Healthcare Industry 2023

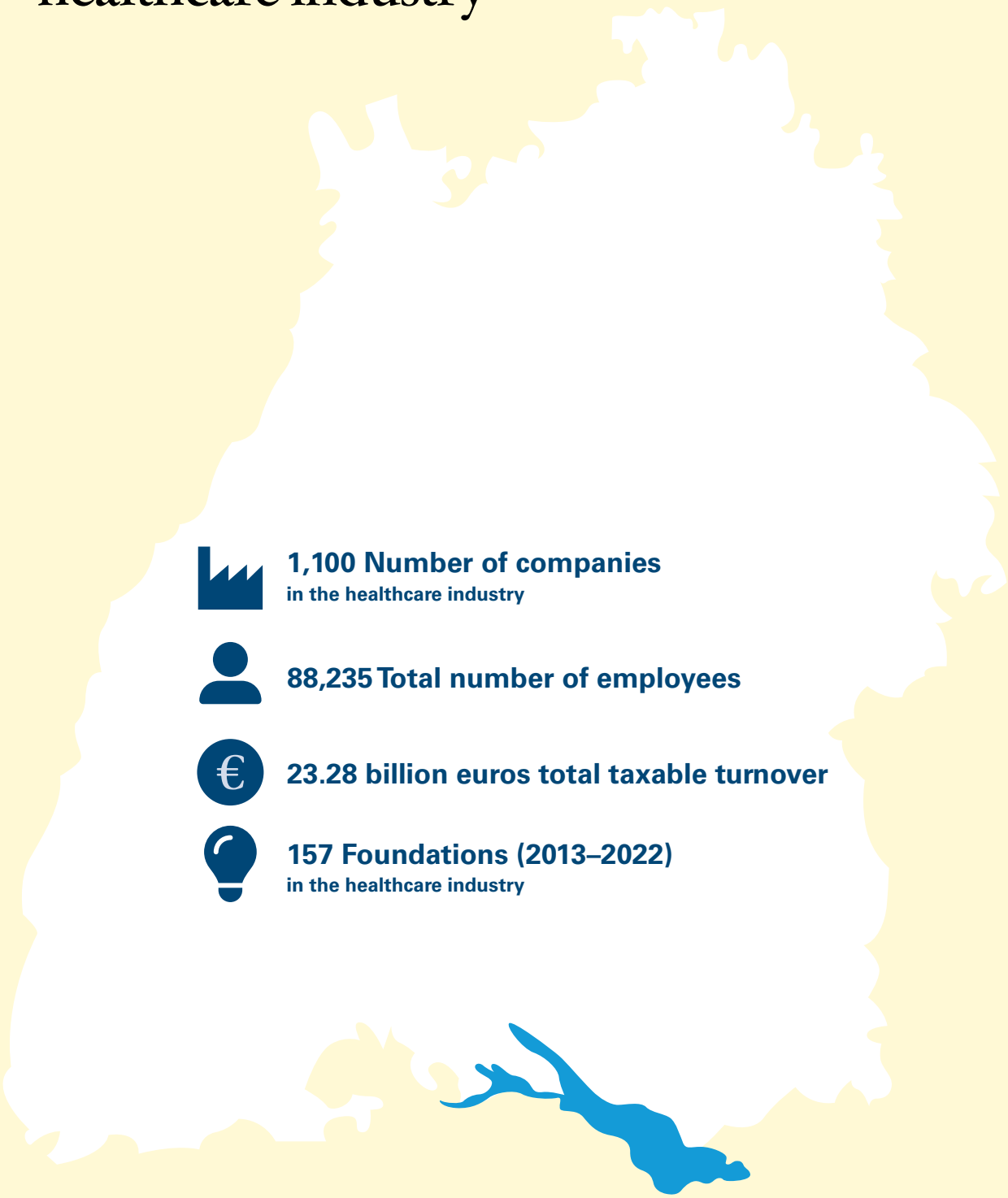
Facts and Figures for Baden-Württemberg

MEDTECH – PHARMA – BIOTECH

BIO PRO Baden-Württemberg GmbH

Baden-Württemberg
MINISTERIUM FÜR WIRTSCHAFT, ARBEIT UND TOURISMUS

Baden-Württemberg – an excellent location for the healthcare industry



1,100 Number of companies
in the healthcare industry

88,235 Total number of employees

23.28 billion euros total taxable turnover

157 Foundations (2013–2022)
in the healthcare industry

Contents

Welcome address

Ladies and Gentlemen,

Alongside the top-ranking sectors in the state of Baden-Württemberg, namely mechanical engineering and the automotive industry, the healthcare industry, comprising the pharmaceutical industry, medical technology and biotechnology sectors, is becoming increasingly important. These are industries that are increasingly, and decisively, driving growth and creating jobs. BIOPRO Baden-Württemberg's 2023 Healthcare Industry Report clearly demonstrates this.

The healthcare industry is currently undergoing substantial changes that are both a challenge and an opportunity. Key technologies such as microsystems technology, biotechnology and digitalisation are creating the necessary conditions for the ongoing development of new therapies and medical devices. Exploiting these innovation potentials will generate fantastic opportunities for diversifying into new markets and product fields. The Baden-Württemberg Ministry of Economic Affairs, Labour and Tourism supports individual companies' innovation projects through various measures such as the Invest BW programme or different kinds of innovation vouchers.

Currently, there are major challenges in the area of regulatory requirements. One such example is the implementation of the Medical Device Regulation (MDR), which significantly increases the time, effort and cost for companies seeking to get their medical devices CE-marked. The consequences are already being felt in the form of changes to product portfolios and innovations that have not gone ahead, ultimately leading to supply bottlenecks in clinics and surgeries. During the coronavirus pandemic in particular, we all discovered that supply chains can be very vulnerable and bottlenecks can have serious consequences, especially with regard to shortages of essential everyday products and critical healthcare sector supplies.

We have therefore already begun implementing various measures to counteract such scenarios. For example, we were the first German state to launch a fast-track support programme to assist companies in implementing the MDR. The programme was managed by BIOPRO Baden-Württemberg GmbH.

It is my firm belief that regulatory requirements must remain manageable for our companies, particularly to ensure that they do not face any financial disadvantage vis-à-vis international competition. I will therefore continue to advocate business-friendly regulations so that Baden-Württemberg remains a successful healthcare location well into the future.

Dr. Nicole Hoffmeister-Kraut
Baden-Württemberg Minister of Economic Affairs,
Labour and Tourism

Foreword

Dear readers,

There is no doubt that Baden-Württemberg's economy and society are in the midst of a tremendous process of change that poses many challenges. However, it is also undisputed that innovation projects offer huge opportunities during periods of major upheaval. Such opportunities must be developed and exploited together. Because the current problems we have to solve can only be overcome through a common understanding and through cooperation.

For more than two years, we have been in a „permanent crisis mode" and, if you believe one or the other opinion leader, this will continue to be the case in the future. The challenges of our time are immense and the future will show how different solutions and developments can contribute to solving crises. Despite or precisely because of these challenges – climate change, political controversies, as well as more stringent regulatory requirements and healthcare cost pressures – we must make sure we do not bury our heads in the sand, but instead work constructively and proactively and act in a way that will help us to find solutions with all those involved.

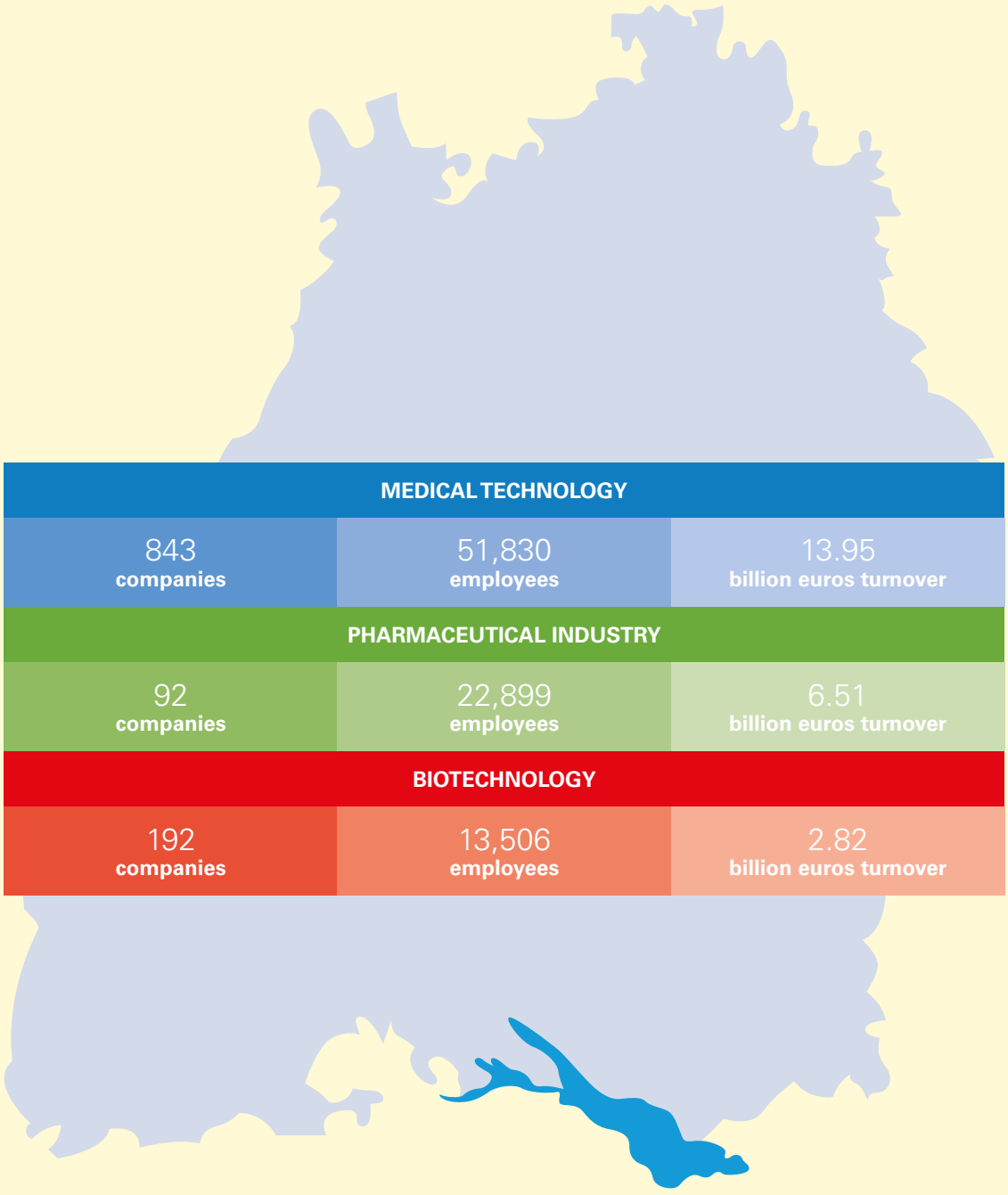
The healthcare industry is one of the strong economic factors and employment drivers for Baden-Württemberg. This is impressively demonstrated by the new facts and figures provided in the 2023 Healthcare Industry Report. The healthcare industry is progressively becoming a new leading industry in Baden-Württemberg and is in a position to make a decisive contribution to meeting the challenges of our time. Digitalization will advance, physical and digital medicine will grow together through access to structured and high-quality health data, diseases can be detected in the future even before their actual onset or in an initial outbreak phase, and new, personalized treatment methods will be developed in this context. The use of key technologies such as biotechnology, microtechnology, nanotechnology and quantum technology will contribute to the further development of the healthcare industry. Prerequisites include a well-positioned digital infrastructure, cooperation networks and the positive promotion of change processes (an innovation mindset). The development of patient-centred healthcare will be at the centre of these changes. In addition, the three dimensions of sustainability – environmental, social and economic sustainability – must form the starting point for all new developments, also and especially in the healthcare sector.

