MEDTECH, BIOTECH & PHARMA | 2021

# LSN MAGAZINE

THE INDUSTRY JOURNAL OF HAMBURG & SCHLESWIG-HOLSTEIN

LIFE SCIENCE NORD


## DESTINATION DESY

The DESY campus has developed into a go-to-hub for life science companies and is the nucleus of the new Science City

## MEDTECH AI ECOSYSTEM

How the consortium KI-SIGS connects players from the North to bring artificial intelligence into clinical application

# A STRONG RESPONSE

Life science players in the North of Germany make high impact contributions to combat the pandemic at many fronts

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# CLUSTER MEMBERS

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→ Please find our Gold and Silver members on **page 51**.

**DR. HINRICH HABECK**
MANAGING DIRECTOR
LIFE SCIENCE NORD MANAGEMENT GMBH

# *Dear readers,*

*surely some of you have missed the LSN magazine over the past year. We took some time to put our communication about the cluster and its stakeholders on a new footing. We revamped our digital channels and worked on a new magazine to provide a better and more comprehensive look at the life science industry in northern Germany. From now on, the magazine will be published once a year.*

*Hereby, we are very pleased to present you with our first issue here – with a re-design and with some fresh categories for content. What can you expect from our new-look magazine?*

*Our main story focuses on COVID-19. We explore the broad spectrum of expertise in the cluster and the variety of stakeholders working on solutions to help fight the pandemic – be it on new therapies, vaccines and diagnostics, or even masks and ventilators.*

*There is a lot of exciting work going on in our region which is not related to the coronavirus. Numerous players from the North are making a worthy contribution to fields such as stem cell research, digital health applications and artificial intelligence. We report on current projects and the latest developments. In addition, this magazine will introduce you to exciting locations in the North – such as the DESY as nucleus of the new Science City Bahrenfeld in Hamburg and the start-up accelerator Gateway49 in Lübeck which welcomed its first entrepreneurs in 2020.*

*You are cordially invited to discover all those and further stories. We very much hope you like our new magazine!*

*Yours sincerely,*

## IMPRINT

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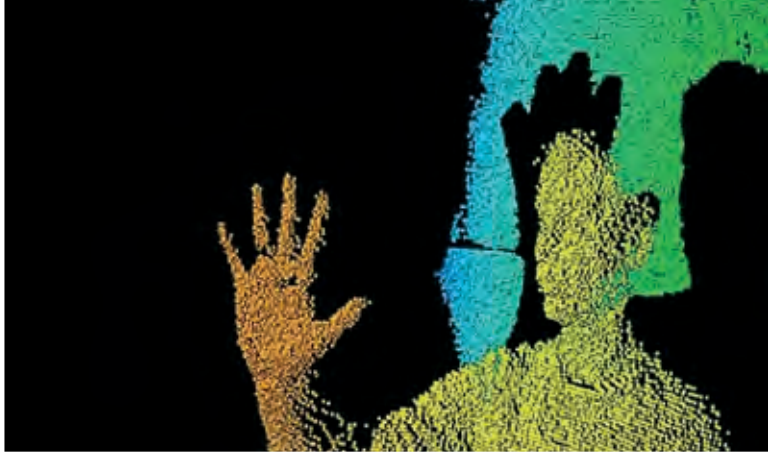



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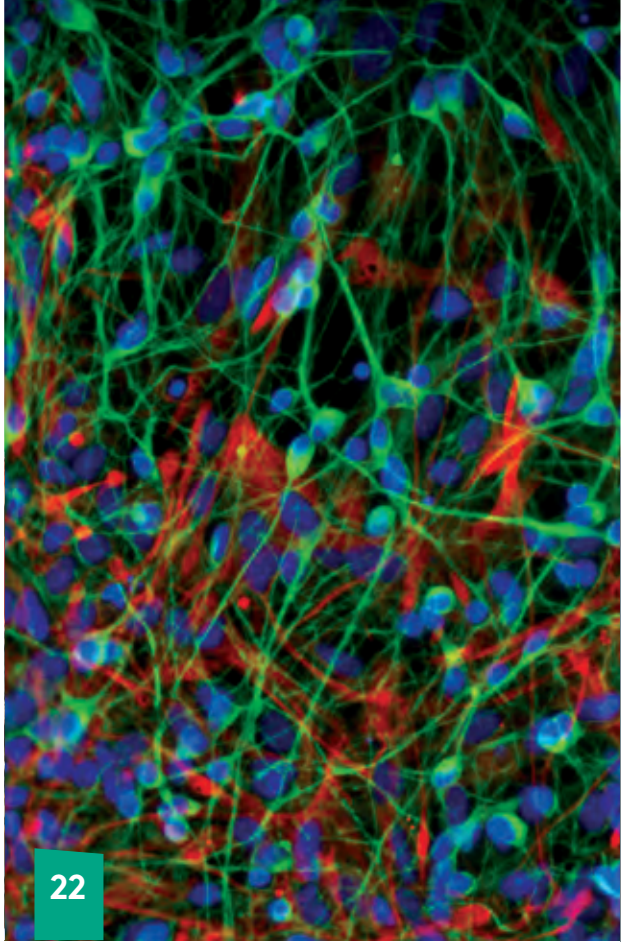



