Germany

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Part II

Main issues and executive summary

Germany

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Germany

«The German R&D model is characterized by a strong support system and cooperation between industry and science and for innovative business start-ups.»

Executive summary

Sales of biopharmaceuticals (in the pharmacy and hospital market) in 2020 increased by 14 percent from 2019, amounting to €14.6 billion

€14.6 billion

35 %

of biopharmaceutical agents in the clinical pipeline are for cancer treatments

350+

companies active in medical biotechnology

120K

Germany has the largest European labor pool in Health sector

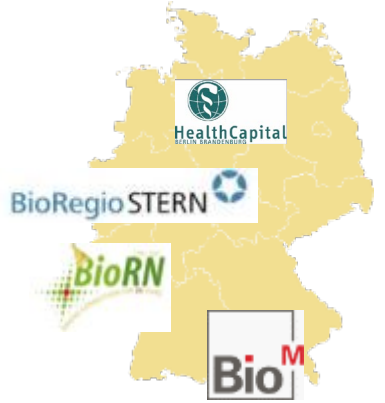
5.4 %

In 2020, companies active in medical biotechnology continue to hire. With expansion of 5.4%, the workforce grew considerably, to over 44,600—a new record

82

on recombinant antibodies. By the end of 2020, 82 molecules in this class of active substances had been approved in Germany, twice as many as five years before.

Main BioClusters



Focus

The German pharmaceutical sector shows the highest research intensity across all major German industries- – about 12.5% of revenues were reinvested in R&D in 2018.

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COUNTRY

Key recommendations

	Pain points	Success stories	Opportunities
Education	• For manufacturers to embrace the opportunity of Industry 4.0 successfully, investing in technology alone is not sufficient. • This must be accompanied with significant investment in talent, skills and training to help the workforce adapt to this.	• 2 German universities in Europe's top 15 in life sciences and medicine. • OECD #3 in number of new PhD graduates in biological and related sciences.	• In 2020, companies active in medical biotechnology continue to hire. • With expansion of 5.4%, the workforce grew considerably, to over 44,600—a new record.
Innovation	• A report published by vfa bio and Boston Consulting Group assessing the state of biotech in Germany revealed the country is falling behind in production capacity when compared globally to other countries.	• Disposable fermenters, significantly increase flexibility with rapid switching between different products in multi-purpose plants and faster ramp-up of capacities. • Translational approach to innovation, brining all stakeholders together (Leipzig, Stuttgart or Berlin)	• Securing and expanding production in Germany, • Using the opportunities of digitalization, • Removing administrative hurdles in clinical trials.
Business	• In terms of European production capacities (based on the volume of fermenters), the country is falling two places since 2018. • One reason for this is the tax framework which is not competitive compared to other countries with more investments in biopharmaceutical production.	• Only from Ludwig-Maximilians-Universität München, 75 spin-offs have been founded over the past 10 years. • Pharmaceutical industry (being 90% of drug manufacturers SMEs) is one of the main suppliers of novel biopharmaceuticals	• Improving framework conditions for the supply of venture and innovation capital, and • Strengthening the networking and cooperation of all stakeholders.

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Contributors to this report

Dr. Kai Uwe Bindseil,
Cluster manager
HealthCaptial Berlin-Brandenburg

Julia Schaft,
Managing Director
BioRN

Stephanie Wehnelt,
Head of International Affairs
BioM

Margot Jehle
Project Leader
BioRegio Stern

Horst Domdey,
Managing Director/CEO
BioM

Contributions

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GERMANY

Context specificity

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Key economic data on medical biotechnology in Germany for 2020 at a glance:

- **Sales of biopharmaceuticals (in the pharmacy and hospital market) increased** by 14% relative to 2019, to €14.6 billion. The share of this revenue as a percentage of the total pharmaceuticals market increased from 29.0% to 30.8%. Nearly all fields of medical application saw growth.

- **Biosimilars grow quickly in Germany after their market launch**; within the first year after launch, they achieved significant market share of up to 60%, some of them even more. On average, they made up 52% of sales in the corresponding biopharmaceutical segment in 2020.

- **25 newly approved biopharmaceuticals** accounted for 45% of all new approvals.

- **The pipeline grew by 2.7%,** with the number of biopharmaceutical compounds in clinical development rising within the space of one year from 640 to 657.

- **Companies active in medical biotechnology continue to hire**. With expansion of 5.4%, the workforce grew considerably, to over 44,600—a new record.

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Part II.A

Tackling the talent gap and the talent crunch in biomanufacturing in Europe

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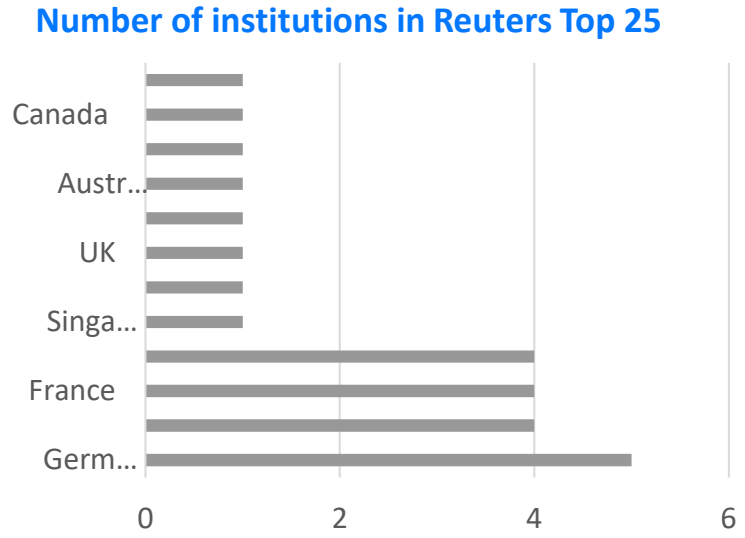
Germany has strong academics & research centres

Germany leads the 2019 most innovative research institutions list with five institutions in the top 25

Source:
Clarivate Analytics



Academic ecosystem

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Talent Policy and future Workforce

"In 2020, companies active in medical biotechnology continue to hire. With expansion of 5.4%, the workforce grew considerably, to over 44,600—a new record".

