

TRANSFER FROM HEALTH RESEARCH TO APPLICATION

Mission and overall strategy of
Helmholtz Health
August 2021 (2nd edition)

Contents

1. Summary.....	2
2. Importance of biomedical research.....	2
3. Helmholtz Health.....	3
4. Successful transfer activities in Helmholtz Health	4
5. Measures	8
6. Monitoring success	10
7. Final comments on transfer in the biomedical sector.....	10



1. Summary

Excellent research is one of the main factors in facilitating innovation that generates social capital. Grouping together Europe's leading centers of cutting-edge biomedical research, the Helmholtz Association's Research Field Health (Helmholtz Health) is addressing this global social challenge of an unprecedented scale. Our mission is to lead top international research for the medicine of the future and to make a significant contribution to ensuring that these results are translated into progress for society, for our health system, and for the economy as quickly as possible. In order to steadily expand the transfer portfolio, further accelerate the speed of this transfer, and make essential contributions to society, health care, and the economy even more effectively, the centers involved in Helmholtz Health have teamed up to develop a joint **Seven-Point Charter** to further optimize the transfer process in Helmholtz Health. That alone will not be sufficient, however. In addition, the fiscal and investment framework in place in Germany needs to become competitive on the international stage. Despite and because of these challenges, Helmholtz Health believes that it has a responsibility to turn an internationally unique research partnership into a globally successful translational unit and to deliver the medical solutions that tomorrow's world will require.

2. Importance of biomedical research

More than anything else that has happened, the COVID-19 pandemic underlines the huge importance of biomedical research and its far-reaching influence – on the health sector, society, and the global economy. The mRNA technology developed in Germany led to the first vaccine to be approved to combat SARS-CoV-2 and is thus playing a crucial role in containing the pandemic. This gives Germany the chance to become a global leader in the biomedical field again, as it once was when the country was known as the 'world's pharmacy'.

Excellent research is one of the main factors in facilitating innovation that generates social capital. Internationally reputed and competitive basic research is traditionally one of the great strengths of German universities and research organizations. However, there have been numerous examples in the past of the ideas of excellent researchers being transferred to commercial applications more efficiently in other countries, primarily in the United States, and generating greater economic value there. This has resulted in disadvantageous strategic and economic dependencies for Germany and other European countries.

In addition to the current SARS CoV-2 pandemic, other widespread illnesses such as cardiovascular diseases, cancer, diabetes, obesity, lung disease, and dementia are creating

huge challenges for societies. Global health crises of the future, which we and a large number of experts believe are unavoidable, will exacerbate the situation. This calls for an intelligent strategy to set the right course, ensuring that Germany, as a top site for biomedicine in the future, can make effective contributions to large-scale solutions and better health across the globe. What is at stake is no less than the ability of future generations to hold their own against international competitors.

The Helmholtz Association's Research Field Health (Helmholtz Health) is addressing this global social challenge of an unprecedented scale. Helmholtz Health is thus launching a joint initiative that will bring together academic institutions and partners from industry, the health sector, society, regulatory bodies, and politics to significantly increase transfer efforts from basic biomedical research in Germany.

3. Helmholtz Health

With more than 5,000 scientists, Helmholtz Health is by far Europe's largest, strongest, and most reputed organization conducting cutting-edge biomedical research and fostering young talent. It is thus one of the leading global health research institutions, comparable with the metropolitan regions Boston and the Bay Area in the USA and the constituent institutes of the National Institutes of Health (NIH). As a member of the Helmholtz Association of German Research Centers, Helmholtz Health's six centers¹ achieve critical mass in carrying out biomedical research into major widespread diseases – cancer, cardiovascular and metabolic diseases, pulmonary illnesses, neurodegenerative diseases, and infectious diseases. The Helmholtz Health centers are linked, among other things, through the nationwide National Cohort (NAKO) health study, a pioneering longitudinal study with more than 200,000 participants. Over the past 20 years, several top researchers at Helmholtz Health centers have been awarded international prizes, including Nobel prizes, Lasker awards, and Leibniz prizes. Helmholtz Health researchers regularly acquire the largest share in Germany of the internationally recognized grants from the European Research Council (ERC) in the field of health research. Helmholtz Health generates numerous discoveries, a large proportion of which are implemented throughout the world in innovative diagnostic and treatment methods. To transfer these findings to medical application, Helmholtz Health has teamed up with university-based medical institutions to establish pioneering, internationally exemplary translational platforms, thus considerably accelerating the clinical translation process. The Helmholtz Health programs for junior researchers set new standards and attract the best young talent from both Germany and abroad. In close transdisciplinary cooperation with the Helmholtz Association's other research fields and other university-based and non-university partners,

