizens to date. However, the opt-out only relates to creation of the ePA; the patient must still actively consent to the sharing of personalised data for different service providers. As a central data collection site, the ePA is the access point for the use of data in research. At present, there are no regulations in place for consent to data sharing for research purposes or for secondary use in general. However, one example of a successful opt-out solution that has achieved very high acceptance is the electronic health record (elektronische Gesundheitsakte – ELGA) system in Austria. The German Federal Commissioner for Data Protection and Freedom of Information (Bundesbeauftragte für den Datenschutz und die Informationsfreiheit – BfDI) has also already confirmed that this system could, in principle, be implemented within the framework of the GDPR.[44] However, this once again raises the issue of the specific interpretation of data protection in the data protection laws enacted by each of Germany's 16 federal states, which makes implementation more complex. In this context, gematik is currently developing a concept for the ePA, though it is not currently clear whether data transfer without consent can be implemented without amendments to the German Social Code (Sozialgesetzbuch – SGB). Data processing is handled in a similar but even stricter way in some existing medical registers: the cancer register is subject to a statutory obligation to report data, while patients can also only object to the retrieval of data that can be used to identify them, while medical data on the disease remains in the register.

All the same, a study of the different consent methods should not concentrate solely on data protection-related concerns. Instead, it should also consider the risks and potential disadvantages of not using data. Improved and new treatments and potential risk factors can only be identified with a sufficient data basis. The opportunities presented by the use of data in the healthcare sector are too great to set them aside due to potential risks and data protection concerns. Data use also consolidates the competitive power of Germany – and that of Europe overall – in the healthcare sector and strengthens resilience in this area.

As noted previously, existing legislation such as the German Federal Data Protection Act (BDSG), the GDPR and state data protection laws account for the added societal value generated through data use, insofar as they define exceptions for permission to process health data, primarily in instances concerning administration in the healthcare system and public health issues. In future, however, patient sovereignty should be ensured for broad support to data sharing. This will require infrastructure and a governance structure designed to build the necessary patient trust so that they will provide their data. To do this, it must be based on high standards of transparency and security. Surveys show that fear of data misuse and violation of data protection requirements still remain the main reasons for refusing to provide data[45]

In view of the complex context outlined here, it is clear that mixed solutions will be required in future, as opposed to one-size-fits-all concepts. From a technological perspective, flexible applications capable of combining and interconnecting different consent solutions (for example as an app) are realisable today. It is conceivable, for example, that such a data sharing "passport" would include graduated levels of required consent depending on the sensitivity of the data. This approach could guarantee data sovereignty, especially in relation to non-anonymisable datasets (genome, biomaterials) and personalised datasets without having to completely exclude this data from use. Aggregated, anonymised datasets would still be available with low-threshold access. Likewise, a system in which patients give selective consent

44 | See ÄrzteZeitung 2023.
45 | See PWC 2023.

depending on the user and/or intended use would also be possible. Existing health data could be made available through an opt-out solution in order to generate added value from data use in the near term and build trust in data sharing among the public and service providers. A central aspect is that patients must be able to withdraw or amend this consent as easily as they gave it. Additionally, it should also be possible to share data in non-digital formats. Nevertheless, this information should be stored digitally, and data subjects should be supported on this point if necessary. This would reduce the barriers to entry and potential consent bias in data sharing. Patients should be offered a detailed factsheet with comprehensive information before sharing their data.

3.2 Data quality

Data quality is a decisive factor in justifying the public's willingness and trust in data use through enhanced quality of care. High-quality, standardised, machine-readable data in interoperable formats is essential for the effective application of AI and big data technologies and for the development of innovative treatments, medical devices, digital health applications, etc. Data should therefore be collected and handled in accordance with the FAIR principles in order to maximise the data's value and produce semantically correctly structured datasets. Beyond these guidelines, however, national and European data security guidelines are also required, including in relation to testing procedures for the quality of data anonymisation and pseudonymisation. In addition to existing international standards for certain areas (FHIR, SNOMED, LOINC, ATC), standards should also be defined and used for non-standardised areas (for example ECG data) to replace proprietary data standards in all healthcare provision processes. In this context, a data integration centre could serve in an advisory and organising role (Figure 2).

Existing international standards are already used in some cases, such as in certain hospitals and in scientific projects. However, the proposal for the European Health Data Space relies on a broad definition of health data. In addition to data from the healthcare system (electronic patient records, billing data from health insurance providers, disease registers, genome data, etc.), it also includes factors that can influence health, such as the consumption of certain substances, homelessness, minimum income, employment status, environmental factors, etc. It also extends to data generated by patients themselves, such as through the use of medical devices and wellness/fitness apps on smartphones and other portable devices. The definition used in the EHDS therefore goes considerably beyond our understanding of health data to date: the definition of health data in the GDPR, for example, does not include information that only indirectly provides indications about a person's health, such as whether they are homeless or their employment status. This raises several questions, one the one hand regarding the scope of the definition of health data and, on the other hand, regulating how data quality can be ensured while integrating very different data sources.

In terms of the scope of health-related data, the added value of having the broadest possible data resource is evident from a scientific perspective and, above all, in relation to diseases and syndromes such as cancer and dementia. These conditions are influenced by numerous factors, some of which remain unknown, and will presumably only become clear with access to the most comprehensive data resource possible. However, this is in opposition to the GDPR principle of data minimisation and, as the level of detail in the recorded data increases, so too does the potential for re-identification. This represents a security risk for patients and examples from research have shown that it is already possible to re-identify individuals by combining health data with data from other sources due to small overlaps in the datasets.[46]

Nevertheless, it is also important to consider that much data is already willingly shared – first and foremost the data recorded on personal devices, as evidenced by the roughly 20 million users of digital health apps and fitness apps in Germany in 2020. At present, the data collected by these apps is usually only accessible by the manufacturer and therefore only serves the greater good, and supports improvement in healthcare provision to a limited extent. As this data is already collected and shared by users, it would make sense to transfer this data into the planned European Health Data Space so that it can be used for the general good and thus at the same time counteract third-party use, in particular by non-European companies. However, such an approach would be in opposition to the business model followed by digital health app and fitness app providers, which relies on ownership of a proprietary, high-quality dataset.

Despite such objections, the use of real-world data should also be incorporated. In this case, as noted at the outset, regardless of the source of the data, the quality of the data must be ensured in order to provide added value for public health and to justify data sharing. This will require a qualification procedure and a corresponding quality seal – similar to CE marking – as a precondition for participation in a shared data space. This should create trust among the users of these apps, with incentives for manufacturers to develop health monitoring products and applications that

46 | See Sweeney 2018.

actually generate added value with regard to data use. Policymakers must set out clear guidelines so that the relevant institutions can develop corresponding technical standards. Such efforts should avoid structural and regulatory overlaps and promote interoperability, which is why corresponding regulations should be enacted to establish HL7 FHIR as a general standard in the healthcare sector in line with the European eHealth Network.