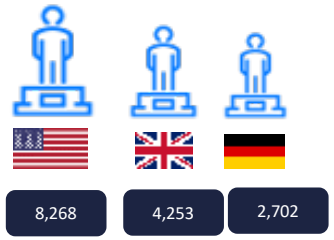
vfa bio

BCG BOSTON CONSULTING GROUP

Ecosystem & key figures

2 German universities in Europe's top 15 in life sciences and medicine

OECD #3 in number of new PhD graduates in biological and related sciences



18,580 Students finishing studies in biological and related sciences including VET (2018)

21,627 New-entry tertiary education students in biological and related sciences (2018)

Workforce in the pharma industry in Germany

TOTAL JOBS
2019

120.000+

GERMANY HAS THE LARGEST EUROPEAN LABOR POOL

One of the highest employees motivation levels in Europe

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Germany has a proactive talent development policy

Dual Education System

Based on a combination of **vocational education and training** embedded in a real-life work environment

- Cooperation between SMEs and schools
- Low youth unemployment
- Highly qualified personnel

"Excellence Strategy"

State-led funding program aimed at promoting cutting-edge research at universities to strengthen Germany's international competitiveness in science.

Two funding lines:

- **Clusters of Excellence:** project-based funding in internationally competitive fields of research at universities.
- **Universities of Excellence:** funding to strengthen universities/university alliances and their leading international position in research

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Success Story - Education

Heidelberg Institute of Pharmacy and Molecular Biotechnology (IPMB)

Research at the IPMB is focused on the development, investigation and application of drugs and bioactive compounds, as well as on the elucidation of molecular and cellular mechanisms of action.

This research integrates experimental approaches of chemistry, molecular and cellular biology, pharmacology, bioinformatics, and pharmaceutics.

Main research areas of our institute include nucleic acids as tools and drug targets, development of new anti-infective drugs, molecular evolution & proteomics, research on neurodegenerative diseases, systems biology as well as drug targeting and transport.

The degree programme in Molecular Biotechnology offers students a modern, interdisciplinary education in which the primary areas of focus are substance research, bioinformatics, and biophysical chemistry.

What types of molecular changes result in disease, and how can these changes be influenced?
To currently be able to answer such questions, it is critical not only to be familiar with biochemical and cell biology techniques, but also to have a solid understanding of chemical and pharmacological fundamentals, physical measurement methods, and bioinformatics.

The foundation of the degree programme is the breadth of the natural science education it provides as well as its emphasis on research. Importance is placed on promoting students' individual areas of interest, allowing students to conduct their own research projects even during their Bachelor's degree studies, while providing Master's students with an international flexibility that can be put to advantage in pursuit of their own research.

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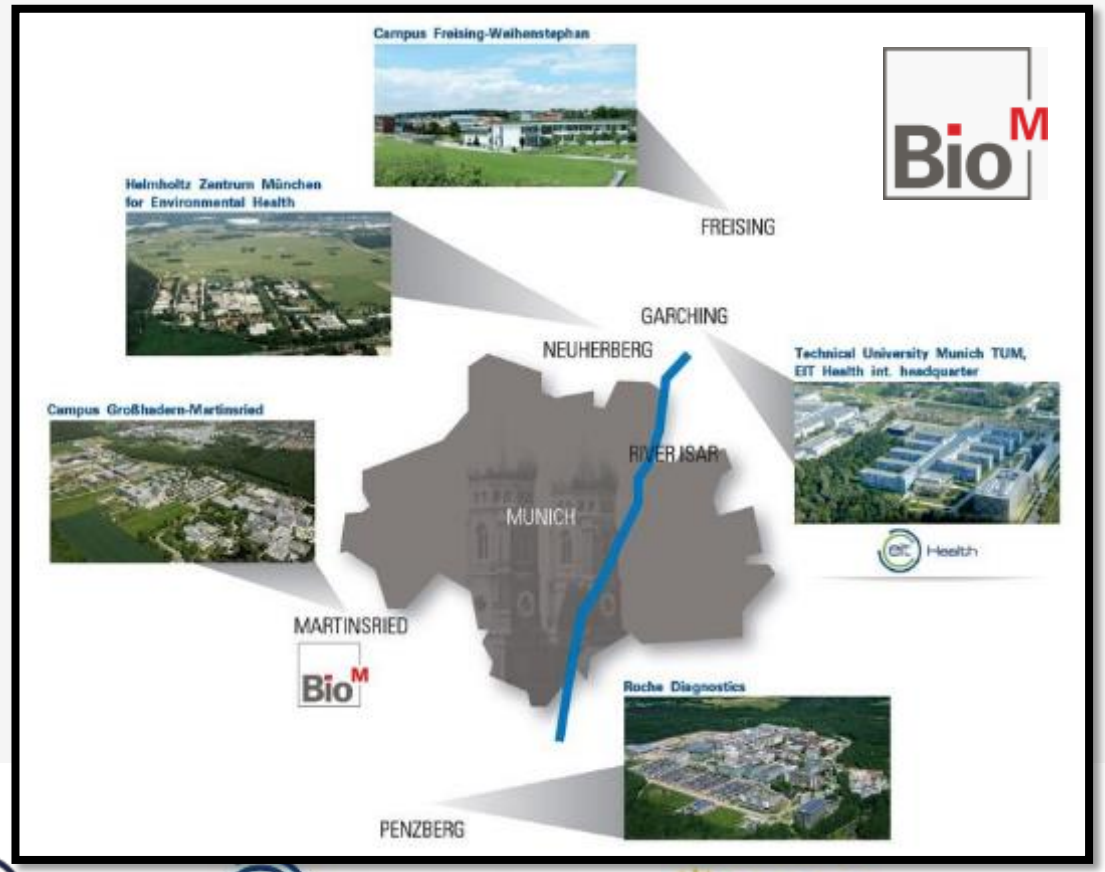
Opportunity - Education

Ludwig-Maximilians-Universität München

Only from Ludwig-Maximilians-Universität München, 75 spin-offs have been founded over the past 10 years. The trend of creating life-sciences-related spin-offs has increased considerably in the last years.