¹ German Cancer Research Center (DKFZ), Helmholtz Zentrum München – German Research Center for Environmental Health (HMGU), German Center for Neurodegenerative Diseases (DZNE), Helmholtz-Zentrum Dresden-Rossendorf (HZDR), Helmholtz Centre for Infection Research (HZI), Max Delbrück Center for Molecular Medicine (MDC)

Helmholtz Health is breaking new ground as a health research pioneer to develop innovative medical solutions and improve people’s health. Our mission is to lead international cutting-edge research for the medicine of the future and to make a significant contribution to translating these results into progress for our society, our health system, and the economy as quickly as possible.

4. Successful transfer activities in Helmholtz Health

Helmholtz Health has adopted a modern strategy to transfer the results of top research to benefit society, health systems, and the economy. The experience gained during the COVID-19 pandemic is now being used to accelerate and hence transform the strategic transfer processes already planned. Since the Helmholtz Association of German Research Centers was founded in 1995, the Helmholtz Health centers have made major contributions to research, shaping current medical care in Germany and across the globe.

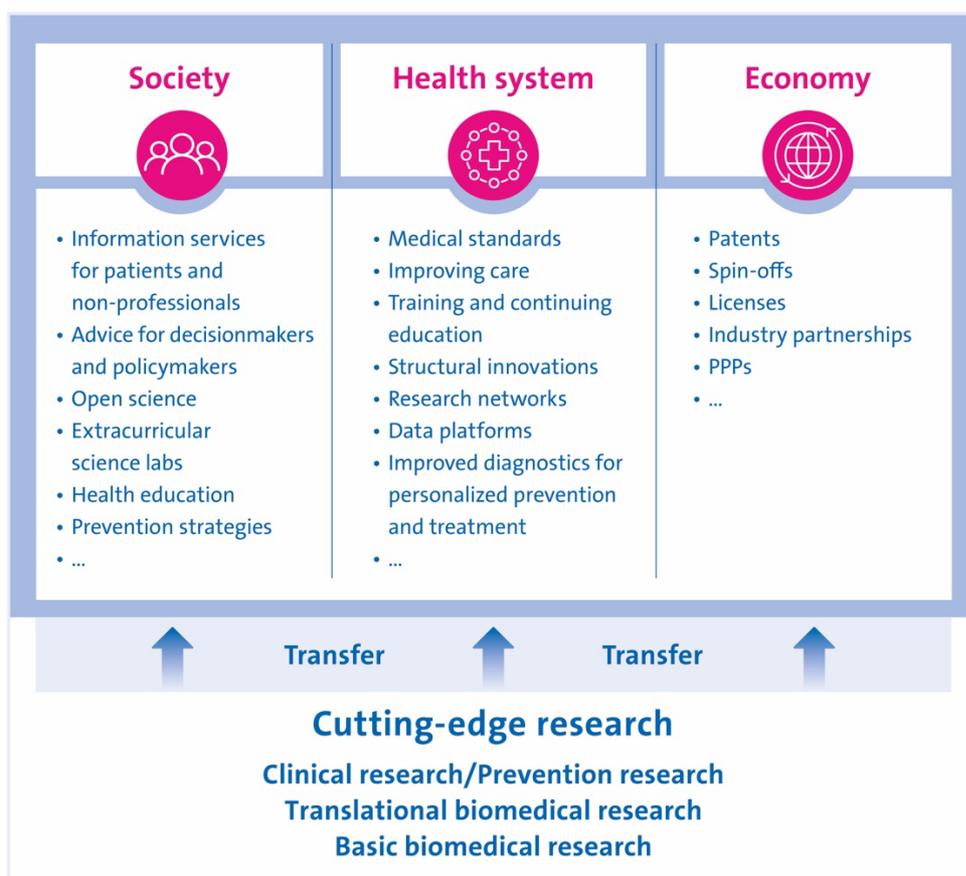


Fig. 1: Transfer and translation at Helmholtz Health

The recent increase in successful transfer activities at Helmholtz Health is based on the outstanding breadth and depth of basic research (see Fig. 1). As a result of interdisciplinary integration of information and data science, including artificial intelligence (AI), next-generation omics, imaging and bioengineering technologies, the excellent biomedical research is

providing fresh impetus and becoming an even more effective driver of transfer in the Helmholtz Health centers. Outstanding translational research is leading to the identification of novel molecular target structures and drug candidates, but also of new diagnostic markers and technologies. A key unique selling point of Helmholtz Health is the combination of diagnostic and therapeutic innovations in particular, acting as a catalyst for the integrated transfer process. These core activities are enshrined in our mission and lay the foundation for Helmholtz Health from which key contributions are generated for all three areas: society, health systems, and the economy.

The first pillar of transfer activities in health research involves answering questions from people affected, their relatives, and the general public on all aspects of diseases such as cancer, diabetes, neurodegenerative illnesses, and pulmonary diseases, particularly by providing information services. Helmholtz Health has also launched numerous knowledge transfer projects, such as open science and citizen science projects, extracurricular science labs for schoolchildren, and health education measures. These activities enable Helmholtz Health to reach many millions of people each year in Germany alone, hence making a key contribution to a healthier society. This area of knowledge transfer at Helmholtz Health is geared to achieving better educated, responsible patients and promoting personalized preventive measures. Other socially relevant aspects include informing the media about the latest evidence and offering consultations on biomedical issues and on technologies and the innovations that they can be expected to generate, thus providing support for policymakers to help them improve the general conditions in the health sector and beyond.