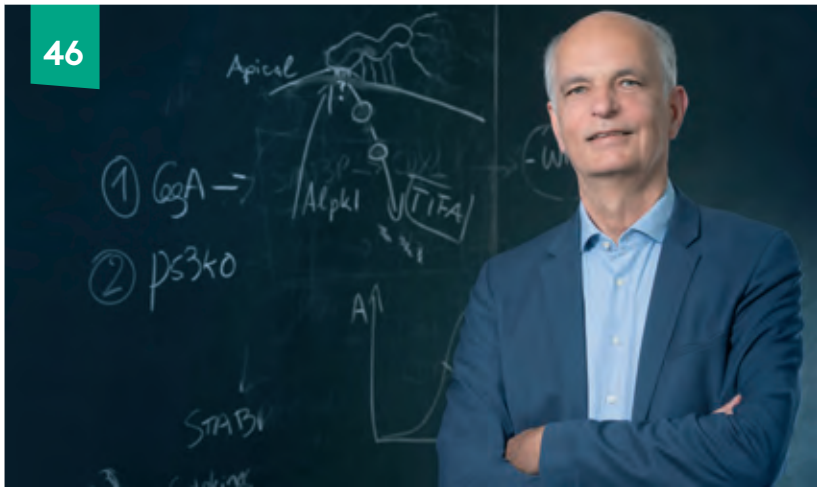



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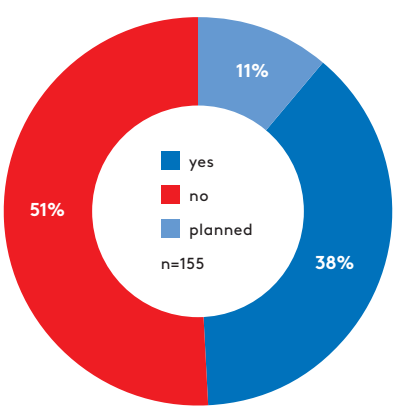
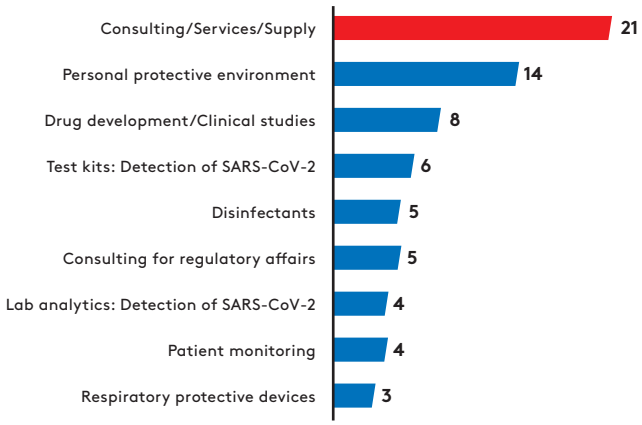
## NORTHERN HEALTH CARE COMPANIES FIGHTING COVID-19

**Are you active in relation to COVID-19?**




**Overview of companies & their activities (in absolute numbers)**






➔ Health companies in Hamburg and Schleswig-Holstein are heavily involved in the fight against COVID-19. When the pandemic started in spring 2020, the Life Science Nord Cluster conducted a survey among its members to find out how the current health crisis is affecting regional companies in the medtech, biotech and pharma sector. One of the results is shown above: of the 155 companies surveyed, 38% have business activities in sectors related to COVID-19. In addition, the survey revealed strong motivation to collaborate among the different stakeholders in the region. "We have seen numerous offers of cooperation across all health-related sectors, which reflect the high degree of cohesion in the cluster," summarizes Life Science Nord cluster manager Hinrich Habeck. "We will actively incorporate this input into our advisory and networking activities,"he adds. The survey helped the cluster management with the needs-based alignment of further assistance and support during the pandemic. The results also served as important information for the state governments in Hamburg and Schleswig-Holstein (see also the COVID-19 special on ➔ pages 8–19).

## THE NUMBER 22

million euros were raised by Hamburg-based biopharma company Topas Therapeutics GmbH in a financing B round in October 2020. Topas develops functionalized nanoparticles that induce antigen-specific immune tolerance.

## AI HOTSPOT LÜBECK

➔ The German Research Center for Artificial Intelligence (DFKI), based in Kaiserslautern, Saarbrücken, and Bremen, has decided to establish an additional branch office in Lübeck. Over the next three years, up to three working groups will be set up on different sub-areas of artificial intelligence in medicine and medical technology. The state of Schleswig-Holstein is supporting the establishment of the new DFKI office with 3 million euros in funding. To a large extend, the University of Lübeck will provide the rooms and working hours of professors (see also interview ➔ page 36).

**DR BERND BUCHHOLZ**
Minister of Economic Affairs,Transport, Employment, Technology and Tourism; Federal State of Schleswig-Holstein

### THE NORTH STANDS FOR ...

*"... a health industry sector with stable and steady growth. It is a tail-wind market, and we hope that the healthcare industry will belong to the drivers of economic growth after the second wave of the coronavirus pandemic in the North."*

➔ see also page 20/21

## DUAL SUCCESS AT KIEL

The German Research Foundation (DFG) is funding the new Collaborative Research Centre (SFB) 1461 "Neurotronics: Bio-inspired Information Pathways" at Kiel University with 11.5 million euros. In addition to that, the DFG will extend funding for the SFB 1261 "Magnetoelectric Sensors: From Composite Materials to Biomagnetic Diagnostics", which started in 2016, by a further four years and 13.5 million euros. The interdisciplinary research projects on bio-inspired information processing and on magnetic field sensors in medical diagnostics are both located at the priority research area "Kiel Nano, Surface and Interface Science (KiNSIS)".

## NEW BUILDING

➔ The new Campus Research II and Hamburg Center for Translational Immunology (HCTI) building will accommodate 150 labs for medical research at the University Medical Center Hamburg-Eppendorf (UKE). The construction started in 2020 and will be finished in 2023. 45.4 million euros will be invested in the project.

## A STRONG RESPONSE TO THE PANDEMIC

Players from the Life Science Nord Cluster are making major contributions to combat the coronavirus pandemic. This COVID-19 special highlights their activities at many fronts.


| | |
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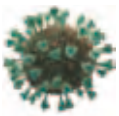
# DRUG HUNTERS

**ANTIVIRAL DRUGS** **There is still an urgent need for effective antiviral drugs that can stop the replication of SARS-CoV-2. Research teams in Hamburg and Lübeck have identified highly promising targets and compounds.**

Stopping SARS-CoV-2 at molecular level has become a major venture amongst research teams and clinicians in the North of Germany. Several teams are searching for new active ingredients, or they are investigating the structural biology of the virus and the infection. Proteins that play a key role for the multiplication of the virus are promising starting points for antiviral drugs. If one of these key proteins can be blocked, it may be possible to stop the replication of the virus and thus defeat the infection. At the → **DESY** research center, the X-ray light source PETRA III has been used by a research team led by biophysicist Alke Meents to identify several candidates for possible drugs that bind to an important protein of the coronavirus SARS-CoV-2. The main protease is a key protein for the replication of the virus in human cells.



