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GIHF AI

German Israeli Health Forum for Artificial Intelligence

GIHF-AI Year-in-review 2022

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The GERMAN ISRAELI HEALTH FORUM FOR ARTIFICIAL INTELLIGENCE (GIHF-AI) connects experts from Germany and Israel in the field of digital health with a focus on artificial intelligence (AI) and machine learning (ML) and has a board of trustees aside.

Dear Reader,

The global healthcare system is facing an urgently needed digital transformation process. Digital health applications (DiGA), the electronic patient record (ePA), the e-prescription, and online appointment bookings are the first examples of the transformation in Germany. Nevertheless, by far not all potential is being exploited. Israel, meanwhile, is considered an international pioneer. Since the start of the Covid pandemic, many countries have been expanding their cooperation with the Startup Nation, also in the healthcare sector. With the German Israeli Health Forum for Artificial Intelligence (GIHF-AI), the European Leadership Network (ELNET) is making an important contribution to this in the German-Israeli context.

Experts from the fields of politics, science, medicine, and society are now meeting in Israel for the first annual conference of the GIHF-AI, which is funded by the German Federal Ministry of Health. At the invitation of the Israeli Ministry of Health, the status quo, political recommendations for action, and medical trends will be discussed in Tel Aviv. Interactive workshops will complement the program.

The event will also look back on an intense first year of the GIHF-AI project. While the kickoff event in Berlin brought together the health ministers of both countries as well as more than 200 guests, smart minds from Germany and Israel, technology and security, regulation, as well as communication and trust in the context of digital health and AI were discussed in roundtable formats.

In addition, the GIHF-AI participated in various Digital Health conferences such as DMEA and Big Bang Health in Germany, as well as in dialogue formats in Israel such as a dedicated Mental Health Day as part of a GINSUM Digital Health Delegation.

The dialogue rounds will focus especially on the European Health Data Space, interoperability, ePA, networking of startups, trust as a cornerstone for data use, and AI development. Within a very short period, the GIHF-AI was able to establish itself as an expert, thanks to a board of renowned trustees from both countries, who contribute their experience from science, politics and the health care sector as well as carry forward the project‘s recommendations for action.

In addition, GIHF-AI made its mark in educational work and published its own explanatory videos on various social media platforms. Furthermore, parliamentary rounds were held for members of the German Bundestag.

The annual conference will also set the content framework for the second project year. Once again, dialog formats, conferences, and delegation trips as well as various publications will serve to exchange expertise, expand networking between the two countries and build bridges to the European Union. For the first time, there will be a binational comparative study under the scientific responsibility of Charité- Universitätsmedizin Berlin and Clalit Health Services, Israel‘s largest health insurance company, on attitudes regarding the use of patient data.

Finally, we would like to thank both Ministries of Health for their support and all participating experts for their contribution to GIHF-AI. This brochure summarizes the publications to date: briefings, statements as well as an outline paper- supplemented by political recommendations for action.

We wish you an inspiring read.

Carsten Ovens
Executive Director

Summary

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GIHF AI

German Israeli Health Forum for Artificial Intelligence

(Date: 03.03.2022)

An inventory

Digitization and innovation in German and Israeli healthcare

The German healthcare system is among the best in the world. According to the Prosperity Index published by the London-based think tank Legatum Institute in 2019, Germany ranks 12th out of 167 countries. Leading are Singapore, Japan and Switzerland, followed by South Korea and Norway.[1]

Israel is ranked 11th and thus directly ahead of Germany. Its efficient and modern healthcare system attracted international attention at the latest during the corona pandemic, which earned the young Middle Eastern state with a population of around 9 million the titles "vaccination world champion," "laboratory of the world" or "corona role model".

This was helped in particular by the country's highly digitized healthcare system and the effective use of artificial intelligence (AI) in the medical context. With a score of over 70 percent on the Bertelsmann Digital-Health-Index, which is considered a reliable measure of the degree of digitization in the healthcare sector, Israel ranks fourth internationally. By comparison, Germany ranks second to last out of 17 countries analyzed and thus has an urgent need to catch up in the area of digital health.[2]

A close exchange with Israel, where the digitization of the healthcare system began more than 25 years ago and whose healthcare industry is now one of the leading beneficiaries of artificial intelligence (AI) and machine learning (ML), brings enormous potential. To understand what such cooperation might look like, it is essential to take a close look at the emergence and development of Germany's and Israel's healthcare ecosystems.

The German healthcare system

Around 1,900 hospitals, 150,000 physicians and approximately 28,000 psychotherapists working in outpatient care serve the German population. In 2019, healthcare spending amounted to 411 billion euros, which is 11.9 percent of the gross domestic product. This is supported by the solidarity-based health insurance system, which is based on the state social insurance system introduced by Imperial Chancellor Otto von Bismarck in 1883 – the first in the world. The social insurance contributions paid by employers and employees to the health insurance funds finance the medical services. The legal basis of social insurance is the Social Security Code.[3]

Today, there are about 100 statutory health insurance funds (Gesetzliche Krankenversicherungen; GKV), in which 88 percent of citizens are insured. All insured persons receive the same benefits and the general contribution rate is based on salary: those who earn more also pay in more. In contrast, the insurance contribution for private health insurance (Private Krankenversicherung; PKV) is generally

based on the risk of the insured. With around 7.9 million members, Techniker Krankenkasse is currently the largest statutory health insurance fund in Germany. The private health insurers have a total of less than 9 million insured.[4] Since 2007, insurance has been compulsory for statutory health insurers, and since 2009 also for private health insurers.

By way of comparison, there are two other types of health care systems in the global context besides the social insurance system. These are, on the one hand, state health care systems, such as in Sweden, where medical care is financed entirely from the state budget.
On the other hand, there are market-based systems, as in the USA. Here, private actors are responsible for financing and managing health care.[5]

> *"The public health system in Israel, built on the foundations of social democracy, has saved more lives than anything else in the fight against Corona, and we will strengthen it."*
>
> Nitzan Horowitz, Minister of Health Israel, during the GIHF-AI kick-off event

The Israeli health care system

Analogous to Germany, the medical care of the Israeli population is covered by the social insurance system, secured since 1954 by the State Insurance Institute under the auspices of the Ministry of Labor and Social Affairs.[6]

The foundation for this was laid by the Jewish community and the British military administration during the British Mandate time (1918 to 1948). At the time of the establishment of the state in 1948, the medical infrastructure of the Jewish state was relatively well-developed. The British Mandate Health Office was replaced by the Ministry of Health (Misrad HaBriut) in 1948, and regional health offices and an epidemiological service were established.

Medical services were already then provided by health insurance companies, known as Kupat Holim (Kupot Holim in plural) or HMOs (Health Maintenance Organizations). The largest and also Israel's first health insurance fund, Kupat Holim Clalit (Clalit for short), was founded in 1911 by a small group of agricultural workers. By the end of 1948, only 53 percent of Israel's Jewish population was insured. In the years that followed, Israel's health care system expanded, and within a decade, about 90 percent of Israelis had health insurance. In addition to Kupat Holim Clalit, there are three other health insurance companies in Israel today: Kupat Holim Maccabi, Kupat Holim Meuhedet and Kupat Holim Leumit.[7]

Unlike in Germany, where hospitals and clinics are funded by government or private agencies, HMOs maintain their own medical facilities. Insurance has been mandatory since the National Health Insurance Law was passed in 1995.

Today, 99 percent of the Israeli population is insured. They have access to a medical network consisting of around 350 hospitals and nearly 30,000 physicians.[8] The majority of medical care facilities belong to health insurance companies, while a small proportion are privately owned. The four HMOs are required by law to provide all their members with a minimum package of health care services and treatments known as the "health basket" (Sal HaBriut). This "basket" is financed by social security contributions from employers and employees.

The Ministry of Health supervises the HMOs, and certain services are under the direct administration of the state. Measured against the high quality of Israel's health care system, health care spending at 8 percent of GDP in 2020 was low compared with that of other OECD countries, which averaged 9.9 percent. Before the corona pandemic (2000-2019), it was only between 6.9 and 7.4 percent.[9] On the one hand, this speaks for the effectiveness of the

healthcare system and, on the other hand, explains the development urge for innovative and, above all, efficient healthcare applications.[10]

Digitization and AI in healthcare

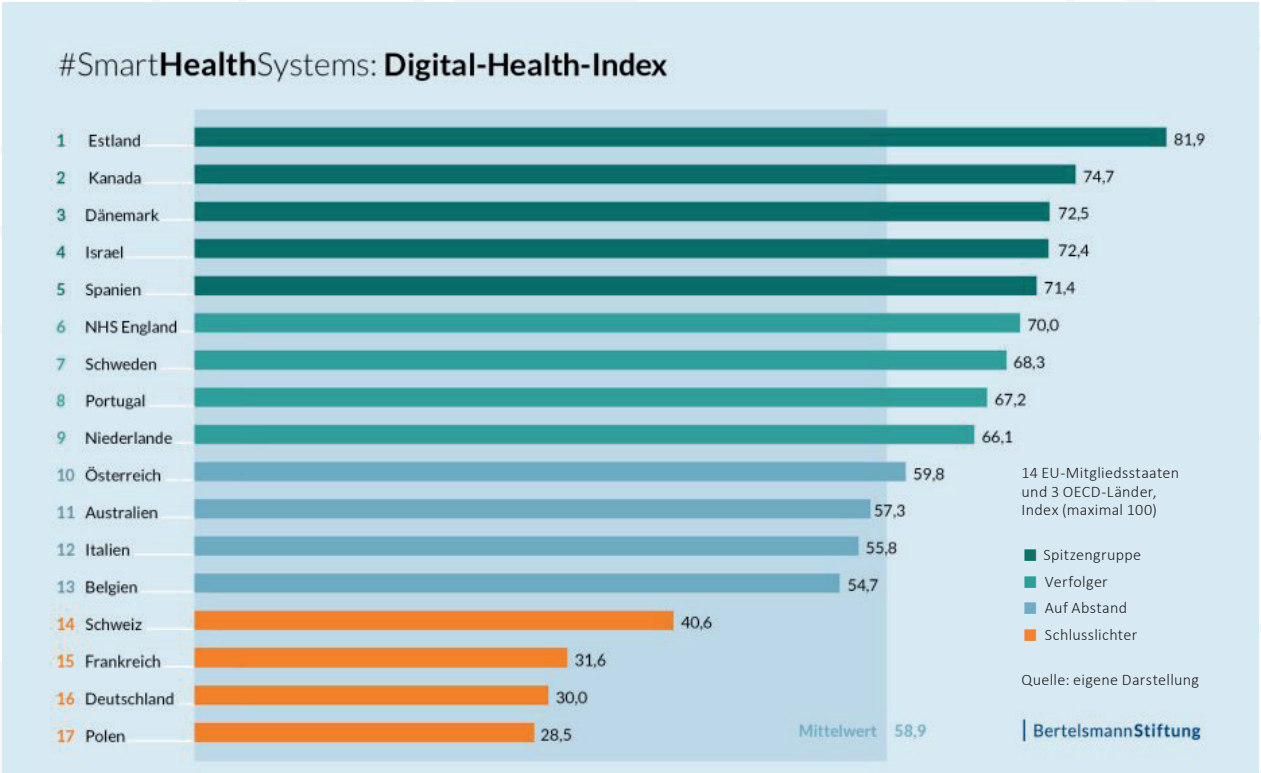
Data is the gold of the digital age and the essence of AI

Whether in diagnostics, drug development, personalization of treatments and genome editing, AI applications are being used in a wide variety of ways in medicine. By strikingly improving diagnostic and treatment options on the one hand and increasing productivity on the other, they have the potential to revolutionize our healthcare system.

This is not about replacing doctors or nurses with AI but supporting their work and giving them more time for their patients. AI can take over certain activities, such as analyzing X-ray images or measuring vital signs. In addition, it can help with the development of drugs for rare diseases or personalized cancer therapies.[11] If we talk about the use of artificial intelligence in healthcare, it quickly becomes clear that digitized patient data is the basic prerequisite for the effective use of AI in medicine. Artificial intelligence thrives on data, and the more data it has available for its learning process, the more precisely it can work. The keyword is Big Data, i.e. the availability of complex, multifaceted data sets.

In addition to quantity, the quality of the data and interoperability, i.e. the ability of different data systems to work together, are also important. The use of AI applications can therefore not take place without a digitized healthcare system with big data volumes.