Munich is a leading biotechnology location

The European metropolitan area of Munich is the leading biotechnology location in Germany and enjoys a leading position in Europe. History

- About 250 life sciences companies including 130 SMEs
- 2 elite-universities: Ludwig-Maximilians-Universität and Technische Universität München
- Helmholtz Zentrum München – German Research Center for Environmental Health
- 3 biological/medical Max Planck Institutes: biochemistry, neurobiology und psychiatry
- 2 university hospitals: Klinikum rechts der Isar and Klinikum der Universität München as well as 60 other hospitals
- University of Weihenstephan-Triesdorf
- University of applied sciences Munich
- 2 Innovation- and start-up centers specializing in biotechnology

Focus on drug development

The location is particularly benefiting from close networking between academic research and the biotech industry. Most medium-sized biotechnology companies are spin-offs of scientific institutions. **The region is dynamic: over the last five years there have been around 40 new start-ups. The region is concentrated: companies emphasize "red biotechnology", that is: the development of therapeutics and diagnostics.**

Incubators

The Biotechnology Innovation and Start-up Centers (IZB) offer state-of-the-art laboratories and office space for young biotechnology companies. The start-ups benefit from the proximity to academic research at the universities in Weihenstephan and Martinsried.

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Part II.B

Research to

Innovation

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Innovation capabilities in Germany

R&D Excellence and InnovationGermany provides the perfect environment for the development and production of research-intensive, high-grade products

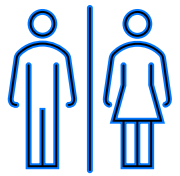
7.4 Billion € — In 2018, the pharmaceutical industry in Germany invested almost EUR 7.4 billion in R&D – more than in any other European country.

1st — The German phar-maceutical sector shows the highest research intensity across all major German industries- – about 12.5 percent of revenues were reinvested in R&D in 2018.

5th — With 499 clinical trials financed by research-based pharmaceutical companies in 2019, Germany ranks fifth worldwide

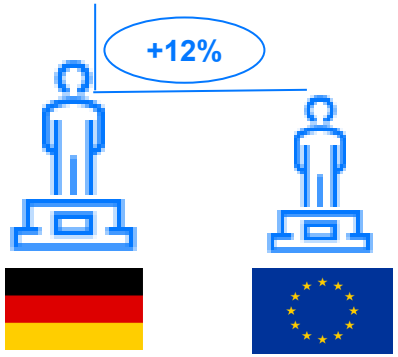
1st — Based on the number of patent applications, the country is leading in pharmaceutical innovation in Europe. In 2018, some 584 patents were registered with European patent office

The pharmaceutical industry has **more than 118,000 employees active in R&D**



28% of researchers in Germany are women

More researchers per 1,000 employees in Germany than the EU average



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Germany innovation policy

State-led support system to strengthen R&D and innovation in Germany

€ **INVESTMENTS**
2019

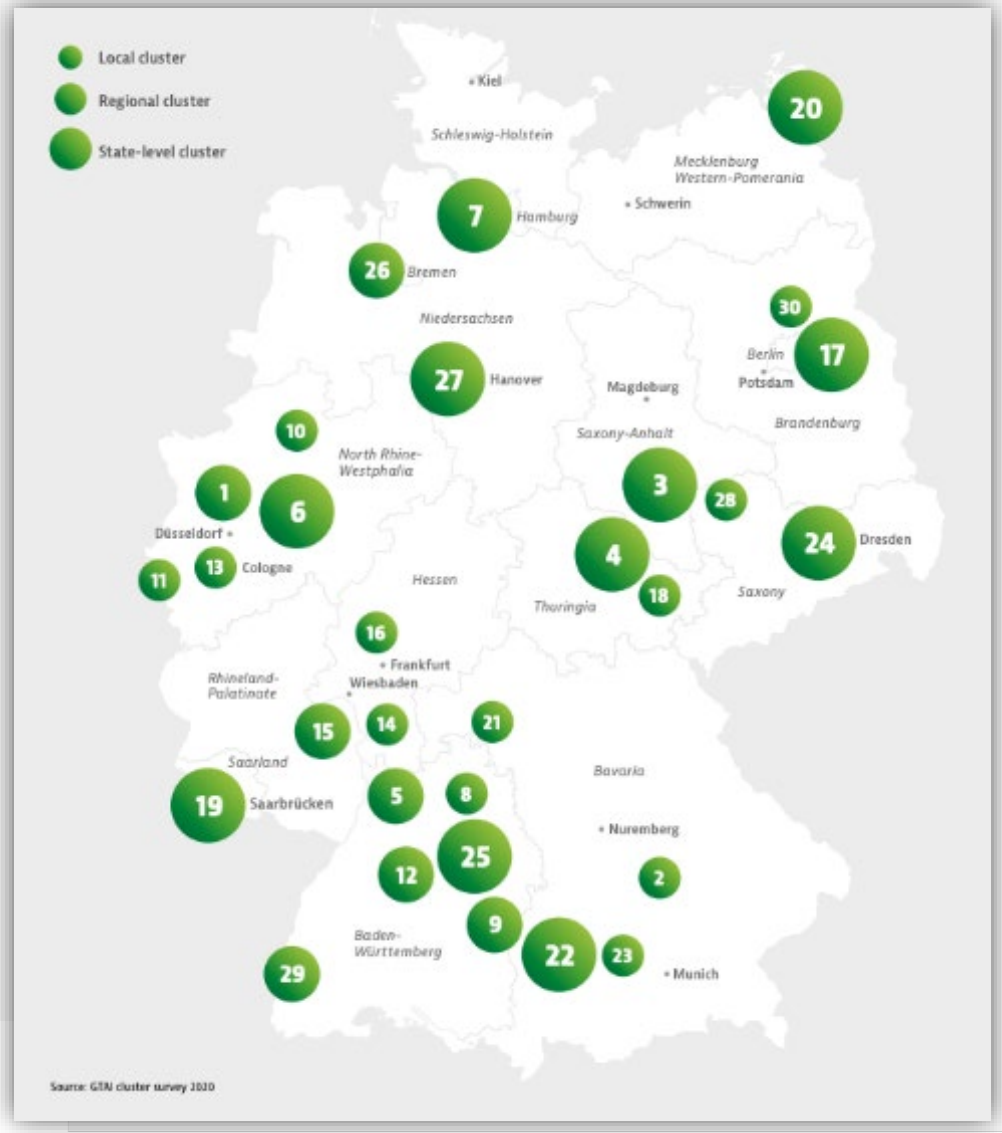
Germany's biotechnology industry spending in R&D

1,8 B €

+21% than the previous year

- **It encompasses financial aid to R&D and innovation activities in firms and research institutions, support of cooperation, networking and cluster formation, funding** of technology-oriented start-ups, as well as institutional support for research institutions and knowledge transfer facilities.
- The main actors in innovation policy are **the federal government, the European Union (EU) and the BioRegions.**

Biotechnology Clusters in Germany



Innovation policy

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Success Story – Innovation
LIFE SCIENCES IN THE LEIPZIG REGION

Leipzig is one of one of the most diverse and dynamic life sciences clusters in Germany and Central Europe.