3.3 Data provision

A data sharing system includes patients and data users as well as other stakeholders who input data into the shared infrastructure and make it usable. These include service providers, such as doctor's practices and pharmacies, as well as university-based research groups and the private sector, which also collect data – in the course of clinical studies, for example, or by operating medical devices and wellness devices (see Figure 2, "Service providers"). In principle, the expanded collection and provision of data entails additional costs for service providers and the private sector, such as to implement the necessary infrastructure. However, these additional costs should not present an obstacle to data provision, so the relevant stakeholders should be supported in this regard.

The current proposal for the European Health Data Space includes an obligation for all stakeholders, with the exception of micro-enterprises, to input any health data they collect into the shared infrastructure. This approach aims to create the broadest possible data resource in order to maximise the added value of data use for the healthcare sector. Where data is generated or processed with the support of public funding, the use of this data in the public interest is reasonable. However, a problem in relation to scientific publications, for example, is that this approach requires publishers to share content that is confidential or has not yet been published. This problem is compounded for data originating from the private sector, as the duty to share data could have a negative competitive impact – for example, if a company is obligated to share data that contains business secrets or intellectual property. This could reduce private companies' willingness to generate their own data. Furthermore, current regulations on the use of health data lack specific provisions on the protection of patent-related content and intellectual property in general. Therefore, the direct sharing of data as currently required is not practicable.

This raises the question of whether stakeholders, and in particular companies with a business model primarily based on the collection of proprietary data, or on the structuring and processing of such data (for example using AI), will require special protection in order to preserve their ability to compete. This relates in particular to companies in the pharmaceutical industry, which collect health data in the course of clinical studies, and companies that develop software for medical devices. Protections for such business models could, for example, take the form of a temporary hold on sharing data (or parts of data) – a waiting period – to preserve the competitive advantages generated through generation or processing of the data. Stakeholders should also have the ability to refuse access to data from which other parties could draw inferences about business secrets or intellectual property. By contrast, data that is predominantly generated or produced with the help of public funding should be shared as directly and completely as possible. Even in such cases, however, a waiting period of six months, for example, would ensure that a university research group could publish its data first. The intention behind such a regulation would be to ensure that institutions and companies that generate genuine added value for the data space by collecting, processing or using health data are motivated to continue their development efforts. At the same time, they would also benefit from the data space structure through the access it provides to up-to-date data from other, previously inaccessible sources, such as public institutions.

Another potential means of protecting competitiveness would be to obligate data sharing only when a full dataset is available. This way, research projects could coordinate with the data sharing body at an early stage to clarify the purpose and scope of data collection and to agree corresponding waiting periods. This would also support data quality and facilitate parallel processes for certification/patenting and development. This would generate added value for the companies involved by optimising and accelerating these processes. In addition, companies must be permitted to refuse to share data if doing so would put business secrets and intellectual property at risk.

Alternatively, the duty of disclosure could also apply to predominantly publicly financed data; companies might then share the data they collect on a voluntary basis. Companies' access to the common data resource would then be fee-based; these fees could also vary depending on the scope of data shared by the respective company. This way, companies could benefit from the data space without having to accept competitive disadvantages. However, the available data resource would likely be significantly smaller and it is doubtful whether such a system could generate the necessary public trust in the data space, given that the majority have a sceptical view of data use by stakeholders in the private sector. Another compromise solution would be to distinguish between data users: for example, companies could share their data freely with academic research institutions, but only grant other companies access where the data generator's

intellectual property rights are guaranteed. In this case, however, companies should also have the right to refuse to share data if it would jeopardise their competitiveness. Another topic of discussion in this context is whether companies should only be permitted to apply for and receive access rights in association with a public scientific institution. The scientific institution would then be obligated to publish the results and the company could then use the data on a proprietary basis for product development. However, this option would significantly limit the innovative capacity of companies conducting research, as the additional application procedure and finding an academic partner would inhibit the development process.

3.4 Data transfer

Proceeding from the willingness of patients and data-collecting institutions to share their data in a common system, the question arises as to the form in which this data should be transmitted and made available. As outlined above, it is important in this context to draw a distinction between personalised, pseudonymised and anonymised data during this period when no uniform standards and or testing procedures have been produced as yet for data anonymisation or pseudonymisation. Due to the complexity and scope of the patient-specific dataset condensed under the term "health data", there is an entire continuum of measures to disassociate these datasets from individuals – ranging from the removal and/or pseudonymisation of basic personal information (name, address, age, sex) to the deliberate masking of datasets, such as by shuffling numerous datasets. This means data can only be transmitted in aggregated datasets, though this does meet high security requirements.

This approach is built around the aspiration of making it impossible to identify individuals from transmitted datasets. Although pseudonymised data prevents a person being identified directly from a given data set, it still presents the risk of re-identification through the use of other data sources. Various examples show that this is a real possibility – above all due to the extensive collection of personal data, including by hyperscalers, i.e. providers of cloud systems, operating systems and social media platforms, and through the use of other public databases. By contrast, anonymised data should ideally exclude the possibility of re-identification within the scope of current technical possibilities. As yet, however, this method is rarely practicable for medical data, such as genomic data or data on rare diseases or medical records. In a similar way, even relatively small excerpts from the results of imaging procedures such as computed tomography (CT) and magnetic resonance imaging (MRI) scans are sufficient for re-identification. Non-disclosure and masking procedures must be applied to prevent this. It would be presumably possible to compensate for any bias caused by the loss of data due to anonymisation,[47] although there have been no systematic findings on this issue to date. However, in relation to genomic data specifically, there is the question of whether such data should be made available for use at all given that anonymisation is not currently possible – at least in cases when a large portion of the genome has been sequenced. One alternative would be to focus on genotyping, meaning that genetic information is only collected in on a case-specific basis and never in conjunction with other data. However, this would reduce the significance of the data, specifically in relation to diffuse syndromes and, above all, in relation to potential avenues for personalised medicine. Certain study formats, such as long-term monitoring, benefit from personal data in order to assess personal influencing factors. Given the distribution of responsibilities in this area, cross-ministry initiatives between the Federal Ministry of Health (Bundesministerium für Gesundheit – BMG), which is tasked with ensuring healthcare provision, and the Federal Ministry for Education and Research (Bundesministerium für Bildung und Forschung – BMBF), which is responsible for research, may be needed to promote and evaluate study formats with personalised data.