A look at Germany's digitization status in the healthcare sector shows that we are still at the very beginning in this country, especially by international standards. In the above-mentioned Digital Health Index of the Bertelsmann Foundation, which compares 14 EU member states and 3 OECD countries in its study, Germany found itself in second-to-last place with 30 percent in 2018. By comparison, Israel landed in fourth place with 72.4 percent.[12]



Since the Bertelsmann Stiftung published its data, many important steps have been taken in this country toward a digitized healthcare system. Numerous new laws have been passed, such as the "Act for Better Care through Digitization and Innovation" (Digitale-Versorgung-Gesetz; DVG), which came into force in December 2019. It enables health applications to be obtained on prescription, the use of online consultations, and the access of the secure healthcare data network for treatments anywhere.

In terms of the reimbursability of digital health applications (Digitale Gesundheitsanwendungen; DiGA), Germany is even taking a pioneering role in a European comparison. In the meantime, the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte; BfArM) has added 30 DiGAs to its list, often within a few months thanks to the DiGA fast-track procedure.[13]

The same applies to the "Patient Data Protection Act," (Patientendaten-Schutz-Gesetz; PDSG) which was passed by the cabinet in 2020 to make, for example, the electronic patient record (elektronische Patientenakte; ePA) and the e-prescription usable. Additionally, medical findings, doctor's reports or X-rays, the vaccination card, the maternity passport, the examination booklet for children and the dental bonus booklet can also be stored in the electronic patient file as of this year. Use of the electronic patient file is voluntary for insured persons. They can decide for themselves who has access to which data.[14]

The Hospital Future Act (Krankenhauszukunftsgesetz; KHZG), which was passed in 2021, was also a special milestone for the digitization of hospitals. Within this framework, the federal and state governments will provide 4.3 billion euros for hospital digitization. The current results of the "DigitalRadar Krankenhaus," an evaluation of the maturity of German hospitals with regard to their digitization, make it clear that Germany has made significant progress in an international comparison.

However, there is still a great need for development, especially in the areas of clinical processes, information exchange, telemedicine and patient participation. There is also room for improvement in the sharing of structured data in the hospital sector and in interoperability between the prevailing software solutions. The average score of the so-called DigitalRadar-Score of German hospitals is 33.25 points out of a maximum of 100.[15]

Last but not least, the Research Data Center Health (Forschungsdatenzentrum Gesundheit; FDZ) at the BfArM needs to be mentioned. It is currently in the development stage and aims to give researchers access to the data of all people with statutory health insurance in Germany, with the goal of making the data usable for research purposes. From 2023, insured persons will also have the option of voluntarily making the data stored in the ePA available to research as part of a data donation.[16]

INFO

Artificial intelligence (AI):
"Artificial intelligence is the umbrella term for applications in which machines perform human-like intelligence tasks. This includes machine learning, natural language processing (NLP) and deep learning.
The basic idea is to use machines to approximate important functions of the human brain - learning, judgment and problem solving."[17]
(Source: SAP)

- AI is being trained using large amounts of data. The more data the AI is being made available for its learning process, the more precisely it can work. Furthermore, the quality and interoperability of the data are crucial.
- In the medical field, AI is being used in diagnostics, drug development, peronalization of treatments and genome editing.

Artificial Intelligence (AI)

The current developments in Germany are certainly a step in the right direction. In addition, the corona pandemic clearly demonstrated the advantages of digital health and made them tangible. Due to quarantine and fear of infection, many patients had to rely on online therapy services for the first time, apply for their sick leave digitally, or receive a diagnosis via telemedicine.
Still, progress is slow. Healthcare institutions complain about not having enough financial resources for digitization. In addition, there are problems to be solved with IT security, technical implementation and data protection. And although German research in the field of AI and health is growing significantly, it has so far had to rely on data that is already available or conduct research in international collaborations: with Israeli researchers for example, who have patient data of 99 percent of the 9 million inhabitants available almost entirely in digital form.[18]

Israel began digitizing patient data as early as 1995 as part of the aforementioned National Hospital Insurance Law. The 1996 Law for the Protection of Patients' Rights[19] established binding standards of conduct and codes for the protection of patient data. However, the data resided exclusively with the patients' respective HMOs. There was a lack of government regulation and coordination and cross-insurance data sharing. While this led to HMOs outdoing each other in developing and investing in digital health applications due to high competition among them, the data was not universally available for research and privacy issues also arose.

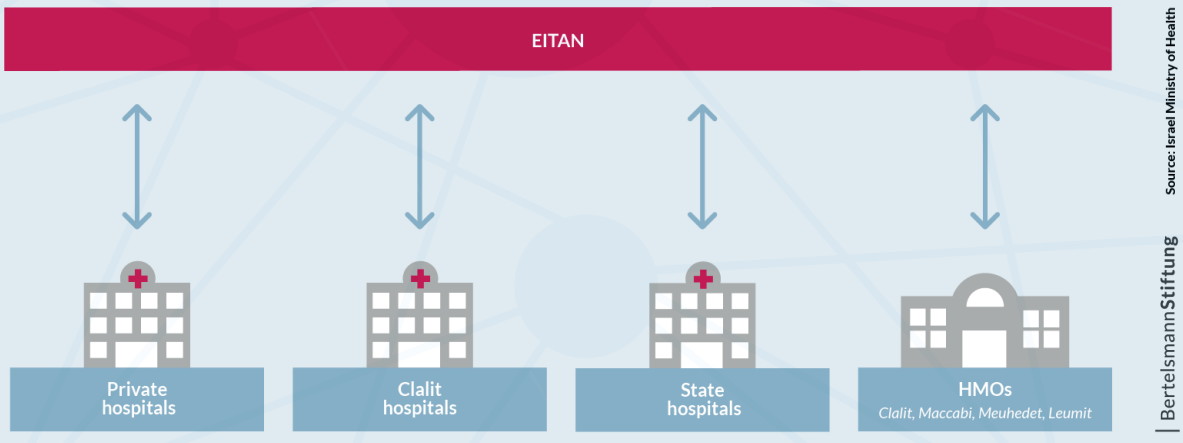
A turning point was reached in 2018 with the adoption of a national digital health development plan. As part of the approximately $270 million government initiative, innovative projects were funded and the population's health data was further digitized.

Among other things, a Big Data platform called "EITAN" was built under the supervision of the Ministry of Health to use the data of all patients simultaneously and make it available to researchers, entrepreneurs and medical institutions. The data does not reside in a central database; rather, EITAN acts as a data exchange platform.[20]

EITAN: Health information exchange platform

The data exchange functions as follows

Access to patient data: limited, and only for the duration of treatment



This same digital backbone of the healthcare system was instrumental in combating the COVID-19 pandemic, in Israel and beyond. The anonymized patient data available in the system related to vaccination was made available to a pharmaceutical company for COVID-19 vaccine research. It is important to understand that real-world data sets are scarce, and at the same time very important for drug and vaccine development.
The results of the vaccination studies supported by Israel's data pool could subsequently be used in various countries to develop vaccination and pandemic management strategies. Thus, not only Israel benefited, but the international community as well.[21]

AI in medicine - Germany

According to a 2017 study by PricewaterhouseCoopers (PwC) on AI in the healthcare industry, AI solutions were already being used in Germany before the corona pandemic: around 30 percent of German healthcare companies were using them in diagnostics, prophylaxis and the treatment of diseases or the prevention of severe disease progression.[22]

Furthermore, numerous companies in the healthcare industry are conducting research on artificial intelligence and initiating innovative projects. And the government has also invested heavily in innovative AI-based healthcare applications in recent years: In 2018, the German government adopted the "Artificial Intelligence Strategy". With the strategy, it wants to render Germany and Europe into a leading location for AI, secure competitiveness as well as promote the diverse application possibilities of artificial intelligence in all areas of society.

Within this framework, the German Federal Ministry of Education and Research (BMBF) is providing around 230 million euros from 2018 to 2025, for example.[23] However, the technology has so far only made a very limited impact on patient therapy. According to a PwC study, 64 percent of stakeholders in the healthcare sector are convinced that AI will fundamentally change our healthcare system in the next ten years.[24]
In order to be able to benefit from the technological progress that AI brings with it, in addition to Big Data, it is above all necessary to adapt regulatory procedures, both at national and EU level (for example in the form of the Artificial Intelligence Act - AIA). Regulation is of utmost importance, especially when it comes to ethically sensitive issues regarding the use of AI, yet it must be prevented that patients are deprived of their right to innovative AI medical solutions through overregulation.

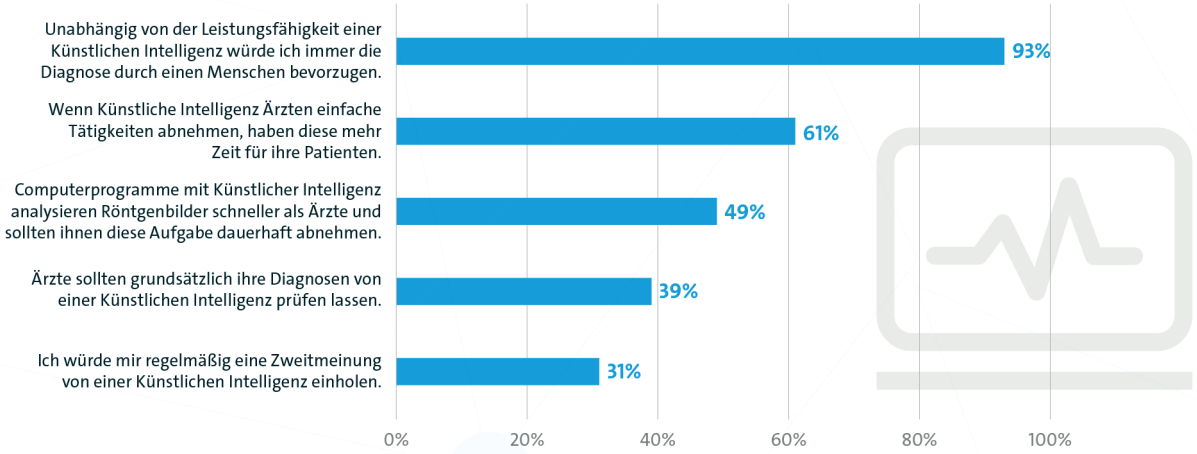
Fittingly, the German Bundestag's Enquete Commission "Artificial Intelligence- Social Responsibility and Economic, Social and Ecological Potentials" published its final report at the end of 2020 and called, among other things, for "politicians to decide to push for the framework conditions needed [for the introduction of AI in healthcare]."[25]

In addition, AI must be made more understandable and the benefits of AI applications must be clearly demonstrated through trust-inspiring best practices. Because even though more and more people are recognizing the opportunities that artificial intelligence brings, and a majority expect AI to noticeably change society as early as the next five years (Bitkom 2019), skepticism prevails.

93 percent of respondents would prefer to be diagnosed by a human, and only 31 percent of respondents would regularly seek a second opinion from an AI in the future. In turn, 61 percent of respondents said that doctors would have more time for their patients if AI relieved them of simple tasks. So, on the one hand, there is still a lack of confidence in AI applications in medicine, and on the other hand, one of their greatest benefits is recognized: The workload reduction it provides to healthcare professionals, enabling them to treat their patients even better.[26]

Jeder Dritte würde Zweitmeinung von einer KI einholen

bitkom



Translation graphic above:

One in three would seek a second opinion from an AI

1. Unrelated to the performance of an artificial intelligence, I would always prefer the diagnosis of a human- 93%.
2. When an artifical intelligence takes over easy tasks form doctors, they gain more time for their patients- 61%.
3. AI-based computer programs analyse X-ray images faster than doctors and should take over this task permanently- 49%.
4. Doctors should generally let their diagnoses be verified by an artificial intelligence- 39%.
5. I would get a second opinion from an artificial intelligence on a regular basis 31%.

AI in medicine - Israel

While regulatory barriers to the use of AI-enabled healthcare applications are debated in Germany and many people are rather skeptical of them, they have already made their way into the daily lives of many Israelis. This trend was further fueled by the Corona crisis. This is because, in addition to digitized patient data, there were three groups of digital technologies that served Israel in its pandemic response: First, systems related to surveillance, contact tracking, and reporting. For example, the Israeli Ministry of Health partnered with a startup to develop one of the world's first voluntary digital applications for contact tracking in the wake of the COVID-19 pandemic.