Let us tackle the challenges of our time together, by setting new impulses and further and deeper networking of those involved. We will be happy to take you on this journey into the future.

Stay curious and in exchange with each other!

Prof. Dr. Ralf Kindervater
CEO
BIOPRO Baden-Württemberg GmbH

The Healthcare Industry at a Glance



MEDICAL TECHNOLOGY		
843 companies	51,830 employees	13.95 billion euros turnover
PHARMACEUTICAL INDUSTRY		
92 companies	22,899 employees	6.51 billion euros turnover
BIOTECHNOLOGY		
192 companies	13,506 employees	2.82 billion euros turnover

The health economy has great potential for the future and needs to continuously adapt to changes. On the one hand, the use of artificial intelligence, quantum technologies, gene and cell therapies will lead to major technological innovations. On the other, we will have to deal with demographic changes, multimorbidity, cost pressures, scarcity of raw resources in the area of raw materials and energy, and changes triggered by climate change, such as heat waves or floods, all of which impact the delivery of healthcare.

The economic contribution of the health economy to the overall economy in Germany is enormous: in 2021, the sector's gross value added (GVA) amounted to 391.8 billion euros, which represents 12.1 percent of the country's overall gross value added. The German healthcare sector employs 7.7 million people. With an average growth rate of 3.8 percent since 2012, the German health economy is growing faster than the German economy as a whole.[1] In the Corona-related crisis year 2020, the healthcare industry recorded a decline in GVA of minus 3.7 percent , 0.7 percentage points above that of the German economy as a whole, which recorded a decline of 3.0 percent compared to 2019. The reasons for this included border closures, export restrictions and reduced patient care provision in hospitals.[2]

The healthcare industry is a strong economic factor and employment driver for Baden-Württemberg. It is represented by 1,100 companies that research, develop and/or manufacture in Baden-Württemberg. In 2020, these companies generated a taxable turnover of 23.28 billion euros and employed 88,235 people. Baden-Württemberg's characteristic mix of small and medium-sized enterprises as well as large companies ensures the stability of the healthcare industry. In the last ten years, 157 companies were established in the healthcare industry. Over the same period, BIOPRO Baden-Württemberg GmbH recorded the closure of 74 businesses.

With a total GVA of 17.1 billion euros, Baden-Württemberg is Germany's largest industrial healthcare location, which includes the healthcare industry as well as the distribution and wholesale sectors. Compared to other German states, the largest number of people working in the healthcare industry are employed in Baden-Württemberg. They account for 19.9 percent of Baden-Württemberg's health economy. Baden-Württemberg is also the top state in terms of iGW exports, with EUR 40.3 billion.[3]

Although the economic situation of Baden-Württemberg's healthcare companies is clearly excellent, they still face quite a number of challenges, including China's zero-COVID policy (until end of 2022), the Russian war of aggression in Ukraine as well as climate change. The disruption and unpredictability of supplies puts companies under enormous pressure. A recent survey by the German Chamber of Industry and Commerce (DIHK) shows that companies across all sectors in Germany are cutting back production in Germany due to sharply rising energy prices: 63 percent of the companies surveyed rate high electricity and gas prices as a threat to Germany as a business location. In addition, increasing scarcity and the high cost of raw materials negatively impact manufacturing companies.[4/5]

Healthcare companies also foresee increasing pressure due to stricter regulatory framework conditions.

Regulatory framework

The harmonisation efforts of the European Union (EU) and new technological developments have led to new, stricter regulations such as the MDR and IVDR, the Draft Regulation on Artificial Intelligence and the European Health Data Space (EHDS), to name just a few. Small and medium-sized enterprises (SMEs) in particular need help with the classification and implementation of new regulations due to scarce time,

human and financial resources. BIOPRO Baden-Württemberg offers assistance by providing support with regulatory issues; information can be found on our regulatory guide for healthcare industry companies.

In addition to the challenges for the healthcare industry described above, the healthcare sector holds great potential for its economic development, among other things due to the continued increase in health awareness among the population, the digitalization in healthcare accelerated by the pandemic, and data-driven innovations.

The future of healthcare

Patent applications are an indicator of companies' investments in research and development (R&D) and thus innovations. On the EU level, 4.5 percent more patent applications were filed in 2021 compared to the previous year. The majority of patent applications came from the USA (25 percent), followed by Germany (14 percent). The medical technology, pharmaceutical industry and biotechnology are among the top 10 technology fields. The pharmaceutical industry and biotechnology sectors experienced a particularly high growth rate (up 6.9 and 6.6 percent, respectively). The growth rate of the medical technology sector was much lower (0.8 percent).[6]

The rapid translation of scientific findings into medical solutions and products geared to medical needs requires the efficient transfer of knowledge and technologies. Baden-Württemberg is home to two 'Cluster4Future' groups that bring together academia and industry. Both are funded by the German Federal Ministry of Education and Research and focus on advanced technologies: the QSens cluster focuses on the utilisation of quantum technology/sensor technology for application in medical and other devices, and the nanodiag BW cluster uses nanopore technology for the early detection of epigenetic diseases.[7]

Medical translation and change processes can also be accelerated when they take place in living labs, which enable transdisciplinary collaboration in treatment and care under real, everyday clinical conditions. The Inspire Living Lab at the University Medical Centre Mannheim is such an example. Here, companies can test their technological products in a test ward under real conditions and validate them through patient use of the equipment.[8]

The first German BioLabs incubator is currently being established in Heidelberg. BioLabs is a globally successful operator of incubators in the life sciences, which has a special focus on the particular challenges of the industry. BioLabs Heidelberg offers a unique environment to develop game-changing ideas with great transformative potential for future diagnostics and therapy and for attracting start-up companies.[9]

The Forum Health Region Baden-Württemberg was initiated by Minister-President Winfried Kretschmann in 2018 and currently comprises over 500 experts from the Baden-Württemberg healthcare sector. Through exchange, networking and interdisciplinary collaboration, new knowledge is to be gained and health care is to be further developed.

3 questions for Dr. Eike Wenzel, Director of the Institut für Trend- und Zukunftsforschungs GmbH (ITZ)

What (mega) trends are you seeing in healthcare?

We at ITZ believe that health is itself one of 15 megatrends that we describe as the most important change drivers over the next three to five decades. We believe that in the coming years digitalisation and the use of artificial intelligence are two areas that will specifically contribute to transforming healthcare. Digital health solutions have already been increasing the effectiveness of healthcare in the past two decades. In the years to come, digital health platforms will transform the way we deliver healthcare services. At present, many major companies are working on the development of platforms that will attribute – without exception – new roles to all healthcare players; health will acquire a different status (prevention), medical research will follow different paradigms (keyword: molecular biology) and value creation architectures (from pill makers to healthcare service providers) will undergo fundamental changes.

What does a sustainable company in the healthcare industry look like?

Sustainable healthcare companies must first and foremost understand the significance of the megatrends of digitalisation and decentralisation. In addition, they must pay close attention to megatrends such as climate change, energy transition (who would have thought it) and demographic change. Many people have started to see health as a key resource for competitiveness and a good life. In fact, living healthily is increasingly becoming a lifestyle choice. Health has become much more than the absence of disease. Innovations involving artificial intelligence and biomolecular research increasingly help people to lead healthy lives without having to resort to traditional pharmaceuticals (keyword: digital therapeutics).

What role will sustainability play for companies in the healthcare industry in the future?

More than anything, sustainability in health means that we must respect planetary boundaries in our goal to produce innovative medical products and make medical progress. In the coming years, we will have to invest billions of euros in mitigating the effects of global warming on people's health. This starts with how cities can be cooled in summer, continues with climate-sensitive nutrition and does not stop there.

The potential of data in a networked and interoperable world

Tomorrow's healthcare will be characterised by the fusion of conventional and digital medicine that puts patients at the centre. It will be based on a digital infrastructure that makes valuable health data accessible via electronic patient records as an interface for high-quality treatment or the development of new conventional and digital therapeutics. The linking of a large volume of structured, high-quality data holds great potential for, among other things, personalised prevention, better treatment options for rare diseases or the targeted fight against pandemics, as well as efficiency improvements and cost reductions. Data protection and security is particularly challenging, as a number of hurdles – such as the lack of standards and interoperability, access to high-quality data, anonymised or pseudonymised exchange of data from the real world of care – still need to be overcome. The European Commission intends to use the EHDS to create the legal basis and a common infrastructure for secure access to and processing of health data.

The Forum Health Region Baden-Württemberg has been working at full speed on a roadmap for the use of health data. The goal is to create the legal, technical and organisational prerequisites to advance the use of health data.

Into the future with technology

Artificial intelligence (AI) is considered a key 21st century technology. The Innovation Park for Artificial Intelligence (Ipai) is currently being established in the Steinäcker industrial park in the city of Heilbronn. It has an investment volume of 100 million euros, 50 million euros of which are being provided by the Baden-Württemberg government. By providing optimal innovation and location conditions, the Innovation Park is expected to attract specialists, talents, companies and new start-ups and make a significant contribution to the commercialization of AI from Baden-Württemberg. Ipai complements the excellent AI research landscape in Baden-Württemberg, which includes Cyber Valley Stuttgart-Tübingen and its Cyber Valley Health Initiative as well as the FZI Research Center for Information Technology in Karlsruhe and many other institutions.[10]

Quantum computers that use the laws of quantum mechanics are another key 21st century technology. Europe's first commercial quantum computer has been installed at the Quantum Computing Baden-Württemberg competence centre in the city of Ehningen. Under the direction of the Fraunhofer Society, the quantum computer can be used by companies, start-ups and research institutions that wish to develop concrete applications. The QSens cluster investigates innovative quantum sensors that can be used in personalised medicine, among other things. The aim of the cluster is to establish a regional innovation ecosystem to decisively advance the application of quantum technology.[11]

3 questions for Prof. Dr. Jens Anders, Director of the Institute for Intelligent Sensor Technology and Theoretical Electrical Engineering (IIS), University of Stuttgart and spokesperson of the QSens cluster

Quantum technology is a key technology of the 21st century. Why?

First-generation quantum technologies such as lasers, atomic clocks for GPS and magnetic resonance imaging have already changed our lives. The second generation of quantum technologies is now making its way into our everyday lives. Quantum effects are no longer just used, but also generated in a targeted manner. This opens up previously unimaginable possibilities and will lead to disruptive changes in three fields of application: computing, communication and sensor technology.

Quantum sensors will soon be used in everyday applications and thus generate added economic value. The technology is already relatively mature, which will make it possible to launch the first quantum sensor products on the market in large quantities in the near future.

What potential does quantum technology hold for Germany and Baden-Württemberg as business locations?

German researchers and industrial companies lead the world in the field of sensor technology and also in some of the enabling technologies required for quantum technologies; these are technologies that are needed to manufacture quantum devices in a scalable and economically viable way. This is particularly true for Baden-Württemberg, which has an extraordinarily high density of scientific and industrial excellence in the fields of sensor technology, photonics and microelectronics. Quantum technologies offer the opportunity to sustainably consolidate this leading position.

What potential does the technology hold specifically for the healthcare industry?

In healthcare, quantum sensors can be used, for example, for high-precision, non-contact measurement of neural currents. We therefore believe that in the future this will allow locked-in patients to communicate with their environment or prostheses to be intelligently controlled by the natural signals of intact neural pathways. The immense specificity of the quantum sensors currently being investigated can be used to accelerate screening for new pharmaceutical agents at a fraction of the current cost. The highly accurate measurement of trace gases in exhaled air is another example where quantum sensors can be used in medicine. In this field, Rydberg atom-based quantum sensors can hopefully set a new standard in the future.