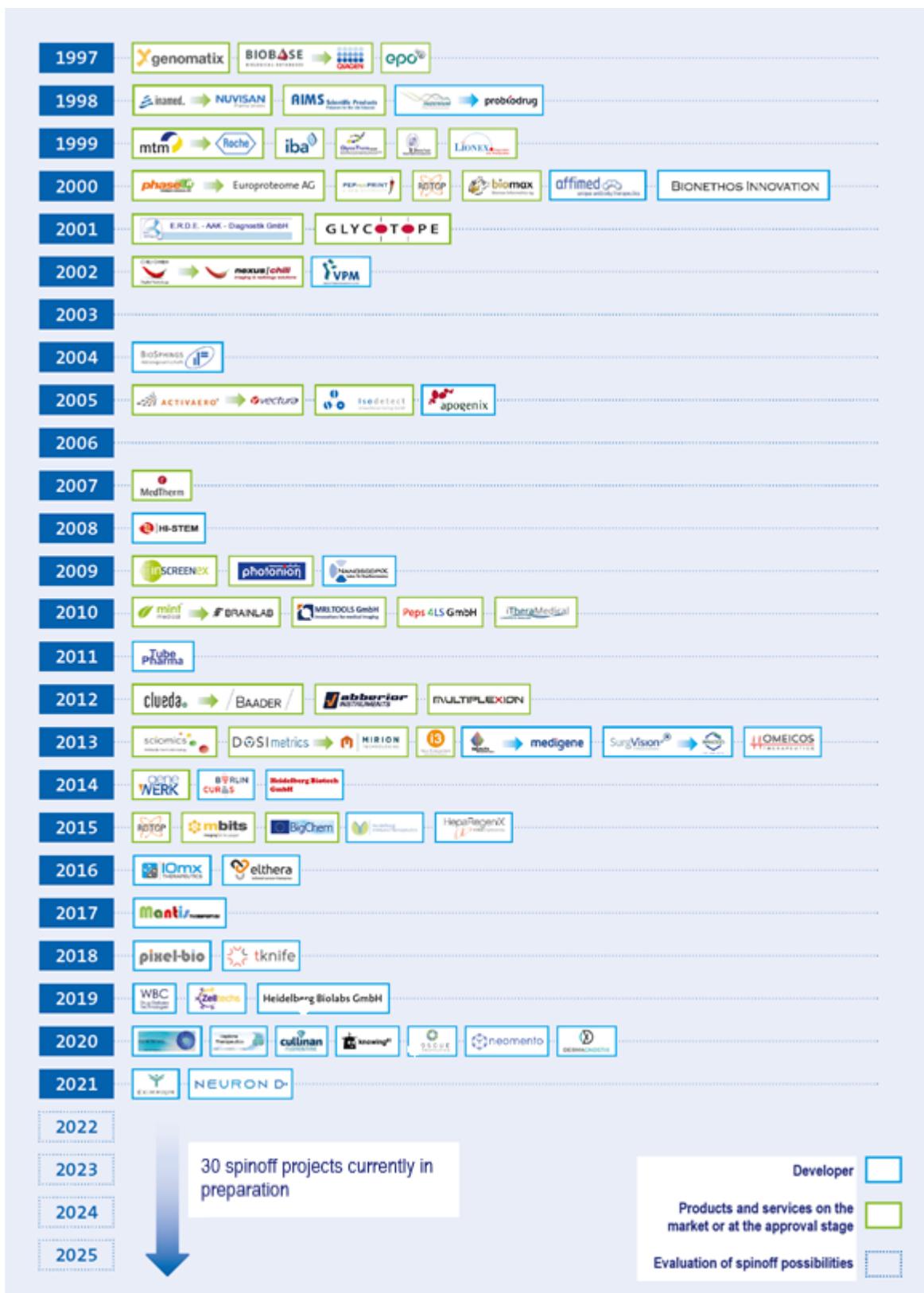
Harnessing the new scientific discoveries – translational medicine – is a top priority for Helmholtz Health and forms the second pillar. Helmholtz Health's transfer activities have a direct impact on the health sector when new findings are translated into clinical strategies, and medical guidelines, treatments, and prevention strategies are improved and used to set up interdisciplinary and international research networks and technology platforms. Examples of this include the human papillomavirus (HPV) vaccine to prevent cancer, which is already protecting more than 250 million young women from developing cervical cancer; diagnostic tests to detect prostate cancer using prostate-specific membrane antigen (PSMA) imaging, which is increasingly being used across the world; progress in preventing and treating type 1 and type 2 diabetes; multispectral optoacoustic tomography (MSOP), a new imaging technique for non-invasive diagnostics; and the use of molecular diagnostics for personalized, targeted treatment of disease. At the same time, the results obtained in these projects and partnerships are fed back into research in a cycle – successfully established with various partners over a period of decades – of excellent research work, trailblazing results, and systemic added value in medical practice. In recent years, Helmholtz Health has also promoted key structural changes. The German Centers for Health Research (DZG), the Berlin Institute of Health (BIH), the National Centers for Tumor Diseases (NCT), and the digital management system SORMAS² should be mentioned here; the latter has been providing important support to the health authorities during the coronavirus pandemic.

² Surveillance, Outbreak Response Management and Analysis System

The third transfer pillar of Helmholtz Health generates added economic value through spinoffs, strategic partnerships with industry, licenses, and patents. This not only benefits the partners but also in particular Germany as a research and innovation site. Figure 2 shows the outstanding performance of Helmholtz Health. Over the past 25 years, the centers have brought a large number of products and solutions to market and refined their expertise in various spinoffs. Eighty percent of these happened in the two most recent periods of program-oriented funding, i.e., in the last 10 years. Examples include the successful round of financing for T-knife (EUR 66 million) and the takeover of Mint Medical by Brainlab, of SurgVision by Bracco Imaging, and of Trianta Immunotherapies by Medigene. Center-specific transfer strategies include spinoffs where they are expedient. In areas in which drug development poses particular challenges, such as for neurodegenerative diseases, the focus is on strategic cooperation with partners from industry and health care (Orion Pharmaceuticals, Eisai Corp., ChemDiv/Torrey Pines, Hewlett Packard Enterprises) with a view to harnessing specific expertise for product development and innovative data processing technology, for example.

