# A Biobank Platform for Germany







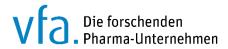


















# **Executive summary**

Denmark, Finland and the United Kingdom have led the way: cross-institutional, service-oriented biobanks are opening up new dimensions for access to health data and human biosamples. Germany is also taking this path: the establishment of a 'National Biobank' has been established in the coalition agreement as the basis for preventive, precision and personalised medicine.

The basic requirements are in place: with the support of the Federal Ministry of Research, Technology and Space (BMFTR), the Network of University Medicine (NUM) and the German Biobank Network (GBN) have laid a strong foundation. Since 2020, the NUM has brought together all 37 university hospitals and created structures for cross-location research. The GBN has networked 43 academic biobanks throughout Germany, introduced quality assurance standards and developed a 'Sample Locator' (samplelocator.bbmri.de). As the 'National Node' of the European research infrastructure BBMRI-ERIC, the GBN also promotes international exchange in biobanking. In 2025, NUM and GBN were merged — an ideal starting point for expanding into a biobank platform for Germany. With a central 'one-stop shop' for researchers and industry, this will significantly accelerate access to high-quality data and samples. At the same time, it will be open to non-university partners such as the Fraunhofer biobank structures, thus opening up further prospects for technological development.

The economic dimension is considerable: international examples such as the UK Biobank show that easier access to health data and biosamples represents an enormous economic lever. Studies estimate that the use of data from the UK Biobank and the National Health Service could generate annual GDP growth of over £10 billion. Applied to Germany, this means a potential of several billion euros per year – through accelerated drug development, Al-supported diagnostics and new business models in the field of biotechnology. The biobank platform for Germany is therefore not only a research project, but a strategic infrastructure project with high macroeconomic added value

In addition, the platform will be compatible with large cohort studies such as NAPKON and NAKO, as well as cancer registries, which — as envisioned in the BMFTR's high-tech agenda — will provide large amounts of data in the future. This integration enables the systematic linking of biological samples with clinical data and creates the basis for research, state-of-the-art diagnostics, personalised therapies and innovative prevention strategies that directly benefit patients. The close connection to the data integration centres of university hospitals ensures that data quality and interoperability meet the highest standards.

The National Pandemic Cohort Network within NUM (NAPKON) shows that such an initiative can be successful: with 34 university medical centres, a recruitment platform for COVID-19 patients was created in a short period of time with uniform standards and a structured use and access process, which is also used for other NUM studies. NAPKON is now used scientifically as an established data basis in many research projects. One exemplary result is a widely cited post-COVID score that enables the clinical classification of post-COVID patients. The task now is to build on this successful model with the structured development of a national biobank platform.

With sustainable funding, the platform will become a key driver of research, innovation and economic growth. Now is the time to act and position Germany for the future in an international comparison.

# **Operational areas:**

- 1. Expansion of existing decentralised biobank structures and efficient interface management under the umbrella of the Network of University Medicine (NUM): The integration of the German Biobank Network (GBN) into the NUM on 1 July 2025 promotes close links with university medical research, clinical researchers and data integration centres central IT structures at university hospitals that standardise medical data from healthcare and make it available for research. The integration of the GBN into the NUM simplifies the linking of biosamples with data from healthcare, thus creating substantial added value for research. The existing decentralised biobank structures are to be expanded under the NUM umbrella into a comprehensive, internationally competitive biobank platform an infrastructure and resource available to the general public, which is used equally by universities, non-universities, the private sector and public-private partnerships and designed to be synergistic. At the same time, the decentralised structure is an essential aspect of a stable and resilient research infrastructure in Germany.
- **2. Integration of sample analysis data in a biobank:** Tailored to the requirements of users, biobanks and their partners provide support in sample collection and preparation (e.g. isolation of DNA/RNA), sample analysis, long-term storage, data analysis and research-related services. In addition to providing samples, there will be a special focus on expanding data use: through the targeted integration of associated centres of expertise, complex analysis data (e.g. OMICS data) can be generated and made available including as a basis for AI applications.
- **3.** Easy access via a central enquiry portal with expert advice: In line with the 'one-stop shop' approach at NUM, the entry point for researchers will be a central digital portal offering fast and transparent access to NUM services: this includes not only available clinical data with the corresponding samples for retrospective analyses, but also access to an infrastructure for prospective sample collection. The portal will be managed by professional and competent staff who will offer qualified advice and support on biosample issues and act as a central point of contact for all enquiries.
- **4. Precise legal framework conditions and transparent ethics and data protection processes:** a practical set of rules is intended to provide legal certainty for the efficient use of the biobank platform. Standardised contracts similar to the templates used for clinical studies are to be introduced as binding for industrial collaborations in order to accelerate processes. A structured framework for data exchange and the use of biological samples, coordinated with the Federal Commissioner for Data Protection and Freedom of Information (BfDI) and meeting the highest security standards, will ensure that data protection and patient rights are respected and will build trust among patients, the partners involved and the general public. Uniform processes for ethical approvals and data privacy clearances throughout Germany increase planning security and shorten access times.
- **5. Uniform quality standards, FAIRness and responsible use:** Strict and transparent standards (e.g. according to DIN EN ISO 20387), which ensure comparability and regulatory acceptance, are crucial for all users of the biobank platform. In addition to consistently ensuring quality,