### High-throughput testing of crystals

For the study, the researchers use a biotechnological process to produce large quantities of the main protease, enabling them to grow small crystals of the viral protein in combination with a potential active ingredient. They then investigate these crystals using X-rays to determine their detailed atomic structure and thus find out whether and where the active ingredient binds to the viral protein. In a high-throughput procedure, the team uses this method to test several thousand known active ingredients from a library at the → **Fraunhofer Institute for Molecular Biology and Applied Ecology (IME) ScreeningPort**. Thanks to a fully automated sample change process using a robotic arm, each measurement takes only three minutes. After measuring more than 10,000 samples containing about 5,500 active substances, the scientists have so far been able to identify a total of 37 substances that bind to the viral protein. The interdisciplinary team has then investigated whether these substances inhibit protein activity and slow down the multiplication of the virus. In subsequent studies at the → **Bernhard Nocht Institute for Tropical Medicine (BNITM)**

Rolf Hilgenfeld with a 3D model of a viral protease.

in Hamburg, these 37 substances were tested for their antiviral activity in cell cultures. Six of the substances led to a clear reduction of virus replication in the cells, two of them so promising that they were investigated further. In addition, the team discovered two new drug-binding sites on the main protease on the SARS-CoV-2 virus that were not previously known. Currently, the team is performing these drug screening experiments on other important proteins of the SARS-CoV-2 virus. Another promising study from DESY´s light source PETRA III involves screening hundreds of synthetic mini antibodies called sybodies. A group of scientists has identified one that might stop SARS-CoV-2 from infecting human cells. The team was able to unravel how the sybody interacts with the virus. The scientists from the Hamburg branch of the **→ European Molecular Biology Laboratory (EMBL)** and the Centre for Structural Systems Biology (CSSB ) at DESY reported their findings in the journal "Nature Communications".

**In spring 2020, the crystal structure of the main protease of the novel coronavirus was published.**

## Structural virology luminary

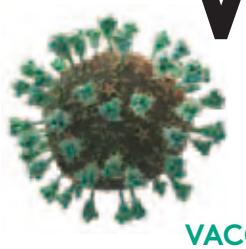
Determining the three-dimensional crystal structure of the main protease of SARS-CoV2 in record time, has attracted worldwide attention to the work of structural biologist Rolf Hilgenfeld, now a senior professor at **→ Lübeck University** and the German Center for Infection Research (DZIF). Hilgenfeld is well known for his research in structural virology. During the SARS epidemic of 2003, he managed to publish the structure of the main protease and a preliminary inhibitor. When the genomic information of the novel coronavirus SARS-CoV-2 became available on January 11, Hilgenfeld's team put all its efforts into purifying enough protease enzyme in the lab and to grow crystals from it. They irradiated them with strong X-rays at the BESSY synchrotron in Berlin on February 1. The refracted X-rays reveal detailed information on the localization of every atom in three-dimensional space. Using sophisticated computer power, Hilgenfeld's co-worker Linlin Zhang was able to determine the 3D structure of the viral protease within a few hours. In March 2020, the team published their much sought-after data in the top journal "Science". Based on the crystal structure of the main protease of the novel coronavirus, the group could turn a lead compound developed earlier in the lab into a potent inhibitor of the novel coronavirus named "13b". "But for sure, it will take several years until our inhibitor will be turned into an anti-coronavirus drug," says Hilgenfeld.

## An osteoporosis drug blocks the virus

A promising clinical stage therapeutic against COVID-19 has been identified by Hamburg-based Fraunhofer IME ScreeningPort as part of a drug repurposing effort. The drug raloxifene, which is normally used to treat osteoarthritis was identified in the European Union funded EXSCALATE4CoV (E4C) consortium, in collaboration with teams in Italy, Spain, Sweden and Belgium. The E4C consortium combines high throughput in-vitro screening systems with large-scale supercomputing resources for rational identification of anti-viral compounds able to block SARS-CoV-2 replication. The Fraunhofer IME ScreeningPort has a repurposing set of approximately 5,500 compounds including over 3,000 marketed drugs active against 600 indications. In late 2020, the Italian Medicines Agency greenlighted a clinical phase 3 trial with raloxifene in patients with mild symptoms caused by the infection of the SARS-CoV-2 virus. Philip Gribbon, one of the team leaders at Fraunhofer IME-SP, says: "For the foreseeable future, the wider Fraunhofer organization will work to deliver the multiple strategies necessary to help societies worldwide take control of the pandemic." pg

**STUDY TEAM**
**Prof Dr Marylyn Addo** (left) is Head of Infectious Diseases at University Medical Center Hamburg-Eppendorf (UKE). **Dr Saskia Borregaard** is a member of the management team of medical contract institute CTC North.

# "WE MAKE A GOOD TEAM"



**VACCINE TRIAL** The publicly funded COVID-19 vaccine consortium from the German Center for Infection Research (DZIF) and IDT Biologika has entered clinical trials at the clinical study center of service provider CTC North at the University Medical Center Hamburg-Eppendorf (UKE). For Marylyn Addo and Saskia Borregaard, it marks the third joint vaccine project after MERS and Ebola.

**In October 2020 you started the Phase I clinical trial for the viral vector vaccine MVA-SARS-2-S in Hamburg. How did the study begin?**

**PROF MARYLYN ADDO** We have been working towards clinical trial phases with our highly motivated teams since March. At the end of September, the Paul-Ehrlich-Institut, the Federal Institute for Vaccines and Biomedicines, approved the clinical trial and the Ethics Commission of the Hamburg Medical Association also gave its consent. The first female volunteer was vaccinated on October 7. By mid-December, all 30 subjects have received their second dose of the vaccine.

**DR SASKIA BORREGAARD** This achievement was only possible because everyone worked closely together and with great commitment. We make a good team and benefit from the joint experience gained from previous vaccine projects. The project partners worked in parallel, and the authorities prioritized the assessments. It goes without saying that it was also crucial that major funding was made available quickly by the DZIF and, subsequently, by the Federal Ministry of Education and Research. Our vaccination study is one of the few fully publicly funded investigator-initiated trials in Germany.

**Could you describe the study design?**

**BORREGAARD** We received more than 2,500 emails from people interested in participating in the clinical trial. Immediately after the study was initiated, the CTC North recruitment team began contacting these people. They invited potential study participants by telephone to a preliminary screening, based on initial questions about their suitability for participation in the research. In the Phase I trial, we have tested the vaccine on a total of 30 study participants aged 18 to 55 years.

