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GIHF AI

German Israeli Health Forum for Artificial Intelligence

*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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