Transformating the healthcare industry toward greater environmental sustainability

Climate change – the increase in extreme weather conditions such as heatwaves and floods – is affecting our life and health. Healthcare also contributes to the problem. The global healthcare sector is responsible for 4.4 percent of harmful emissions. Scope three emissions, i.e. emissions resulting from manufacturing and transporting pharmaceuticals and medical technology products, account for 71 percent of these emissions.[12] In order to reach Germany's goal to become climate-neutral by 2045, harmful emissions must therefore also be reduced in the healthcare sector. The initial goal is to reduce emissions by 65 percent by 2030 (compared to 1990).[13] The appeal made by the 125th German Doctors' Conference to all decision-makers in November 2021 goes even further. It calls for the healthcare sector to be climate-neutral by 2030.[14] In order to achieve this major goal – climate neutrality – new strategies must be designed and processes approached in a different way. SMEs in particular need incentives, information, cooperation partners and financial support. Transsectoral cooperation is of particular importance as other sectors have been able to gain more experience and goals can be achieved more quickly together.

There are many ways to increase environmental sustainability in healthcare: disease prediction and prevention can reduce the need for treatment; expired drugs can be recalled and their active ingredients re-isolated; the quantity of packaging materials can be reduced; and the use of single-use instruments can be minimised. In addition, digitalisation can be a driver for more sustainability and support the identification of ideal treatment options, track down promising active ingredient candidates without requiring years or decades of research, as well as speed up the process of clinical validation.

Biological transformation can be another significant building block on the path towards achieving greater environmental sustainability: the use of biological or bioinspired processes, procedures and principles has potential for innovative and sustainable value creation. It can therefore also be a way to reduce environmental impacts that harm the climate. According to a recent survey by the Chamber of Commerce and Industry in the Stuttgart region, in which more than 800 regional companies participated, two-thirds of respondents saw biological transformation as the next industrial revolution and said it needed to be pushed forward in a timely manner.[15]

Learn more about sustainability in the healthcare industry in BIOPRO's current publication „Success Factor Sustainability: Ecodesign and Circular Economy in Medical Technology; Transformation Approaches for Baden-Württemberg".

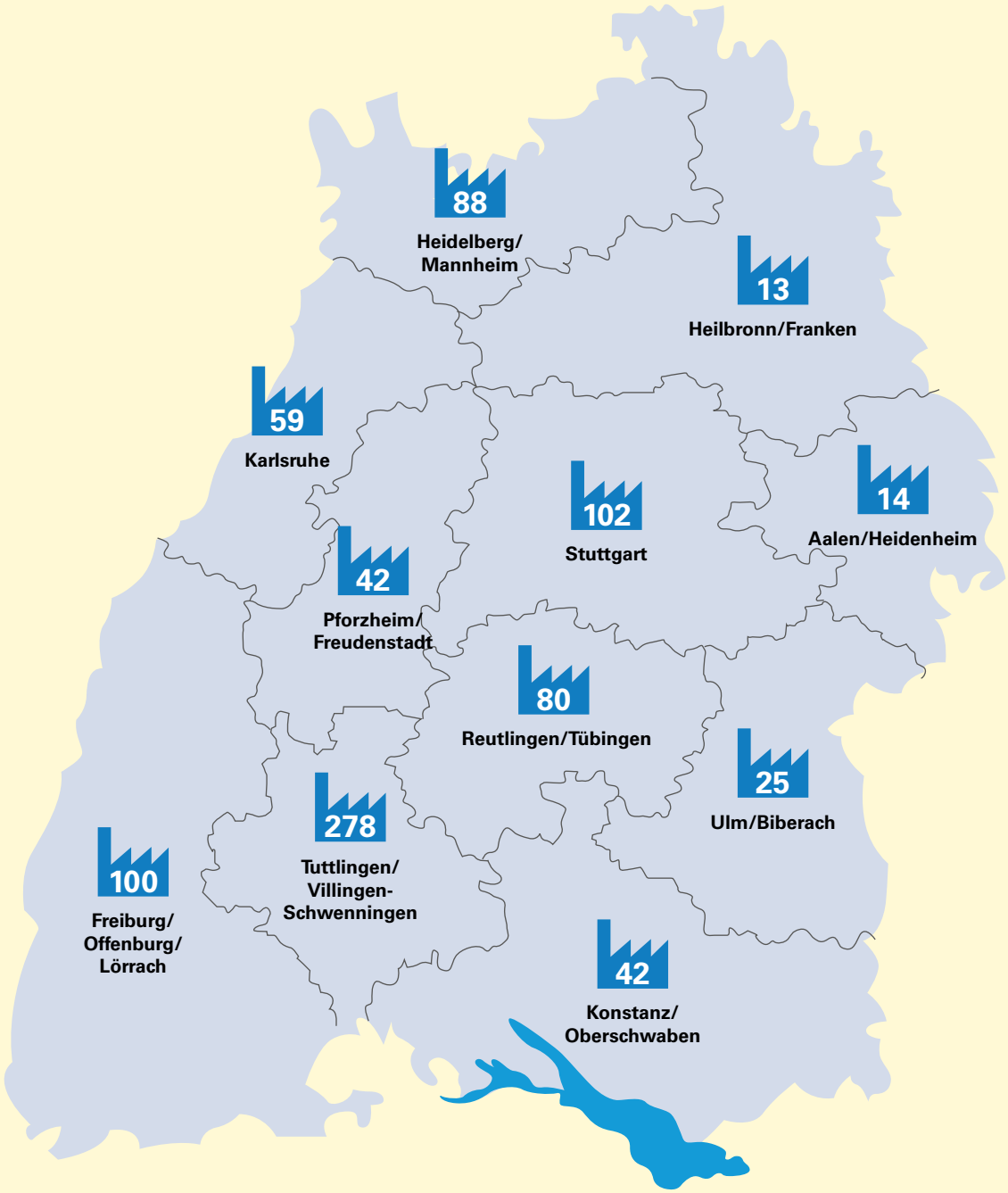
„Hospitals have an enormous impact in terms of sustainability and climate protection in healthcare. When it comes to energy consumption, this means reducing primary energy requirements through new, digital systems. Climate-damaging effects need to be reduced via sustainable procurement and converting to recyclable products. It is also possible to reduce emissions from narcotics. By switching to alternative anaesthetic gases and anaesthetic gas collection systems, we have already been able to reduce climate-damaging emissions in the operating room.

Green – Smart – Healthy. For me, this motto stands for the sustainable hospital of the future."

Prof. Dr. Dr. h.c. Frederik Wenz, Chief Medical Director, Freiburg University Medical Centre

The Medical Technology Sector

MEDICAL TECHNOLOGY		
843 **companies**	51,830 **employees**	13.95 **billion euros turnover**

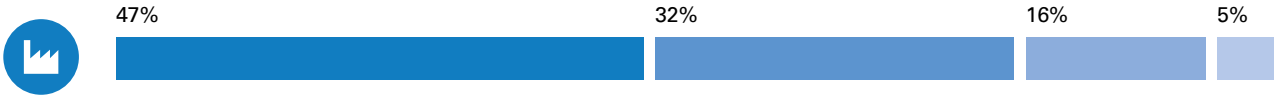


Medical technology products, ranging from wound dressings, high-resolution diagnostics to digital health applications and implants play a major role in our lives. They assist in the prevention, cure and diagnosis of diseases as well as in rehabilitation. Medical products were in the spotlight during the coronavirus pandemic, providing vital ventilators or enabling doctor-patient contact through telemedicine applications.

Over 500,000 medical products are approved in Europe under the Medical Devices Directive 93/42/EEC, which is currently still in force. However, this could soon change as these certifications will become invalid by May 27, 2024. All medical products will have to be recertified under the new EU Medical Device Regulation (MDR) 2017/745 and In Vitro Diagnostic Device Regulation (IVDR) 2017/746.

This will mainly (but not exclusively) pose problems for SMEs, of which there are many in Baden-Württemberg. Of a total of 843 companies, 95 percent have less than 250 employees. Just under half of these companies (47 percent) have less than ten employees and thus fall into the category of micro-enterprises. Together, these companies form Baden-Württemberg's characteristic ecosystem of large companies and SMEs, whose interaction and cooperation are extremely important for the location – as an economic factor, an employment driver, and as a source of new ideas and innovations for the treatment methods of tomorrow.

The economic success of the companies is demonstrated by the following figures. Medical technology companies generated taxable turnover of 13.95 billion euros in 2020 (up 9.06 percent compared to the 2019 financial year with a turnover of 12.68 billion euros). The industry employs 51,830 people (up 2.44 percent from 50,563 employees in 2019). According to the Baden-Württemberg Statistics Office, the export ratio of medical technology products was 65.8 percent in 2020. In the period from 2020 to July 2022, 20 new start-ups emerged and 16 businesses in the Baden-Württemberg medical technology sector closed down. A total of 80 medical technology companies were founded in the last ten years.



Medical technology companies in Baden-Württemberg in 2020 according to employee size classes

Turnover of medical technology companies in Baden-Württemberg in 2020 according to employee size classes

0–9 10–49 50–249 ≥ 250

The regulatory dilemma

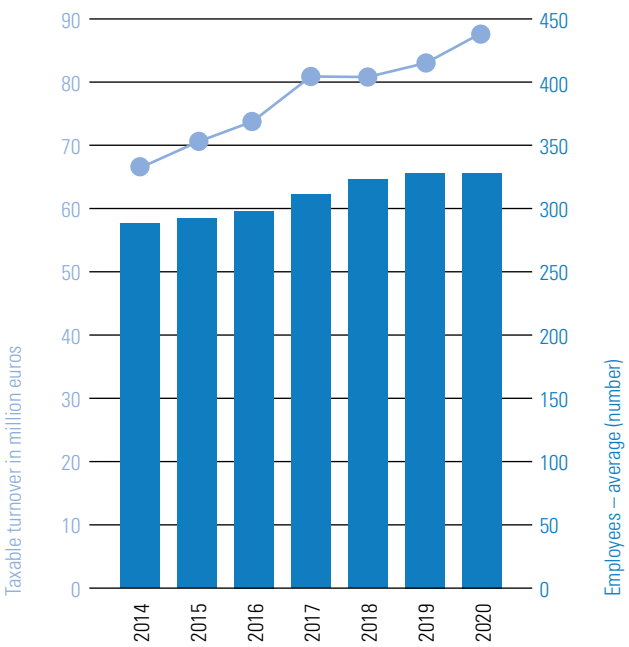
The two new regulations, MDR and IVDR, came into force in 2017 and have been mandatory since 2021 and 2022, respectively. A recent survey by the MDCG Task Force (Medical Device Coordination Group) came to the following conclusions:

- Currently, 85 percent of the 500,000 medical devices within the EU have not been issued certificates according to MDR.
- The average processing time by the Notified Bodies until certification is 13 to 18 months.
- Half of the companies that participated in the survey plan to reduce their product portfolio.
- The emerging shortage in the healthcare sector affects all categories of medical devices.[16]

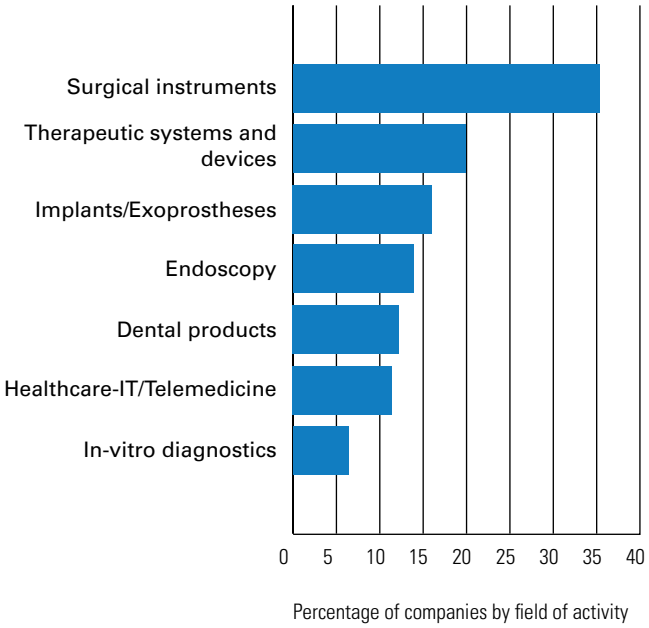
The central objectives of the new regulations, i.e. to ensure a high level of health protection and at the same time to promote innovation, are not achievable against the background of the current implementation challenges.