World-class institutions on location conducting ground-breaking research in the field include the German Centre for Integrative Biodiversity Research (iDiv), the Max Planck Institute for Evolutionary Anthropology, the Max Planck Institute for Human Cognitive and Brain Sciences, and the German Biomass Research Center (DBFZ). Moreover, Leipzig's life sciences cluster integrates fundamental research with industrial ambitions.

From its inception in the year 2000, Leipzig's life sciences cluster has been geared towards becoming a leader in applied medical research and marketable healthcare innovation. The rapid translation and introduction of new therapies, devices and solutions into the EU's primary, secondary, and tertiary healthcare systems is its stated aim.

To this aim, Leipzig continues to build the physical and organizational infrastructure that fosters innovation, paves the way to commercialization, spurs business formation and supports business growth in the life sciences. Companies from the biopharma, biotechnology, medical devices, and digital health sectors will find ideal conditions for setting-up R&D, business, manufacturing or sales and distribution operations in the Leipzig Region.

Regenerative, Cell & Gene Therapies

In recent years, **Leipzig has become a leading location for the development of regenerative therapies in Europe.**

- Two out of the currently eight advanced therapy medicinal products (ATMPs) with EU regulatory approval are manufactured here.
- Companies, hospitals, diagnostic laboratories, and research institutes operating in the field of biotechnology, biopharma, and medical engineering greatly benefit from the Leipzig-based **Fraunhofer Institute for Cell Therapy and Immunology (IZI).**
- Aside from its own research on oncology as well as on immunological, infectious and neurodegenerative diseases, the **Fraunhofer IZI acts as a full service CDMO.**
- Its core competencies include the development, optimization, validation, and automation of GMP-compliant manufacturing processes. **The production process for Novartis' CAR-T-Cell product Kymriah® has been established in cooperation with the Fraunhofer IZI**.

Success story Innovation

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Success Story – Translational approach

Success story Innovation

Stuttgart – Tübingen – Reutlingen
Connecting competencies in Life Sciences

Drivers of innovation in biomanucaturing are first and foremost the **University & University Hospital in Tübingen** and the **Natural and Medical Sciences Institute (NMI) at University Tübingen in Reutlingen**, as well as the **Fraunhofer Institutes in Stuttgart**.

The direct dialogue between research, clinics and industry boosts the translational approach in the field of personalised and regenerative medicine. Researchers and clinicians act as the catalyst, developing new biobased solutions in cooperation with companies. These include therapies for oncology, such as CAR-T cell therapy, cartilage replacement from biobased fibres, or vaccines against infections and cancer.

"Einschnitte - Einblicke" (Incision - Insights) the innovative workshop

The annual "Einschnitte - Einblicke" event brings together clinicians and medical device manufacturers. Hosted by the Clinical Anatomy Department of the University of Tübingen, the workshop gives surgeons the opportunity to express their medical needs. This enables medical device manufacturers to develop customised medical devices.

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Success Story – Innovation
Biomanufacturing in the Berlin-Brandenburg Region

With more than 250 companies in the field of biotechnology and more than 30 pharmaceutical companies as well as more than 30 universities and research institutions with biotechnological expertise, a wide range of biomanufacturing topics are covered:

- Generation and use of new production lines
- Development and optimization of production processes
- Synthesis and use of new and innovative materials

The resulting biomolecules and products cover all areas in biotechnology, pharmaceuticals and medicine. But also applications in the field of food ("novel food") are becoming increasingly stronger. Focussing on the sustainable use of available resources and the generation as well as the integration of latest knowledge in IoT or Industry 4.0 prepares the regional value chains optimally for the future.

Best practices:

- BIH-CRT, Charité and MDC with internationally renowned expertise in R&D of advanced therapies including gene and cell therapies. BeCAT and Si-M will complement this focus area with 3D cell cultivation and the development of multi-organ chips in the near future.
- NetPhaSol as network for joint development of solutions for biomedical production
- BioPAT as Network for optimization of biotechnological production processes
- Cluster HealthCapital for a constant and professional networking of all stakeholders

Success story Innovation

Opportunity - Innovation

Transfer of technology policy in Germany

The **Munich Multiscale Biofabrication Network** brings together scientists from research institutions in the greater Munich area who are actively engaged in the design and control of biological matter across a wide range of spatial scales.

Using a unique combination of tools from nanotechnology, additive manufacturing, and synthetic biology, **Munich BioFab** researchers attempt to build functional bioinspired structures from biological and non-biological components, which are structured in three dimensions with nanometer precision up to the macroscopic scale.

Applications for such synthetic biological structures range from intelligent biomaterials and biomimetic systems over advanced biomedical sensors, soft nano- and micro robotics, to the realization of biomolecular synthesis machines.