Furthermore, patient monitoring and diagnostics technologies have been deployed, with local startups rapidly developing numerous new tools. For example, an AI-powered remote triage system of COVID-19 symptoms in real time, or an app for early detection of symptom deterioration based on vital signs measurement. Telemedicine also played a major role, allowing patients to continue to have access to medical examinations during a lockdown or when concerned about infection. In a very short time, considerable progress was made here in the development of eHealth products. Exemplary is an all-in-one solution for remote medical examinations that allows physicians to connect with patients at home to check their health status. In this context, these technological innovations, which were almost indispensable in Israel in the wake of the corona pandemic, have one thing in particular in common: they are based on artificial intelligence.

In addition, there are numerous other AI-based digital health applications that are being developed and used in Israel, as well as being used around the world. For example, a portable device (a so-called wearable) that enables blind, visually impaired, reading or otherwise disabled people to read. Or an analytics and diagnostics platform that helps diagnose and plan treatment for cancer, as well as a tool that interprets medical data to indicate life-threat-

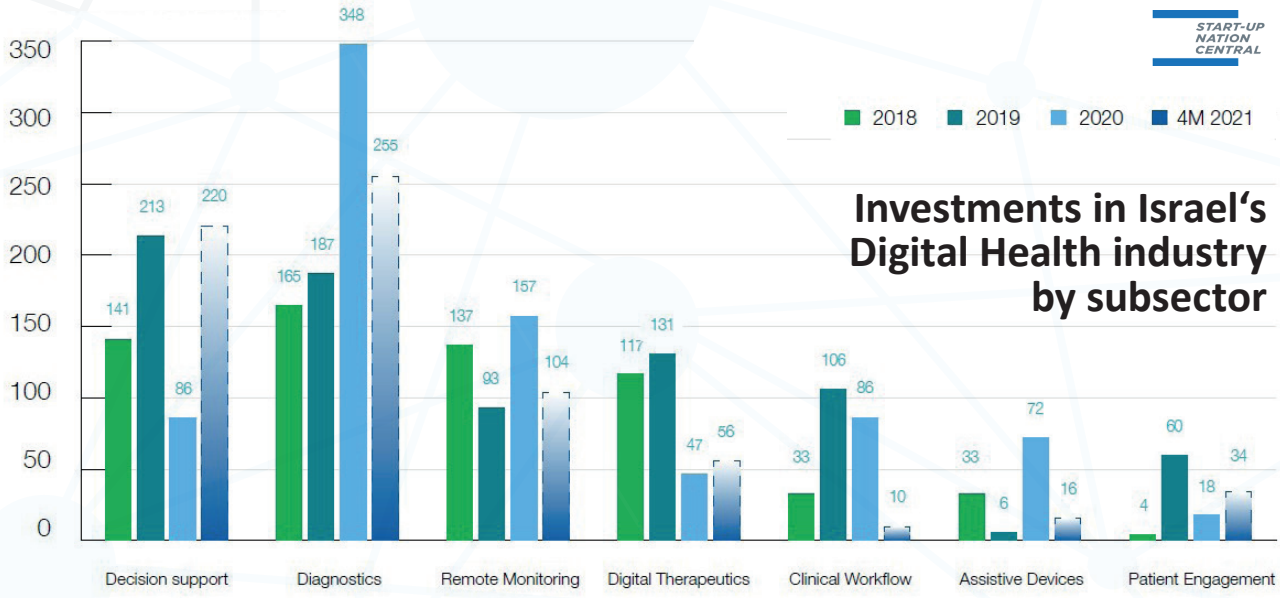
ening conditions early. An app, on the other hand, only needs a quick glance at the smartphone to determine how high the blood pressure is and whether the oxygen saturation is sufficient. This is not science fiction, but reality. The range of possibilities that IT-supported systems are taking on in healthcare is almost endless. Since patients themselves decide whether and how they use the tools and which data may be passed on to treatment providers as well as healthcare institutions, they are 100 percent privacy-compliant.[27]

Artificial intelligence is now the fastest growing technology in the digital health sector in Israel, with 85% of total investments going to companies using AI solutions. As of today, there are more than 700 Digital Health startups – 85% of which are applying AI solutions. In 2018, the digital health ecosystem in Israel consisted of 537 startups, 4 HMOs, 32 multinationals, 4 incubators, and around 100 active investors. In 2019, $662 million were allocated, in 2020 it were already $813 million, and in 2021, $700 million in the first quarter alone. Growth is difficult to forecast. However, it is certain that things are looking up. The question is only how fast that will happen.[28]

Israel certainly has a major competitive advantage when it comes to developing AI-based health applications. The wealth of healthcare data, coupled with great expertise in the IT field and a strong culture of innovation, are the perfect breeding ground. Germany benefits from a medical ecosystem that has grown over generations, an established network of excellent scientists, and a large market for AI-based health applications. In addition to health insurers, pharmaceutical companies, medical technology manufacturers and software companies, this market is made up not least of the more than 80 million end users.

In the medical, scientific, economic and also political fields, both countries have a lot in common on the one hand. Both healthcare systems are based on social insurance, have a strong focus on digital health, and have been close trading partners for years. On the other hand, they complement each other. Israel's hands-on mentality and innovative spirit as well as IT know-how meet Germany's traditional healthcare and high density of medical research institutions and pharmaceutical companies.

An exchange of knowledge and cross-border cooperation between Germany and Israel on the application of AI in medicine therefore seems indispensable, not only against the background of close German-Israeli relations.



German Israeli Health Forum for Artificial Intelligence (GIHF-AI)

To exploit the recognised potential of German-Israeli cooperation in the field of digital health, the European Leaders Network (ELNET) founded a new initiative in 2021, the German Israeli Health Forum for Artificial Intelligence (GIHF-AI).

The GIHF-AI is funded by the German Federal Ministry of Health (BMG). It supports the exchange of knowledge and experience between Germany and Israel in the field of Digital Health with a focus on Artificial Intelligence (AI) and Machine Learning (ML).

The forum brings together experts from science, medicine, industry, research and politics and takes a multi-sectoral approach: it addresses the three core areas of technology and security, regulation, and communication and trust. The aim is to develop recommendations for action for policymakers through regular publications, dialog formats, workshops and annual conferences.

In addition, the forum also serves as a platform to build new bridges between the two countries. After all, the corona pandemic has once again made it clear to us: health knows no borders.

What added value can the responsible use of AI have in medicine?

Patients benefit from comprehensive applications that support their diagnoses and treatments.

The workload for healthcare staff is reduced and therefore it can better concentrate on patient care.

The increased productivity leads to cost savings, which favors investments in other areas.

About ELNET

ELNET aims to promote European-Israeli relations on the basis of common democratic interests and values in a non-partisan way. Our focus is on foreign and security policy, fighting anti-Semitism and promoting innovation. We are independent, non-partisan and nonprofit.

Our offices in Berlin, Brussels, London, Paris, Tel Aviv and Warsaw, as well as activities in Italy and Spain, strengthen the dialogue between European and Israeli decision-makers in politics, business and society. To this end, we have been supporting existing networks since 2007 with specialist publications, strategic dialogue events and delegation trips.

ELNET-Germany is supported by a large number of private individuals, foundations, institutional partners and companies. We receive project-related funding from various federal ministries.

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GIHF AI

German Israeli Health Forum for Artificial Intelligence

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Policy Briefing "Technology and Security"

Innovation through interoperable, linked health data and collaboration in science

An overwhelming amount of medical data is generated every day. Whether it's from blood pressure measurements, X-rays, and electrocardiogram (ECG) examinations in doctors' offices and hospitals, or genetic analysis in research institutions. The potential that Big Data in the healthcare sector holds for medical care and thus for patients is enormous.

With the help of artificial intelligence (AI), it is possible, for example, to discover patterns in data that are not recognizable to the human brain. Programs trained on this can suggest evidence-based diagnoses and therapies, resulting in faster, more personalized, and more effective treatment for patients. This results in a reduction of unnecessary treatments and examinations, which relieves medical staff and patients alike. It also saves resources that can be used more efficiently elsewhere.[1]

However, data from research and care are recorded differently in each laboratory and hospital. They are formatted, formulated, and stored in a different manner, are subject to different software systems or, in some cases, even exist only in paper form. Yet, data are indispensable for translational medicine, the transfer of research and development processes into medical application.[2]

To exploit the enormous potential of medical data, they must be made usable, i.e., prepared and laid out in such a way that they can be used and transmitted for treatment, research, diagnostic and other purposes.[3]

Health data - Interoperability for better health care

The need to communicate medical data within an institution has existed since the first electronic patient records of the 1960s, which were mainframe-based. Today, there is an increasing demand for solutions able to communicate data across institutions, sectors, and states. In addition, the increased use of digital health applications (DiGA) requires support for mobile and cloud-based applications.[4]

Wearables and health apps, for example, are used by about thirty percent of the German population and provide valuable data and information on the health status of their users.[5] To ensure that existing data can also be used in diagnosis, treatment and research, interoperability must be guaranteed above all. The word, which comes from Latin, refers to "the ability of specific communication and collaboration between systems. Interoperability is a functional property of a system or program. The system's interfaces are open so that collaboration with other programs or systems is possible."[6]

In the field of health research and care, organiza-

tions such as Health Level 7 (HL7) or DICOM are concerned with the interoperability of these data for health care and health research.[7]

In Germany, HL7 is a registered association that was founded in Berlin in 1993 and aims to enable "more efficient communication and FAIR (= findability, accessibility, interoperability, reusability) data use, which improves diagnostics, therapy, and patient safety". Its 300 members include the National Agency for Digital Medicine (gematik), the National Association of Statutory Health Insurance Physicians (KBV), the Federal Institute for Drugs and Medical Devices (BfArM), and the Robert Koch Institute (RKI).[8]

Over the years, HL7 has developed several healthcare data exchange standards, including HL7 version 2 and the current "gold standard" FHIR (Fast Healthcare Interoperability Resources). Although they were developed by the same organization and share some common goals and functions, they are different standards.
Both enable interoperability of disparate systems within healthcare. These include Hospital Information Systems (HIS), Laboratory Information Management Systems (LIMS), Practice Management Systems (PVS), and Medical Billing and Electronic Health Record (ePA) systems. FHIR combines the advantages of previous standards with current web standards as known from Google, Twitter, and Facebook (e.g., XML, JSON, HTTPS, OAuth). FHIR's design is easy for software developers to learn and puts a focus on widely applied use cases. Data can always be exchanged and represented in human-readable form, even if any machine-readable interoperability fails. In addition, FHIR is based on an open-source license.[9]

"By using uniform languages such as FHIR, SNOMED and LOINC, the data can be interpreted unambiguously and can even be merged internationally and used for research purposes,"[10] says Prof. Dr. Sylvia Thun, Director of the Core Unit eHealth and Interoperability at the Berlin Institute of Health at Charité (BIH). A flagship for this is the Standard Dataset for COVID-19 patients, the "German Corona Consensus Dataset" (GECCO), which gives the scientific community a common language and working basis.

GECCO was used, among other things, in the Corona-Warning-App and was created by Professor Sylvia Thun and her team. It considers elements specified by the World Health Organization (WHO), such as the "International Statistical Classification of Diseases and Related Health Problems" (ICD).
Thus, the dataset can be used in Germany and internationally, as in the European ORCHESTRA project, where data from all over the world were merged and harmonized to answer questions about indications, side effects and drug interactions very precisely.[11]

Standard Datasets of this type can and should be created for any medical condition and have the potential to revolutionize medical care. As GECCO demonstrates, they enable scientists from around the world to collaborate on research into diseases, which consequently has a huge impact on their treatability.

This is particularly true in relation to rare diseases, for which one has very few data sets in a national context. Also, in the treatment of patient groups

that are underrepresented in clinical trials – such as women, since clinical trials are predominantly conducted on men – the resulting increase and diversification of research data can lead to significant advances in treatment.[12]

German Israeli Science Cooperation: "The International Health-Tech Pilot Program"

Standard Datasets also have enormous added value for researchers in the context of international research projects. This is particularly true for Israel, which is one of the leading countries in digital health with over 700 digital health startups.
Around 85 percent of these young technology companies rely on artificial intelligence. As FHIR is increasingly becoming the leading standard in Israel as well, thanks to the efforts of the country's Ministry of Health and the Israeli HL7 community, comprehensive interoperability is guaranteed. That is especially important with regard to German Israeli scientific cooperation.[13]

One such initiative is the International Health-Tech Pilot Program, which emerged in 2019 from a cooperation agreement between Charité - Universitätsmedizin Berlin, the Berlin Institute of Health (BIH), and the Israel Innovation Authority. It aims to make medical innovations and new technologies available more quickly for global patient care through international collaboration. Selected startups receive financial support from the Israel Innovation Authority and the opportunity to test their medical innovations in studies at the Clinical Study Center of Charité and BIH in Berlin.[14]

In order for researchers to be able to cooperate even more closely in the national as well as international context and, above all, across institutions and borders, an efficient data infrastructure is needed above all in addition to data interoperability.
This also includes data platforms and research centers that meet national and international standards for data protection and data security as well as intellectual property rights, in addition to those within the institution.