MDR & IVDR Fast-Track BW, financed by the Baden-Württemberg Ministry of Economic Affairs, Labour and Tourism and coordinated by BIOPRO, supports SMEs in Baden-Württemberg in the implementation of the regulations through a series of practical and pragmatic measures. The relevant documents, articles, guidelines and sample contracts can be requested through mdr-ivdr.bio-pro.de. In the future, this guide will be supplemented by further regulatory requirements for the healthcare industry.

Medical Technology Index for Baden-Württemberg: Development of turnover and number of employees between 2014 and 2020



Proportion of companies per field of activity (selection) as a percentage, companies may be active in several fields of activity



Investment and innovation in Baden-Württemberg

The industrial healthcare sector in Germany generated a gross value added (GVA) of 85.2 billion euros in 2021. Of this, 10.6 billion euros GVA is attributable to the R&D subsegment, of which 10 percent were generated by the medical technology sector.

The innovative nature of the industry can also be deduced from the number of patent applications: with 15,321 patent applications (up 0.8 percent on the previous year 2020), the medical technology sector comes second to digital communication. However, according to a DIHK study, only just under half of medical technology companies still intend to invest in product innovations. The reasons for this include a shortage of skilled workers, a shortage of raw materials, supply bottlenecks and the previously mentioned regulatory requirements.[17]

Two Baden-Württemberg companies, living brain GmbH and Dermagnostix GmbH, successfully closed high financing rounds. In July 2022, living brain GmbH, a Heidelberg-based start-up company founded in 2019 that develops software for use in personalised neurorehabilitation, closed a seven-figure financing round. In August 2022, Dermagnostix GmbH, a Freiburg- and Friedberg-based company founded in 2020 that markets molecular diagnostic products for skin diseases based on Hahn-Schickard's LabDisk technology, closed a €4.6 million founding round. The Photon-Counting-CT Consortium has recently installed next-generation imaging, so-called photon-counting computed tomography, in cooperation with Siemens Healthineers AG at the University Hospitals of Mannheim, Freiburg and Tübingen. The project, which is supported by BIOPRO Baden-Württemberg GmbH, investigates the new CT devices and the possibility of connecting them to a digitalised healthcare system.

Erbe Elektromedizin GmbH in Tübingen is one of the companies investing in Baden-Württemberg with a new, sustainable building for the development and production of surgical instruments in Rangendingen. The new building is expected to be ready sometime in 2023 and will provide space for 400 people.

„At Erbe, we are currently mainly concerned with three topics. One is our new building in Rangendingen, in which we have invested seventy million euros. We are following the sustainability concept of our group strategy by, for example, building one of the largest roof-mounted photovoltaic systems in Baden-Württemberg and constructing one of the first industrial buildings of this kind in accordance with the KfW-40-EE-standard.

The second topic is our entry into the field of endoscopy with new technologies for processing image and video data. Our third major focus is the miniaturisation of components. Not only are electronic components becoming ever smaller, mechanically complex components are also making products increasingly efficient. To achieve this goal, we are relying on our technological research and development."

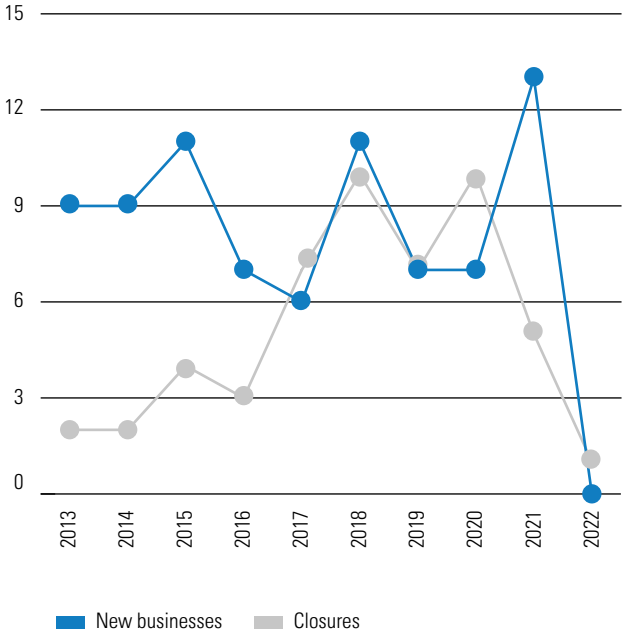
Dr. Helmut Scherer, Chief Technology Officer, Erbe Elektromedizin GmbH

Smart Health

A lot is happening in the healthcare market in the area of digital health applications (DiGA). Of the 20 medical technology companies established between 2020 and 2022, 13 focus specifically on eHealth (table page 19). These include the newly founded Health Data Technologies GmbH, which aims to build honic®, a secure platform for medical health data made in Germany, to enable R&D based on healthcare data. Medicalvalues GmbH, based in Karlsruhe, is working on bringing together clinical health data via a proprietary platform and evaluating it for leveraging better medical diagnostics with the help of artificial intelligence. The Karlsruhe-based pharmaceutical company Dr. Willmar Schwabe GmbH & Co. KG and Hamburg-based Sonormed GmbH have jointly developed an app for treating tinnitus, a digital health application which was included in the BfArM's DiGA directory in March 2022.

There is no doubt that digitalisation will fundamentally change healthcare. How quickly this will happen depends on various developments, including that of the European Health Data Space (EHDS), which is part of the European data strategy. In May 2022, the European Commission presented a draft regulation on the European Health Data Space, thus laying the foundation for the future usability of high-quality health data, for primary use (healthcare) and, under strict conditions, also for secondary use (health research and policy).[18]

New medical technology businesses and company closures (dissolutions, insolvencies, liquidations) in Baden-Württemberg between 2013 and 2022



Medical technology companies founded in Baden-Württemberg between 2020 and 2022

	Company	Location	Field of activity
2020	Delta theranostics	Heidelberg	In-vitro and point-of-care diagnostics
	eye2you GmbH	Tübingen	Healthcare IT/Telemedicine
	HomeCyte GmbH	Heidelberg	In-vitro and point-of-care diagnostics
	Institut Digitale Frauengesundheit GmbH (IDFG GmbH)	Heidelberg	Healthcare IT/Telemedicine
	Midaia GmbH	Heidelberg	Healthcare IT/Telemedicine
	NichtraucherHelden GmbH	Stuttgart	Healthcare IT/Telemedicine
	Odilia Vision GmbH	Tübingen	Healthcare IT/Telemedicine, therapeutic devices and systems
2021	Actimi GmbH	Stuttgart	Healthcare IT/Telemedicine
	BioHeart UG	Mannheim	Tissue Engineering/Regenerative Medizin
	digifoot GmbH	Heidelberg	Healthcare IT/Telemedicine, therapeutic devices and systems, consumables
	Digitineers GmbH & Co. KG	Tübingen	Healthcare IT/Telemedicine
	Fysor GmbH	Weil im Schönbuch	Healthcare IT/Telemedicine, therapeutic devices and systems
	Glanzify UG (limited liability)	Heidelberg	Dental products
	Health Data Technologies GmbH	Neckar-sulm	Healthcare IT/Telemedicine
	imdroi GmbH	Nußloch	Healthcare IT/Telemedicine
	medicalvalues GmbH	Karlsruhe	Healthcare IT/Telemedicine
	mollicool GmbH	Reutlingen	Therapy
	Nocubi GmbH	Metzingen	Surgery/hospital equipment
	PAICON GmbH	Heidelberg	Healthcare IT/Telemedicine
	Solios diagnostics GmbH	Tübingen	In-vitro and point-of-care diagnostics

Selected investments, acquisitions, cooperation and licensing agreements as well as IPOs of medical technology companies in Baden-Württemberg from 01/2020 to 07/2022

Investments

	Company	Location	Field of activity
2020	Curetis GmbH	Holzgerlingen	Molecular diagnostics products
2021	Inovedis GmbH	Albstadt	Implants
2021	Hellstern medical GmbH	Wannweil	Surgery/hospital equipment
2021	Dermagnostix GmbH	Freiburg i. Br./ Friedberg	Diagnostics
2022	living brain GmbH	Heidelberg	Rehabilitation software
2022	Dermagnostix GmbH	Freiburg i. Br./ Friedberg	Diagnostics

Acquisitions

	Company	Location	Field of activity
2021	Dosing GmbH	Heidelberg	Healthcare IT/Telemedicine
2022	A.S.S.I.S.T.	Tübingen	Healthcare IT/Telemedicine

Cooperation and licencing agreements

	Company	Location	Partner company
2021	neuroloop GmbH	Freiburg i. Br.	Merck KGaA
2021	Stryker GmbH & Co. KG	Duisburg/ Freiburg i. Br.	Freiburg University Medical Centre, University of Freiburg
2021	CorTec GmbH	Freiburg i. Br.	Blackrock Neurotech, LLC, USA

Investment volume	Type of financing	Investors
20 million euros	Convertible loan	Issuance of convertible funds by Curetis N.V.
1.8 million euros	Seed financing	High-Tech Gründerfonds (HTGF), MBG Mittelständische Beteiligungsgesellschaft Baden-Württemberg, Volksbank Albstadt ChancenKapital and angel investors
1.5 million euros	Start-up financing	L-Bank BW with support from Technologieförderung Tübingen-Reutlingen
seven-figure financing round	Seed financing	Network of investors from the medical and financial sectors
seven-figure financing round	Seed financing	Private investor network Companisto, Ina Schlie and Dorit Posdorf from encourageventures
4.6 million euros	Seed plus funding	Seed investors as well as private investors and Family Offices

Acquired by
Dedalus HealthCare, Bonn
OnlineDoctor 24 GmbH, Hamburg

Category
Cooperation agreement for the development of a neurostimulator
Strategic cooperation in the fields of robotics, personalised medical technology and artificial intelligence
Strategic partnership in the fields of neurodevices/ brain-computer interfaces

3 questions for Christian Wörne, CEO, Qatna Medical GmbH

Qatna Medical develops innovative implants based on biological materials. Why is Qatna Medical GmbH using biological materials?

The advantage of biological over synthetic materials is that they cause fewer immune reactions and are therefore very biocompatible. Therefore, our patients do not need lifelong medical therapies to prevent blood clots forming. The biological implants help reduce undesired drug-related health risks and thus improve quality of life. This is our mission.

Which issues are particularly challenging for Qatna Medical GmbH at the moment and in which areas are things going particularly well?

The specially developed manufacturing process for processing and drying a biomaterial that will later serve as an implant is now securely established. Currently, we are experiencing particular challenges with the lack of availability of materials and components. We need to carry out and test different approaches during the product development phase, and identifying a suitable material in a timely manner is extremely important. The time-consuming and costly procurement of materials has an impact on the capital base and the time taken to bring the product to market. The certification process according to the regulations (EU) 2017/745 (MDR) and 2017/746 (IVDR) and EN ISO 13485 is also an additional challenge for a young medical technology company like Qatna Medical with limited resources.Our dedicated and qualified team will now implement the next development milestones in close collaboration with consulting cardiologists.

Where are you hoping to see incentives in the future?

Many regulatory requirements make sustainability quite difficult. We regard this as a major challenge for the future in relation to our goal of using sustainable materials for our products and packing. However, the new regulations prohibit us from switching to more sustainable packaging materials or from continuing to use paper instructions.

Medical technology companies, especially small start-ups, need greater support from the federal government and more financial support in order to be able to compete with global companies and at the same time implement sustainable processes for future generations. Innovation clusters and organisations such as BIOPRO Baden-Württemberg and Medical Valley Hechingen play a hugely important role in this, as they act as a communication bridge between manufacturers, suppliers, hospitals and also the regulatory authorities.

