Editorial

Germany and Europe lead digital innovation and AI with collaborative health data use at continental level

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Collaborative use of population-level health data and artificial intelligence is essential for achieving precision health through a learning health system. Two groundbreaking initiatives—the European Health Data Space (EHDS), covering 449 million EU citizens, and Germany's forthcoming Health Data Lab, providing access to data from 75 million insured individuals (90% of the country's population)—offer unprecedented opportunities to advance digital health innovation and research with global impact.

Bienzeisler et al.[1] show how federated access to 7.9 million data sets representing 2 million patients enables the nationwide secondary use of emergency medicine records while adhering to national and European law. It is an exemplary use case and an early glimpse of where Germany and Europe are headed for building health data research capacity at scale and trust among citizens.

National Emergency Department Data Registry. The National Emergency Department Data Registry is a federated research infrastructure. It is one pillar of and operated within the German Network of University Medicine (see below) and provides federated access to standardized, structured electronic health records from emergency rooms[1–3]. Individual informed consent can be forgone because records remain locally stored, thereby adhering to general medical confidentiality and data privacy legislation. Researchers can file requests with a data use and access committee for review and approval to enforce ethical and scientific standards. After authorization, data are collected and analyzed in a trusted research environment. Bienzeisler et al.[1] should be commended not only for the high level of coordinated structured data collection in their system but perhaps even more so for successfully taking on the challenge of decentralized data governance, where each of the 16 German federal states has its own medical and general data processing regulations combined with the European General Data Protection Regulation (GDPR) provisions. Alternatives to this complexity would be the Canadian Province of Alberta, where the entire population's health records are stored in one provincial electronic health record in a structured and coordinated fashion, allowing easy implementation of disease-specific care pathways and decision support tools at the provincial level[4–6] or the United Kingdoms' Emergency Care Data Set (ECDS)[7].

Rapid digital transformation of the German healthcare system. Germany provides healthcare to its eighty-three million citizens through the world's first social insurance system introduced in 1883 by German chancellor Otto von Bismarck, who laid the foundation for the current statutory health insurance system covering most Germans and inspired other health systems ever since. Its origins date back to the Middle Ages when guilds and selected businesses assumed responsibility for financing medical and nursing care for their members and employees[8].

Today, some 1900 hospitals and 430,000 doctors look after the country's population, costing more than one billion € per day, i.e., over 10% of Germany's gross domestic product. Like all Group of Seven (G7) and Organization for Economic Cooperation and Development (OECD) countries, Germany has been struggling with increasing healthcare expenditures. Germany fell behind when the United States, Canada, and the European Nordic countries decided to deploy digital technologies to take on the challenge in the late nineties and the beginning of this century. The recent pandemic was a wake-up call exposing Germany's weakness when crisis management was hampered due to the lack of centralized health data systems to nationally coordinate resources requiring manual transcription of fax messages. In contrast, other jurisdictions like the Canadian Province of Alberta, with a provincially rolled out electronic health record system, operated a fully digital emergency command center[9].

The first initiative to overcome this problem was launched in 2020 as the Network of University Medicine, a nationwide academic medical center network for crisis management, and coordinated COVID-19[10] research. Its mission has evolved to promote clinical research and accelerated knowledge transfer comparable to the Canadian Institute of Health Research's strategy for patient-oriented research[11]. Around the same time, Germany launched its 500 million € medical informatics funding scheme to make secondary life science data more accessible to strengthen biomedical research and improve patient care. The Medical Informatics Initiative unites stakeholders in academic medicine and all research institutions, businesses, payors, and patient advocacy groups[12] (Fig. 1).

The biggest boost, however, comes from this year's launch of the National Health Data Lab[13]. It makes pseudonymized health data from all people (some 75 million or roughly 90% of Germany's population) insured in Germany's statutory health system available for research purposes. The strategic goal is to ensure efficient and effective medical care through the complete digitalization of the entire healthcare system. Additional supporting initiatives are Germany's artificial intelligence (AI) strategy[14], including both an online platform for learning systems[15], where experts from academia, industry, politics, and civic organizations discuss the development and responsible use, as well as a national artificial intelligence observatory[16] monitoring the impact of AI at the workplace and on society.