"Data for Health" and Germany's Data Infrastructure

The German Federal Ministry of Education and Research (BMBF), the German Federal Ministry of Health (BMG) and the German Federal Ministry for Economic Affairs and Energy (BMWi), now the German Federal Ministry for Economic Affairs and Climate Action (BMWK), have launched the "Data for Health" innovation initiative to establish such a data infrastructure in 2020.
This is intended to pave the way for the collection, archiving, and evaluation of digital health-related data in compliance with Germany's Patient Data Protection Act (PDSG). With the Medical Informatics Initiative, the BMBF is promoting the establishment of research data platforms as well as consortia that make data from research and patient care accessible to each other and open them up for medical research, as in the context of GECCO.[15]

The Research Data Center Health (FDZ) at the BfArM, which is currently being set up, will also make it possible to access the medical billing data of all people with statutory health insurance in Germany. From 2023, insured persons will also have the option of voluntarily making the data stored in the ePA available to research as part of a data donation. Since health data are subject to special protection in Germany and Europe, citizens should be able to decide for themselves whether personal health data are also made available for research.[16]

TIMNA, EITAN and Medical Innovation Centers: Israel's advanced data infrastructure

In Israel, the Ministry of Health coordinates Big Data projects such as the "EITAN" data platform, which was created as part of some $270 million government initiative in 2018 to further promote digitization in healthcare. It complements the existing "OFEK" platform, which has been collecting data from the four health insurance companies (Kupot Holim), hospitals and healthcare organizations in Israel for more than 20 years. As in Germany, work is underway in Israel to guarantee the widespread

adoption of ICD-11, which comes into effect in 2022, and to ensure the uniform naming of diseases. In addition to EITAN, the Big Data research platform "TIMNA," the national project to promote data collection, storage, and analysis, promotes the creation of comprehensive analyses. According to Moshe Bar Siman Tov, former director general of the Israeli Ministry of Health, TIMNA "is a repository of anonymized data from various sources that serves as a basis for research and contains Big Data that enables scientists to gain insights and identify patterns that can later be used in decision support systems."[17]

In addition, the Israeli government supports healthcare organizations in establishing the technical infrastructure to promote digital health research and development with up to $2.5 million per institution, for example, to implement the FHIR standard. Innovation hubs, such as the I-Medata at Tel Aviv Sourasky Medical Center (Ichilov), which is directly connected to the hospital, also provide a comprehensive research ecosystem for data-based solutions to clinical issues.[18]

Privacy Preserving Record Linkage (PPRL) and Federated Learning (FL)

Until the research data center in Germany is fully established, Open Data can be used to a sufficient extent, an EU-wide Health Data Space facilitates access to Big Health Data, and outstanding data protection and cybersecurity issues are resolved, other solutions for linking data are needed, such as Federated Learning (FL). AI calculations that are important for training the algorithm are performed directly on the end device. Only the results of the algorithm's calculations are transmitted and merged, so that sensitive data does not even have to be exchanged.[19]

Another possibility that is already finding application is the exchange of data via coded values. This process of linking records without disclosing sensitive or confidential information about the entities represented by those records is known as Privacy Preserving Record Linkage (PPRL). PPRL is used, for example, in technologies that are blockchain-based or use homomorphic encryption. Relevant data can be made available without identifying data. Using this method, data owners such as hospitals, research institutions, and laboratories can link their data and collaborate on joint research projects.[20]

Conclusion and outlook

Since the "Act for Better Care through Digitization and Innovation" (Digitale-Versorgung-Gesetz; DVG) came into force in December 2019, German policymakers have spared little expense or effort in advancing digitization in the German healthcare system.[21]

Cross-ministerial initiatives such as "Data for Health," which have already led to improved data interoperability and linkage, are proof of this. However, it will be several years before patient data is digitized with the help of the ePA and available for research via the FDZ and Open Data platforms, for example. Neither scientists nor patients, who could benefit from more efficient therapies, have this time. Therefore, it is essential to enter international research collaborations with highly digitized countries such as Israel. Interoperable data and privacy-sensitive linking methods make it possible.

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German Israeli Health Forum for Artificial Intelligence

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Report "Technology and Security"

Data Access and Data Linkage: More data, better data, more connected data - but how?

This report is a summary of the first German Israeli Health Forum for Artificial Intelligence (GIHF-AI) Digital Health Roundtable-Workshop on April 7, 2022 and addresses health data access and linkage with a focus on data interoperability, cybersecurity, privacy, and regulation. It complements the GIHF-AI Policy Briefing "Innovation through interoperable linked health data and collaboration in science" from April 1, 2022. The video recording of the roundtable can be found on the ELNET YouTube Channel.

RECOMMENDATIONS FOR ACTION

- **The introduction of interoperable data standards such as LOINC, SNOMED and FHIR in the public and private sectors should be a top priority to guarantee the usability of data.** This is because the meaningful use of AI in healthcare depends on the quality, standardization, and quantity of available medical data. **Political regulation and the creation of incentives** can accelerate the implementation of data standards in the public and non-public sectors; the experience of the Israeli government has shown this. In addition, this can and should avoid the creation of parallel structures.

- **Health data protection should follow a risk-benefit approach, be sector-specific and be organized in a centralized manner.** The large number of cross-sectoral data protection authorities in Germany leads to dilution and unmanageable as well as unnecessary regulation, which not only creates intransparency, but in many cases is a concrete hindrance to research and science. Project-based and risk-based evaluation, based on the GDPR, minimizes data protection errors while enabling (collaborative) research. In addition, a **cybersecurity framework in the sense of Protect, Detect, Restore** should be applied to minimize data protection risks from cyberattacks.

- **The Federal Government of Germany should create and drive the appropriate infrastructure to accelerate the development process of a European Health Data Space. This also includes the rapid and widespread introduction of the new ePA 2.0,** including implementation and support for users (doctors and patients) and communication. This is because the creation of a European Health Data Space and further support for national initiatives such as the Health Data Lab (HDL) at the BfArM will ensure efficient exchange of and direct access to various health data in health care, health research and health policy.

RECOMMENDATIONS FOR ACTION

- To enable cross-institutional scientific collaboration, including in an international context, the **use of Privacy Preserving Record Linkage (PPRL) and Privacy Enhancing Technologies (PET)** should be considered. Where necessary, appropriate **regulatory adjustments** should take place. These methods offer researchers, with the help of specialized service providers, the ability to link data sets securely and in a privacy compliant manner.

- **Health data should be understood as a public good.** The use of FAIR (= findability, accessibility, interoperability, reusability) health data, while respecting the GDPR, can create the needed trust of the population in the use of their data. A **corresponding communication campaign** to educate and inform is recommended in addition to regulatory alignment.

- **The promotion and funding of a bilateral research project in the form of a call for proposals for a digital AI-based health application is recommended.** This is because Germany currently does not have the health data it needs and can therefore benefit from Israel's wealth of data, especially in the field of AI. Such a bilateral research project can act as a use pilot program for further research projects. The **call for proposals should address both public and non-public institutions** to achieve the best possible outcome. Israel's Ministry of Health has already been able to launch numerous successful projects with such tenders.[1]

International collaboration in digital health: interoperability is key

International scientific cooperation in the field of medicine depends on interoperable data, as recently demonstrated by the Corona pandemic. Exemplary for this is the standard data set for COVID-19 patients, the "German Corona Consensus Dataset" (GECCO). The dataset provides the scientific community with a common language and working basis.

It was used, among other things, in the Corona-Warn-App and the international research project ORCHESTRA, where data from all over the world were combined and harmonized to answer questions about indications, side effects and drug interactions. In addition, high-quality, standardized data is needed to validate AI analyses. Higher validity, in turn, leads to greater confidence in AI-based systems.

Furthermore, a healthcare system digitized by interoperable data facilitates medical documentation, mitigates communication-related treatment errors, and eases the flow of information. Institutions such as the German Institute for Standards (DIN) and, in the international context, the Joint Initiative Council for Global Health Informatics Standardization (JIC), with around 300 standards, are responsible for standardizing health data. These include LOINC, SNOMED and HL7, as well as the Global Digital Health Partnership (GDHP) under the umbrella of the WHO, or the Global Alliance for Genomics and Health (GA4GH) in the field of genomic data.

The institutions are committed to constant flow of health data, which requires, among other things, the use of an International Patient Summary (IPS). It contains essential health information as specified in EN 17269 and ISO/DIS 27269 and is designed to support, but not limited to, the unplanned, cross-border care application scenario.

In Germany, the electronic patient record (ePA) was introduced in 2022. Expected in 2023, ePA 2.0. will be even more patient-centric (patients will decide independently how their data may be used), have enhanced functionality, and most importantly, be

interoperable as it is based on FHIR (Fast Healthcare Interoperability Resources).

The healthcare data exchange standard developed by Health Level 7 (HL7) is considered the current "gold standard" and is increasingly used in an international context. The Israeli Ministry of Health is working at full speed to introduce FHIR standards across the board in the public and non-public sectors. The implementation of FHIR in Germany will be accompanied by facilitation for collaboration.

Nevertheless, there are challenges, such as the integration of results from DIGA (Digital Health Application) or MIO (Medical Information Objects) as well as the feed of radiological findings and AI-based data. The Interop Council for digital health in Germany, consisting of more than 100 experts, has been coordinating processes around data interoperability since December 2021 and will address these.

In the area of research, the Medical Informatics Initiative (MII) of the 34 German university hospitals, which is funded by the German Federal Ministry of Education and Research (BMBF), is primarily concerned with collaboration on medical data. As with all cross-institutional collaborations, the challenges include, in particular, maintaining the privacy of sensitive patient data. For this reason, federated learning techniques are used. Here, AI calculations that are important for training the algorithm are performed directly on the end device. With these methods, the data does not leave the facilities.

In addition, standardized data sets such as GECCO should be used. The LOINC (Logical Observation Identifiers Names and Codes) terminology, which has existed for 15 years and contains 90,000 terms, is part of the data set. Furthermore, SNOMED CT is used, the most comprehensive terminology with 340,000 medical terms. Germany joined the SNOMED community in 2021. By comparison, Israel joined the SNOMED community as early as 2012 and therefore has valuable experience in data standardization.

Additively, the ISO standard "Identification of Medical Products" (IDMP) is increasingly being used at university hospitals such as the Charité – Universitätsmedizin Berlin. Further data standards in the area of pharmaceuticals are to be made available (soon) by the Federal Institute for Drugs and Medical Devices (BfArM). Private software companies, on the other hand, often use their own standards, which are a hindrance in the context of interoperability. Expanded regulation of data standards would remedy this problem.

For the international statistical classification of diseases and health problems, both Israel and Germany use the International Classification of Diseases (ICD) standard specified by the World Health Organization (WHO). The current ICD-10 is used in 100 countries and has over 11,400 codes. In both Germany and Israel, work is underway to introduce the new, improved ICD-11 across the country, which came into force in 2022.[2]

Protecting patient data: privacy and cybersecurity in healthcare

Data protection and cybersecurity should be a top priority, especially in the healthcare sector, as it involves highly sensitive data. In order to build trust in digitized applications, guarantee the smooth running of clinics, practices and research institutions, and serve research, healthcare data must follow the highest data protection and cybersecurity standards. Nevertheless, it is important to keep in mind that innovative and timely science and patient care depend on data being allowed to be used and shared. A risk-based approach including quantitative and qualitative risk evaluation prior to each project can prevent overregulation from stifling scientific progress.