3 questions for Barbara Stegmann, CEO and Co-Founder, living brain GmbH

The MDR classifies the product teora® mind as a class 2a medical device. How has living brain GmbH implemented the requirements according to MDR?

When we set up our first 'QMS concept', we received outstanding support from some of our investors who themselves have experience in this area and who shared their tips and tricks with us. We did the setup of the QMS and the complete documentation in-house. Most of the steps involved were very time- and energy-intensive processes, especially for our small team. However, we made a conscious decision to do all this and become familiar with QM systems and the MDR, so that we understood everything and were able to implement everything that was required.

We had already figured out how much funding we would need to do this in our last financing round and we established contact with the Notified Body back in January 2020 in order to plan the certification and audit processes in good time.

We have digitally mapped the implementation of the requirements on an ongoing basis and set our QMS up using Confluence, which saves us from having to do the time-consuming release and archiving processes.

Just recently, living brain GmbH successfully completed a seven-figure financing round. What will the capital primarily be used for?

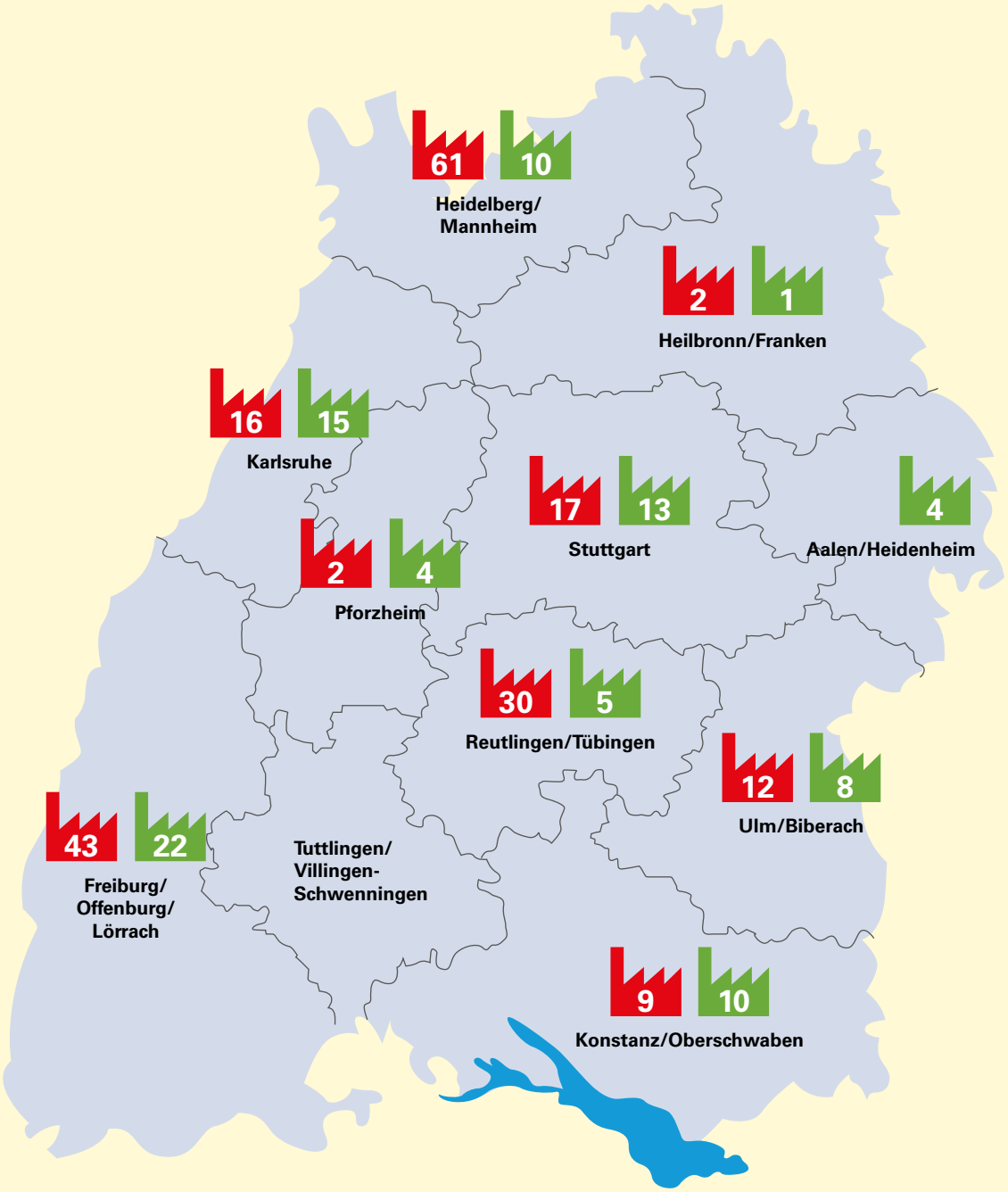
The new capital now enables us to invest further in the product in order to integrate it into care on a widespread and sustainable basis, to make it available to practitioners and patients, and thus to support even more people as they endeavour to return to their everyday lives. Our top priorities are now the further establishment of teora® mind in the market and the development of effective and economical solutions for use in the healthcare market. We are grateful for the trust placed in us by all our investors and supporters who have been with us for a long time and we are proud to now have new partners at our side who will support us in our further growth.

What has been the biggest learning for living brain GmbH so far, what can you pass on to other companies?

As of today, I would say the following three things taught us the most: things never turn out the way you imagined or planned them. And that's okay. It's not about knowing everything in advance – some things just happen unexpectedly along the way. Enthusiasm. Love. Passion. Call it whatever you want, but you can't do without it. Setbacks or mistakes will occur; the question is whether to see them as learning opportunities or as a reason to give up. A network really is as important as people say it is. With the right people supporting or guiding you, many things become much easier.

Pharmaceutical industry and biotechnology

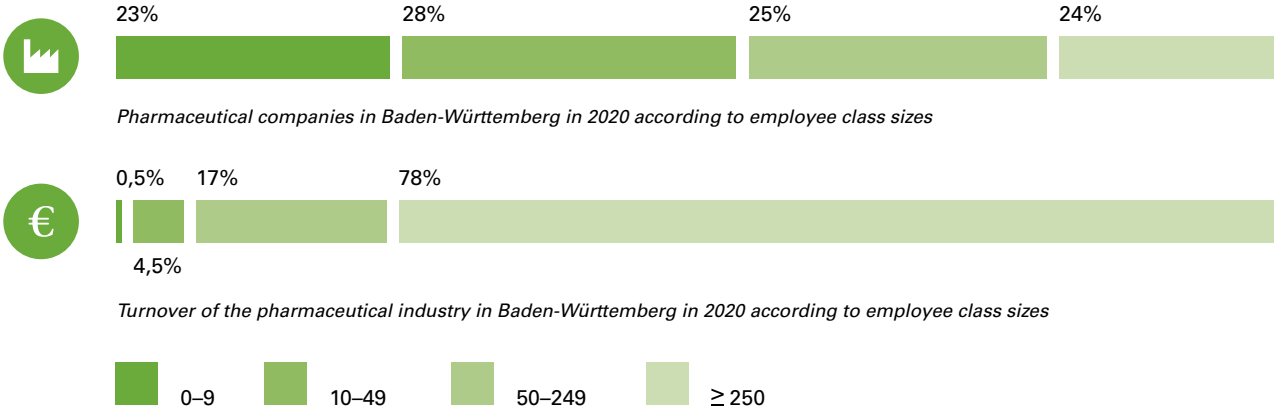
PHARMACEUTICAL INDUSTRY		
92 companies	22,899 employees	6.51 billion euros turnover
BIOTECHNOLOGY		
192 companies	13,506 employees	2.82 billion euros turnover



Medium-sized and large companies loyal to location

Even if one almost automatically thinks of the really big global players such as Boehringer Ingelheim, Pfizer and Roche, Baden-Württemberg's industry is made up primarily of small and medium-sized companies (69 percent). In addition, Baden-Württemberg companies are loyal to their location. This becomes obvious from the number of pharmaceutical companies, which has remained constant for many years. In addition to a large number of family-owned companies, small and micro-enterprises, Baden-Württemberg is home to several subsidiaries of multinational corporations, whose product portfolios range from novel drugs and generics to the production of herbal and homoeopathic medicines.

At present, 92 companies are researching, developing and producing in Baden-Württemberg. In 2020, their 22,899 employees (up 0.79 percent compared to the 2019 financial year) generated a taxable turnover of 6.51 billion euros (up 1.77 percent compared to 2019). Rhine-Neckar, Danube-Iller and Upper Rhine-Lake Constance are the regions with the highest turnover. Most employees work in the Lake Constance-Upper Swabia and Rhine-Neckar regions. Six pharmaceutical companies have been founded in Baden-Württemberg in the last decade. The most recent, ViMREX GmbH from Heidelberg, was founded in July 2021 and is aiming to develop products for application in cancer therapy and prevention. During the same period, i.e. between 2013 and 2022, BIOPRO recorded six closures of pharmaceutical companies in Baden-Württemberg.



Pharmaceutical companies in Baden-Württemberg in 2020 according to employee class sizes

Turnover of the pharmaceutical industry in Baden-Württemberg in 2020 according to employee class sizes

The pharmaceutical industry is the most research-intensive sector in Germany. It reinvests 13 percent of its turnover, and makes above-average investments in R&D.[19/20] In 2021, the R&D activities of the healthcare sector generated a GVA of 10.6 billion euros. Of this, R&D activities aimed at the development of human pharmaceuticals comprised the largest share, i.e. 47 percent. In the same year, pharmaceutical companies filed 9,026 patent applications, 6.9 percent more than in 2020. In addition, these companies placed 46 drugs with new active ingredients on the German market.

Anti-viral drugs against Sars-CoV-2

Pfizer is producing the first antiviral drug Paxlovid against severe COVID courses for the global market in Freiburg,

Germany, at its high-containment factory, which opened in May 2022. According to the latest Industry 4.0 standards, Pfizer has invested almost 300 million euros in the construction of this plant. Atriva Therapeutics GmbH in Tübingen is working on the provision of novel and highly effective therapies that have immunomodulatory and antiviral effects. The company presented promising results from clinical trials with the kinase inhibitor Zapnometinib in September 2022.

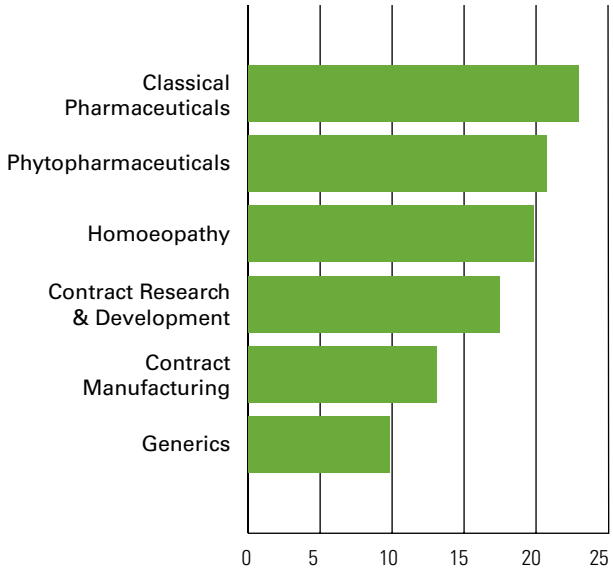
In the cycle of nature

Phytopharmaceuticals are herbal medicines whose effects are based exclusively on herbal ingredients. Within Europe, Germany is the largest market for herbal medicines. Together with homoeopathic and anthroposophic medicinal products, phytopharmaceuticals are classified as "special therapeutic disciplines". All three classes of medication are complementary to conventional therapy. More than 150 companies manufacture anthroposophic, homoeopathic and herbal products in Germany. They are mainly located in Bavaria and Baden-Württemberg. More than 22 percent of all pharmaceutical companies in Baden-Württemberg (also) produce phytopharmaceuticals. Among them is the family-owned company Dr. Willmar Schwabe GmbH & Co. KG. The company is the global market leader in the production of phytopharmaceuticals and invests 35 million euros in R&D every year. Other phytopharmaceutical manufacturers include Weleda AG and Wala Heilmittel GmbH.