sustainable access in accordance with the FAIR principles (Findable, Accessible, Interoperable, Reusable) is of key importance. In order to maximise scientific and societal benefits in the long term, data and samples must be systematically made available to researchers via the platform. Professional biobanks thus replace individual collections and ownership logics and enable the effective and sustainable use of valuable resources — a key motivation for patients to make their data and biosamples available.

- **6. Competent specialist staff and the promotion of young talent** are essential for the sustainable operation of the biobank platform. This requires targeted programmes for practical training of all professional groups involved, continuous further education and the encouragement of young professionals. Expertise from medical fields such as laboratory medicine and pathology must be integrated to ensure excellence in the collection and handling of samples.
- **7. Regional networks:** Existing professional biobanks are to be developed into regional hubs. In the future, these hubs will coordinate cooperation with participating regional institutions, thereby enabling the involvement of smaller hospitals and medical practices. This will close an important healthcare gap: disease progression can be researched comprehensively, and patients outside of university healthcare settings can also contribute relevant information to research.
- **8. European and international networks:** Connecting the national platform to European structures such as the BBMRI-ERIC biobank network enables researchers from academia and companies to access international samples and supports Germany's participation in multinational research projects. The biobank platform is already being developed in line with the procedures, structures and usage options of the European Health Data Space (EHDS) and will therefore be 'EHDS-ready'.
- **9.** Participatory further development through cooperative and licence-based models: Joint ventures, service partnerships and the involvement of industry in strategic decision-making processes with the contribution of its own resources form the basis for effective knowledge transfer and the development of new diagnostics and therapies. The focus is on close, structurally anchored cooperation between university and non-university science and industry, involving all relevant stakeholders: academic institutions, companies, scientific societies, associations, patient representatives and, of course, funding agencies. This enables the sharing of resources and promotes mutual inspiration. A practical contribution from industry is the return of data generated from samples, provided there are no economic reasons preventing this. In addition, licensing models for access to data are being developed and expenses for samples are being charged in order to generate appropriate profit contributions and ensure the long-term operation of the infrastructure.

**10. Considering sustainability from the start:** Through optimal sample storage, the use of energy-efficient technologies and optimised processes, the platform uses its resources in an economically and ecologically responsible manner. Investments in innovative solutions will contribute to operating the platform in a climate-neutral manner in the long term.

# Long-term financing:

Subsequent to project funding, the sustainable financing of the biobank platform for Germany should be based on stable, institutional core funding from public funds. In contrast to one-time project funding, this core funding will be associated with significantly reduced annual financial requirements. This will be supplemented by income from research projects and services, including those with and from industry. The example of the UK Biobank impressively demonstrates how, over the years, an increasing proportion of revenue is generated through access to data via fee-based services for external users (£6 million in data access fees vs. £0.9 million for samples in 2024). Public-private partnerships, which enable the development of innovative technologies and the expansion of capacities, play a central role in ensuring a sustainable and future-proof infrastructure. Prospectively, the integration into the long-term research infrastructure NUM, combined with the development of sustainable business models, is promising for refinancing.

In addition, there is the economic benefit: the pharmaceutical, in vitro diagnostics and biotechnology industry – one of Germany's key industries with annual sales of around €81.2 billion and research expenditure of over €22 billion – will continue to invest in the region if an ideal environment for translational research and development is in place. An effectively coordinated and service-oriented biobank platform for Germany that provides high-quality data and actively involves this industry is a central component of this innovation ecosystem.

### **Conclusion:**

The biobank platform is a crucial building block for strengthening medical research and innovation in Germany. It connects decentralised structures to form a comprehensive, service-oriented platform that enables the sustainable use of health data and biosamples. Uncomplicated access and uniform quality and data protection standards create trust and reliability. As a participatory project, the platform actively involves researchers, clinics, industry, patients and funding bodies. By feeding back analysis data, users also become designers of the platform, shaping its further development. This creates a dynamic network that brings medical advances into healthcare more quickly and reduces costs in the medium term. With political commitment and targeted funding, this key infrastructure can now be established – for the long-term benefit of patients and to strengthen Germany as a centre of research and business.