**ADDO** We vaccinated 15 subjects with a lower dose and 15 subjects with a higher dose of the MVA vector vaccine injected into muscles of the non-dominant upper arm. The subjects are carefully observed, regularly examined and they keep a vaccination diary. After four weeks, each test subject was given a second vaccination. The Phase I study is intended to clarify how safe and tolerable the vaccine is and whether it triggers an immune response.

**On January 8, you reported on the first results which turned out to be in parts disappointing. What did you observe?**

**ADDO** On the positive side the vaccine has been well tolerated and there have been only mild side effects so far. However, the immune responses in the preliminary results are below our expectations. The data evaluated so far show that immune responses are detectable but have not been generated to the extent expected. While the vaccine had shown robust immune responses and protective efficacy in preclinical models, these were lower in the first phase of clinical testing. The reasons for this are currently being investigated within our DZIF COVID-19 vaccine consortium. In order to achieve the best possible protective effect of the vaccine, we are now working on an optimization of MVA-SARS-2-S.

**BORREGAARD** It also means the Phase II trial planned for the beginning of the year will therefore be postponed pending clarification.

**Why did you choose a MVA vector vaccine as a platform?**

**ADDO** MVA is a weakened smallpox virus that cannot harm humans. We use it as a kind of genetic 'ferry' to introduce a


piece of the genetic information of SARS-CoV-2 to the body. MVA vector vaccines are well tolerated and a lot of safety data is available from recent decades. So far, there have never been any serious adverse events (SAEs).

> **"The volunteers are pioneers that are to thank for the succesful vaccine development worldwide."**
>
> PROF MARYLYN ADDO
> UKE

**BORREGAARD** Our two teams already had experience with an MVA vector vaccine in a Phase I trial for MERS, a coronavirus that emerged in 2012. That research was also conducted here at CTC North under the leadership of Prof Addo. So, we were able to build on the findings from this trial that were published in spring 2020.

### What do you think of the efficacy of the approved BioNTech/Pfizer and Moderna's RNA vaccines, which are 95% effective in phase III trials?

**ADDO** We were generally optimistic because we have seen that people can survive COVID-19 and develop natural immunity, at least temporarily. The data on the immune response in animal models also looked very promising. The news reported in November from Phase III clinical trials by RNA vaccine developers BioNTech/Pfizer and Moderna is without a doubt impressive: the vaccines showed high efficacy in preventing the disease. However, many unanswered questions remain, e.g., do the vaccines also protect against infection with SARS-CoV-2? We still don't know much about the infectivity of the people who have been vaccinated. We expect data on this in the coming weeks and months. They will be critical to our long-term strategies for controlling the spread of the coronavirus.

### What are the next steps for the MVA-SARS-2-S vaccine?

**BORREGAARD** Once our consortium has figured out the issue with the low immune responses observed in Phase I, it remains to be seen how we can progress with the clinical devel-

opment. A Phase II study funded by the Federal Ministry of Education and Research will include up to 600 participants. We plan on also vaccinating subjects over the age of 55. Under the leadership of the UKE and in cooperation with CTC North, 12 research centers nationwide will be involved in this clinical phase.

**With the variety of vaccine approaches currently being pursued, what do you believe is the ideal application for MVA-SARS-2-S?**

**ADDO** Our experience with the MERS vaccine suggests that the SARS-CoV-2 vector vaccine may also have wide-ranging effects on the immune system. Thus, it may be that our vaccine is particularly well suited for booster vaccination to extend or supplement immunity to the virus. The MVA vector vaccine is also highly suitable for combination with other vaccines, as demonstrated by one of the already licensed vaccines against Ebola-Virus Mvabea (MVA).

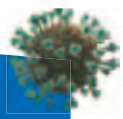
**How do you deal with the pressure of public expectations?**

**ADDO** Public pressure is immense. But we try to ignore that and concentrate on our job. It helps that our teams are very well coordinated. After MERS and Ebola, this is our third DZIF vaccine development project for a worldwide emergency and we have two more scheduled for 2021 and 2022. I personally found the pressure worse with Ebola. However, I have prepared my team for a long winter. Everyone must be sure to manage their resources well.

**There is something you would like to add ...**

**ADDO** At this point, we would like to say thank you to all those who have volunteered as subjects; both in our vaccine project as well as in all other vaccine consortia. These pioneers are to thank for the development of vaccines worldwide. A vaccine is a fantastic achievement that is helping to tackle the Corona pandemic and other infectious threats.

**BORREGAARD** I would like to echo this and thank not only the subjects but also the CTC North team, whose tireless and dedicated efforts over the past few months have played a major role in the success of the study. pg



## PUBLICLY FUNDED ANTI-COVID CONSORTIA

**COVID-19-Vaccine Project:** The MVA-SARS-2-S vaccine is developed by researchers at multiple sites organized within the German Center of Infection Research (DZIF) and contract manufacturer IDT Biologika. The Federal Ministry of Education and Research (BMBF) is providing 114 million euros to the Dessau-based company.

**Network University Medicine:** The University Medical Center Hamburg-Eppendorf (UKE) and the University Hospital Schleswig-Holstein (UKSH) with its sites at Kiel and Lübeck are taking part within the "Netzwerk Universitätsmedizin" (NUM). The BMBF has supported the set-up of this platform with an inital 150 million euros and will invest a further 290 million euros until 2024. 13 projects aim to improve the COVID-19-response of the University hospitals in Germany.


**ANDRÉ SCHULTE,** CEO of Weinmann Emergency and paramedic by training, is convinced that ventilator manufacturers have done a good job during the pandemic so far by quickly increasing capacities which provided the needed amount of products worldwide.

**top above:**
Weinmann Emergency is producing medical products in the area of ventilation and defibrillation.

**below:**
The focus is on small and mobile devices for emergency use cases.

# DEALING WITH HIGH DEMAND

**FROM MASKS TO EMERGENCY VENTILATORS** Companies in Northern Germany have seen a massive demand for medical solutions since early 2020. Within just a few weeks, metal processing specialist F&F Lasertechnik had set up a new production facility for FFP masks. Weinmann Emergency hired staff from the aviation industry to double its production volumes for ventilators.