When it comes to the question of the form in which data transfer should occur, the individual's right to data security stands in opposition to the data's value to the collective body of the insured. In the case of granular data sharing (see Chapter 3.1), the necessary degree of anonymisation could be made dependent on the intended use, in line with the rule: as anonymous as possible, with as little masking as necessary. A legal definition would be helpful in this case: it should determine the point from which health data is considered anonymous and which data types cannot be anonymised. This would create legal certainty and transparency, both for the data users and for patients.

An alternative would be to use a graduated model that links data sensitivity with accessibility. This would, for example, make general clinical data broadly available while only providing access to genomic data in justified cases and subject to a separate application. However, this would require consideration of each individual case and could thwart potentially important findings from research based on large datasets, because data-driven research does not rely on a conventional, hypothesis-based approach and instead works generally to identify patterns and structures in datasets. Consequently, it is not possible to say in advance what degree of dataset detail will be required to make

47 | See Koll 2022.

a valid statement. Such cases should therefore be individually considered by a committee (see Chapter 3.5) in the interest of striking a careful balance between the value of data use for the greater good and the necessary degree of data masking. The committee should treat data-driven research approaches as equal to hypothesis-based approaches. To date, it has only been able to assess the possibilities presented by data-driven approaches to a limited extent. However, in view of their potential to deliver new insights for common illnesses such as cancer, dementia and allergies, such approaches should be given due consideration, with continuous evaluation of the added value they actually provide.

Regardless of the scope of data masking prior to transmission, as noted previously, evaluation standards have still not been produced in relation to anonymisation and pseudonymisation. Furthermore, it is still not clear whether current state-of-the-art procedures are sufficient to guarantee data security in a European Health Data Space. It is therefore necessary to advance the development of new cryptographic techniques and standards, which must be promoted and expedited by policymakers. To this end, the cooperation between the healthcare sector and the Federal Office for Data Security (BSI) should be expanded. The BSI already provides data security-related assistance to hospitals, which are part of Germany's critical infrastructure.

3.5 Infrastructure and data security

Functional technical infrastructure and appropriately structured institutions for secondary use are required for effective and secure sharing and use of data. In addition to stakeholders that provide and use data, these institutions include bodies responsible for the integration, sharing, pseudonymisation and collection of data as well as bodies involved in the application for, evaluation of and consent to data use (see Figure 2). The current European Commission proposal for the European Health Data Space includes a centralised regulation that would combine all these competencies in a national, public health data access body. This body is also intended to cooperate with public health administration institutions, which do not have to apply to use data so long as this data processing is part of their official duties. In the event of capacity constraints, the health data access body would prioritise data use applications from public institutions over applications from the private sector. This centralisation is intended to make data processing and utilisation simpler and more efficient, with all relevant processes supervised and internally coordinated by a single body. The focus is on promoting public health, which is why the new body is intended to be closely networked with existing public health institutions.

However, centralisation also presents a number of problems. For one, a central data repository is generally at greater risk of hacking attacks, as such a wealth of data presents an attractive target. As this body would be responsible for data administration, pseudonymisation and anonymisation prior to transfer, it would store patient data as well as the anonymisation keys, which would be a further security risk. For pseudonymised data, personal information (name, address, etc.) would be stored together with other data, such as billing data from health insurance providers, which could facilitate illegal re-identification. This would also be in opposition to the explanations of data processing in the GDPR; the joining of anonymised data and specific information that could lead to re-identification is only intended in individual cases. Accordingly, private companies should not be permitted to process any health data if they simultaneously hold personal data from other business segments. Strict organisational, legal and technical separation at the provider level is the only way to have due regard for the principle of "privacy by design" in a digitalised health market.

The counterproposal to a central authority is a decentralised infrastructure with competencies divided between different stakeholders, similar to the depiction in Figure 2. The following is a schematic outline of these stakeholders, including their competencies and roles.

Data integration centres

A data integration centre (DIC) aggregates the data within a service provider's system structure and provides support with structuring, quality assurance and data transfer. It aims to ensure that all data entering the data space meets the necessary standards and make sure that data from service providers without extensive technical infrastructure (such as doctor's practices) can also be integrated into the data space. DICs can be organised as local servers or, in the case of pseudonymised data, can also exist as encrypted cloud solutions. DICs also transmit relevant information on data cataloguing to the data sharing body to make it available to other data users.

Data sharing body

The data sharing body is the contact point for queries regarding data use. It examines such queries in technical and formal terms and with regard to the societal and/or medical added value. Furthermore, it conducts assessments of the applicant's data security concept, which is a requirement for data use. In cases involving the sharing of non-anonymised and/or non-aggregated data, an ethics committee including well-informed patient representatives should be involved in the decision-making process. Its function

should be defined in legal, organisational and technical terms so that the data intermediary cannot make a unilateral decision regarding a data use application. Once the body approves an application, data collection can begin, with the data subsequently made available to the user.

At the same time, the data sharing body is responsible for conveying information to patients and data users. Patients receive information about the type, scope and objective of projects seeking to use data, with the aim of building trust in data use, through a corresponding platform – similar to the planned MyHealth@EU portal. As for data users, the body offers a catalogue of available health data, which only lists fundamental information about each dataset (size, data type, level of detail). The body therefore primarily has an intermediary function and does not have medical primary data itself.

Data collection

The pseudonymised data is considered part of the collection once the data sharing body has approved it. During collection, the health data is processed to prepare it for the data user (see data integration centre, Figure 2). The provision and transfer of data requires suitable infrastructure and corresponding services, such as a digital platform. This relates to data aggregation, the use of algorithmic systems to structure data and derive usable secondary data and additional attributes for data users in order to promote secondary use, and procedures to facilitate quality control and link data with data from other databases. A table of contents of the data collection with search functions is provided by the information platform (Figure 2).

Pseudonymisation body

The pseudonymisation body is responsible for separating identifying characteristics in datasets (name date of birth, etc.) from medical data and replacing them with pseudonyms. The pseudonymisation body transfers a process number for each dataset to the service provider supplying the data. Patient data is sent with this process number for data collection and is only then given its final pseudonym as specified by the pseudonymisation body. This means that the hospital providing the data is also not aware of the final pseudonym.

Personalised data is therefore only available in decentralised form and is stored by the respective service provider. The storage of identifiable data and pseudonyms at the same location avoided in the data provision process. This increases data security and also implements an allocation of responsibilities closer to the provisions of the GDPR regarding the integrity and confidentiality of data processing. At the same time, however, it also requires an increased level of coordination, as the process of approval and data provision requires cooperation between different stakeholders, which makes it more time-consuming and bureaucratically complex. In this context, there would be a need for additional auditing processes comparable to formats already established for companies operating in the healthcare sector. Such audits would focus, for example, on data literacy training for employees and the evaluation of internal documentation processes and error analyses.