Munich Multiscale Biofabrication Network

LMU LUDWIG-MAXIMILIANS-UNIVERSITÄT MÜNCHEN

Technische Universität München

HM Hochschule München University of Applied Sciences

max-planck-institut für biochemie

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Part II.C

Business

Innovation

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Germany industrial capacity

Germany ranks among the top pharmaceutical producers In the world

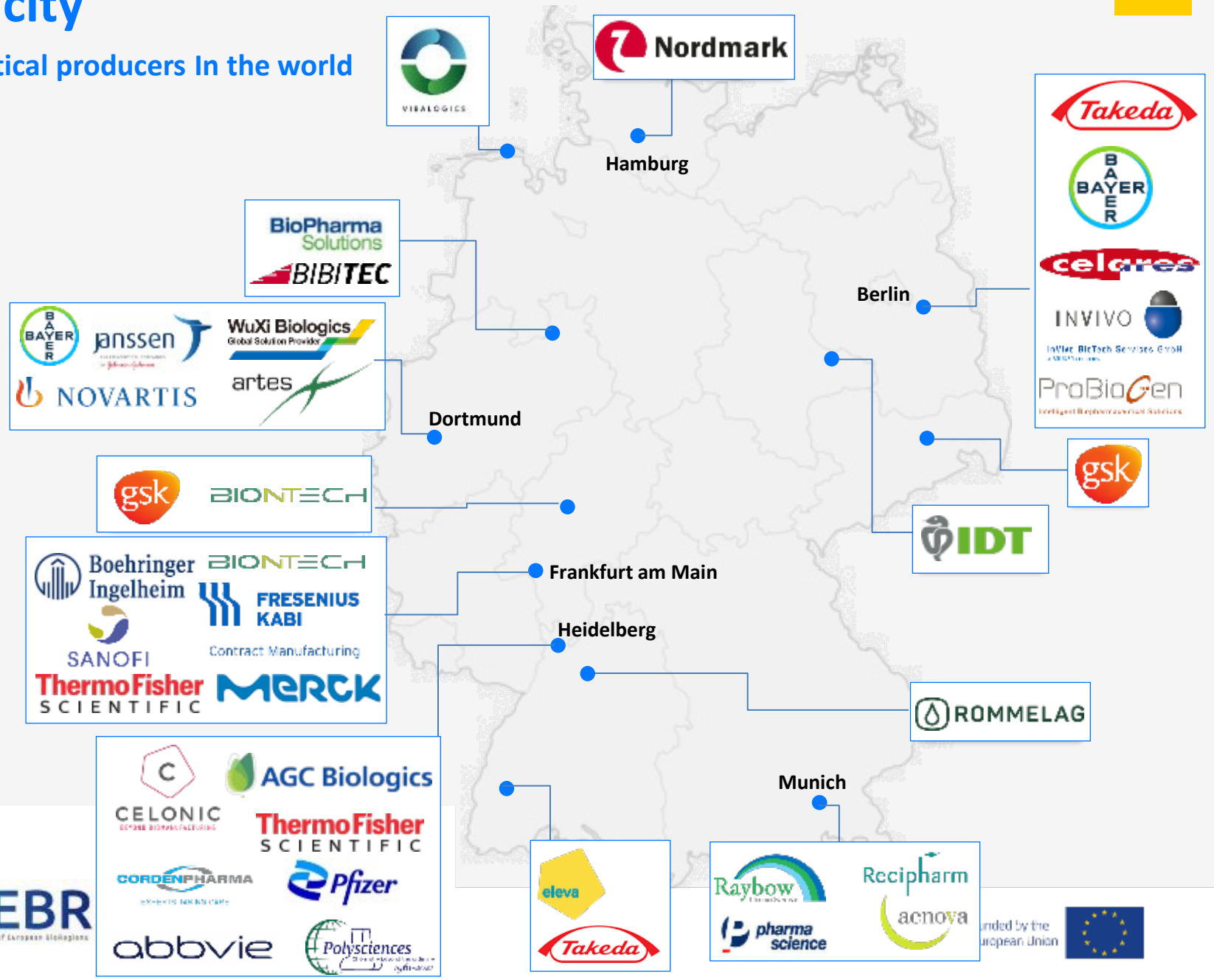
EXPORTATIONS 2019

Worlds' largest exporter of medicinal products

85.6 B €

Germany has a diverse ecosystem of industries and research centers active in the Biomanufacturing field

- **Pharmaceutical industry** (being 90% of drug manufacturers SMEs) is one of the main suppliers of novel biopharmaceuticals
- **International-sized contract** development and manufacturing organizations (CDMO)
- **Products and services in molecular and cellular biology** to optimize bioproduction
- **Products and services companies** in engineering and digital technologies to design the bioprocesses and plan
- **General support** companies (Over 30 biotechnology clusters)
- Country rich in research-based **pharmaceutical companies**



Business ecosystem mapping

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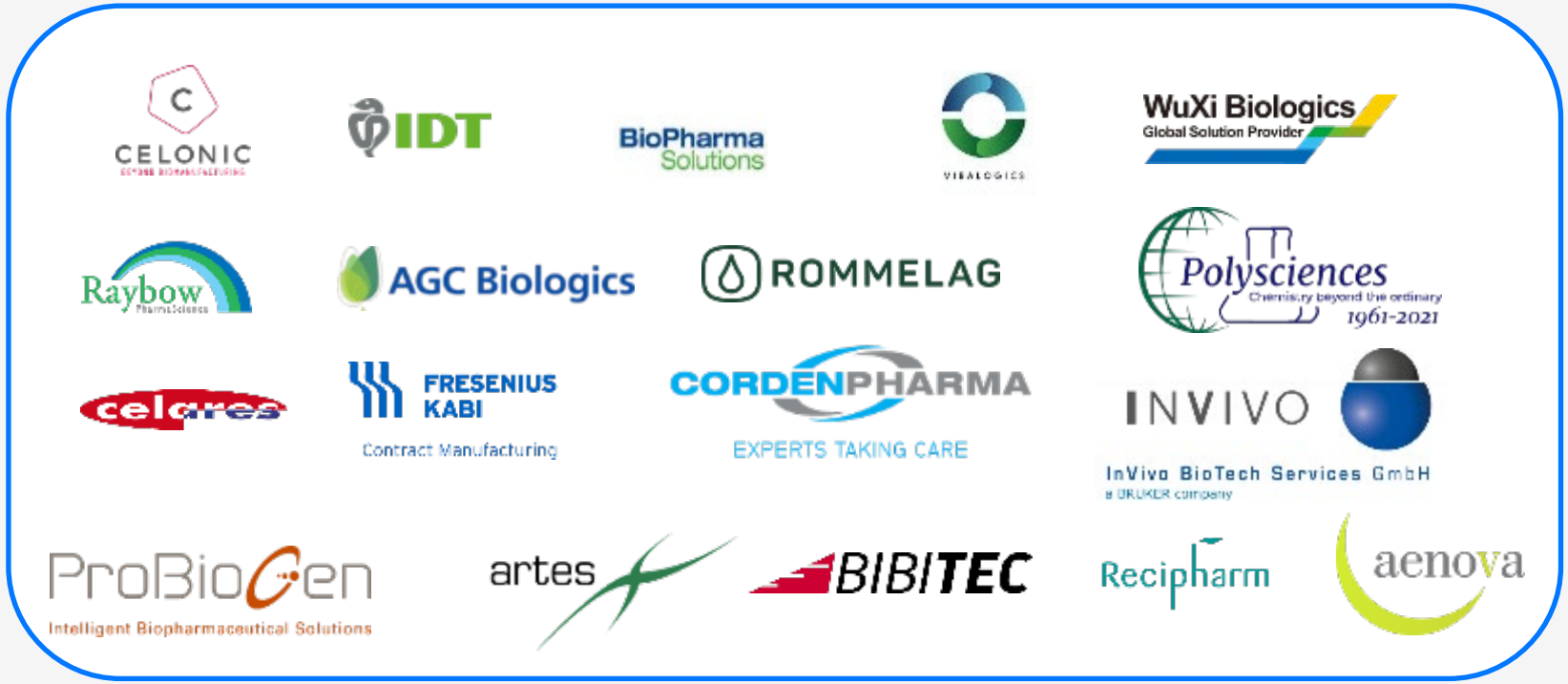
Strategic service providers such as CDMO