→ **Weinmann Emergency** is at the forefront of mobile system solutions for emergency, transport and disaster medicine. For over 100 years, the company has worked closely with professionals from the emergency services, hospitals and medical services to develop innovative medical devices for ventilation and defibrillation. The coronavirus crisis has been particularly tasking for the company. "By January and February, we were receiving the first enquiries from China for our ventilators – and the number of these enquiries continued to grow. We knew that something big was on the cards," recalls André Schulte, CEO at Weinmann Emergency, as he reflects on 2020.

> **"This intense situation was exceptional for us. It was a huge effort, but we managed it."**
>
> ANDRÈ SCHULTE
> CEO, WEINMANN EMERGENCY

## During the first lockdown period production facilities for ventilators doubled

The international enquiries received by the mid-sized enterprise in Hamburg finally hit peak in the period from March to April 2020. In the middle of the lockdown, everything had to be ramped up. Production was doubled, new decision-making processes for delivery were developed, while supply chains and staff protection had to be ensured. When running at full capacity, the management sat together in a daily planning frenzy to decide which orders should take priority. "This intense situation was exceptional for us. It was a huge effort, but we managed it quite well," says Schulte at the end of 2020 as he weighs up the past couple of months. Two-shift operation worked well, and the company was able to hire new production operatives in a short space of time. "We had to be certain that production could run 24/7. The Life Science Nord Cluster gave us access to workers from the aviation industry. That was a huge help to us," says Schulte. The Hamburg-based company, with its global network and wide range of products for the pre-clinical sector, comes in at second place in the ventilators sector. The Dräger plant in nearby Lübeck takes the top spot. Specialising in clinical applications, the Dräger plant also experienced an unprecedented boom in enquiries in 2020. In contrast to its neighbor, Weinmann Emergency provides a diverse range of mobile treatment solutions for patients with breathing difficulties, from simple emergency ventilators to devices for intensive care that can be used while transporting patients and for up to 30 days. "Our equipment was used to transport seriously ill Covid patients from Italy and France to Germany," reports Schulte. By the end of 2020, the demand had stabilized back to a more normal level. The managing director believes he is fully prepared for 2021, especially as profits gained during the pandemic have been immediately reinvested for the advancement of new products. "We want to further diversify, especially in the areas of defibrillation and monitoring, with the aim to offering other product ranges in addition to ventilators, which will allow us to grow," says Schulte.

In the first quarter of 2021, the Meducore product family will be expanded with the introduction of the first 12-channel ECG defibrillator monitor to the market which will also provide options for telemedicine via the company's online platform Weinmann Connect. Furthermore, Weinmann also extended its digital solutions by acquiring the company Tech2go in October. "We want to work with the team at Tech2go to develop data and equipment management software," explains Schulte. The digitalization of emergency medicine is not a new phenomenon

F&F Lasertechnik has established a completly new FFP mask production in 2020. It took only some weeks to set up the manufacturing site.

and the company already implemented this trend in its development for several years. “Corona expedited everything and we could accelerate development processes and preparations for the product market entry, as more financing were available internally,” says Schulte. Likewise, new products such as the Medumat were approved by the FDA, marking another important milestone for the company.

## Tackling the MDR challenge early on

In addition, the company was able to continue with the shift to the new EU Medical Device Regulation despite the crisis. “We began tackling this challenge early on by dedicating a wealth of resources to it and introducing new software. However, updating all our internal documents to satisfy new MDR regulations is still a lengthy task,” says Schulte. It curtailed the speed of innovation in terms of introducing new products to other international markets. (*see a more in-depth article about the MDR challenge during the crisis on p. 30*) Nevertheless, the company feels it is on the right track and will continue to grow in the future. Schulte goes on to state that “our goal is to give workers in the emergency services the best possible support. They need lightweight, mobile equipment with intuitive user navigation that’s easy to use and doesn’t distract them from the job of treating people in dangerous situations and even saving their lives.”

## New production site for FFP masks

Meanwhile, metal processing company → **F&F Lasertechnik** in Neustadt, Schleswig-Holstein, had a very unusual year indeed. In 2020, it took the team headed up by Jens Sager and Andreas Babbe only a few weeks to establish a new production site for FFP respiratory masks, which is expected to continue to operate even once the pandemic is over. In March 2020, they decided to produce the masks on their own. “It all began with an emotional moment at the start of March as my partner Andreas Babbe came into my office, tearing the door open with such force that the handle left a mark on the wall, and said ‘We’re going to make masks, there is huge demand for them now!’ It took me a week to get my head around the idea, as I thought it was just the media exaggerating the problem. But as images of Italy started to flood in, everything changed, and I knew it was serious: We had to do something! After a few phone calls, it was clear that it was a hot issue all around the world and it was all systems go after that.”

## A long-term decision for a new market

It was clear to Sager and his team from the outset that they could only take this new leap of faith by firmly establishing themselves on the market in the long-term with the manufacturing of certified products. “We decided on an FFP range because we work in the mechanical engineering sector. It is feasible for us to think

**"We have orders ensuring we will operate full capacity producing cup masks until October 2021."**

JENS SAGER
COMMERCIAL MANAGING DIRECTOR
F&F LASERTECHNIK

in terms of hydraulic production. We are industrial metal processing specialists, after all, and we can build anything imaginable," says Sager. The company has been operating in the market since 2005, specializing in industrial metal manufacturing. From design, to production and sales, the company can supply any metal components and tools as a prototype, pre-series or series. This expertise was a key factor when deciding to add mask production to their business offering. Alongside the technical textiles such as fibers, heated forming tools are especially useful, such as cup dies that do not damage the fibers or filter materials used for them. "The good thing about steel and aluminum is that they can easily be processed using lasers, chamfer equipment and cutting tools. And as tool makers that is our specific area of expertise. At the end, you have to join and configure many individual components and layers and fit them with elastic bands and nose clips, before packing them. A whole chain of steps and logistics are required to produce a mask," explains Sager, who has been working almost non-stop since the early days of the pandemic in March.