In addition to the question of the type of infrastructure, there is also the question of whether all of the specified responsibilities should be held by national, public institutions. In order to ensure independence, for example, there is an argument for the European Medicines Agency (EMA) to perform pseudonymisation or to issue data sharing approvals as an independent transnational body. This aims to ensure that access to health data cannot be impaired by national political interests. Although the European Commission's proposal for the European Health Data Space states that the data access body will be free to make decisions and not subject to any instructions, the German Federal Ministry of Health (BMG) Digital Strategy assigns the task of issuing data sharing approvals to the Health Data Lab (FDZ), which currently belongs to the Federal Institute for Drugs and Medical Devices (BfArM) and is therefore formally governed by the BMG. Furthermore, there is the question of whether private stakeholders, who could perform data collection or data provision tasks, should be integrated into this decentralised structure. This would create competition, which could lead to identification of the most efficient solution and thereby avoid bureaucracy. Regardless of the structural regulation of data processing in the context of an EU regulation, it is still necessary to provide room for manoeuvre in its national implementation due to the differing levels of digitalisation in EU member states.

In addition to safety-related technical aspects, the central focus of the discussion regarding the infrastructure and governance of health data processing should be the question of which structures generate the most trust among the public, as this is the basis for the comprehensive, long-term utilisation of health data. However, there is widespread scepticism towards the concept of data processing exclusively by state bodies – due to the lack of trust in existing structures and fear of potential misuse of these structures, for example in cases where undemocratic parties have a role in government. At the same time, there are concerns regarding the private sector, which could focus more on maximising profits than on improving public health. An important starting point for building trust would be the data sharing process, specifically the question of which decision-makers it should include. An ethics committee could be implemented as a decision-making body, similar to the system used in clinical studies and as described above

for the data sharing body. It could also integrate well-informed patient representatives to strengthen trust in the process and in patient sovereignty. Options include patient advocacy groups, such as Aktionsbündnis für Patientensicherheit (APS), or the patient representatives already involved in the Federal Joint Committee (Gemeinsamer Bundesausschuss – G-BA).

This infrastructure provides the technical basis for data use. It should therefore build on existing structures, such as gematik and the data integration centres operated by the *Medical Informatics Initiative* (MII), in order to accelerate its implementation and avoid structural overlaps. Besides using and integrating existing structures, the application of automation should be promoted in the transfer of data from documents produced by service providers. This transfer should ideally be facilitated by real-time capable data collection to enable stakeholders to respond directly to changing demand for healthcare provision and ensure optimal networking of various healthcare providers. Furthermore, instead of being guided by current requirements, the infrastructure should be designed for the future, which also means including the increased use of big data technology on the basis of federated learning. In this context, more computing capacity should also be created to facilitate corresponding approaches in the interest of ensuring resilient digitalisation, which would also boost Germany's competitive power as a location for research. The increased use and sharing of data within the system will ultimately require enhanced security structures as well as specific crisis and emergency plans for IT-related security incidents.

Early agreement on national and EU-wide standards is essential to achieving successful digitalisation across the board. In this context, the eHealth Network's adoption of FHIR as the European standard represents an important step forward.[48] It presents a major opportunity for Germany, as future digitalisation measures can now be guided directly by international standards and aforementioned medical information objects (medizinische Informationsobjekte - MIOs). However, these common standards must be expanded to cover all aspects of data use in order ensure interoperability, security and legal certainty. Such standards also simplify training and development as well as staff mobility and facilitate the profitable commercialisation of systems developed in Germany on the European market. If nothing else, the agreement and communication of common standards also builds trust with service providers and manufacturing firms regarding the future viability of their products.

3.6 Data use

The current proposals for laws and regulations relate above all to making data usable. Beyond that, however, it is also important to regulate data use in the interest of public health. In light of current technological capabilities, and, given the development of further capabilities in future, fundamental guidelines on data use and storage should be established, similar to the good manufacturing practice (GMP) rules applied in pharmaceutical production. Such guidelines could set out measures to ensure quality assurance in manufacturing processes and the manufacturing environment. On the one hand, this would create legal framework conditions for the use of data in industry, while on the other hand, it would give public institutions clear quality criteria that could be made conditions of data use.

The improved networking of stakeholders in healthcare provision in conjunction with more powerful technical infrastructure should also be used to support the expansion of the telemedicine service offering. Furthermore, telemedicine services should embedded alongside – and given equal weighting to – analogue services. Low-threshold access should also be ensured. Accordingly, doctors' associations should produce guidelines outlining which services (from consultations to telesurgical services) can also be provided digitally without a negative impact on quality. In combination with a real-time capable database to relieve the burden on service providers, a redistribution of services based on the principles of availability and treatment expertise could therefore ensure better, faster healthcare provision across the board.

Such approaches explicitly targeting prevention should be adopted more often in healthcare provision. This requires improved forecasting of health risks, which will only be possible with an extensive data resource. It will promote public health because a strategy with clearly structures prevention measures could provide improved planning security for health insurance providers. This focus on prevention could reduce health costs, which would benefit health insurance providers as well as the collective body of the insured.

Furthermore, an expanded data resource would also allow for more efficiently personalised treatment. Given the physiological differences between individuals, personalised medicine is the only way to achieve the best possible individual treatment and prevention measures. Not only can it deliver significant benefits for patients, personalised medicine also shows immense potential to transform the overall provision of medical care – hence the anticipation that it will deliver personal added value for individual

48 | See Ärzteblatt 2023.

patients as well as added economic and social value to society as a whole. However, in keeping with a value-based healthcare approach, it is important to evaluate the actual medical value of each measure, as it is not yet clear to what extent the use of personalised approaches is economically feasible.

New methods and objectives in healthcare provision therefore also require new metrics in order to evaluate their actual added value for the healthcare sector and integrate these methods into the existing settlement system. This should take account of savings achieved through prevention as opposed to conventional treatment along with other aspects, including the ability to avoid placing a strain on patients, such as through chemotherapy. Over the long term, this should result in new standards for evaluating health as a combination of numerous factors, with cost reimbursement rewarding quality over quantity in the interest of value-based healthcare.