These developments have created jobs and generated growth; most importantly, however, they have helped to further improve health care across the globe. A well-filled pipeline of promising new developments will continue to improve health care in the years to come and hence help achieve the objectives set out in Helmholtz Health's mission considerably faster.

Successful spinoffs



Using this transfer structure, which focuses on the integrated development of new companion diagnostic and therapeutic agents alongside the establishment of new technologies, Helmholtz Health is realizing unrivalled synergies – from basic biomedical research to added economic and social value. It achieves additional impact through close structural coordination and intensive partnerships with university hospitals and medical faculties.

5. Measures

In the last period of the Pact for Research and Innovation since 2016, the Helmholtz Health centers have become more focused and adopted a more overarching approach to networking in the field of transfer. The relevant innovation and transfer divisions in the centers have been sustainably strengthened, with skills and expertise being developed to provide competent advice and comprehensive support to researchers. In order to steadily expand the transfer portfolio, further accelerate the speed of this transfer, and make essential contributions to society, health care, and the economy even more effectively, the centers involved in Helmholtz Health have teamed up to develop a joint **Seven-Point Charter** designed to further optimize transfer activities in Helmholtz Health:

1) **Overarching integration of the innovation areas**

The existing structures for innovation and transfer will become more closely linked through the individual Helmholtz Health centers. They currently have a joint total of more than 40 full-time equivalent staff and have thus achieved the critical mass required to take the next step in developing the transfer process at Helmholtz Health and generating clear added value through networking. Strategic networking will enable resources to be pooled and projects to be coordinated across the centers; at the same time, a greater degree of specialization for patent, license, development, and product expertise can be achieved. A regular Helmholtz Health Transfer Conference is currently being devised; the conference is designed to be a marketplace for partners from industry, venture capital, and the scientific community and to steadily increase visibility.

2) **Training of young professionals**

Scientists are to receive more extensive support in the field of entrepreneurship. This will include Entrepreneur in Residence programs at the individual centers and a new Entrepreneurship Academy across the Helmholtz Health centers. The academy is designed to help create the organization's own pool of 'hybrid experts' – entrepreneurs engaged in research or entrepreneurial scientists.

3) **New financing options**

The increased need for capital on the part of biomedical startups calls for alternative forms of financing such as validation financing with sufficient funding for the medical sector. Moreover, investment management across Helmholtz Health is to be put on a more professional footing to bring together investors and innovative project ideas using a dedicated marketplace and to set up separate funds for entrepreneurial activities.

4) Greater dialogue

The key areas of patient information services and policy advice from Helmholtz Health experts are being extended to cover a broader range of topics; IT structures and access to information are being improved. This will promote health education for non-professionals and help meet the greatly increasing demand for advice on health policy.

5) Strengthening the Helmholtz Health innovation ecosystem with industry partners

Innovation benefits from close interaction (and the close proximity) between research and industry partners. By continuing to develop the structures we have successfully piloted, such as the Innovation and Industry Labs and the Helmholtz Pioneer Campus, and setting up new structures such as future clusters, we hope to promote joint research and development and thus considerably reduce transfer times. Due to their greater agility and willingness to take risks, spinoffs play a key role in many areas here; in other areas such as neurodegenerative illnesses, due to the particularly time-consuming and cost-intensive development processes involved, the focus is on complementary partnerships with experienced partners from industry. Integrating additional stakeholders in the transfer chain – such as patients, doctors, regulators, and politicians – into the innovation ecosystem can provide additional support in overcoming transfer barriers.