## Invest in innovation and automation

For him, manufacturing and product innovation are part and parcel of the whole process. "We immediately developed a new type of seal for enhanced comfort. Long-term goals include investing in the automation of the production plant." Five million euros have already been dedicated to the development of this new business division, with an additional three million already planned. As he thinks back to last summer, Sager is proud that the new production facility was already in operation by then, complete with cleanroom, test lab and emergency approval.

In the meantime, the FFP2 and FFP3 masks have undergone EU type examination at the notified body DEKRA. Each month, 500,000 thermoformed masks are dispersed from the conveyor belt. An additional one million folding face masks will be added to this production total thanks to a special system installed in fall 2020. Forty new operatives ensure all systems run 24/7. Sager needs not to worry about a lack of customers. "We have orders ensuring we will operate full capacity producing cup masks until October 2021." The company also has novel ideas for the development of its products such as increasing the ease of breathing without comprising the filter. Sager says that is "what is most exciting about products made in Germany; a lot can happen here". He also benefits from being a natural when it comes to networking. Sager got in touch with many suppliers to get hold of raw materials and had to constantly respond to ever changing circumstances. "We are trying to optimize the process, but in crises like this one, we have to remain flexible. If the demand for masks suddenly explodes around the world because of new regulations, then it will be impossible to find elastic bands, and I will have to think about how to source them elsewhere," he says. Such challenges do not discourage Sager, quite the opposite in fact. He grabs the bull by the horns, looks to the future, and finds a solution. "We entered the market to deliver innovative products and that's just what we'll do." SW

**JENS SAGER** is commercial managing director of F&F Lasertechnik with headquarters in Neustadt. Together with its technical managing director Andreas Babbe, he decided to move into production of FFP2 & FFP3 masks.

Manages high volumes of tests: the robotic pipetting workstation from altona Diagnostics.

# TESTING POWER

**INFECTION DIAGNOSTICS** Detecting traces of SARS-CoV-2 by PCR or antibody test has become the linchpin in the fight against the coronavirus pandemic. The diagnostics specialists from the North had reliable test systems on the market in record time and greatly expanded capacity to meet the huge demand.

Novel coronaviruses are old acquaintances for the team at **→ altona Diagnostics GmbH.** In 2003, the predecessor company artus Diagnostics became famous for developing the world's first commercial real-time PCR test for the SARS virus in record time. As MERS emerged in 2013, altona Diagnostics also had a validated test kit up and running in no time. However, there is no doubt that SARS-CoV-2 and the scale of the coronavirus pandemic stretched the limits of imagination. "The world of virology is small, and we are very well connected," says Stephan Ölschläger, who is responsible for marketing at altona Diagnostics. "For this reason, in a way, we were well prepared to start the rapid development of a product for the detection of the novel coronavirus," says Ölschläger. To ensure that the RT-PCR test for SARS-CoV-2 provided reliable results, it was validated in several national and international reference laboratories. By February 2020, the kit was on the market. With the high volume of testing, demand for the kits exploded. This was a major challenge for the Hamburg-based company, which currently has over 300 employees. "We optimized our production processes and increased capacity," says Ölschläger. Among other things, the kit sizes were adapted, and the number of reactions per kit was increased to 384 and 4800 instead of the previous 96. "Processes have also become much more efficient in shipping and logistics," says Ölschläger. Bottlenecks in the supply of critical raw materials for laboratory reagents have so far been avoided. "We produce many of the essential components used in our PCR kits ourselves." However, he says, a bottleneck in the supply of plastic materials, known as consumables, is becoming increasingly apparent. At present, altona Diagnostics is pushing ahead with several new in-house developments. "Because of the con-

tinuing high volume of tests worldwide, we are concentrating on increasing the availability of our fully automated AltoStar pipetting system," says Ölschläger. In addition, the company is developing a combination RT-PCR test kit for the detection of SARS-CoV-2 and influenza which delivers results after just one hour - almost halving the reaction time.

## High demand for synthetic RNA

With the breakthrough in the first approved COVID-19 vaccines from BioNTech/Pfizer and Moderna, everyone is talking about the biomolecules used in the business activities of the Hamburg-based contract manufacturer **→ AmpTec GmbH**: Synthetic ribonucleic acids (RNAs). "The efficacy data from the mRNA vaccine studies are fantastic, this is a real breakthrough for mRNA technology in medicine," says Peter Scheinert, AmpTec's managing director and founder. "Our main product series, synthetic mRNAs for therapeutic applications, is benefitting from this huge global interest in mRNAs," Scheinert says. Demand for mRNAs, whose main applications are not only in the area of mRNA-based vaccine production, but also in cancer therapy and gene therapy via genome editing, has increased significantly, he says. "Demand has also risen sharply for AmpTec's other product category, molecular diagnostics," says Scheinert. "We produce the viral reference RNA material for COVID-19 pathogen diagnostics, which runs as a positive control in every test," continues Scheinert. The purity and homogeneity of the controls is particularly important for reliable test results. Due to high demand, AmpTec has now increased its number of employees to 46 and plans to grow further in 2021. (Shortly before this LSN magazine went to press in early January, AmpTec was acquired by Merck KGaA).

## Test system based on electrical biochips

The team at Schleswig-Holstein-based **→ Campton Diagnostics GmbH** has taken a different approach to corona diagnostics. The spin-off from the **→ Fraunhofer Institute for Silicon Technology ISIT** in Itzehoe ,which was founded in 2016, relies on a test system based on electrical biochips. This method detects biomarkers for infections, cancer, autoimmune or other diseases from a few microliters of whole blood within a couple of minutes. "Our system is portable, easy to use and can detect in 13 minutes whether a person has developed antibodies to coronavirus, for example," says Eric Nebling, Managing Director and Chief Scientific Officer at Campton Diagnostics. "This makes it possible to quickly check a person's immune status, for example, after a vaccination or an illness." The central product, the blood analyzer named Campton Reader 100, is expected to be approved for use in research and development in 2021 and will then be used in serological diagnostics in research or clinical laboratories. The system is fully automated like a small single-use laboratory in a cartridge. In addition, the Itzehoe-based team is developing both a protein and a DNA test for SARS-CoV-2, which can be performed almost simultaneously on a reader. "This detection system is particularly suitable for random point-of-care testing." pg

## HIGHTIME FOR HIHEAL

The **HIHeal Project** links up regional companies, scientific institutions, clinics and health insurance providers in Northern Germany with regard to infection and hygiene. Launched in 2016, the HIHeal network provides a platform for innovative solutions in these fields. It forms a focal point of the Life Science Nord Cluster. Of particular importance are emerging diseases and hospital-acquired infections, with accompanying challenges such as antibiotic resistance and hygiene measures. Finding solutions to combat the corona pandemic became a priority of the activities in 2020.