3.7 Training and development

In addition to the described technical and regulatory requirements for data use, implementation above all requires corresponding expertise on the part of service providers and an improved knowledge base in the general public in order to ensure data sovereignty and informational self-determination. Data use and, in particular, corresponding AI applications will transform existing occupational profiles in the healthcare sector, as AI-based decision support finds its way into day-to-day operations and existing processes are automated or redesigned. This calls for regular qualification measures for specialist medical staff in the form of training and development, specifically in relation to digital skills. This training and development would cover new techniques for use in day-to-day work and ensure they are used in the interest of patient well-being. Furthermore, these qualification measures would help to professionalise and improve the maintenance of clinical data systems. They should be based on the day-to-day work of the staff in question to convey that the direct added value of digital solutions lies in tangibly easing their workload. These qualification measures should therefore be developed through close cooperation between technical developers and service providers' associations. All staff working in healthcare professions should regularly participate in training on how to handle health data responsibly. This should cover, for example, how to deal with security-related infrastructure and raising awareness of the sensitivity of the collected data.

In addition to training and development for existing staff, it will also be necessary to expand the training structure in general because digitalisation will give rise to new requirements and new professions, such as medical data scientists, data documentalists, digital health specialists, process managers for digital health, system architects for digital health, and even doctors specialising in digital medicine. These professions must be anchored in the education and training system at an early stage, including through measures to promote interdisciplinarity, given the need to link skills from the fields of medicine and informatics. The same applies to the increased networking of medicine and molecular biology for personalised medicine in order to encourage the development of personalised treatments. IT specialists will also have to be recruited to develop these new competencies. This could be achieved by funding professorships and research projects on these topics.

As controllers of their own data, patients will also have a greater role to play in relation to digital medicine – a role that will require improved digital skills. However, this upskilling should not rely on compulsory instruction but rather on giving patients the tools they need to engage with data use in an informed way. This will require public information services, which could also be integrated into the healthcare system with patients compensated for their time, in the style of existing bonus systems for using screening services. People should be incentivised to develop their digital skills and, at the same time, encouraged to engage with available health data and how it is used. In this context, however, it is essential to exclude the risk that genetic or other sensitive health data is used to analyse risk and/or health profiles, as this could lead to a practice becoming established in which insurance benefits are individually adjusted as part of a bonus-malus system.

3.8 Shaping public opinion

Communicating the benefits and requirements of digitalisation and the use of research data in the healthcare sector represents a central challenge for implementation. It is essential to create trust among service providers and the public: they must be convinced of the benefit of new applications. Service providers and patients should therefore be actively integrated into development processes to support the creation of requirements profiles. Options must be communicated at different levels, tailored to the respective target groups, to motivate all stakeholders in the healthcare sector to participate. This concerns how policy actions are communicated to the public and service providers as well as communication at the personal level between the service provider and the patient. The significance of data sharing in the healthcare system and the general and personal benefits it provides should be made clear to the public.

This will require transparent communication of the opportunities and risks as the basis for people to form a stable opinion that will lead them from thinking to action. Given that it is above all the risks of data use (including in relation to data security) that have been foregrounded to date, political actors should spend more time accentuating the benefits of data-based and digitalised medicine (including in relation to the use of AI) and communicate these appropriately to target groups. Data use enables transparent co-determination by the public through traceable, clearly documented data movements, which also strengthens patient self-determination. At the same time, it is important to accept and communicate that it is not possible to provide absolute protection against criminal attacks on health data, so the security can only ever claim to provide the best possible protection. Additionally, health authorities and health insurance providers could cooperate to develop an information campaign, including with support from psychologists and even science journalists. In relation to service providers, it must be made clear that data systems, formats and procedures are being developed as tools to relieve the strain on them, and that there is no risk of jobs being jeopardised. Instead, the messaging should emphasise the new occupational profiles and opportunities to spend more time caring for patients directly. This communication should go beyond simply outlining advantages and initiate active exchange with service providers, such as through stakeholder dialogue, even while data sharing systems are being developed. The aim of such a participative development process would be to ensure that service providers' first-hand experiences with digital systems in their day-to-day work also aligns with the proclaimed benefits, thereby promoting public acceptance.

Specific, tangible benefits must also be made evident to patients, and people with limited German language skills must also be able to engage effectively with communications. A survey has shown that the public considers improved healthcare provision and lower health insurance premiums to be a convincing argument in favour of data use.[49] The same survey identified doctors spending too little time on caring for patients as the most significant criticism of healthcare provision at present. Data-driven AI approaches in particular have considerable potential to relieve the strain on service providers.[50] This assessment could be utilised in communications to spell out the benefits of a digitalised healthcare sector and to counteract fears surrounding the loss of data sovereignty. To achieve this, it will be vital to build trust in security structures. Data use also must be structured transparently, such as by including patient representatives in the data sharing process and providing a data use information portal with a low access threshold. Integrating the private sector into the data sharing system will also necessitate clear communicate that its involvement is essential for the development of new and improved diagnostic and treatment services. It is, first and foremost, research-based industry that pursues cost-intensive development projects and, despite the commercial interests of the companies involved, the outcomes of these projects ultimately also benefit society.

In this context, it is also important to address basic health literacy among the general public. The strong demand for popular scientific media (non-fiction books, magazines, podcasts, etc.) shows that many people desire to improve their understanding and, perhaps, to better prepare themselves for a potential illness. A well-founded strengthening of these competencies can also increase an individual's willingness to provide data. The Federal Centre for Health Education (Bundeszentrale für gesundheitliche Aufklärung – BZgA) can and should play an important role here.

The transformation of the healthcare system should be scientifically monitored in order to measure the actual added value. Current surveys show that the public is sceptical of whether the digitalisation of the healthcare sector is even possible in the coming years.[51] Clearly quantifiable successes and added value for treatment during the digitalisation process should effectively counter this trend. In this context, the attitudes of those involved should be made comprehensible through accompanying research in parallel with the expansion of data use. So, swift feedback systems should be established in order to promptly correct any misguided measures and thereby secure the trust of those involved in the use of data.

3.9 Innovation promotion

The previous sections show that the use of data in the healthcare sector can form the basis of new treatment approaches, novel administrative processes and new metrics for evaluating healthcare provision. In the field of personalised medicine in particular, innovations are required in relation to pharmaceutical products as well as medical devices. This includes individual medications, immunological treatments and mRNA vaccines for cancer treatment. Leveraging and maximising this potential will require the establishment of new structures to promote innovation. Even without taking account of the benefits for patients and service

49 | See PWC 2023.
50 | See PLS 2023.
51 | See PWC 2023.

providers, the use of data in the healthcare system is also economically significant for medical research. Utilising the wealth of available data could promote future developments, above all in the pharmaceutical, biotech and medical device industries, which conduct considerable research in Germany. These industries would thereby become a vital positive location factor for Germany.