Contract Development and Manufacturing Organizations proposing biomanufacturing services and facilities

- The research stage of a molecule (process development)
- At time of the bio-production and pre-marketing certification processes (manufacturing).



Boehringer Ingelheim

- **Boehringer Ingelheim is developing a biological development centre** (BDC) within its plant site in Biberach, Germany.
- **The company's BioXcellence unit operates a pilot plant** and two large-scale manufacturing plants for contract manufacturing

Is it open??

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Opportunity Business Creation

Strategic service providers such as CDMO

Business ecosystem mapping

Company and technology overview

The table below gives an overview of the listed companies and their fields of activity

Company	Cell Line Development	Cell Banking	Process Development	Scale Up	Fermentation	Downstream Processing	Bioanalytics	Fill & Finish
apceth Biopharma GmbH		●						
Artes Biotechnology GmbH	●	●	●	●	●			
Axolabs GmbH		●				●		
BIBITEC Gesellschaft für Prozessentwicklung mbH	●	●	●	●	●			
BioGenes GmbH						●		
Bioworx		●			●			
cellasys GmbH		●	●					
Cevec Pharmaceuticals GmbH	●	●						
Cube Biotech GmbH		●			●			
EMP Genetech	●	●			●			
Genaxxon Bioscience GmbH				●		●		
Greenovation Biotech GmbH	●	●	●	●	●	●		
InVivo BioTech Services GmbH	●	●	●	●	●	●		●
Iris Biotech GmbH			●	●				
LEUKOCARE AG						●		
m2p-labs GmbH			●	●	●			
MATRIX Bioscience GmbH			●			●	●	●
MicroMol GmbH	●	●	●			●		

Company and technology overview

The table below gives an overview of the listed companies and their fields of activity

Company	Cell Line Development	Cell Banking	Process Development	Scale Up	Fermentation	Downstream Processing	Bioanalytics	Fill & Finish
Navigo Proteins GmbH			●			●		
Nordmark Arzneimittel GmbH & Co. KG	●	●	●	●	●	●	●	●
Pharmedartis GmbH	●	●	●	●	●	●		
Phyton Biotech GmbH	●	●	●	●	●	●		
PlasmidFactory GmbH & Co. KG				●	●	●		●
ProBioGen AG	●	●	●	●	●	●	●	
ProJect Pharmaceutics GmbH			●	●			●	
ReliaTech GmbH			●		●			
Rentschler Biopharma SE	●	●	●	●	●	●	●	●
Richter-Helm BioLogics GmbH & Co. KG	●	●	●	●	●	●	●	
Sartorius Stedim Cellca GmbH	●	●	●				●	
tgcBIOMICS GmbH	●	●	●	●	●	●	●	●
trenzyme GmbH	●		●	●	●	●		
Vetter Pharma International GmbH			●	●				●
Vibalogics GmbH	●	●	●	●	●	●	●	●
Wacker Biotech GmbH	●	●	●	●	●	●	●	●
Xell AG			●		●		●	

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Access to Finance

Access to Finance: Strong presence of

- **Federal investor**: Bundesrepublik Deutschland - Finanzagentur GmbH
- **Regional investors**: Bayern Kapital, BayernLB Capital Partner, Earlybird Venture Capital, 3i, CHF, Coparion, Global Life Science Ventures, High-Tech Gründerfonds Management, HVB LifeScience, LSP (Life Sciences Partners), TVM Life Science Management, The BioScience Ventures Group, Wellington Partners, Triangle Venture Capital Group, SHS, EMBL Ventures, IBB Ventures, Brandenburg Kapital
- **Banks**: Kreditanstalt für Wiederaufbau, Deutsche Bank LfA Förderbank Bayern, MERCK FINCK & Co Privatbankiers, UniCredit Bank, IBB, ILB
- **Europe**: EIB, EIF, Framework Programme

Issue: Lack of venture capital for German biotech

- **Biotech start-up activity in Germany has slowed** in recent years. German early-stage biotech companies find it harder to raise capital than those in the UK and in the US – proportionally, fewer investments and smaller.
- **The late-stage financing gap** in Germany is large and growing.
- **The success of BioNtech has shone a spotlight** on Germany's biotechnology research strength, which could be an example for the future.
- **The Federal Ministry for Economic Affairs and Energy is looking for** example regions throughout Germany as part of the "Industrial Bioeconomy" funding program.

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The second largest producer of European Union (EU) approved active biopharmaceutical substances

The country continues to be the second largest producer of European Union (EU) approved active biopharmaceutical substances and that revenue from biopharmaceutical sales accounted for 30.8 percent of the total pharmaceuticals market.

State of biopharmaceutical production in Germany

The report shows that Germany retained its position as the second largest production site for EU-approved active biopharmaceutical ingredients, behind the US. However, the report found that, in terms of production capacities (based on the volume of fermenters), the country is now in fifth place, falling two places since 2018. One reason for this is the tax framework, said the reporters, which is not competitive compared to other countries where much more is invested in biopharmaceutical production.