To boost exchange and networking of stakeholders, the new digital event format "Online-Update Hygiene and Infection Prevention" was initiated. The webinar series will go on in 2021.

More information
**www.hiheal.de**

# THE ECONOMIC FOOTPRINT OF THE LIFE SCIENCE NORD CLUSTER

## GROSS VALUE ADDED

From 2016 to 2018, the cluster's gross value added rose by about EUR 0.4 bn and amounted to EUR 5 bn. This corresponds to a price-adjusted average growth of 3.0% a year.

**5.0** EUR bn

GROSS VALUE ADDED OF THE CLUSTER IN 2018

2016: 4.6

**0.4** EUR bn

ADDITIONAL GROSS VALUE ADDED SINCE 2016

2014–16: 0.3

**1,062** EUR

GROSS VALUE ADDED/ INHABITANT IN HH AND S-H

2016: 979

**3.0** %

AVERAGE ANNUAL GROWTH BETWEEN 2016 AND 2018, PRICE-ADJUSTED

2014–16: 1.4

## EMPLOYED PERSONS

Since 2016, the LSN Cluster has reported job growth of 2.4 % a year on average. About 2,400 additional jobs have been created in Hamburg and Schleswig-Holstein since then.

**52,800**

PERSONS IN EMPLOYMENT IN THE CLUSTER IN 2018

2016: 50.400

**2,400**

ADDITIONAL EMPLOYED PERSONS SINCE 2016

2014–16: 700

**94,700** EUR

LABOR PRODUCTIVITY IN 2018

**2.4** %

AVERAGE ANNUAL GROWTH BETWEEN 2016 AND 2018

2014–16: 0.7

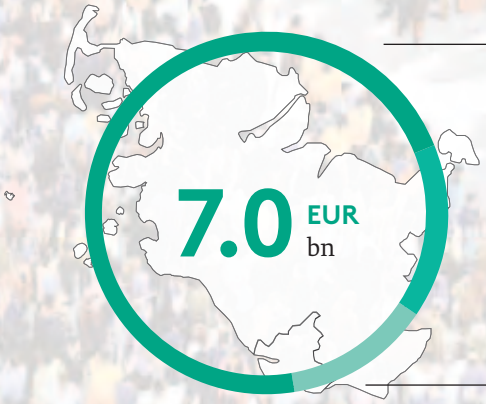
For the third time, the economic research institute WifOR has applied the established "economic footprint" approach across both Hamburg and Schleswig-Holstein to capture the close economic links between the two Federal states in an analysis of the health industry. The health industry includes companies that develop, produce and sell human pharmaceuticals and medical technology products. In the period analyzed (2016–2018) the healthcare industry in the Life Science Nord Cluster showed steady growth and an above-average job growth. The numbers do not reflect the impact of the COVID-19 pandemic. pg

MORE INFORMATION: WWW.LIFESCIENCENORD.DE

## VALUE-ADDED EFFECTS

The purchase of goods and services gives rise to about EUR 1.1 bn of indirect gross value added and the incomes that are spent create a further EUR 0.9 bn of indirect gross value added.

### VALUE-ADDED EFFECTS OF THE CLUSTER IN HAMBURG AND SCHLESWIG-HOLSTEIN




x 1.40 value-added multiplier for HH/SH

**5.0** EUR bn — Direct gross value added

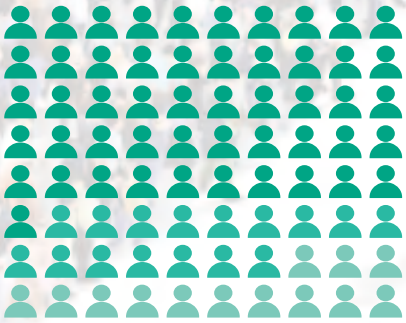
**1.1** EUR bn — Indirect gross value added

**0.9** EUR bn — Induced gross value added

## EMPLOYMENT EFFECTS

The people employed in the LSN Cluster secure about 16.000 jobs in enterprises supplying goods and services to the cluster.