Manufacturers of medicines that are classified as special therapeutic disciplines are often characterised by their sustainable way of working – both environmentally through their own regional medicinal plant gardens and cooperations with organic cultivation projects, among other things, and through their social commitment. The Redel Foundation established by Cesra Arzneimittel GmbH & Co. KG is one such example, and works with Caritas International to support aid projects around the world.

The initiative Phytopharmaceuticals and Valuable Plant Ingredients aims to identify the challenges and needs of phytopharmaceutical manufacturers and the opportunities for Baden-Württemberg agriculture. The initiative brings together all players along the value chain to discuss issues such as the cultivation of medicinal plants and how to keep transport routes short and strengthen domestic agriculture.

Fields of activity of the pharmaceutical industry in Baden-Württemberg, companies may have several fields of activity



The pharmaceutical industry in Baden-Württemberg benefits from the close interaction between basic research and the young, agile biotechnology sector. In the face of global competition, however, it is clear that the acceleration of processes – especially in the area of digitization and artificial intelligence and the harnessing of data – is enormously important for Baden-Württemberg.

Digitally into the data future

Access to health data is increasingly becoming a critical factor in the development of new therapies and treatment methods. Representatives of the pharmaceutical industry discussed this issue with Dr. Nicole Hoffmeister-Kraut, Minister of Economic Affairs, Labour and Tourism at a meeting in February 2022. The Baden-Württemberg government is working hard to improve access to clinical data for companies in order to improve healthcare and to create more value in Baden-Württemberg.[21]

Hand in hand: prevention and precision

In addition to the digital and sustainable transformation processes affecting all industries, another process of change is underway in the pharmaceutical industry. Derived from the principles of personalised medicine, which is specific to small stratified patient groups and is being developed based on new technologies, the pharmaceutical industry is increasingly focussing on preventive therapies. Demographic development and the increased frequency of common diseases such as diabetes and cardiovascular diseases require a preventive approach to mitigate economic and environmental costs associated with patient treatment. The early detection of individual risk factors and health-compliant behaviour is expected to prevent diseases from occurring in the first place or delay the course of a disease for as long as possible.

Framework conditions part I

The German Medicines Market Reorganisation Act, or AMNOG for short, has been in force in Germany since January 2011. Behind this lexical monstrosity lies the price regulation of innovative drugs in Germany. The price of new, patent-protected drugs is determined through an additional benefit assessment that aims to achieve a balance between innovation and affordability for the German healthcare system and its patients. The German Association of Research-Based Pharmaceutical Companies (vfa) states that AMNOG is delivering what is expected of it, which includes keeping the statutory health insurers' expenditures for medicines on a stable level over a period of many years; savings of 9.2 billion euros are expected for 2023.[22]

The Financial Stabilisation of the Statutory Health Insurance System Act (GKVFinStG) is intended to help stabilise the financial situation of the statutory health insurance system, as the name of the act suggests. In the pharmaceutical sector, the GKVFinStG extends the price moratorium by a further four years and the further development of AMNOG.[23]

The pharmaceutical industry has cautioned that this plan will further weaken Germany as a pharmaceutical location, especially in light of the steady rise in the price of energy and raw materials.

3 questions for Dr. Andrea Traube, Managing Director, KyooBe Tech GmbH

The trend toward automation and robotics offers new opportunities for production processes. What role do digitalisation and artificial intelligence play in vaccine manufacturing processes?

Digital transformation is a major challenge for many companies when it comes to the heavily regulated production of pharmaceuticals and vaccines. However, the opportunities are huge: Pharma 4.0 incorporates Industry 4.0-based concepts to adapt digital strategies to the contexts of pharmaceutical manufacturing in order to generate continuously linked and traceable digital data streams. Technologies for real-time capable data acquisition, big data analyses and artificial intelligence ensure a significantly faster gain in knowledge when it comes to analysing the causes and effects of events while they are occurring, identifying corrective measures and subsequently evaluating the measures taken. These are essential building blocks for process optimisation that simultaneously ensure the process reliability and quality of pharmaceutical products.

What does next-generation biotechnological production mean?

At KyooBe Tech, we want to make pharmaceutical production smarter and more resilient. By smart we mean controlling processes intelligently and with a high degree of automation; resilient means that the system can react independently to problems and deviations within a certain framework. The optimal combination of these two factors, smartness and resilience, can help minimise idle time in the future, use resources in the best possible way and independently solve problems that arise.

Which new processes do you use in vaccine production?

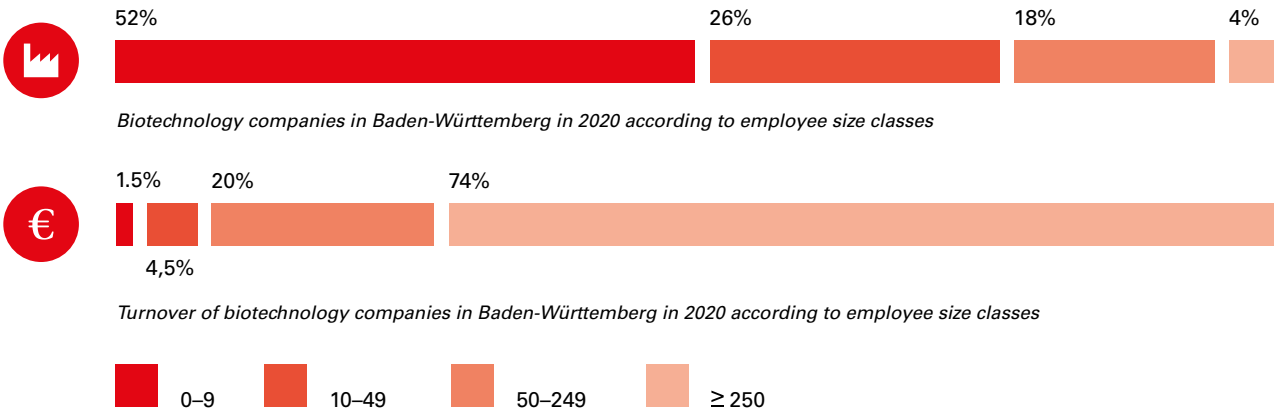
KyooBe Tech focuses on an important process step within the production of live-attenuated vaccines and conventional inactivated vaccines. This involves a process step consisting of the partial or complete inactivation of pathogens in liquid media. The degree of inactivation in our processes is controlled by low-energy electron radiation and the flow rate of the liquid. The advantage of this method lies in the preservation of the antigenic structures, which remain mostly intact. This is highly beneficial for the production of vaccines and the immune response induced.

In addition to vaccine production, we envisage other potential applications, for example in the field of cell therapy or the treatment of raw materials such as serum. The first pilot series will be launched in 2024.

Medical Biotechnology

The years 2020 to 2022 have impressively shown that medical biotechnology plays an important role in medical progress – exemplified by the fight against the Corona pandemic. Baden-Württemberg is home to 192 companies that are active in research, development and/or production in the field of medical biotechnology. The mostly smaller and agile biotech companies or start-ups drive innovation in active ingredient development and drug production. In the 2020 financial year, these companies generated a taxable turnover of 2.82 billion euros (up 15.12 percent compared to 2019). In 2020, the industry employed 13,506 people subject to social security contributions (up 3.9 percent compared to 2020).

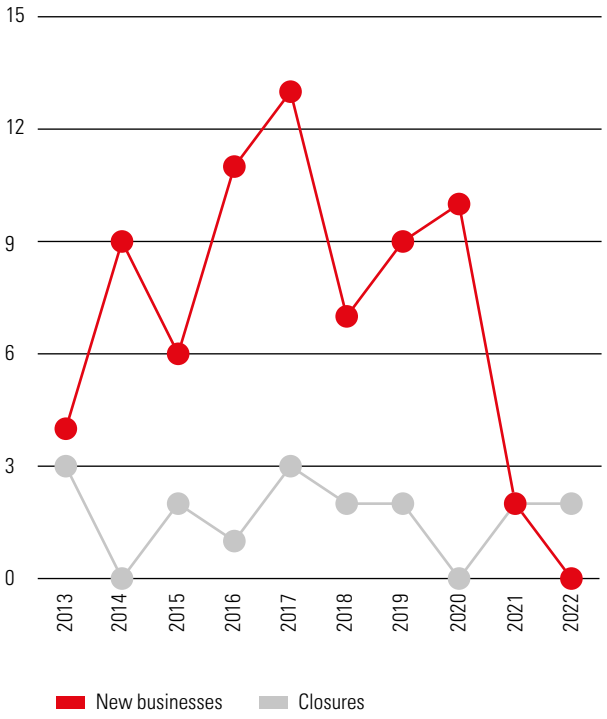
In the last decade, 71 medical technology companies have been founded in Baden-Württemberg. In 2021, however, the number of new start-ups that were established fell considerably. In 2020, there were still ten new start-ups but in 2021 there were only two. BIOPRO does not yet have any information on the number of new start-ups in 2022 (up until 07/2022). The fact that the number of start-ups is relatively low compared to previous years can be attributed to ongoing crises such as the coronavirus pandemic and political disputes. The majority of start-ups (over 40 percent) were active in the field of therapeutics development.



Biotechnology companies in Baden-Württemberg in 2020 according to employee size classes

Turnover of biotechnology companies in Baden-Württemberg in 2020 according to employee size classes

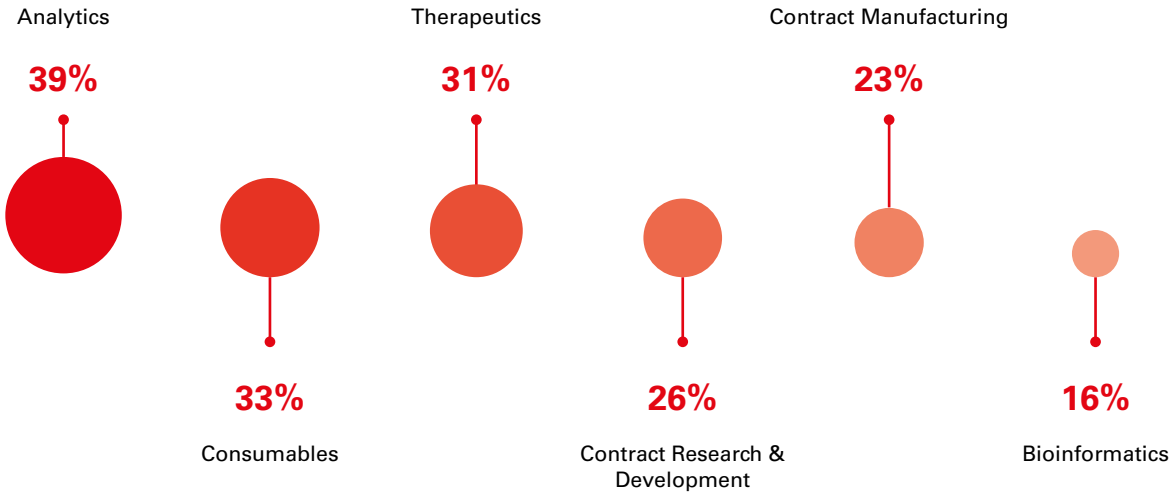
Business establishments and closures (dissolutions, insolvencies, liquidations) of biotechnology companies in Baden-Württemberg between 2013 and 2022



As outlined in the coalition agreement, the new German government plans to develop a preventive, crisis-proof and modern healthcare system that will exploit the opportunities offered by biotechnological and medical processes, thus helping Germany to become a leading international biotechnology location.[24]