At the same time, risks are reduced to a minimum, because sensible risk-benefit prioritization is the key to privacy-compliant science. It should also be noted that the European Union (EU) General Data Protection Regulation, on which Israeli data protection regulation is also based, provides multiple legal bases in the area of data protection. Different guidelines apply depending on whether the data

are to be used for outpatient or inpatient medical care, research, or the creation of patient files. It is often assumed that explicit patient consent is the only legally possible basis, although there are a total of six legal bases in the GDPR for the use of health data. These opportunities for adaptation should be exploited.[3]

It is also important to apply the highest standards in the area of cybersecurity. After all, cyberattacks on medical institutions can bring entire hospitals to a standstill as well as cause major data leaks. Typically, these attacks take place in the institution's Active Directory, the database. A risk-based backup of the Active Directory in the sense of Protect, Detect and Restore therefore leads to additional security and should be implemented across the board. Specialized service providers can help to equip the systems accordingly.[4]

Storing and using health data: Israel and Germany

In Israel, health data has been stored digitally since the 1990s and has therefore been available in completely digital form for over twenty years. The healthcare system is based on the four health insurance companies (Kupot Holim), of which Clalit is the largest. In addition to hospitals, outpatient clinics and pharmacies, they also maintain innovation centers. These centers are responsible for the data of all people insured with the respective health insurance company, who as a rule remain with one health insurance company from birth to death. The data can be used both internally and by external parties in the form of cloud solutions. Interoperable data standards ensure maximum usability, also in the context of international scientific cooperation. By anonymizing the patient data, the data can be made available to researchers without risking data protection errors. In the course of the corona pandemic, the whole world benefited from this wealth of data, which massively facilitated vaccine development.[5]

The German health care system is currently working hard to build a health data ecosystem so that it can benefit from its own enormous wealth of data. The largest nationwide initiative is the Health Data Lab (HDL), Forschungsdatenzentrum Gesundheit (FDZ) in German, at the BfArM, which is currently being set up to provide researchers in particular with patient data for scientific purposes. Data from around 72 million people with statutory health insurance since 2009 are to be made available for research in the future, in particular to health insurance companies, universities and scientific institutions, but not to the private sector. Data from ePA 2.0., DIGA and MIO will provide content to the HDL.[6]

The evolution of healthcare through data linkage

Scientific cooperation in the national and international field depends on data cooperation. The use of large data sets is essential for both the validation of results and the generation of new hypotheses. If an institution does not have enough data, linkage of data from other institutions is required. Using Privacy Preserving Record Linkage (PPRL) and Privacy Enhancing Technologies (PET), which are technologies already successfully in use in Israel's healthcare system today, institutions conduct research together without ever seeing the collaborating partner's data. Data collaboration takes place, for example, through Data Encryption, Synthesis, Differential Privacy (DP), Trusted Execution Environments (TEE), and Federated Learning (FL). In addition, there are software and technologies that have built-in verification mechanisms to avoid sharing sensitive data. A warning message alerts users that there is a privacy issue. In order to ensure interoperability, the data is harmonized to, for example, FHIR standard.[7]

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Statement "Regulation" by Nicole Formica-Schiller

European Health Data Space: Transforming health data access and sharing

This report is an overview of the current proposal for the European Health Data Space (EHDS) and its potential implications for the healthcare system. As outlined by the European Commission (Commission) Proposal, dated 3rd May 2022, for a Regulation of the European Parliament and of the Council on the European Health Data Space, the general objective of the intervention is to establish the rules governing the EHDS to ensure natural persons' access and control over their own health data, to improve the functioning of the single market for the development and use of innovative health products and services based on health data, and to ensure that researchers, innovators, policy-makers and regulators can make the most of the available health data for their work, while preserving trust and security.[1]

Ultimately, the use of this these real-world data would enable healthcare professionals, public authorities, regulators, industry, and innovators to ensure that healthcare practice, health systems, products, innovative technologies, and therapies meet a patient's needs and lead to favourable health outcomes. Such outcomes should include improvement of understanding of health and disease; better anticipation of disease outbreaks; faster prevention and diagnosis as well as development of more effective preventive measures and treatments.

It is planned that by 2025, European member state citizens will have access to their Electronic Health Record (EHR) and be able to share them with healthcare professionals across EU member state borders. This should lead to a real freedom of movement for many patients. In practice however, this would require medical records issued in a common exchange format, interoperability becoming a compulsory requirement and health data becoming more available for secondary purposes such as research and innovation, and policymaking among others. Furthermore, the inclusion of data generated by health and wellness applications etc., that could potentially be used for secondary data, is likely to create privacy risks and other issues as this type of data typically do not have the same level of quality and controls as data generated through medical practice.

Companies and researchers who want to use electronic health data will need a permit from one of the new health data access bodies, to be set up in each EU state. Access will only be granted if the requested data is used for specific purposes, in closed, secure environments and without revealing the identity of the individual it refers to.

The national health data access bodies will be connected to a decentralised EU infrastructure for secondary use, called HealthData@EU, which will be set up to support cross-border projects. Innovators and researchers from outside the EU might also be able to access this European data for secondary use, under the same conditions.

Challenges and Issues with Implementation

International interoperability standards might need to be reviewed and established to avoid uncertainty and complications for industry and users. **Secure data sharing** is fundamental to the success of the EHDS and providing effective collaborative treatments for patients. Despite the importance of sharing healthcare data, currently some healthcare systems often require patients to obtain and share their medical records with other providers by sharing physical paper copies or electronic hard disk copies. This system is far from ideal for many reasons, not least of which is because it is a slow process that may compromise patients in poor health. Furthermore, the ineffective data sharing process in healthcare is partially due to the lack of trust between users and the lack of interoperability between health IT systems and applications. It will be important to make sure that the **additional standards are consistent with current frameworks** to ensure a smooth transition.

The complex governance issues involved in protecting the very personal and private data require a clear need for more **transparency in the areas of consent, anonymisation, and data ownership**. To achieve this, healthcare systems need to overcome the challenges of meeting the combined needs of the **legal and ethical frameworks of both patient care and pan-European data requirements**. Sharing of data is seen as problematic not just because of technical limitations, but also because of the need to meet complex information governance rules, organizational needs and priorities, public expectations of privacy for their health data, and even a distrust between different care providers. Any new legislation that is adopted in connection with the EHDS and its data uses, should provide a **trustworthy framework** for health data collection, access and use that is employed when datasets are made available to users.

How the EHDS will **interplay with other data legislation** will need to be sufficiently addressed. Legislation such as the EU General Data Protection Regulation (GDPR) was perceived to make research more difficult and thereby deterring international investment. The EHDS could provide a unique opportunity to overcome some of these uncertainties by clarifying the legal basis for the use of health data in a way that is consistent with other existing and upcoming regulations, such as e.g., **the Medical Device Regulation, the EU Data Act, and the regulation of Artificial Intelligence (AI) namely the EU AI Act**.

This legal framework should encourage national and regional health data providers, researchers, and health agencies to **increase and coordinate investments** that support the creation and management of data infrastructure. Furthermore, this framework should encourage data integration into EHRs and health systems from consumer devices. This should include **standards and data quality rules** applicable to patient generated data through apps, wearables, sensors etc.

Genome analysis and disease predisposition planning are the cornerstones of precision health, which is an emerging approach focused on improving an individual's health by diagnosing, preventing, and treating a future illness through wellness and prevention interventions. Enabled through integrated AI technologies, precision health combines advances in genomics medicine with enhanced data collection from EHRs, environmental sensors, wearables, and other devices.[2] Determining a diagnosis involves not only assessing clinical information, but also an analysis of data generated by a patient's lifestyle, biometric data, genetics, and socioeconomics. Soon, **precision health is poised to disrupt the business, operational, and technical models of healthcare** to an even greater degree by combining genomic analysis with more robust data and AI capabilities to optimize treatment and reduce the prevalence of certain illnesses. The ability to recognize a future health risk and intervene with preventative measures will **fundamentally alter the paradigm of healthcare**. In the future, it is likely that healthcare organizations will find themselves increasingly focused on **proactively monitoring healthy individuals, performing preventative and wellness interventions**, and managing prevention and wellness for not only at-risk individuals.

These **precision health models will be underpinned by the EHDS**. However, the Commission has not sufficiently clarified **how such data can be shared in a timely manner with third parties**, therefore, impacting innovation and development of new precision medicines. In addition, both the **cost and monetary retribution for data** is uncertain. Any legislation will need to take measures to ensure and improve data quality at health care provider level and guarantee that data from devices and/or reported by patients can migrate to a common health data space.

Finally, **citizens' trust in the data space and its governance rules will likely be one of the most critical issues** to realize the goals of the EHDS.

Implications for Germany

Germany's digital transformation in healthcare has been making substantial progress over recent years. However, there is still room for improvement when it comes to the progress and level of innovation of pioneering EU countries such as Sweden, Estonia and Demark and non-EU countries such as Israel. A recent study has demonstrated that the adoption of digital infrastructure by physicians has increased significantly.[3] However, digitization has not yet resulted in sufficient digital data exchange between hospitals and outpatient physicians. Most of the communication between outpatient physicians and hospitals is still paper-based.

One part of the problem is Germany's fragmentation with different software and standards across the country. Germany's digital health ranking has been at the lower end compared to other countries in recent years.[4] Further compounding this issue is a lack of willingness to share data across federal states and healthcare providers.

The COVID-19 pandemic has catalysed the benefits of digitization and the pace of progress for a national e-health infrastructure must grow exponentially in preparation for the EHDS in 2025, partly because of the significant legislative activity of recent years and still upcoming. "The Health Data Lab" (HDL; German: "Forschungsdatenzentrum Gesundheit") at the German "Federal Institute for Drugs and Medical Devices" (BfArM; German: "Bundesinstitut für Arzneimittel und Medizinprodukte) aims at converting highly sensitive health data into new, "synthetic" datasets for anonymisation purposes. Data will be made available to researchers by the HDL. This involves billing data that is transmitted to the HDL by the German National Association of Statutory Health Insurance Funds in pseudonymised form and contains, e.g., information on diagnoses, treatments, and costs.

The HDL will guarantee security of the data in accordance with state-of-the-art practices and technologies. To ensure this, the HDL works together closely with the "Federal Office for Information Security" (BSI, German: "Bundesamt für Sicherheit in der Informationstechnik") and the "Federal Commissioner for Data Protection and Freedom of Information" (BfDI, German: "Bundesbeauftragter für den Datenschutz und die Informationsfreiheit").

Key Findings and Recommendations

The legislative EHDS proposal will profoundly change how patients, doctors, researchers and policymakers, access and use health data while realising billions in economic gains. In anticipation of the EHDS in 2025, numerous interconnected regulations and frameworks will need to be formulated and communicated to all stakeholders participating in the EHDS. It will therefore be necessary to consider and address the following:

- Provide strong safeguards for security and privacy reconciling the fragmented and sometimes diverse interpretation of GDPR rules. To overcome fragmentation and differing interpretations, ensure that EHDS legislation is to the best extend possible uniformly implemented across member states.
- New legislation should specify the elements of a trustworthy framework for health data collection, access, and use. It should also make provisions for secondary analysis legislation.
- The legal framework should encourage national and regional health data providers, researchers, and

health agencies to increase and coordinate investments that support the creation and management of data infrastructure.

- Furthermore, this framework should encourage data integration into EHRs and health systems from consumer devices.
- This should include standards and data quality rules applicable to patient generated data through apps, wearables, sensors etc.
- Ensure compliance with interoperability standards across member states and embedded in and supported by EU level legislation, which can readily be translated into national or regional level legislations and policies.
- Consider and endorse a Common Data Model approach to ensure standards, consistency, and quality of data across member states.
- Regulations, frameworks, and standards need to be built on international interoperability standards.
- Implement measures to improve data quality at the health care provider level and ensure that data from devices and/or reported by patients can migrate to a common health data space according to established data standards.
- Integrate data from major digital health consumer ecosystems and mobile health solutions.
- Include information on resource usage and health care costs from social insurance registries and funds.
- Integrate disease registries held in health care institutions and appropriate organisations such as rare disease registries.
- Invest in research and development areas particularly for high priority disease areas.
- Enable integration of transformative technologies to leverage the EHDS such as AI, digital twins, wearables etc.
- Ensure scalability to capture and integrate genomic, biomarker and microbiome information.

Based on the above outline including key findings and recommendations about the EHDS, its challenges and implications, it is without any doubt that the potential of the EHDS is significant. In particular, as it would represent one of the largest health databases in the world providing data on over 500 million Europeans and coverage across diverse healthcare systems.

Therefore, the EHDS should be seen as a major opportunity towards an advanced, interconnected digital healthcare ecosystem. In particular for the current German federal government, elected in September 2021, which has placed a specific focus on driving forward the digitalization of the healthcare system.