Recombinant antibodies focus

By the end of 2020, 82 molecules in the class of active substances on recombinant antibodies. had been approved in Germany, twice as many as five years before. Antibodies accounted for 32 percent of all approved biopharmaceuticals, across many different medical applications, including the management of the COVID-19 pandemic. The report highlighted that with the help of recombinant DNA technology, antibody derivatives – completely new antibody formats not found in nature – can also be realised, with functionality benefits such as lower immunogenicity, a longer half-life or the binding of more than one antigen.

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Success Story – Business Creation

Stuttgart – Tübingen – Reutlingen
The Biomanufacturing Triangle

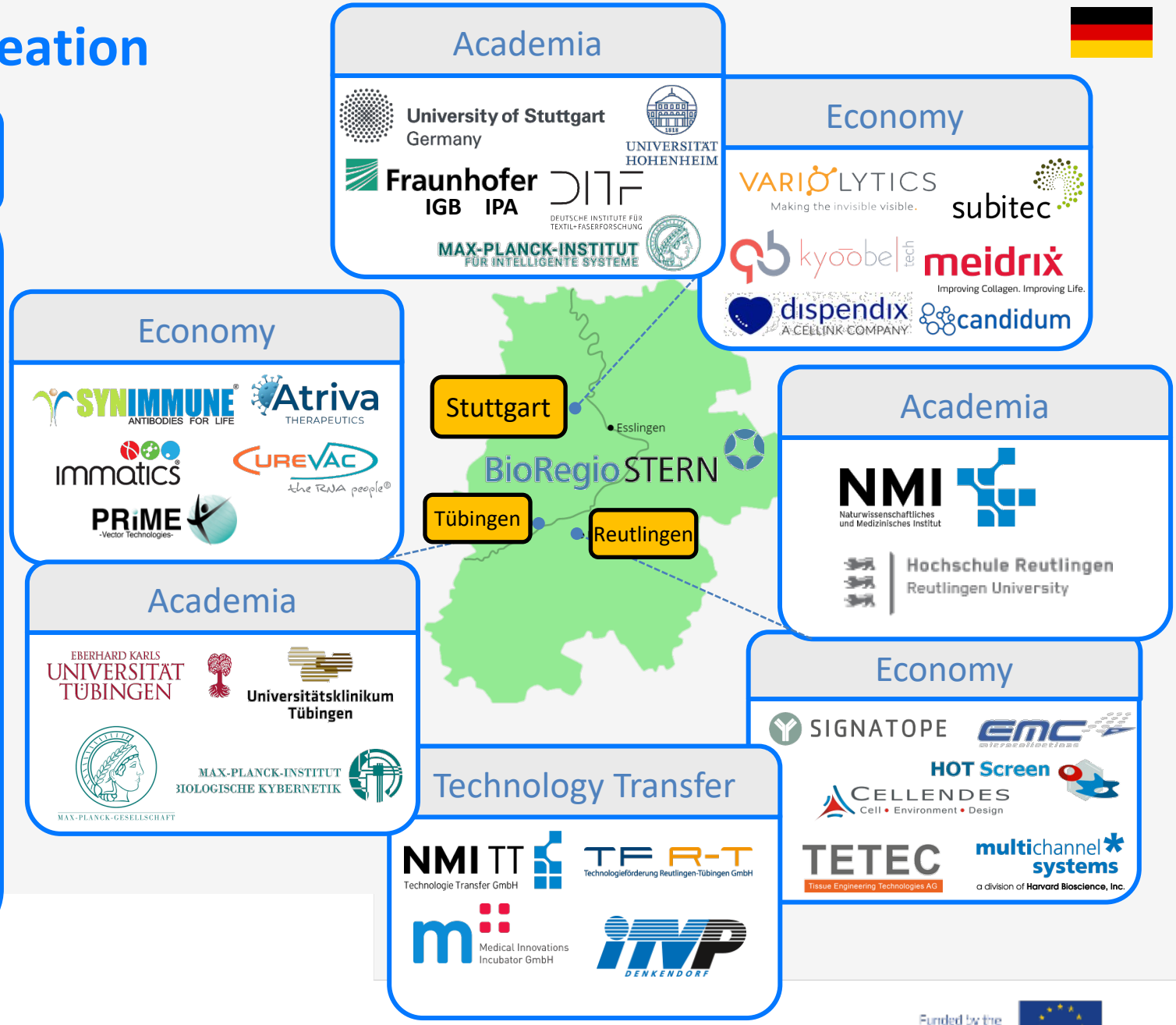
Stuttgart and its nearby cities Tübingen and Reutlingen, is more than just a centre for the automotive industry, it is also an innovative hub for life sciences and engineering. The strong ties between biology and technology and the numerous accelerators for technology transfer make the region an ideal location for biomanufacturing start-ups.

Science2Start – Good ideas deserve a chance

The Science2Start competition challenges young scientists and founders from the field of life sciences to put their business idea to the test. As a result, about two start-ups have been founded per year since 2009.

Biomanufacturing – Figures & Facts

3 Universities & **1** University Hospital Tübingen
3 Max Planck Institutes
2 Fraunhofer Institutes
110 biotech companies
4000 employees in biotech sector
570m VC financing of biotech companies, 2020



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Success story Business Creation

Evotec Rhine Main Neckar Bridge - beLAB2122

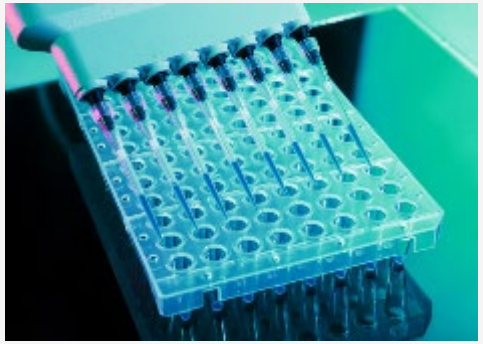
20 million Euro invested by Evotec and Bristol Myers Squibb (BMS) into early drug discovery projects from the four main regional academic institutions (University and clinic Heidelberg, DKFZ, EMBL, University and clinic Tübingen, University Frankfurt) with the goal to develop these to new spinout companies.

The name beLAB2122 refers to the Rhine, Main, and Neckar rivers, which connect the member institutions with one another and which total to 2,122 kilometres in length.