In 2021, the manufacturer of the world's first mRNA vaccine (BioNTech SE) generated revenues of around 19 billion euros. In order to be able to respond quickly to future pandemics and produce vaccines on a large scale, the German government has signed pandemic preparedness agreements with five companies, including CureVac AG and Celonic Deutschland GmbH & Co. KG from Baden-Württemberg.[25]

Field of activities of biotechnology companies in Baden-Württemberg, companies may be active in several fields of activity



Drugs produced using biotechnology – biopharmaceuticals – have a market share of 16.1 billion euros, an increase of 10.2 percent over the previous years. Baden-Württemberg is an important location for biopharmaceuticals production. However, Germany as a whole has lost out significantly on international comparison: despite the expansion of production capacities for the manufacture of vaccines, Germany now ranks fifth in the world in terms of total capacities, instead of third as was the case in previous years.[26]

This is despite the fact that Baden-Württemberg-based companies are continuing to expand their production capacities: Boehringer Ingelheim, for example, plans to invest 25 billion euros in R&D over the next five years, as well as another seven billion euros in new production technologies. Biberach is the company's largest research, development and biopharma site. Nevertheless, other countries are pursuing long-term and, above all, state-supported strategies, as the example of South Korea shows where Celltrion and Samsung Biologics are investing billions to drive the rapid expansion of production capacities for biopharmaceuticals.[27]

Biotechnology companies founded in Baden-Württemberg between 2020 and 2022

	Company	Location	Field of activity
2020	Aptamimetics GmbH	Stegen	Services
	Axxelera UG	Karlsruhe	Bioinformatics
	CapCo Bio GmbH	Freiburg i. Br.	Therapeutics
	Cytolytics GmbH	Tübingen	Bioinformatics
	Fast Forward Discoveries GmbH	Mannheim	Consumables and devices
	HD Therapeutics	Ketsch	Therapeutics
	KyooBe Tech GmbH	Leinfelden-Echterdingen	Devices
	Panosome GmbH	Heidelberg	Therapeutics
	Variolytics GmbH	Stuttgart	Analytics, devices, services
	WMT AG	Heidelberg	Therapeutics
2021	Centaura Therapeutics GmbH	Heidelberg	Therapeutics
	LABMaiTe GmbH	Freiburg i. Br.	Bioinformatics

New technologies, new therapies

In the past, the focus was on treating symptoms. In the future, the focus will be on curing diseases. New technologies and therapeutic approaches such as cell and gene therapies and mRNA vaccines have the potential to cure diseases. The Heidelberg-based biotech company AaviGen GmbH is working on the development of a gene therapy for heart failure. The company uses adeno-associated viruses to introduce therapeutic genes in a highly specific manner into diseased heart muscle cells to support their healing, for example by compensating for the loss of heart tissue. The company expects to be able to carry out the first clinical studies in about six to seven years' time.

CureVac AG intends to accelerate its oncology strategy and advance the development of mRNA-based personalised cancer vaccines through the acquisition of the start-up Frame Cancer Therapeutics from the Netherlands. The acquisition is valued at 32 million euros.

New forms of therapy also require rethinking production processes such as on-demand production and personalised medication. Researchers at the Fraunhofer Institute for Manufacturing Engineering and Automation IPA, the University Hospital Tübingen UKT and the NMI Natural and Medical Sciences Institute Tübingen/Reutlingen are working on the decentralised and on-site production of cell therapies. Their SolidCAR-T project is aimed at being able to produce the therapeutic agent on demand where it is needed – i.e. in the clinic – while maintaining the highest quality standards.

The potential of digitalisation, already mentioned several times in this report, also applies here, for example through smart products – i.e. the expansion of products to include digital functions. Digitalisation also enables the faster commercialisation of research and development processes or the scaling of biopharmaceutical processes based on artificial intelligence.

Cooperation and new business models

Health is a megatrend. Around 30,000 diseases are known worldwide and only for a fraction there are already therapeutics. Networking and cooperation – including across technological boundaries – and the development of new (digital) business models have the potential to transform this situation. The latest EY Report Focus USA discusses new partnership models. The report finds that biotechnology companies are increasingly joining forces with each other in order to pool their knowledge and bring products to market instead of being taken over by large pharmaceutical companies. The strategic biopharmaceuticals cooperation between Rentschler Biopharma SE and Vetter Pharma-Fertigung GmbH & Co. KG is now reinforced by the companies' Xpert Alliance – from substance, to product, to patient – to develop aligned manufacturing approaches. This type of collaboration is an example of the emergence of new partnership models.

Framework conditions part II

Meanwhile, the political decision on the automatic substitution of biopharmaceuticals with biosimilars in pharmacies in the same way as generics already substitute brands, due to come into force in August 2022, was postponed by a year. This is because, in addition to the original biopharmaceutical and the bioidentical, which has the same starting material and manufacturing process as the original drug, the manufacturing process of the biosimilar differs from that of the original drug. Among the ten drugs with the highest sales per patient, six are biopharmaceuticals. In the meantime, the first biosimilars, i.e. biological medicines highly similar to other already approved biological medicines, are available for 16 of the 300 approved biopharmaceuticals in Germany. These are sold for up to 37 percent less than the reference drug, bringing financial relief to the statutory health insurance funds and increasing the cost pressure for manufacturers.[28] The latter may potentially relocate production to low-wage countries to save costs. This would be an unfavourable development for Germany as a pharmaceutical and production location.

Selected investments, acquisitions, cooperation and licensing agreements as well as IPOs of biotechnology companies in Baden-Württemberg between 01/2020 and 07/2022

Investments

	Company	Location	Field of activity
2020	AaviGen GmbH	Heidelberg	Curative gene therapies for cardiovascular and cardiopulmonary diseases
	Atriva Therapeutics GmbH	Tübingen	Development of COVID-19 therapy
	GeneWerk GmbH	Heidelberg	Analysis services for gene and cell therapies
2021	Actome GmbH	Freiburg i. Br.	Patented “Emulsion Coupling“ process
	Apogenix AG	Heidelberg	Immuno-oncological protein therapeutics for the treatment of cancer and viral diseases
	Atriva Therapeutics GmbH	Tübingen	Development of COVID-19 therapy
2022	Heidelberg Pharma AG	Ladenburg	Antibody-targeted conjugates for the treatment of cancer

Type of financing	Investment volume	Investors
Seed financing	5 million euros	DH-LT Investments GmbH
Convertibles	8.6 million euros	Meneldor B.V., High-Tech Gründerfonds (HTGF) and other investors
Expansion financing	–	Ampersand Capital Partners
Seed financing	–	b.value Deutsche Biotechnologie Beteiligungs AG and other investors
Public funding	Funding of 20.7 million euros from German Ministries of Health (BMG) and Education and Research (BMBF) as well as 5.1 million euros from major investor dievini Hopp BioTech Holding GmbH & Co. KG	German Ministries of Health (BMG) and Education and Research (BMBF), dievini Hopp BioTech Holding GmbH & Co. KG
Research funding	Up to 11.4 million euros	German Federal Ministry of Education and Research (BMBF)
Financing commitment from the main shareholder dievini Hopp BioTech holding GmbH & Co. KG	Up to 36 million euros	Dievini Hopp BioTech holding GmbH & Co. KG (major shareholder)

3 questions for Dr. Rainer Lichtenberger, CEO, Atriva Therapeutics GmbH

What contribution does biotechnological research and development make to new diagnostic and therapeutic approaches?

The potential of medical biotechnology was dramatically demonstrated during the COVID 19 pandemic: diagnostics and highly innovative vaccines were developed and produced very quickly, with German companies leading the way globally. This brought enormous value creation, jobs were created and supply chains and production facilities were re-established and expanded in Germany.

Atriva Therapeutics GmbH develops therapies for infectious diseases, COVID-19 for example. What innovative approach does the company take?

Atriva Therapeutics GmbH's lead drug candidate, Zapnometinib (ATR-002), is specifically designed to treat diseases caused by RNA viruses. These include influenza and COVID-19, for example. Zapnometinib is an MEK inhibitor that targets the intracellular Raf/MEK/ERK signalling pathway. Many RNA viruses have to activate this pathway to replicate, including influenza viruses, hantaviruses, the RS virus and coronaviruses, including SARS-CoV-2. Zapnometinib inhibits cellular MEK (MAPK/ERK kinase), blocking the formation of functional viral particles in the host cell. This reduces the viral load in the body.

Zapnometinib also has the ability to modulate the host immune response in a beneficial way and avoid an excessive cytokine/chemokine response caused by viral infections. Zapnometinib thus has the potential to attenuate the excessive inflammatory responses seen, for example, in the lung tissues of patients with severe COVID-19 or influenza, and actively support the cellular immune response – the 'immunological memory'.

What are the advantages over comparable therapies?

Atriva Therapeutics GmbH is a pioneer in the development of antiviral therapies that target host cells. Viruses specialise in adapting to their environment by undergoing frequent changes. Such 'escape mutations' allow them to evade the host's immune response, even when the patient has developed antibodies from previous infections or vaccinations. Drugs aimed at immediately combatting the virus potentially lose efficacy. In contrast, developing resistance in this way is not expected with a host-based approach, which is directed against the multiplication of the virus in the human body.

In COVID-19, for example, we also see prolonged therapeutic activity. That is, the use of Zapnometinib is not limited to immediate medical intervention at the first signs of disease, but seems promising even later, when the patient already has severe symptoms that require hospitalization.

With our therapeutic approach that targets host cells, we are thus getting closer to the goal of providing broadly effective antiviral therapies that could become an important cornerstone in pandemic preparedness.

Research in Baden-Württemberg

The healthcare industry in Baden-Württemberg is enriched by a diverse and efficient academic research landscape. Health research is conducted at eight universities, 15 universities of applied sciences, 21 non-university research institutions and five university hospitals. Baden-Württemberg is also well positioned in the field of translational, patient-oriented cutting-edge research.