However, it needs to be kept in mind that to achieve this important milestone, it needs an efficient alignment in a timely manner between all stakeholders. For a sustainable digital healthcare system and best possible health outcomes for all involved.

About the author

Nicole Formica-Schiller is CEO & Founder of Pamanicor Health AG, a global boutique advisory firm for transformative technologies and Life Science, as well as Member of the Board of Trustees at GIHF-AI (German Israeli Health Forum for Artificial Intelligence). She has been appointed as OECD AI expert and selected by Forbes for "most innovative ideas" in AI & Blockchain. As international digital expert Mrs Formica-Schiller is a sought-after speaker and regularly featured in the media including her latest book ("AI & Blockchain in Healthcare", Elsevier). She sits on various Boards (German AI Association; Head Steering Committee "EU AI-Regulation" etc.) and advises governments, ministries, academia, and industry in digital, geopolitics, and policy. Mrs. Formica-Schiller graduated as an Attorney-at-law with an additional business degree and has been working globally throughout her whole career.

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Policy Briefing "Regulation"

A solid legal framework for the innovation-promoting use of health data

The development and use of artificial intelligence (AI) in healthcare depends to a large extent on the **availability and usability of health data**. The reason is obvious: An AI can only be as good and representative as the data available to train it. After the previous Policy Briefing by the German Israeli Health Forum for Artificial Intelligence (GIHF-AI) dealt with the technological and security aspects of this data, the focus of this briefing are the **most important regulatory mechanisms regarding primary use (use for health care) and secondary use (use for research and development) of health data** in Germany, especially focusing on the latter. For that, we draw a comparison to a country that is about 20 years ahead of Germany when it comes to Digital Health: Israel. The Middle Eastern country already has over 700 digital health startups and a thriving infrastructure of AI-based health applications, used by the majority of its population of just over nine million.[1]

When it comes to the use of health data, Germany is not in a legal vacuum. Quite the opposite: there is a large number of municipal, national and state-dependent regulations that influence the primary and secondary use of health data. **As part of the European Union, German legislation must furthermore be considered in an EU context, given that AI Made in Germany also means AI Made in Europe**. Many laws and requirements on health data are sensible and necessary, as we are dealing with highly sensitive data. Others, however, lead to legal uncertainty and overregulation, which in comparison (also in a European context) make it difficult for developers, startups and smaller companies in Germany to develop innovations and bring them to market. A **rapid implementation of the Health Data Use Act (GDNG)** planned in the coalition agreement for better scientific use of health data **in line with the EU's General Data Protection Regulation (GDPR)**, as well as the **rapid establishment of a decentralized research data infrastructure**, can provide a remedy.[2]

Legislation and the Status Quo in Germany

A milestone in the promotion of Digital Health in Germany was the **Digital Healthcare Act, known as Digitale-Versorgung-Gesetz (DVG)**, that came into effect in December 2019 and provided the foundation for the Digital Health Applications Regulation (DiGAV) and the Patient Data Protection Act (PDSG). In addition to extending the Innovation Fund with 200 million euros annually until 2024, it includes the obligation of pharmacies and hospitals to provide incentives for physicians, midwives, physiotherapists, as well as nursing and rehabilitation facilities to connect to the telematics infrastructure (TI). According to the German government's current digital strategy, the aim is furthermore to achieve widespread use of the electronic patient file (ePA). At least 80 percent of those with statutory health insurance

should have an ePA by 2025 and the establishment of the e-prescription should be the standard.[3]

However, prophecies that Germany, Europe's largest healthcare market, will become a global player in the digital health sector, have not yet materialized. Currently, **the digital health application directory by the Federal Institute for Drugs and Medical Devices (BfArM) lists just 33 applications**[4] and the absolute number of prescriptions is at merely 45,000 – an almost negligible number compared to the 444 million prescriptions for conventional drugs and medical aids.[5] In addition, there is the **almost non-existent uptake of the ePA**. Only 0.5 percent of respondents to a Bitkom survey conducted in November 2021, stated that they had used the electronic patient record, despite expressing great interest in it.[6]

Even though there are various reasons for these sobering numbers, ranging from inadequate education to a lack of trust, the **lack of a clear legal framework for the use of health data** is one of the most crucial ones. Recently, the Conference of State Health Ministers asked the Federal Ministry of Health to identify the reasons for the low uptake of digital applications (for instance the ePA) to evaluate the opt-out solution for the ePA, a demand by the 126th meeting of the German Medical Association.[7] This view is gaining increasing support and is shared by the German Council of Experts on the Assessment of Developments in the Health Care System (SVR), as well as the German Medical Association.[8] Another example is the increased urgency with which physicians, patients, health insurers, researchers, civil societies, and businesses call for the **swift implementation of the Health Data Use Act**, agreed upon in the coalition agreement. This law intends to ensure that health data can be better used for research while being in agreement with the EU's GDPR. At the same time, the misuse of data is to be prevented through higher technical data security and tougher penalties.[9]

As the signatories of the paper "Cornerstones for a Health Data Use Act" argue, **"the use of health data is based on the idea that in a solidarity-based health care system, the general availability of digital health data is an expression of a person's communal responsibility, insofar as personal disadvantages ensue"**.[10]

„Data sharing is caring": A European Health Data Space

In addition to the above-mentioned arguments, the wider use of the electronic patient file creates the basis for further standardized and open interfaces, such as the **connection to the European Health Data Space (EHDS)**. The EHDS can be seen as a regulatory framework for the use of health data in a pan-European context. It provides clear rules, common standards and practices, infrastructures, and a governance framework for the use of electronic health data for the benefit of patients, research, innovation, policymaking, patient safety, statistics, and regulation.

On May 3, 2022, the European Commission published a regulation proposal, which the EU Commissioner for Health and Food Safety, Stella Kyriakides, sums up as follows: "Today we are putting in place another pillar for the European Health Union. Our vision is becoming a reality. The European Health Data Space is a fundamental game changer for the digital transformation of healthcare in the EU. It places the citizens at its center, empowering them with full control over their data to obtain better healthcare across the EU. This data, accessed under strong safeguards for security and privacy, will also be a treasure trove for scientists, researchers, innovators and policy-makers working on the next life-saving treatment. The EU is taking a truly historic step forward towards digital healthcare in the EU."[11]

The basic principle of the EHDS is that EU citizens can jointly use and profit from health data, while at the same time, the rights of the individual are protected. This principle is based on the GDPR, the proposal of the Data Governance Act, the draft of a data law, and the NIS Directive.[12] It has three main objectives: First, **users throughout the EU should be able to control their personal health data**. For instance,

by accessing data like their medical history, test results or prescriptions and be able to share them with hospitals and practitioners, as well as between member states. This would change the primary use of data, as it gives patients significantly more rights and possibilities to use their data. Second, it strives to create a **coherent framework for the use of individuals' health data for research, innovation, policymaking and regulation**, i.e., for secondary use. This too will have significant benefits for patients, as the use of data on vaccination effects during the Covid pandemic in Israel exemplified. Third, unleashing the data economy by promoting a single market for digital health services and products (EHR systems) will have a significant positive impact on AI Made in Germany and AI Made in Europe. This required a more effective law enforcement in the field of AI, however, for instance through the enactment an EU regulation for Artificial Intelligence (EU AI Act).[13]

> "The European Health Data Space is a fundamental game changer for the digital transformation of healthcare in the EU. It places the citizens at its center, empowering them with full control over their data to obtain better healthcare across the EU."
>
> Stella Kyriakides, EU Commissioner for Health and Food Safety[11]

Looking beyond the horizon: Handling health data in Israel

The **German top-down** strategy in terms of regulation stands in contrast to the **Israeli bottom-up** approach. Long before the introduction of an electronic patient file was seriously discussed in Germany in 2017, Israel had already digitized its population's health data for the last two decades and used it for healthcare and the research and development of innovative digital health apps and wearables.[14]

Israel began with the digitization of patient data as early as 1995, in the wake of its National Hospital Insurance Law. The 1996 Law for the Protection of Patients' Rights also established binding standards of conduct for the protection of patient data. However, the data in question was held exclusively by one of the four health maintenance organizations (HMO). There was a lack of regulation by the state, as well as a lack of coordination in cross-insurance data sharing. In consequence, the HMOs engaged in a high level of competition and tried to succeed each other in developing and investing in digital health applications. However, data was fully available for research and privacy issues occurred.[15]

Therefore, **Israel's use of data for research** purposes was very low, according to the 2013 OECD report on the connectivity of health data in member countries. Regulatory adjustments, such as the **National Program for Promoting the Digital Health Field**, adopted in 2018, marked a turning point, highlighting the viability of a solid regulatory framework. Particularly secondary use of health data has been facilitated through the related **development of Big Data platforms and data sharing platforms by the Israeli Ministry of Health** such as "PSIFAS". Especially in relation to rare diseases, personalized medicine and general development of medicines, the benefits of using big data cannot be denied.[16]

In addition to continuous regulatory adjustments in the secondary use of data, the Ministry of Health in Israel is eager to establish the legal framework for the primary use of health data. The laws for the protection privacy and medical data were enacted in the 1980s and most recently amended in the 1990s. **Existing patient data should be protected even better in the future, in line with the GDPR**.

In addition, access to one's own data is to be improved. In particular, the use of health data for the research of Covid vaccines by a pharmaceutical company recently led to an increased desire among the Israeli people for **transparency regarding their own patient records**, even though the consensus on sharing data was very high among the population and the data was completely anonymized any-

way. Ironically, the legislative changes pushed by the Ministry of Health have been delayed by COVID-19. Also, the proposal for a change in the law published by the Ministry of Justice last summer has so far failed to achieve any significant success.[17]

Conclusion and Outlook

Health data is much more than a collection of laboratory values, X-ray findings and doctor's letters. Their use has the potential to revolutionize medical care because they act as **fuel for innovative treatment options**. Due to their high sensitivity, they are rightly considered to be particularly worthy of protection in the GDPR. The individual wellbeing and self-determination of each person must have top priority.

However, when regulating the use of patient data, one should not forget, that this data is also a **common good**, as the research results on corona vaccinations from Israel show. A health data use law in line with the GDPR, the introduction of an opt-out solution for the ePA, and an integration into the EHDS, may be useful measurements to adopt a **sustainable regulatory framework** that promotes **solidary data use**, conducive to research and ultimately health care.

In addition, there should be **legal certainty for AI-based applications and confidence in AI Made in Europe** through the swift enactment of an **EU Artificial Intelligence Act (EU AI Act)** and clear supplementary guidelines. In this context, it should generally apply that a **solid legal framework** for the innovation-promoting use of health data may replace the existing overregulation.

Excitingly, Germany and Israel face similar issues about the use of patient data, even if Israel is miles ahead when it comes to implementation. This is another reason why **close cooperation and knowledge sharing** on this issue are so **central and should be promoted and encouraged**.

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GIHF AI

German Israeli Health Forum for Artificial Intelligence

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Report "Regulation"

Health data regulation in Europe, Germany, and Israel

The contents and recommendations of this report result from the second Digital Health Roundtable of the German Israeli Health Forum for Artificial Intelligence (GIHF-AI) on September 20, 2022, in which high-ranking experts from the German[1] and Israeli[2] healthcare sectors exchanged views on the topic of "Health data regulation in Europe, Germany, and Israel – the EHDS as an example for health data portability". The focus was on EU regulation and the proposal for a European Health Data Space (EHDS). The report complements the GIHF-AI Policy Briefing "A solid legal framework for the innovation-promoting use of health data" from September 1, 2022. The following is an initial summary of the recommendations for action that were developed and are further explained in the subsequent text. The video recording of the roundtable can be found on the ELNET YouTube channel.