6) Promoting digitization for research, development, and patients

Digitization of the flow of information within partnerships is a key factor for their success. A cross-center digital platform will help optimize coordination between internal Helmholtz partners and external partners from the scientific community and industry and help them achieve their objectives more rapidly. This will be linked to options for storing very large datasets, for data management and for the latest analytic methods, including new artificial intelligence methods. As a result, data for research, development, and information services and for patients themselves will be able to be used more effectively.

7) Leveraging the potential of prevention in the health sector

Developments in curative medicine will lead to greater precision and predictability along with additional prevention measures. The results obtained by basic biomedical research provide the key to drive these developments and promote prevention and early detection in the health sector through effective interfaces to population-based public health approaches. The National Cancer Prevention Center is already supporting this approach in the field of oncology. Similar activities by the Helmholtz Health centers have been planned in order to establish additional effective prevention measures in the field of curative medicine, thus helping to prevent disease.

6. Monitoring success

Helmholtz Health attaches great importance to measuring its transfer results and has set itself the ambitious goal of becoming one of the world leaders in this area too. Our Seven-Point Charter to further optimize transfer measures constitutes a clear set of tasks for us in the coming years. The aim is to establish, adopt, and refine these measures to fulfil our translational mission to the best of our abilities. In order to report on our progress, in addition to the criteria set out by the Joint Science Conference in the Pact for Research and Innovation, the first step will involve setting up a senior-level joint Transfer Advisory Council as part of the aforementioned Helmholtz Health Transfer Conference. The Transfer Advisory Council will be made up of leading representatives from society, the health sector, and the private sector and will explore all three pillars of the transfer process in the field of modern health research together in an international context. This council can evaluate successes, but is also designed to act as a sounding board for further developments. For us, ongoing open dialogue between all stakeholders is a key factor for success.

In addition, Helmholtz Health will continue to make major contributions to the current global debate on defining suitable key performance indicators (KPIs) for health research. To do so, we will play an active role in discussions in national forums, for example the Forum of the German Centers for Health Research and the Health Research Forum of the German Federal Ministry of Education and Research (BMBF); we will also maintain an ongoing dialogue with major biomedical research organizations in other countries, such as NIH in the United States. In contrast to and in addition to very simple KPIs that provide only limited information and are geared solely to economic factors, such as the number of new spinoffs or the amount of revenue from licensing, the particular social demands made of transfer activities in the field of health research – to achieve a healthier future and better medicine – are of outstanding and unique importance. While the number of jobs directly created may be a suitable transfer KPI that is easy to measure in the field of engineering, the number of years of disease that have been prevented is at least as relevant to society in the field of health research. However, KPIs that do justice to the particular role of biomedical research are currently not easily identified; yet if the center directors were only to use easily measurable KPIs, neglecting other aspects of health transfer, this would create perverse incentives that might ultimately even lead to Helmholtz Health losing its position as a global leader of biomedical research.

7. Final comments on transfer in the biomedical sector

The effective transfer of basic biomedical research to applications and products and of knowledge for society creates particular challenges for researchers working to achieve a healthier future and better medicine. These challenges differ considerably from those in other sectors. Due to the complex interactions in systems biology, the very considerable resources needed for clinical studies and medical approval processes, and the long follow-up periods often required to demonstrate benefit, the time and costs involved are many times higher than in other sectors that involve purely technical operations, such as IT, chemistry, and automation

technology. In terms of the general investment climate, Germany still lags considerably behind other countries such as the United States. As a result, the added social and economic value made possible by Germany's excellent basic biomedical research has in many cases been generated instead in capital markets that are more attractive for investors. If Germany hopes to regain the leading position it once held as the world's pharmacy, the aforementioned measures envisaged by Helmholtz Health and other research organizations will not be sufficient. In addition, the fiscal and investment framework in place in Germany needs to become competitive on the international stage. Despite and because of these challenges, Helmholtz Health believes that it has a responsibility to turn an internationally unique research partnership into a globally successful translational unit and to deliver the medical solutions that tomorrow's world will require.