Regulatory framework conditions, which provide legal certainty while also encouraging innovation, are fundamental to this. Therefore, in the course of establishing the European Health Data Space and implementing the German Health Data Use Act (GDNG), it will be important to identify overlaps and avoid regulatory conflicts with other guidelines and laws such as the GDPR, the Federal Data Protection Act (BDSG), the Research Data Act (Forschungsgesetz), the Medical Device Regulation, the AI Act and the Data Act. At the national level, access to data must be standardised with regard to federally administrated healthcare data and state-specific interpretations of the GDPR. The responsibilities of different data protection supervisory authorities must also be simplified. Although the German Federal Data Protection Act (BDSG) and the 16 different state data protection acts are all based on the EU GDPR, their differing interpretations create a highly complex and fragmented landscape in urgent need of streamlining and harmonisation. Regulatory overlaps and contradictory legal interpretations must be avoided to provide legal certainty for innovative development.

At the same time, a data sharing system must also provide protection for developments in terms of the resulting intellectual property and business secrets in order to ensure companies' ability to compete and offer incentives for product innovation. This will require clear regulations in relation to health data (see Chapter 3.3). Firstly, it should be possible to implement exemptions to data sharing obligations if business secrets demonstrably cannot be removed from some data. Secondly, measures should be implemented to preclude the sharing of data with direct competitors, give companies the right to decline to share data or, alternatively, to adjust waiting periods for data provision accordingly. This applies in particular to start-ups, as data sharing presents a threat above all to the development of early-stage start-ups. These exemptions should go beyond micro-enterprises, as small and medium-sized enterprises are also often unable to cover the costs of establishing and operating data sharing infrastructure or the associated personnel costs. Companies should receive financial support in establishing the necessary HR and technical infrastructure, such as by offering tax relief in return for corresponding investments. This approach aims to ensure extensive participation in the data space without limiting companies' economic agility, because the financial outlay involved in data sharing will only generate added economic value for companies over the medium to long term.

Furthermore, approval procedures will have to be developed to accommodate the expected novel products. In doing so, relevant authorities should be integrated at an early stage in qualification processes on the basis of the data sharing infrastructure. At the same time, new content will become relevant for product qualification, such as data analysed using AI, preventive approaches that do not generate measurable added value immediately, and smaller subject groups than in clinical studies to date (due to the personalisation of treatment). Alternative approaches will therefore be required to assess the benefit of a medical application in order to facilitate its integration into the reimbursement system.

Cooperation between science and business should be intensified to promote innovation, especially where projects are based on the shared data infrastructure. In this context, establishing research infrastructures and shared databases is particularly relevant in the initial stages in order to advance the utilisation of data. The data space should therefore also be used to simplify funding applications and communicate information on funding opportunities more broadly. This would also allow the health data space to be used to establish a Germany-wide/Europe-wide innovation ecosystem through simplified cross-border networking. At the same time, the principle of reciprocity must be applied at the international level so that non-EU actors can only participate in the data space if they provide added value for the European community and use data in accordance with EU law.

4 Outlook

A digitalised, data-based healthcare system offers significant potential to overcome current and future challenges in this area by enabling service providers to deliver high-quality care with fewer burdens. Integrating the private sector opens the door to new business models and creates development potential. Overall, patients benefit from improved healthcare provision and, consequently, society as a whole benefits from an improved quality of life. This will require, first and foremost, a change in attitudes towards data use, with opportunities and risks discussed in equal measure. The focus on risks and dangers often stands in the way of the discussion of specific technical obstacles and inhibits the development of innovative approaches.

To this end, this IMPULSE report highlights the degrees of freedom to shape future data use, including in the context of applicable data protection provisions. Rather than seeking to trivialise problems related to data security, ambiguity arising from overlapping legal standards and conflicts between European, national and federal structures, this report strives to discuss this issue from a solution-oriented perspective. It is intended, above all, as guidance for policymakers in the development of clear targets and in shifting the focus onto framework conditions and areas where technical developments are needed. Europe should leverage its internationally leading position in data protection and see this not as an obstacle but rather as an opportunity and the basis for establishing a just system for the use of health data.

Targets should focus not only on existing needs but also on the future. Furthermore, this is not about the complete digitalisation of all analogue healthcare processes, but rather the (re-)development of such processes. Examples include approval procedures, which can be more dynamically structured by facilitating parallel development and approval for new products and procedures, or through distributed, Europe-wide clinical studies. The same applies to the implementation of prevention services in the healthcare system, and specifically for personalised medicine. In this context, digitalisation provides a basis for new treatments and approaches that must be realisable in a future health system.

Through automation and personalisation, digitalisation and data are making it possible to create a sustainable, future-ready healthcare sector that puts patients front and centre and adopts a holistic view of health. Drawing on the World Health Organization (WHO) definition of health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"[52], rather than focusing solely on treating illnesses and symptoms, the overall aim of healthcare should be to optimise patients' quality of life.

52 | See WHO 2020.

References

acatech 2021
Kagermann, H./Süssenguth, F./Körner, J./Liepold, A./Behrens, J. H. (Eds.): *Resilienz der Gesundheitsindustrien: Qualität und Versorgungssicherheit in komplexen Wertschöpfungsnetzwerken* (acatech IMPULS), Munich 2021.

acatech 2022
acatech – Deutsche Akademie der Technikwissenschaften/Körber-Stiftung (Ed.): *TechnikRadar 2022. Was die Deutschen über Technik denken*, Munich 2022.

Ärzteblatt 2023
Ärzteblatt: "Gesundheitsdaten: FHIR wird europaweiter Standard" (Press release, 31/03/2022). URL: https://www.aerzteblatt.de/nachrichten/142159/Gesundheitsdaten-FHIR-wird-europaweiter-Standard [Retrieved: 16/05/2023].

ÄrzteZeitung 2015
Wallenfels, M.: *Zeitfresser Dokumentation*. URL: https://www.aerztezeitung.de/Wirtschaft/Zeitfresser-Dokumentation-249186.html [Retrieved: 16/05/2023].

ÄrzteZeitung 2023
ÄrzteZeitung: "Datenschützer Kelber hat keine grundsätzlichen Bedenken wegen Opt-out-Lösung bei ePA" (Press release, 15/03/2023). URL: https://www.aerztezeitung.de/Wirtschaft/Datenschuetzer-Kelber-hat-keine-grundsaetzlichen-Bedenken-wegen-Opt-out-437466.html [Retrieved: 16/05/2023].

