Country visit – Germany

Objectives of the country visits

The objective of the TEHDAS country visits is to provide an overview of the status of national health data management in different European countries. This mapping exercise takes place in the form of country visits in which national stakeholders working with health data or exchanging health data are interviewed.

The Joint Action Towards the European Health Data Space (TEHDAS) supports EU member states and the European Commission in developing and promoting concepts for the secondary use of health data to benefit public health and health research and innovation in Europe.

Any questions?

Contact us at
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Information about all country visits is available on tehdas.eu/country-visits.

When did it take place?

The visit to Germany took place virtually between **24 November and 12 December 2022.**

Who was involved?

15 stakeholder organisations were interviewed: Federal Commissioner for Data Protection and Freedom of Information; Federal Ministry of Health, Division 511; Federal Ministry of Education and Research; Federal Statistical Office; gematik GmbH (National Digital Health Agency); German Biobank Node; German Human Genome-Phenome Archive (GHGA); German National Research Data Infrastructure for Personal Health Data (NFDI4Health consortium); Health Data Lab at the Federal Institute for Drugs and Medical Devices (BfArM); Institute for Quality Assurance and Transparency in Health Care (IQTIG); Integrating genomics into healthcare (genomDE); Medical Informatics Initiative (MII); National Cohort Study (NAKO); Network of University Medicine (NUM); Robert Koch Institute (RKI).

Germany in brief

The Federal Republic of Germany consists of 16 states (Länder), with a high degree of autonomy. Germany has a highly decentralised and complex health data management system. The health and care system is mainly financed through the statutory health insurance provided by approximately 100 insurance funds, covering about 90% of the population. Currently, health records are not fully digitalised. The digitalisation process is ongoing. There is no personal unique identifier used in health or across sectors. There is a health insurance number for the residents covered by statutory health insurance but this is not generally linked to clinical data or used to link individual level datasets. However, there are several projects and initiatives ongoing that aim to facilitate the findability and accessibility of health-related data for secondary use.

Data collections/sources

- Germany has a fragmented landscape of data collections, with hundreds of collections across levels (local, Länder, national). Several recent initiatives aim to improve harmonisation and accessibility.
- gematik GmbH has set up the telematics infrastructure (TI) and electronic patient records (ePA). Currently, using the ePA based on an opt-in system but will become opt-out to increase coverage.
- The Health Data Lab is being built at BfArM, including health claims data from statutory health insurances. There are plans to integrate data from the ePA in the future.
- The MII aims to facilitate the use of health care data from university hospitals. It is a decentralised infrastructure: data remains in the hospitals' data integration centres.
- The NUM is a network of university hospitals, formed in light of the COVID-19 pandemic to facilitate research. Different studies collect and link clinical, biosample and imaging data.
- There is a long history of cohorts to study population health in Germany. NFDI4Health built a platform to make these studies centrally discoverable and accessible. The largest population-based cohort study (NAKO) directly links their data to health insurance data.
- The RKI carries out surveys (e.g., Health Interview Survey) and maintains some registries. The German Centre for Cancer Registry Data (ZfKD) at RKI receives a core dataset from state-level cancer registries to produce national statistics on cancer epidemiology.
- Destatis maintains several health-related statistics.
- The German Biobank Alliance is an umbrella organisation for most biobanks in university hospitals.
- genomDE, in close cooperation with the GHGA, facilitates access to whole genome sequencing, with genome computing centers.

Data quality

- Multiple validation checks are used by different stakeholders, as well as standardised methodologies.
- Claims data at the Health Data Lab is of high quality and completeness as it relies on reimbursement data and the use of standards. The Health Data Lab reported quality checks are in place.
- Surveys have different quality checks implemented (e.g., plausibility checks). There is a strong focus on training interviewers to ensure high quality of data collection.
- NFDI4Health uses data quality analysis pipelines. Further quality metrics are under development.

Data infrastructure

- In general, data storage is highly decentralised in Germany.
- Access to data is generally requested separately to each institute.
- If approval from the data protection authority is required, this must be sought from the authority in each state from which data is requested.
- There is a complex landscape of initiatives to facilitate access and re-use of health data.
- The MII, together with the NUM, is developing the German Portal for Medical Research Data (FDPG) as a one-stop shop to facilitate access to routine health data from university hospitals.
- NFDI4Health is building a domain-specific health research data infrastructure. It includes data from clinical trials, epidemiological and public health studies.
- In general, data is pseudonymised. There are several trusted third parties (TTPs).
- Fees and times to access data differ. In general, foreign researchers have similar processes to access data as national researchers. Some stakeholders reported different access rights and fees for industry.
- There is no national metadata catalogue. Some institutions have their own (e.g., RKI, FDPG of the MII).
- There are multiple secure processing environments across institutes (e.g., NUM, NAKO). Some are developing SPEs (e.g., HDL, ZfKD), and others use distributed analysis platforms (e.g., NFDI4Health).
- With the support of gematik GmbH as coordination office, the Interop Council has developed a National Interoperability Roadmap for 2023-2024, which aims to provide terminology services, as well as develop guidelines and recommendations for harmonising different standards.
- Semantic standards used include ICD-10 and SNOMED CT. There is broad use of FHIR for data exchange.