RECOMMENDATIONS FOR ACTION

- **FHIR** (Fast Healthcare Interoperability Resources) **as a global standard** for the exchange of health data should also be **clearly defined in laws and regulations such as the proposal for a EHDS**. Only a global standard can guarantee that health data can be used for research (secondary use).
- The **proposal for a EHDS should also specify how health data can be shared with third parties**. Among other things, the development of precision medicines, personalized medicine and other innovations depend on this. **EU-wide regulation** would **ensure greater transparency and trust** here and support developers.
- **With regard to the use of patient data, the opt-out procedure is preferable to the opt-in procedure for secondary use**, both in the national and international context. This is necessary to ensure that the majority of patient data can be used for research. The current opt-in process does not make enough data usable. Moreover, an opt-out procedure allows **patients to equally retain sovereignty over their health data.**

RECOMMENDATIONS FOR ACTION

- The **implementation of the requirements** (nationwide introduction of standards such as FHIR, opt-out for ePA) **must be consistently enforced at the federal and state level**. In addition to a clear regulatory framework at the EU level, this requires active, timely and mandatory implementation by all healthcare providers (hospitals, outpatient care, etc.).
- **Better communication of the benefits of data use** and **greater transparency** will lead to greater trust. Therefore, it is recommended to initiate a **nationwide campaign on health data use**. This will lead to involving and informing the population as well as medical staff.
- The **exchange between Germany and Israel** regarding the regulation of health data within the framework of GIHF-AI shows that the systems and digitization status of the two countries differ greatly. At the same, time both Israel and Germany are addressing the core issues such as **data interoperability, primary and secondary data use, data sovereignty and trust of the population** in the health context. **Maintaining and deepening the dialogue between the two countries** is essential, as these topics are of particular importance in the the context of artificial intelligence in the healthcare sector.

FHIR for all: Israel is working hard on health data interoperability

The **Israeli government** has been **working diligently in recent years to introduce data exchange standards for the four healthcare organizations** which function simultaneously as health plans and healthcare providers (HMOs), namely FHIR (Fast Healthcare Interoperability Standards), and Nomenclature (SNOMED CT). In addition to the voluntary-based incentive structure to switch to FHIR, a bill is currently being drafted that will make it mandatory for all health organizations.

For their own legislation-making process, Israel is looking primarily at the U.S., where FHIR is already the standard, and Europe, where the EU Commission's recently published European Health Data Space (EHDS) regulation takes a major step toward uniform regulation of health data in Europe.

However, **there is no obligation to use FHIR in the EHDS regulation**. The Israeli Ministry of Health assumes that countries that do not use the FHIR standard will become unattractive for innovative digital health companies and could therefore miss their opportunity in terms of international competition. The **U.S. government has already written FHIR into all regulations as a standard**, many startups are primarily oriented to the U.S. as the largest market when developing health applications, and the private sector (e.g., Google, Amazon, and Apple) also uses FHIR. It therefore makes sense for the EU and Israel to keep this in mind when setting data standards.

Regulation of health data in the context of the EHDS: daring to innovate more

To improve health care across borders, health and health data should be considered not only at the national level, but also in a global and interdisciplinary context. This lesson can be learned not least from the corona pandemic. In this context, there is a consensus in both Israel and Germany that **no modern healthcare system will endure without digital innovation or the use of AI. Sufficiently large data sets are absolutely essential** for this. At the same time, neither in the public discussion nor in regulation should we lose sight of the fact that the modernization of the healthcare system can alleviate human suffering caused by diseases and even save human lives.

The EHDS brings great potential in this regard, possibly harmonizing data of over 500 million Europeans. **Unified EHDS regulation could also remove many uncertainties regarding existing and future EU regulations, such as the Medical Device Regulation, the EU Data Act, and the draft of the EU AI Act**. Although there are some major challenges, including the multitude of EU member states with

different standards and laws, the EHDS could fundamentally revolutionize healthcare and foster innovation. To **avoid technical and legal uncertainties, international interoperability standards need to be reviewed, and secure data transfer**, both in terms of privacy and cybersecurity, **needs to be ensured**.

Patients should have sovereignty over data

In addition to regulating technical standards, both countries are increasingly addressing the question of how patients can gain both more access to and more sovereignty over their health data. This includes for example deciding whether or not to share data with third parties. **Answering open questions about data privacy and data ethics** is essential to alleviating fears about the digitization of healthcare. In this area, Israel is strongly oriented towards Europe and is therefore following regulatory proposals with great interest.

Israel sees an uncontrolled transfer of data to third parties that are not regulated, such as in the U.S., as impractical. One option **Israel is currently considering, is regulating apps, wearables, etc. with a two-phase model**. When these application are subsidies by public entities (e.g. healthcare organizations, government), private insurance companies, or by the patients paying for the service, they would be subject mainly to cybersecurity and privacy requirements, but if they have a different revenue model (e.g. a pharma company is subsiding the service) they would likely be more heavily regulated and reviewed.

Another interesting question is **whether patients can give access to their data for research purposes** and what regulatory measures should apply here. So far, there are no answers to this in the EHDS proposal. Conceivable scenarios would be project-dependent permits for exclusive use of the data for research, or tariffs prescribed by the legislature that would have to be paid to the data owners (in this case healthcare organizations).

German legislation should also be strongly oriented toward EHDS regulation. There is a consensus in both Israel and Germany that the **increased right of co-decision and greater transparency will ensure more trust in digital health on the part of the population. This trust** is indispensable for innovations in the healthcare sector, precisely because sensitive, personal data is involved. At the same time, it is needed for the development of innovative medical technology, diagnostics, preventive measures, and so on.

For this purpose, it also makes sense to clearly communicate what the data is used for and what benefits result from the use of large amounts of data. **Patients should therefore not only be given data sovereignty.** Government regulation needs to ensure that data protection and cybersecurity are guaranteed and that the benefits of sharing data with third parties are clear. To communicate this transparently, a **nationwide campaign to educate the population** would be useful.

Health data use and AI: A trustworthy legal framework for more innovation in healthcare

What Germany can learn from Israel is the mindset of approaching innovation in healthcare. Health data has been used for research in the so-called Startup Nation for decades, as in the Corona vaccine development, and innovations are explicitly encouraged by the government. The large number of Israeli digital health startups exporting their applications worldwide illustrates this. Privacy, cybersecurity, and data sovereignty issues should be openly discussed, and regulation needs to be constantly optimized, because **to be advanced, development and regulation must go hand in hand**.

Particularly with regard to the use of Artificial Intelligence, the regulation of health data will have a major impact. Even within Europe, glaring differences exist in terms of the acceptance of digitalization in healthcare and AI applications that have the potential to improve our medical care. Europe in general and Germany in particular should avoid preventing innovation and causing a brain drain through over-regulation. Rather, **human-centered, trustworthy, and transparent AI regulation has to ensure that AI is used in the best interest of patients**.[3]

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GIHF AI

German Israeli Health Forum for Artificial Intelligence

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Policy Briefing "Communication & Trust"

Trustworthy use of artificial intelligence in the healthcare sector

A fundamental prerequisite for the use of artificial intelligence (AI) is trust in digital innovation. This is also emphasized by the European Commission in its proposal for an order on the regulation of AI systems (EU AI ACT). It proclaims that "Europe should become the global hub for trustworthy artificial intelligence".[1] Legislative proposals based on this, such as the revised EU Product Liability Directive of September 28, 2022, also underline that **AI technologies can only flourish in the EU if people trust digital innovations**.

Trust plays a particularly important role in the healthcare sector, as AI requires large amounts of data for its „training", and health data is particularly sensitive according to the GDPR, therefore requiring utmost protection. The **EU AI ACT also reflects the special importance of trust in AI in healthcare**.[2]

The previous policy briefings of the German Israeli Health Forum for Artificial Intelligence (GIHF-AI) dealt with technical, security-related, and regulatory aspects regarding the use of health data for AI in Germany and Israel. The focus in the following lies on trust in artificial intelligence in both countries. In doing so, **not only is the relationship of trust to the technology itself considered, but also the relationship to and between the relevant actors**. The **doctor-patient relationship (DPR) is given special attention** in this paper. In addition, the **influence of evidence on trust** is examined in particular.[3]

Trust and Artificial Intelligence: (Also) A Question of Definition

In the context of this paper, the following definition of trust is adopted: *"***Trust denotes a specific relationship quality between a trust giver and a trust object** *(communication). In the case of generalized trust, it is about the generalized willingness to trust a person, in the case of interpersonal trust, trust refers to a specific person, and in the case of system trust, it refers to organizations or institutions."*[4] The **doctor-patient relationship can be understood as inter-personal trust**, the **user-developer relationship or health insurance company-doctor relationship as well as evidence-based trust as system-trust**.

Even though artificial intelligence by definition **"imitates human cognitive abilities by recognizing and sorting information from input data."**[5], it is not considered a person, but a system. Thus, when one speaks of **trust in AI, they mean system-trust**. AI cannot be "trust-worthy" in a sense that a human being can be. But people can have confidence that the AI system in question has been tested, is subject to regulation, and is therefore safe.[6] Another definition that is particularly appropriate in the context of trust regarding AI is that of the sociologist and philosopher Georg Simmel. It describes "the mechanism of trust as a **state between knowing and not knowing, in which the available information**

is exaggerated or overinterpreted."[7] In the context of AI, this approach seems particularly appropriate because AI systems are complex systems that work with algorithms. Their exact functioning is difficult for many people to comprehend due to their complexity, which is why one has to rely on the **reduction of complexity**. In this respect, **trust that reduces complexity** seems to be a sensible approach.

A good doctor-patient relationship as the key to trust in AI

93 percent of respondents to a Bitkom study would prefer a diagnosis by a human being and only 31 percent of respondents would regularly seek a second opinion from an artificial intelligence in the future. In turn, 61 percent of respondents said that doctors would have more time for their patients if AI relieved them of simple tasks. So, on the one hand, there is still a lack of trust in AI applications in medicine, and on the other hand, one of their greatest benefits is recognized: The workload reduction it provides to healthcare professionals so that they can treat their patients even better.[8] It should be noted that the study was conducted in 2019. Therefore, it would be useful to examine how the relationship between patients and AI has developed in the meantime.

At the same time, according to a **study by the German Association of Statutory Health In-surance Physicians (Kassenärztliche Bundesvereinigung) from 2021, the doctor-patient trust ratio is at 90 percent and thus at a very high level**.[9] In conclusion, patients also have great trust in their practitioners when it comes to questions about digitalization and AI use.

Measurable evidence for more trust in AI

At the same time, **doctors must have a trusting relationship with AI systems** in order to be able to work with them confidently and to convey security to their patients. To this end, **evidence-based projects such as the "Responsibility Gaps in Human-Machine Interactions: The Ambivalence of Trust in AI"** of the Ingolstadt University of Technology (THI) and the Catholic University of Eichstätt-Ingolstadt (KU) or the **joint project FRAIM** of the Federal Ministry of Education and Research are particularly useful in Germany. FRAIM aims to provide an ethically and legally sound as well as empirically validated evaluation framework for AI procedures. *"In sub-projects, detailed* **ethical, legal and empirical analyses are carried out to determine the acceptance of AI-based procedure***s, especially in neuromedicine. The researchers are among others investigating the following questions:* **What is relevant for patients and doctors to assess the trustworthiness and usefulness of AI technology? How does the use of AI for diagnosis and decision-making affect the doctor-patient relationship? How can weaknesses in current law be addressed and viable legal solutions developed?**"[10] The THI and KU project will also explore how best to present algorithmic results and uncertainties to doctors in order to properly weigh and use the trust in the advice of AI systems.[11]

Israel is already several steps ahead on this point. **To ensure that clinicians are involved in the early design phase of AI-based projects, many Israeli hospitals have their own innovation hubs**. There, doctors are brought together with startups, scientists, or specialized analytics providers to work together on solutions. The hospitals provide data while clinical expertise and the industry partner brings along the technical skills. This builds a **collectively beneficial relationship** that leads to **mutual trust and understanding**. Also, working closely with the Ministry of Health and the Ministry of Justice in areas such as patient data confidentiality and secondary use of medical data paves the way for faster legislation and greater trust."[12]

Stakeholders and patient representatives

Evidence-based trust on the part of users does not only arise in the context of medical consultations. **Positive experiences with AI-based applications, i.e. practical evidence, can also strengthen trust in innovations**. There are many examples: For people who speak with a substitute voice due to a missing larynx, new technologies can improve communication and thus also participation in society. Onco-

logical patients who are treated with the help of a medical AI assistance system can have significantly better chances of survival or recovery thanks to the improved flow of information between the doctors treating them. **AI systems help in preventive care as well as in diagnosis and therapy up to aftercare**, because they check existing findings on the basis of countless comparative data and make a recommendation.[13]

Patient advocacy groups also emphasize the great benefits of AI systems for those affected in terms of diagnosis, treatment, and safety. AI health apps or care robots that assist in taking medication through reminders or monitor health status create trust in treatment and medical staff as well as AI. At the same time, they point out that self-learning AI systems must justify their recommendations, ethical rules must be discussed and programmed, and risks such as data misuse and cybercrime must be seen and prevented at all costs. Moreover, AI systems should not want to replace doctors, but support them in their work. **In order to create trust among patients, it is also essential to involve them transparently in all processes**.[14]

> *"Patients should be transparently involved in the processes. Transparency creates not only trust, it can also be ensured that the respective technologies be applied."*
>
> Federal Association of Laryngectomy Patients e.V.[13]

Leading the way in trust through an ethos of innovation: AI development in Israel

The **ethos of innovation is deeply rooted in Israeli culture**. It is based on Israel's ability to act flexibly and react quickly to unexpected circumstances in order to sustain itself. This also explains the **rapid growth of Israel's high-tech industry**. Moreover, Israel is now one of the leading countries in AI development. Since the small country has few natural resources and its economic strength depends heavily on the high-tech industry, **AI contributes greatly to economic growth and to improving the health system**.[15] Innovations such as AI may therefore have a confidence advantage compared to Germany, especially when used in the health sector.