AOK 2023
AOK-Bundesverband: "Studie belegt Überlebensvorteile für Krebspatienten bei Behandlung in zertifizierten Zentren" (Press release, 26/04/2022). URL: https://aok-bv.de/presse/pressemitteilungen/2022/index_25508.html [Retrieved: 16/05/2023].

BDI 2022
Bundesverband der deutschen Industrie e.V.: *Kollaborativer Datenraum Gesundheitswesen Vorstudie über die konzeptionellen Grundlagen*. URL: https://www.transforming-healthcare.com/wp-content/uploads/2022/08/BDI-idigiT-2022-Kollaborativer-Datenraum-Gesundheitswesen.pdf [Retrieved: 18/04/2023].

BMG 2020
Bundesministerium für Gesundheit (German Federal Ministry of Health): *„Datenspende" – Bedarf für die Forschung, ethische Bewertung, rechtliche, informationstechnologische und organisatorische Rahmenbedingungen*. URL: https://www.bundesgesundheitsministerium.de/service/publikationen/details/datenspende-bedarf-fuer-die-forschung-ethische-bewertung-rechtliche-informationstechnologische-und-organisatorische-rahmenbedingungen.html [Retrieved: 18/04/2023].

BMG 2023
Bundesministerium für Gesundheit (German Federal Ministry of Health): *Gemeinsam digital – Digitalisierungsstrategie für das Gesundheitswesen und die Pflege*. URL: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/D/Digitalisierungsstrategie/BMG_Broschuere_Digitalisierungsstrategie_bf.pdf [Retrieved: 18/04/2023].

Bundesärztekammer 2023
Zentrale Ethikkommission bei der Bundesärztekammer (Central Ethics Committee of the German Medical Association): *Stellungnahme Bereitstellung und Nutzung von Behandlungsdaten zu Forschungszwecken*. URL: https://www.zentrale-ethikkommission.de/fileadmin/user_upload/zentrale-ethikkommission/BAEK_SN_Behandlungsdaten.pdf [Retrieved: 05/05/2023].

BSI 2020
Bundesamt für Sicherheit in der Informationstechnik (Federal Office for Data Security): "Cyber-Angriff auf Uniklinik Düsseldorf: BSI warnt vor akuter Ausnutzung bekannter Schwachstelle" (Press release, 17/09/2020). URL: https://www.bsi.bund.de/DE/Service-Navi/Presse/Pressemitteilungen/Presse2020/UKDuesseldorf_170920.html [Retrieved: 16/05/2023].

bvitg 2023
Bundesverband Gesundheits-IT: *Parlamentarischer Abend am 16. März 2023*, 2023. URL: https://www.bvitg.de/parlamentarischer-abend-am-16-maerz-2023/ [Retrieved: 16/05/2023].

BZgA 2023
Bundeszentrale für gesundheitliche Aufklärung (Federal Centre for Health Education): *Wissen, Einstellung und Verhalten zur Organ- und Gewebespende*, 2023. URL: https://www.organspende-info.de/zahlen-und-fakten/einstellungen-und-wissen/ [Retrieved: 16/05/2023].

DAlzG 2022
Deutsche Alzheimer Gesellschaft e. V. Selbsthilfe Demenz: *Informationsblatt 1 Die Häufigkeit von Demenzerkrankungen*, 2022. URL: https://www.deutsche-alzheimer.de/fileadmin/Alz/pdf/factsheets/infoblatt1_haeufigkeit_demenzerkrankungen_dalzg.pdf [Retrieved: 05/05/2023].

Destatis 2017
Statistisches Bundesamt (Federal Statistical Office): *Gesundheit Todesursachen in Deutschland 2015, Fachserie 12 Reihe 4*. URL: https://www.destatis.de/DE/Themen/Gesellschaft-Umwelt/Gesundheit/Todesursachen/_inhalt.html#_5188n6fzl [Retrieved: 18/04/2023].

Destatis 2019
Statistisches Bundesamt (Federal Statistical Office): *Finanzen und Steuern Ausgaben, Einnahmen und Personal der öffentlichen und öffentlich geförderten Einrichtungen für Wissenschaft, Forschung und Entwicklung Fachserie 14 Reihe 3.6*. URL: https://www.destatis.de/DE/Themen/Gesellschaft-Umwelt/Bildung-Forschung-Kultur/Forschung-Entwicklung/Publikationen/Downloads-Forschung-Entwicklung/ausgaben-einnahmen-personal-2140360197004.pdf?__blob=publicationFile [Retrieved: 18/04/2023].

Dierks 2019
Dierks, C.: *Sekundärnutzung von Sozial- und Gesundheitsdaten, Rechtliche Rahmenbedingungen*, Berlin: MWV Medizinisch Wissenschaftliche Verlagsgesellschaft mbH & Co. KG, 2019.

Die Zeit 2023
Wolfangel, E.: *Wenn alle erfahren, was einem fehlt*. URL: https://www.zeit.de/2023/13/elektronische-patientenakte-datenschutz-karl-lauterbach [Retrieved: 16/05/2023].

EU Kommission 2022a
European Commission: *Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space*. URL: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197 [Retrieved: 18/04/2023].

European Commission 2022b
European Commission: "European Health Union: Commission Welcomes Adoption of new EU Cancer Screening Recommendations" (Press release, 09/12/2020). URL: https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7548 [Retrieved: 16/05/2023].

EUnetHTA 2020
HTA Austria – Austrian Institute for Health Technology Assessement GmbH: *Lungenkarzinomscreening in Risikogruppen Systematischer Review zum Nutzen/Schaden und zu Informationsstrategien (Teil 1)*. URL: https://eprints.aihta.at/1282/1/HTA-Projektbericht_Nr.132a.pdf [Retrieved: 16/05/2023].

Haserück 2022a
Haserück A.: "Telematikinfrastruktur: Ärzte bemängeln technische Probleme bei eAU und E-Rezept". In: *Deutsches Ärzteblatt*, 119: 19, 2022, A-844.

Haserück 2022b
Haserück A.: "Gesundheitsdaten: Wie man datenschutzkonform und effektiv forschen kann". In: *Deutsches Ärzteblatt*, 119: 48, 2022, A-2125.

Initiative D21 2022
Initiative D21 e. V.: *Datenraum Gesundheit: Die Lösung ethischer Fragestellungen als Voraussetzung für Innovationen im Gesundheitswesen*. URL: https://initiative21.de/app/uploads/2022/06/d21_denkimpuls_datenraumgesundheit.pdf [Retrieved: 18/04/2023].