Data governance

- There has been increased strategic focus on digitalisation in Germany in recent years.
- The Federal Ministry of Health is responsible for organising the national health data ecosystem.
- The Federal Ministry of Education and Research is funding initiatives, projects, and data infrastructure for secondary use of health data (e.g., MII, NUM, NAKO, NFDI, DZG).
- There are several institutes that guide evidence-based policy making (e.g., RKI, BfArM).
- The main laws governing the use and re-use of health data in Germany include: GDPR, Federal Data Protection Law, Social codebooks 5 and 10, Data Transparency Regulation, state-level data protection laws and Federal Cancer Registry Data Act.
- A new legislation for the secondary use of health data is being drafted, in preparation for the EHDS.
- Currently there are 18 Data Protection Authorities across the 16 states and at the Federal level. In terms of data protection, there is a focus on decentralisation of data and avoidance of data accumulation.
- Ethical committees in Germany are also decentralised at state-level.
- The legal basis for the secondary use of health data is mainly consent or federal and state law.
- Stakeholders note some challenges for researchers to perform research. The multiplication of ethical committees and data protection laws makes it difficult to identify which one is relevant in what case.
- Regarding citizens' involvement, it was reported that there is generally high willingness of patients to share clinical data for research. For example, a German study on cancer patients noted the willingness is mainly linked to the trust in the institution collecting that data, and in the consent model used.
- Citizens are able to access their ePA data and those using appropriate end devices can indicate who can have access to their ePA. Several activities to consult the citizens were described (e.g., stakeholder working groups in the setting up of the Health Data Lab).

Resources (human, technical, financial)

- Human resource needs identified by stakeholders mainly related to skilled staff e.g.:
  - IT specialists
  - Legal advisers
  - IT experts with knowledge on coding
  - Clinicians with knowledge and expertise in genomics. Possibly, an increase in genetics departments in hospitals
- Technical resource needs:
  - General need for development of the IT infrastructure for health data
  - Data hosting capacities (both software and hardware)
- Financial resource needs:
  - Funding to establish the infrastructure to become a part of the EHDS
  - Sustainable funding for the initiatives in place

Capacity building

- Stakeholders reported several training opportunities, such as:
  - Federal Commissioner for Data Protection and Freedom of Information offers a symposium on data protection in research
  - de.NBI/ELIXIR-DE provides training on health data management as part of ELIXIR, with 1500 to 2000 participants per year
  - MII has a task force dedicated to further research, a Master's programme and exchange between university hospitals and researchers. An MII project, starting in January 2023, is coordinating basic services for training and continuous education within the MII.
- Stakeholders noted that there is a need for sharing among Member States on best practices and guidance, for example from FHIR experts

Best practices

Some best practices were noted during the country visit to Germany, such as:

- The Data Saves Lives toolkit has been translated into German language and adapted to local circumstances. This toolkit aims to equip patient groups and health influencers with the information and materials they need to have a positive dialogue with their communities about health data.
- Every ministry is establishing a data laboratory for evidence-based decision making. Data scientists are employed in all ministries.
- The Joint Science Conference (GWK) brings together federal and state governments to set joint priorities for science and research. The Conference deals with questions of research funding, science and research policy strategies that jointly affect the Federal Government and the states.

European Health Data Space (EHDS)

- There is support for the EHDS at political level in Germany. It is viewed as a good opportunity to streamline the national situation.
- It was noted that the EHDS objectives align with the federal government's data policy to expand data infrastructures in an interoperable, energy and resource saving, and decentralised manner.
- At the time of the country visit (December 2022), it had not yet been decided how the infrastructure for the EHDS would be structured in Germany, for instance what institute would be the national contact point for secondary use. It was noted that there may be multiple HDABs, depending on the data type. A final legislative text is needed prior to such decisions being made.
- Stakeholders noted that there is a need to find a unified structure for the different German initiatives to be part of the EHDS.

- Some needs that were noted are:
  - Additional EU funding to achieve the necessary changes for implementation of the EHDS
  - Use cases clarifying the added value for secondary use and cross border health data sharing
  - A longer timeline for implementation (e.g., 10 years) as the current timeline is viewed as too tight for the decentralised German data ecosystem.

- Some of the expectations that were reported with regards to the EHDS are:
  - Recognise the difference in systems across member states, allowing flexibility in implementation of EHDS in different countries
  - Implement a robust framework in line with the provisions of the GDPR and data protection
  - Demonstrate clear benefit for citizens, for instance through monitoring and reporting to citizens on their data that was used
  - Reduce the burden for small data holders