A milestone for the European Health Data Space (EHDS). Germany's recent substantial investments in the digital transformation of its national healthcare system mark a critical milestone for the European Health Data Space (EHDS) launched this month. The European Union (EU) appreciates the importance of meaningful transnational data use. The EHDS aims to enhance individuals' access to and control over their personal electronic health data while enabling secondary data use for public interest, policy
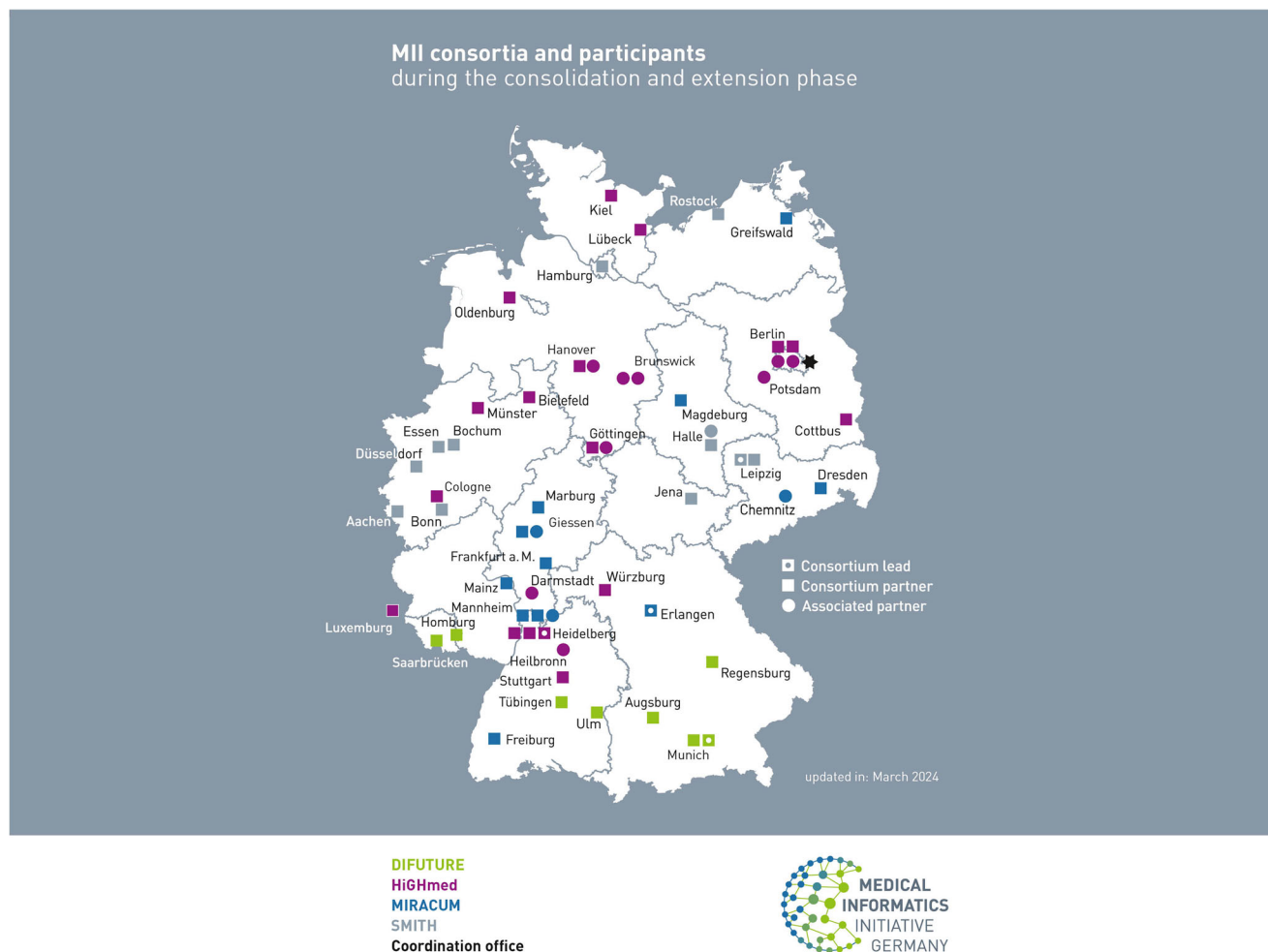
Fig. 1 | **Overview of the Medical Informatics Initiative (MII) in Germany**[12]. Used with permission.

support, and scientific research. It includes establishment of a harmonized legal and technical frameworks for electronic health record systems[17].

Impact on North America and outlook for the world. The United States has created and is home to some of the most iconic resources for life science research, such as the fully digitalized National Library of Medicine or the Health Level Seven International (HL7) organization standardizing interoperability[3] and also most of the world's largest digital technology companies including those focused on artificial intelligence. Canada was an early adopter of digital health, including telemedicine, to deliver healthcare across its vast geography. It was the first country to have a national AI strategy[18] and profoundly advanced deep learning and reinforcement learning.