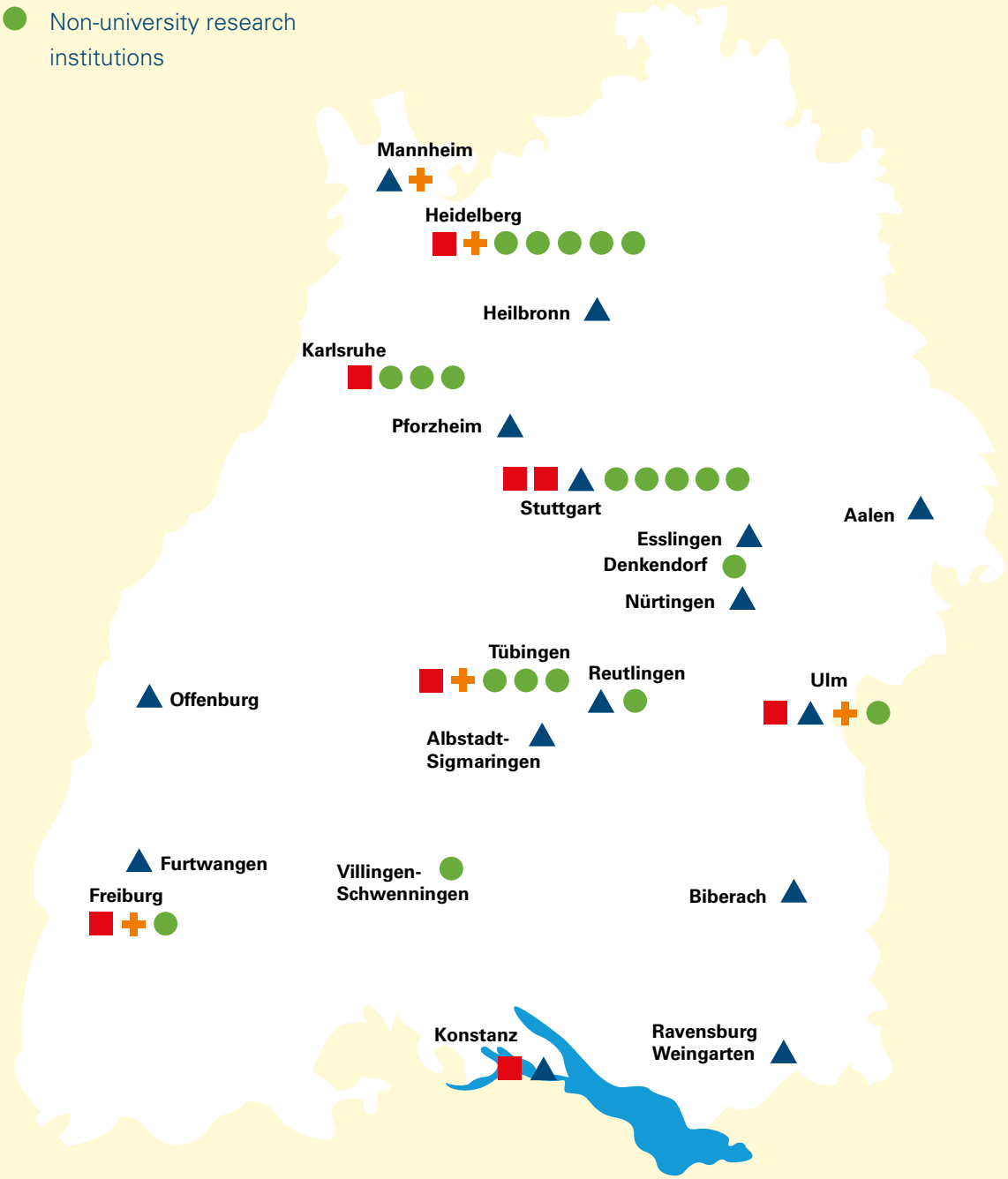
The University Medicine Baden-Württemberg association, founded in June 2021, is expected to facilitate greater resilience and cooperation across different sites. Four Baden-Württemberg university hospitals (Freiburg, Heidelberg, Tübingen and Ulm) and five university medical faculties (including the Mannheim Medical Faculty at the University of Heidelberg) have joined forces with the goal to develop innovative solutions for patient care with the help of digitalisation and artificial intelligence.

'Strong through networking' – this is the motto of the three Innovation Campus projects in Baden-Württemberg: artificial intelligence, mobility and the life sciences.

The Baden-Württemberg government is providing 40 million euros for the establishment of the third Innovation Campus (life sciences), the Heidelberg Mannheim Health & Life Science Alliance (August 2021). In addition to the two university hospitals in Heidelberg and Mannheim, the Innovation Campus brings together the German Cancer Research Center, the European Molecular Biology Laboratory, the Max Planck Institute for Medical Research and the Central Institute of Mental Health. The full value-added and translational potential of the region is to be exploited through the development of an innovation ecosystem.

The Cyber Valley in Tübingen, which was founded in 2016, is also part of the Innovation Campus strategy. The Cyber Valley Health Initiative, launched in 2020, aims to make Baden-Württemberg an internationally visible location for medical applications involving AI.

University
University of Applied Sciences
University Hospital
Non-university research institutions



3 questions for Dr. Christian Haverkamp, Specialist in Neurology, Translational Centre – Digitalisation in Medicine – at the Freiburg University Medical Centre

How does the translational centre – Digitalisation in Medicine – work?

As a living lab, the translational centre is a protected area in the Neurocentre, which is managed jointly by the Institute of Digitalisation in Medicine, the Department of Neurosurgery and the Department of Neurology and is integrated into clinical care. The focus is on the high-tech areas of the Stroke Unit and the EEG Monitoring Ward, and a second pillar is also being established in the neurosurgical OR. It functions both as a bridge for innovative ideas from the concrete clinical treatment context to potential solution partners, and as a living laboratory for innovative solutions from industry partners. The focus is on sensor-based neurological diagnostics and the real-time analysis of processes with the aid of AI for quality-assured, cutting-edge university medicine.

Where in the development process of new technologies and treatment methods is the translational centre active?

Through its integrative approach, the translational centre seeks both to launch very early innovative ideas towards implementation through technology consulting, interfaces with start-up accelerators, and joint research applications, as well as to test the use of near-finished products in real-world settings. For this purpose, the translational centre offers a standardised consulting model based on an hourly rate. This also applies to innovative products from the European market or from other sectors such as logistics.

Who uses or benefits from the translation centre?

Both customers and partners benefit from the living lab. The centre is still being established, but the feedback so far has been very positive. The hospital also benefits from the centre. Potential building blocks for the IT strategy can be identified and innovative ones tried out. After all, only consistent digitalisation can free up the resources needed to relieve the increased workload of doctors and nursing staff resulting from demographic change and collect the data required for quality-assured, cutting-edge university medicine.

Company foundation and financing in Baden-Württemberg

Baden-Württemberg is an attractive location for start-ups. The state offers a wide range of support services and interesting funding and financing opportunities. In addition, the diverse and innovative company and research landscape, strong clusters and networks, and technology parks focussed on life sciences companies create a stimulating environment. The state government has been focussing more strongly on this issue for several years and has steadily expanded its portfolio of support programmes and financing measures. Via the state campaign 'Start-up BW', the platform www.startupbw.de provides a good overview of start-up ecosystems, relevant institutions and contacts, as well as current funding and financing measures. BIOPRO Baden-Württemberg is an important life sciences partner that complements the state's general support for start-ups and provides cross-regional support.

State-wide financing	
Bürgschaftsbank Baden-Württemberg GmbH	https://bw.ermoeglicher.de
LBBW Venture Capital GmbH	www.lbbwvc.de
L-Bank	www.l-bank.de
LEA Venturepartner	www.leapartners.de/en
MBG Mittelständische Beteiligungsgesellschaft Baden-Württemberg GmbH	mbg.de/ueber-uns/unternehmen/beteiligungsfonds
SHS Gesellschaft für Beteiligungsmanagement mbH	www.shs-capital.eu/en

Regional funding	
Beteiligungsfonds Wirtschaftsförderung Mannheim	www.mannheim.de/de/wirtschaft-entwickeln/existenzgruendung/foerderprogramme/beteiligungsfonds-mannheim
Zukunftsfonds Heilbronn	www.zf-hn.de

Initiatives	
Angels4Health e. V.	www.angelsforhealth.com
Boehringer Ingelheim Venture Fund	www.boehringer-ingelheim-venture.com
Business Angels Region Stuttgart e. V.	www.business-angels-region-stuttgart.de
Business Angels Start-up Region Ostwürttemberg	www.startup-wow.de/business-angels-netzwerk
Start-up Angels Alb-Bodensee e. V.	www.startupangels.de
Vector Venture Capital GmbH	www.vector.com/en
venture forum neckar e. V.	www.vf-n.de/en

Funding	
Digitalisierungsprämie Plus	www.wirtschaft-digital-bw.de/foerderprogramme/digitalisierungspraemie-plus
EXI Start-up Voucher	www.bio-pro.de/exi
Innovationsgutscheine	www.innovationsgutscheine.de
Invest BW	www.invest-bw.de
Junge Innovatoren	www.junge-innovatoren.de
Start-up BW Accelerators	www.startupbw.de/beratung-qualifizierung/start-up-bw-acceleratoren-fuer-high-potential-start-ups
Start-up BW Pre-Seed	www.startupbw.de/finanzierung-foerderung/finance/pre-seed

* This list does not claim to be complete.

3 questions for Dr. Ramona Samba, CEO, sync2brain GmbH

Sync2brain GmbH was founded in 2019 and has been developing steadily and successfully ever since. What helpful tips and advice on support measures and funding can you give to other company founders?

The Medical Innovations Incubator (MII) is the place to go for start-ups in the medical technology sector. Here you will learn everything a medical technology company needs to take into consideration right from the very start. Networking with other founders and more experienced entrepreneurs is always helpful. Finding a mentor who already has experience in the industry early on in the process also helps.

Public funding such as EXIST, state and federal funding for research and development help a company remain independent of investors for as long as possible.

The MDR/IVDR regulations are also a considerable hurdle for start-ups. How does sync2brain GmbH meet this challenge and what helpful tips can you give to future founders?

'Take a deep breath and get down to work!' That's what I would recommend. Familiarise yourself with the regulations, find out what is needed and then implement it. We have developed our own know-how and implemented it ourselves – with outside help from various sources where needed. You have to understand and assimilate the topic yourself. So in my opinion it's no use handing it over to expensive external consultants. We received fantastic assistance through networking with other MedTech start-ups and from the MII.

Knowing what you know today, what would you do differently?

I can't think of anything off the top of my head. Establishing a start-up involves a lot of individual forks in the road, ups and downs, so it's hard to say what might have been different. We are satisfied with the path we have taken so far and look forward to the coming years!

LinkHealth@BW – the Life Sciences Innovation Ecosystem

Start-ups are the fuel for progress and essential for the successful development of a business location. Most start-ups are technology-based and emerge from universities. In the life sciences/healthcare sector in particular, specialised knowledge on topics such as financing, regulations and access to the healthcare system is required in addition to general start-up knowledge. In this regard, Baden-Württemberg offers a wide range of support for start-up teams, often at the regional level. It is difficult for founders to navigate this complex range of services, especially with regard to the specific issues life sciences start-ups have to deal with. Through better networking of support services, Baden-Württemberg has the potential to become a leading region in Europe in the field of health. To make this possible, more than 25 partners from 20 organisations have joined forces to form the LinkHealth@BW initiative. The idea is that no matter where a start-up in the life sciences sector is founded, the founders are given guidance that points them in the right direction to find answers to questions and concerns they may have.

LinkHealth@BW offers companies, start-ups, research and development institutions, municipalities, networks and talents help in their search for information, support, networking and cooperation opportunities as well as systematic and needs-based information and services, thus strengthening innovations and new technologies in the health sector in a targeted manner.

In contrast to other ecosystems, LinkHealth@ BW features a central platform and therefore provides the most diverse and far-reaching range of possibilities for all health-focused national and international networks in which LinkHealth@ BW partners are involved. These possibilities are made possible through the excellent cooperation of the participating organisations, networks and companies. This cooperation, accompanied by the possibility to provide central access and guidance, is something that is likely to make Baden-Württemberg significantly more attractive for investors.

The LinkHealth@BW initiative was developed within the Forum Health Region Baden-Württemberg with the aim of increasing innovation capacity, accelerating start-up and innovation processes, and boosting the international appeal of Baden-Württemberg as a location for start-ups and innovation.

Database and methods

This industry report is based on the company database managed by BIOPRO Baden-Württemberg GmbH, which – based on available data – includes all companies in the healthcare industry that conduct research, development and/or production in Baden-Württemberg. Companies engaged exclusively in distribution or wholesale are not included.

Based on the entries in BIOPRO's company database, the Baden-Württemberg Statistics Office determines the key figures for taxable turnover and employees subject to social security contributions and those with low-income jobs, provided these figures were available at the time of retrieval (July 2022). The key figures presented in this report refer to the 2020 financial year. Forecasts were not made.

If companies are active in more than one sector, the key figures per sector were included on a pro-rata basis according to BIOPRO's assessment and were only included once in the total figure.

In the case of legal entities with several branches in different German states, only total sales for the whole of Germany were provided. The Baden-Württemberg Statistics Office calculates the share of sales attributable to Baden-Württemberg on the basis of dependent employees.

Due to methodological changes, the figures for turnover and dependent employees are not comparable with those published in previous years.

BIOPRO's company database is constantly being updated. Therefore, the allocation of a company to a specific sector may be revised when additional data sources become available, new business areas emerge or a product portfolio is expanded. The Baden-Württemberg Medical Technology Index was compiled by the Baden-Württemberg Statistics Office on behalf of BIOPRO. Ten companies in the industry were randomly selected for each employee size class for which continuous figures on turnover and employees have been available for the last 14 years. The mean value of the key figures generated the Medical Technology Index.

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