IW 2022
Institut der deutschen Wirtschaft (German Economic Institute): *Die Berufe mit den aktuell größten Fachkräftelücken*, IW-Kurzbericht, Nr. 67, Cologne. URL: https://www.iwkoeln.de/studien/helen-hickmann-filiz-koneberg-die-berufe-mit-den-aktuell-groessten-fachkraefteluecken.html [Retrieved: 18/04/2023].

KOG Mammographie 2020
Kooperationsgemeinschaft Mammographie: *Jahresbericht Evaluation 2020 Deutsches Mammographie-Screening-Programm*. URL: https://www.mammo-programm.de/download/downloads/berichte/Jahresbericht-Evaluation-2020.pdf [Retrieved: 16/05/2023].

Koll 2022
Koll C. E. M. et al.: "Statistical Biases Due to Anonymization Evaluated in an Open Clinical Dataset from COVID-19 Patients". In: *Scientific Data*, 9, 2022, p. 776.

Livingston 2022
Livingston G. et al.: "Dementia Prevention, Intervention, and Care: 2020 Report of the Lancet Commission". In: *The Lancet Commissions*, 396: 10248, 2022, pp. 413–446.

Martini-Klinik 2023
Martini-Klinik am UKE GmbH: Fakten zählen: *Einzigartiges Wissen über Therapieerfolge*. URL https://www.martini-klinik.de/klinik/resultate [Retrieved: 16/05/2023].

MLP 2022
MLP Finanzberatung SE: *MLP Gesundheitsreport 2022*. URL: https://mlp-se.de/redaktion/mlp-se-de/gesundheitsreport-microsite/2022/report/mlp-gesundheitsreport-2022.pdf [Retrieved: 28/04/2023].

Mora 2022
Mora C. et al.: "Over Half of Known Human Pathogenic Diseases Can be Aggravated by Climate Change". In: *Nature Climate Change*, 12, 2022, pp. 869–875.

PLS 2023
Lernende Systeme – Die Plattform für Künstliche Intelligenz: *KI für Gesundheitsfachkräfte – Chancen und Herausforderungen von medizinischen und pflegerischen KI-Anwendungen*, Whitepaper from Plattform Lernende Systeme. URL: https://www.plattform-lernende-systeme.de/files/Downloads/Publikationen/AG6_WP_KI_f%C3%BCr_Gesundheitsfachkr%C3%A4fte.pdf [Retrieved: 28/04/2023].

PWC 2023
PricewaterhouseCoopers GmbH Wirtschaftsprüfungsgesellschaft: *Healthcare Barometer 2023*. URL: https://www.pwc.de/de/gesundheitswesen-und-pharma/healthcare-barometer.html [Retrieved: 18/04/2023].

RKI 2015
Robert Koch-Institut (Robert Koch Institute): *Gesundheit in Deutschland. Gesundheitsberichterstattung des Bundes*. URL: https://www.rki.de/DE/Content/Gesundheitsmonitoring/Gesundheitsberichterstattung/GBEDownloadsGiD/2015/09_gesundheit_in_deutschland.pdf?__blob=publicationFile [Retrieved: 28/04/2023].

Schröder 2022
Schröder D.: *Sachverständigengutachten zum Schutz medizinischer Daten*. URL: https://freiheitsrechte.org/uploads/documents/Freiheit-im-digitalen-Zeitalter/Gesundheitsdaten/2022-04-25-Gutachten_Schroeder-Gesundheitsdaten-Gesellschaft_fuer_Freiheitsrechte.pdf [Retrieved: 08/05/2023].

SVR 2021
hogrefe Verlag GmbH & Co. KG *Digitalisierung für Gesundheit Ziele und Rahmenbedingungen eines dynamisch lernenden Gesundheitssystems – Gutachten 2021 von Sachverständigenrat Gesundheitswesen*. URL: https://www.svr-gesundheit.de/gutachten/gutachten-2021/ [Retrieved: 18/04/2023].

Sweeney 2015
Sweeney L.: "Only You, Your Doctor, and Many Others May Know." In: *Technology Science*, 2015, 2015092903.

Sweeney 2018
Sweeney L.: "Risks to Patient Privacy: A Re-identification of Patients in Maine and Vermont Statewide Hospital Data." In: *Technology Science*, 2015, 2018100901.

TAB 2022
Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag (Office of Technology Assessment at the German Bundestag): *Data-Mining – gesellschaftspolitische und rechtliche Herausforderungen*. URL: https://publikationen.bibliothek.kit.edu/1000156297/150443794 [Retrieved: 28/04/2023].

TMF 2022
Technologie- und Methodenplattform für die vernetzte medizinische Forschung e. V.: *„Datenspende" für die medizinische Forschung: Ergebnisse einer aktuellen Umfrage*. URL: https://www.tmf-ev.de/News/articleType/ArticleView/articleId/4456.aspx [Retrieved: 18/04/2023].

TMF 2023
Technologie- und Methodenplattform für die vernetzte medizinische Forschung e. V.: *Forschen für Gesundheit*. URL: https://forschen-fuer-gesundheit.de/ [Retrieved: 16/05/2023].

UBA 2016
Umweltbundesamt (German Federal Environment Agency): *Das Environmental Burden of Disease (EBD)-Konzept und Gesundheitskostenanalysen als Instrumente zur Prioritätensetzung im gesundheitsbezogenen Umweltschutz (Gesundheitsökonomie u. Environmental Burden Disease im Umweltschutz, GEniUS)*. URL: https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/umwelt_und_gesundheit_02_2016_das_environmental_burden_of_disease_konzept.pdf [Retrieved: 28/04/2023].

Wissenschaftsrat 2022
Wissenschaftsrat (German Council of Science and Humanities): *Digitalisierung und Datennutzung für Gesundheitsforschung und Versorgung – Positionen und Empfehlungen.* URL: https://www.wissenschaftsrat.de/download/2022/9825-22.html [Retrieved: 18/04/2023].

WHO 2020
World Health Organization: *Constitution of the World Health Organization*. URL: https://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf [Retrieved: 16/05/2023].

WHO 2023
World Health Organization: "Supporting Digital Health Transformation in Eastern Europe and Central Asia" (Press release, 11/04/2023). URL: https://www.who.int/europe/news/item/11-04-2023-supporting-digital-health-transformation-in-eastern-europe-and-central-asia [Retrieved: 16/05/2023].

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Digitalisation in the German healthcare sector remains far short of the possibilities. There are numerous opportunities to improve the provision of healthcare in Germany and avoid unnecessary costs. The advantages of data use are now so obvious that it would be negligent not to seize them.

This IMPULSE report aims to drive progress towards the secure, controlled use of health data. It identifies opportunities, obstacles and discussion points as well as fields of action, relating them to current legislative proposals in this area.