The digital health and life science AI race will be ultimately determined by access to population-representative health data to train dependable models. This is where countries like Germany and the EU are leading the way now. All countries are invited to follow their initiative and are welcome to join. Non-EU European countries, like the United Kingdom (UK) have developed national strategies for federated health data sharing like their Health Data Research Gateway (HDR UK), National Health Service Data Federated Data Platform (NHS FDP), the NHS Artificial Intelligence Laboratory and the associated UK Biobank. The United States and the EU introduced the data privacy framework with cross-border data transfer agreements[19]. Canada has recently joined Horizon Europe, with its strong life science and technology focus, and has also taken steps towards transnational data

sharing[20]. However, despite efforts like the multinational Data for Health Initiative, their focus has been mostly on privacy[21] (Fig. 2).

Bienzeisler et al.'s[1] work impressively demonstrates the potential of collaborative health data sharing and how to master complex legal constraints. Global health, life science research, and the biomedical industry would benefit most if more nations and continents followed Germany's and Europe's lead and contemplated national and continental health data spaces for the greater good of humankind.

Data availability
No datasets were generated or analysed during the current study.

Daniel C. Baumgart[1,2] ✉ **& Joseph C. Kvedar**[3]
[1]College of Health Sciences, University of Alberta, Edmonton, AB, Canada. [2]College of
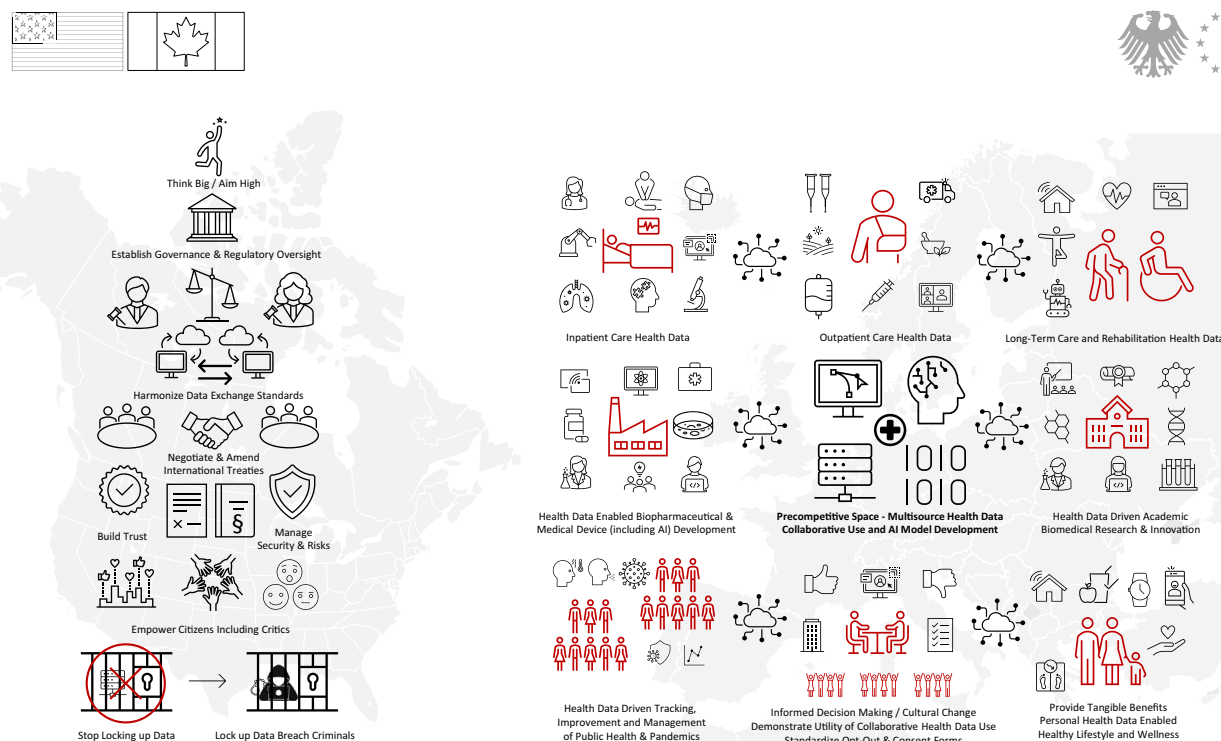
Fig. 2 | A vision for transatlantic collaborative health data sharing[21]. Health (relevant) and life science (related) data originates not only in primary health care or research environments. Instead, stakeholders in healthcare, academia, industry, society, and government all contribute to it. Collaborative use of multisource health and life science data to enable digital innovation requires cultural change, establishing trust among all stakeholders, harmonizing technical and legal standards, aligned regulatory processes, and a streamlined exchange platform for citizens, researchers, developers, and innovators. Reproduced with permission.

Natural and Applied Sciences, University of Alberta, Edmonton, AB, Canada. [3]Harvard Medical School, Harvard University, Boston, MA, USA.

✉e-mail: baumgart@ualberta.ca

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D.C.B. had the idea and wrote the first draft. J.C.K. provided critical revisions. Both authors have read and approved the final manuscript.

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