Who is EIT Health?

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

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

The EIT Health Think Tank

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

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

Introduction

Digitalisation in healthcare: Germany on its way to implementation

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

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

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

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

Key participants of the event

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

From discussion to action

1. General assessment

Satisfaction with the legal situation

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

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

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

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

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

Obstacles to further development

Barriers to further development are well known

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

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