Examples of the scope of projects that are likely to receive support include (approx. 1.5M€ funding per project)

- **Antibody development** – Where the target dictates, novel antibody identification and subsequent optimization is available. Generated antibodies are then applied to disease relevant in vitro and in vivo assays to demonstrate the proposed mechanism-of-action
- **Medicinal chemistry** – designing, synthesizing and scaling up the analogues required to test compounds in the most relevant biological systems and to develop them further to safe and efficacious treatments while securing a route to novel IP
- **RNA, cell and gene therapy** – In bespoke cases, the target might require the exploitation of alternative therapeutic formats. These could be antisense RNA to modulate protein expression levels, cell therapy to replace malfunctioning tissue or gene therapy to restore activity of a gene or add additional functionality

beLAB2122



Opportunity Business Creation

eit Health eit Manufacturing CEBR

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Part VI

Conclusions and

next steps

Germany

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Conclusions & next steps

The success of the COUNTRY R&D model is characterized by a strong integration of university-industry collaboration with a strong support of the government and regulatory authorities

Recommendations for medical biotechnology in Germany (From VFA & BCG report on Biomanufacturing in Germany, 2020)

The Covid-19 pandemic poses major challenges for Germany, Europe and the world. Rather than a return to the status quo ante, **the pandemic should be used as an opportunity to reduce bureaucracy and specifically strengthen promising and innovative industries and technologies** such as drug research, development and production, including medical biotechnology in Germany. More precisely, this means:

- securing and expanding production in Germany,
- using the opportunities of digitalization,
- removing administrative hurdles in clinical trials,
- improving framework conditions for the supply of venture and innovation capital, and
- strengthening the networking and cooperation of all stakeholders of the healthcare system.

If all involved players work together to implement these points, Germany's chances of standing its ground in international competition will be good—to the benefit of patients, society and the country as a whole.

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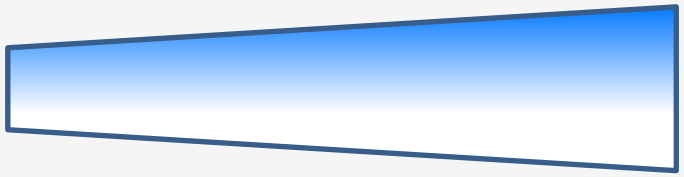
EIT Health Germany members engagement

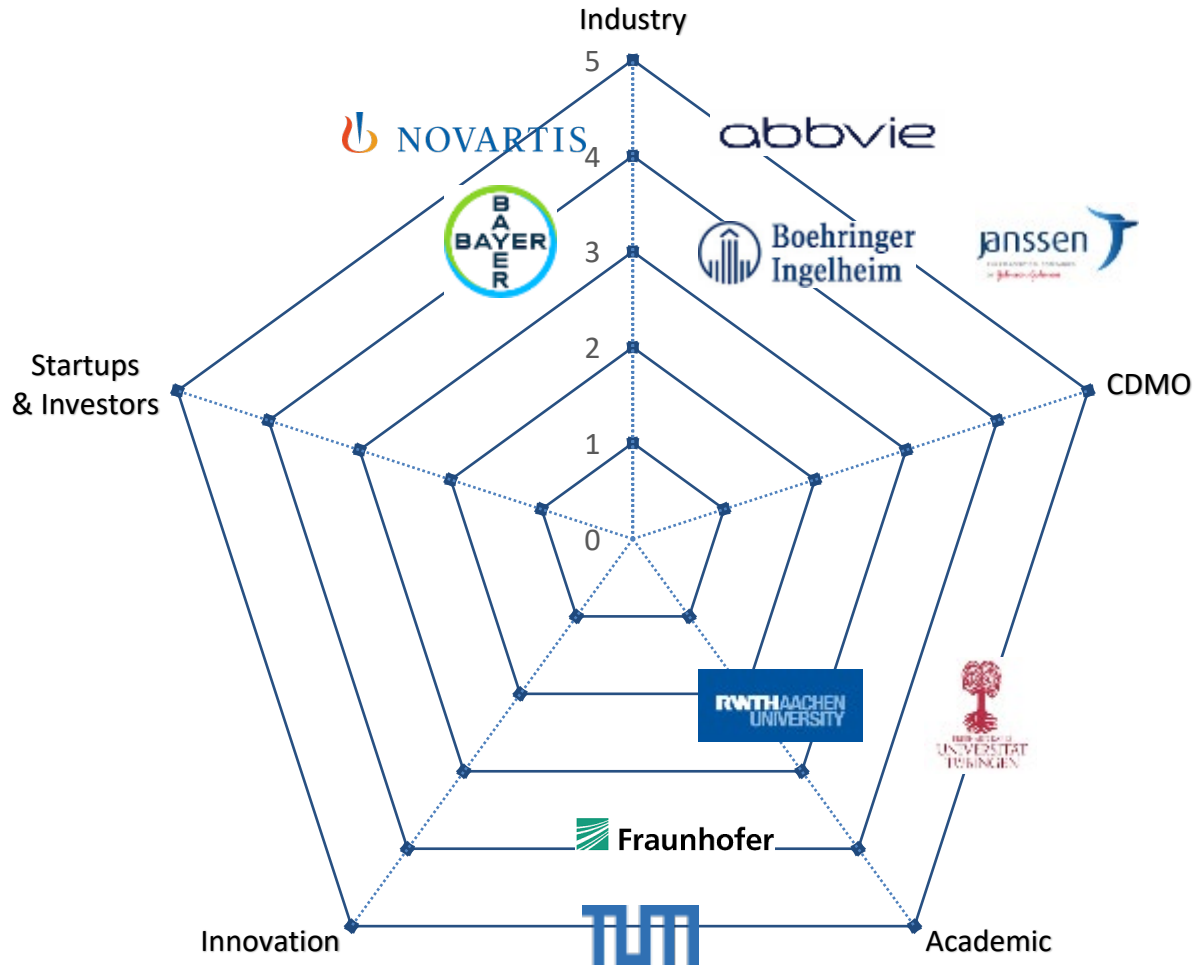
1. Neutral
2. Academic
3. Innovation
4. Start-ups & Investors

Scoring - Partners engagement with EIT Health

Neutral High



Germany EIT partners position radar



EIT Health footprint radar

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