Nevertheless, in particular the use of health data for research into Covid vaccines by a pharmaceutical company recently led to calls among the Israeli population for more transparency and a say in the use of sensitive health data.[16] Experts have since stepped up calls for legislation to clearly regulate when patient data can and cannot be used, and for people to be informed when their data is being used for a particular project. The **Israeli government has understood that a confidence advantage does not mean that it is infinite. Therefore, it is currently working on a new regulation for health data use**. This illustrates the influence of politics and the legislature on the public's trust.[17] In terms of legislation, the Israeli Ministry of Health, for example, is also guided by European legislation such as the EU AI ACT.

Summary and outlook

Evidence creates trust in AI, both in the context of evaluation of AI and in the sense of practice-related evidence. This refers both to the trust of doctors and of patients in AI. At the same time, people's trust in their doctors is very high in Germany. It can be concluded from this that **both personalized trust in the context of the doctor-patient relationship and trust in evidence-based information led to greater trust in AI**. In addition to functionality and the **added value created for prevention, diagnostics, treatment and aftercare**, data security also plays a major role here. Therefore, the influence of all relevant stakeholders such as political actors, scientists and the health industry must always be considered. **Trustworthy regulation and transparent communication** by policymakers, thoroughly researched and developed AI by the scien-

tific community, and transparent application by the healthcare industry will create **sustainable trust**.

This becomes particularly clear when one looks at Israel. **Doctors, startups, businesses, and politics are working together in hospital innovation hubs to establish trustworthy AI applications**. The Israeli government's look to Europe for regulation underscores the need for an ethically and legally trustworthy framework. Years of experience with tech innovation and the resulting system-trust also benefit the Startup Nation. Through numerous AI-based applications from which patients already benefit, there is also a high level of practice-related evidence. This again promotes trust.

Close **cooperation between Germany and Israel** on trust in AI therefore makes sense both in terms of **establishing trust-promoting development and regulation of AI in the health sector**. Based on the results, Germany should develop a **communication campaign for the population** for a better understanding of AI use and processing of health data.

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GIHF AI

German Israeli Health Forum for Artificial Intelligence

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Report "Communication & Trust"

More confidence in AI - from evidence to data use and trust

On October 19, 2022, the German Israeli Health Forum for Artificial Intelligence (GIHF-AI) held its Digital Health Roundtable on "Communication and Trust". High-level experts from the German[1] and Israeli[2] healthcare sectors exchanged ideas on the topic of "How to achieve greater confidence in AI – from evidence to data use and trust". The particular focus of the third GIHF-AI Roundtable was on the doctor-patient relationship, transparent communication, and evidence that promotes trust through the use of "Good Health Data". Accordingly, this report complements the GIHF-AI Policy Briefing "Trustworthy use of artificial intelligence in the healthcare sector" from October 14, 2022. The following is an initial summary of the recommendations for action developed, which are further explained in the subsequent text. The video recording of the roundtable can be found on the ELNET YouTube-Channel.

RECOMMENDATIONS FOR ACTION

- **The proposal for a regulation laying down harmonised rules on Artificial Intelligence (EU AI ACT) of the European Commission should revise the definition of AI**. The current definition is still too broad. A differentiation between ML and AI as well as between weak and strong AI is also needed. In addition, the definition should subsequently be adopted by legislators at the federal and state levels. **A clear, unambiguous definition is required to gain trust in the use of AI in healthcare from physicians, patients, as well as policy makers and society**.

- **Successful AI requires "Good Data" that follow the FAIR principle and are voluntarily made available for research** (for example, through an opt-out option in electronic health records). **This can minimize concerns related to potential data misuse**. The use of health data for AI use must not only be about "Big Data", i.e., the largest possible data sets. The **quality of the data, via the training of the AI, largely determines its susceptibility to faults**. Errors in turn reduce confidence in the functionality.

- **The EU Commission's Proposal for a Regulation on the European Health Data Space (EHDS) should act as a regulatory framework for the use of health data**. A clear, regulatory framework for the privacy-compliant and ethical secondary use of health data, used across countries, would lead to **greater confidence in the use of health data for AI development**. It could also save researchers and industry from regulatory mistakes.

RECOMMENDATIONS FOR ACTION

- **Physicians should be closely involved in the development of AI**, since the doctor-patient relationship plays a supporting role with regard to the use of AI-based health applications by patients. The trust in AI use gained by doctors through the increased flow of information would thus be transferred to their patients.

- **A broad-based communication campaign that presents how AI is applied in the context of healthcare, in an understandable manner, should be launched.** It should showcase that AI can complement and enhance the treatment provided by healthcare professionals. This can simultaneously educate and build trust. For many people, it is very difficult to grasp how AI works. They fear, for instance, that AI will replace treatments by humans (doctors and patients).

- **Close exchange with countries like Israel, which already widely apply AI in healthcare, should be increased to build evidence-based trust**. AI-based treatments by physicians are already used extensively in Israel, which leads to low error rates in diagnoses, predictions of the effect of medications, the occurrence of certain symptoms, etc. by AI-based systems **in terms of causal inference**.

More trust in AI through clear definitions and unambiguous regulation

Although **artificial intelligence (AI)** is already used in many areas, it is **often met with great skepticism, especially in the medical context**. The reasons are obvious. AI requires a lot of health data for its training. However, these are very sensitive datasets and particularly worthy of protection. At the same time, in medicine, the high good of health is at stake, which is generally preferred to be entrusted to known physicians than to an AI. Due to its complexity, AI is also a black box for many people, and they have little idea what it is. In addition, there is the **fear that AI could replace doctors and nurses**, dehumanize medical care, or make diagnoses that are not checked by a human being and are therefore incorrect.

In order for stakeholders from the medical field, patients, science, politics, business, and society to place more trust in AI-based systems in medical care, **first and foremost a clear definition and classification of artificial intelligence in the medical context is required**. It should be emphasized, that in this context, we are talking about AI usage that supports doctors in making faster and better diagnoses, interpreting symptoms at an early stage, and improving care through personalized medicine. It is therefore seen as **complementary to the role of physicians and nurses and does not replace them**.

A clear **demarcation of Machine Learning (ML) is just as important as the distinction between weak and strong artificial intelligence**. Neither is done in the current regulatory frameworks. A **clear definition would make it easier for policy makers to create a clear regulatory framework for the use of AI**. This, in turn, would make it easier for physicians to decide whether and how to use AI systems for diagnosis and treatment, and would give developers and the healthcare industry confidence that their applications meet the strict requirements for AI. This would benefit not only doctors, whose work would be made easier and more precise, but above all patients.

The **proposal for a regulation laying down harmonised rules on Artificial Intelligence (EU AI ACT) of the European Commission** can provide such a regulatory framework for a clear definition. However, the existing **AI definition there must be formulated much more narrowly** to leave less room for interpretation. The definition should then be adopted by governments at the federal and state level so that researchers, AI developers and the healthcare

industry in Germany, have a legal framework for trustworthy AI.

In addition, the **EU Commission's Proposal for a Regulation on the European Health Data Space (EHDS) can define the extent to which health data can be used for the development of AI**. As long as these regulatory frameworks do not exist, there is a risk that AI-based healthcare applications will not be approved in Germany and developers will look to other healthcare markets where there are clearer or fewer regulations. This means that the German healthcare system is missing out on great potential for improving diagnosis and treatment.

The doctor-patient relationship in the context of trust in AI

It is primarily physicians and patients who are expected to use or benefit from AI-based systems and applications. Nevertheless, **physicians are not involved strongly enough in the development yet, although their trust as main users is indispensable**. The same applies to the digitization of hospitals in general. For this reason, many healthcare facilities in this country appoint Chief Transformation Officers (CTO) who are responsible for the digital transformation of those facilities and act as facilitators. The resulting digitization, especially of healthcare data, lays the foundation for AI use.

In Israel, the largest hospitals have their own innovation hubs, where doctors, researchers, and startups work together on innovative solutions for better healthcare. The **strong involvement of physicians not only improves development, but also creates a great deal of trust**. The motto here is **"doctor-in-the-loop"**: the doctor is presented as an authority inside a loop, supplying an expert system with information about current patient data, treatment results, and possible additional (side) effects, returning treatment recommendations to the doctor himself.[3]

Patients generally have a high level of trust in their treating physicians.[4] **By strengthening the medical profession's trust in AI-based applications, this can have a positive impact on patients' relationship with the use of AI in treatment**. This includes a greater willingness to donate health data for research and development of AI-based applications. In addition to the doctor-patient relationship, patients themselves also play an important role in trusting AI use. Patient initiatives and petitions seeking increased data use and AI application, for instance in the oncology field, are evidence of this. **Patients' voices should be heard more**, as they are both data providers and beneficiaries.

Evidence and the use of "Good Data" builds trust

Trustworthy, data-driven predictions, as well as successful data-based treatments, build trust by **causally demonstrating the benefits of AI in medical treatment.** By **using "Good Data" according to the FAIR Data principles** that "data must be findable, accessible, interoperable, and reusable"[5], trust is added to the use of sensitive health data. In addition, **to obtain "Good Data," national and international data exchange is critical**. This is because the more data that can be linked, the better the functioning of the AI system will be. At the same time, this has the advantage of avoiding bias (distortion of the result) due to one-sided data sets and making medicine more personalized.

In Israel, in the wake of the corona pandemic, an AI-based *computational predictive medicine* **model was developed in cooperation with one of the largest hospitals to predict the deterioration of patients with Covid-19**. Physicians were closely involved in the development and application in order to be able to explain and understand the predictions, so that they could be implemented in practice. In addition to the predictive capability, the model needed to be paired with actionable insights. The system was also monitored and controlled over time to ensure its reliability and compliance. Based on the **successful use of the model, trust was built, and skepticism was reduced**.

Another example of data-driven decisions about health management and treatment of patients from

Israel is the analysis of **causal relationships (causal inference) in health care. They allow estimation of causal effects when randomized controlled trials are not available. This allows decision-making processes to move from "best guess" to concrete answers based on data.**

Transparency and communication

In addition to a **trustworthy legal framework for the use of AI in healthcare** and **illustrative models of data-based diagnostic and treatment tools based on AI** that provide better understanding, **transparency and communication among the relevant stakeholders** are needed above all. This refers to communication between AI developers and physicians, as well as in the context of the doctor-patient relationship. At the same time, **politics should be closely involved in the discourse** in order to be able to initiate regulations that promote innovation. An **evidence-based communication campaign** that educates society about the application of AI in healthcare and counters possible fears and skepticism with information is recommended, as is the **close involvement of patient representatives** in decision-making processes.[6]

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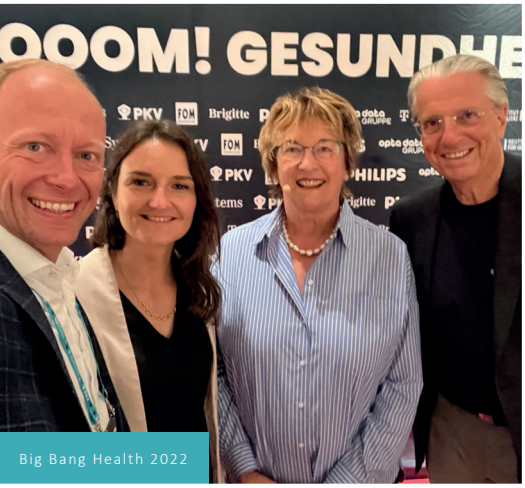

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