### EMPLOYMENT EFFECTS OF THE CLUSTER IN HAMBURG AND SCHLESWIG-HOLSTEIN



**82,500** — **Overall effect**

**52,800** — Direct effect

**16,000** — Indirect effect

**13,700** — Induced effect

## EXPORTS

**6.6** EUR bn

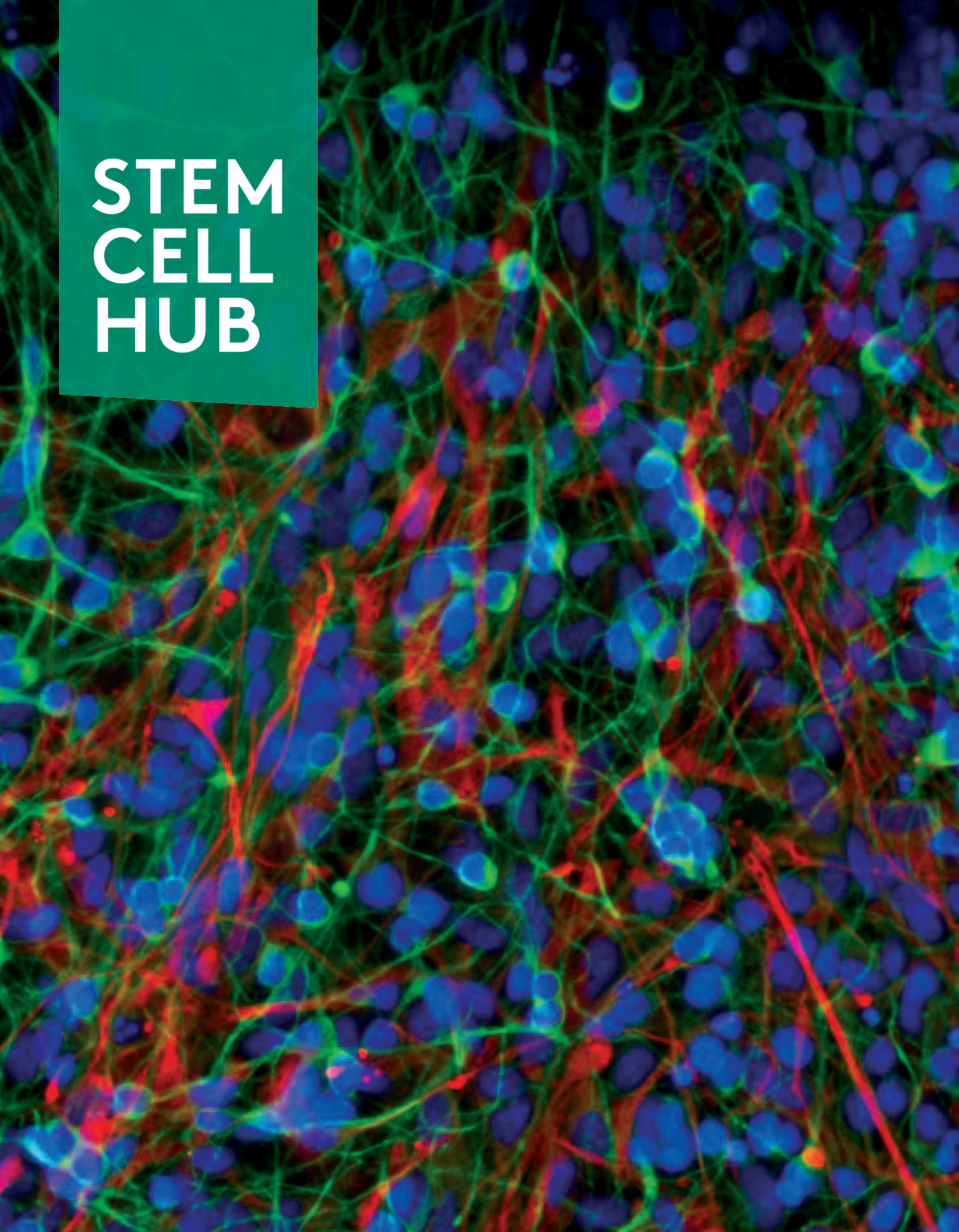
**CLUSTER'S EXPORTS IN 2018**

**5.6** %

**AVERAGE ANNUAL GROWTH BETWEEN 2016 AND 2018**

**Source:** WifOR 2020, own calculations. Data sources: Federal Ministry for Economic Affairs and Energy (BMWi, 2020): Accounts for the health industry (GGR) federal states results, issue 2019; Federal Statistical Office; Arbeitskreis Volkswirtschaftliche Gesamtrechnungen der Länder.

# STEM CELL HUB



**STEM CELL-BASED TRANSLATION** There are several high-ranking translational stem cell-based approaches being developed in the North today. They aim to pave the way for new therapeutic approaches, innovative drugs, and the potential reduction in the use of animal experiments in medical research.

> **"We are pleased that the ISSCR Annual Meeting will be in Hamburg 2024."**
>
> NANCY WITTY
> CEO, INTERNATIONAL SOCIETY FOR STEM CELL RESEARCH (ISSCR)

The North as a hub for global stem cell research: The 2021 Annual Meeting of the International Society for Stem Cell Research (ISSCR) was scheduled to take part from June 23 to 26. The event, which would have been co-sponsored by the Cluster Life Science Nord and the City of Hamburg, was supposed to host the world's largest get-together of 4,000 stem cell professionals from 60+ countries in the new CCH - Congress Center Hamburg. Unfortunately, and like other international events, the corona pandemic destroyed these plans. Now it will be a virtual event only. The CEO of ISSCR, Nancy Witty, is still convinced that Hamburg is a beautiful city that would make a great destination for ISSCR's Annual Meeting. "The tremendous support and strong scientific German stem cell community, Life Science Nord, and the City of Hamburg were all significant considerations in our selection of Hamburg as our host city. While we are disappointed that we will not be able to gather in person in June, we are pleased that we will be in Hamburg for our 2024 annual meeting," Witty says.

## Dynamic translational landscape

"We were enthusiastic about the ISSCR decision for Hamburg", says Ole Pless, Head of Translational Drug Discovery at **→ Fraunhofer IME/ITMP ScreeningPort**, who coordinated the pitch for the congress as scientific adviser and is well connected in the scientific stem cell community. Apart from being an ideal location for top tier scientific conferences, Hamburg and Schleswig-Holstein can indeed build on a very dynamic research and development landscape in the field of stem cells. This article highlights just some of the current translational stem cell-based approaches that are being developed in the North. As a constant source of new living cells, stem cells come in two types: Adult stem cells represent the body's natural reserve for the regeneration of tissues and organs. These stem cells reside in the tissues of the body and produce a constant supply of new cells to replace cells that are worn out or damaged. The other type of cells are pluripotent stem cells. These cells can develop into almost any of the more than 200 variants in the human body. Pluripotent stem cells include both embryonic stem cells (ES cells) and induced pluripotent stem cells (iPS cells). The latter can be obtained by reprogramming - a technology that has revolutionized the field in the past decade. Reprogramming converts adult human cells into iPS cells using a range of transcription factors. iPS cells are an infinite source for the generation of any cell type.

The Fraunhofer Institute for Molecular Biology and Applied Ecology IME ScreeningPort (as of January 1, 2021, the Fraunhofer Institute for Translational Medicine and Pharmacology ITMP ScreeningPort) is a translational medicine research center, based in Hamburg, which specializes in searching through its huge collections of small molecules for hits with the potential to be developed into drugs. "Stem cells help us to build better and more realistic disease models for pharmaceutical research and preclinical development," explains Pless. One example of a neurodegenerative disease studied by the Fraunhofer researchers is multiple sclerosis (MS). MS is the most common chronic inflammatory disease of the central nervous system. A novel strategy that MS researchers are pursuing worldwide in academics and the pharmaceutical industry is to make nerve cells in the brain more resilient to stressors: They are keen to find drugs with neuroprotective properties. The Fraunhofer researchers collaborate closely with Prof. Manuel Friese, the director of the Institute of Neuroimmunology and Multiple Sclerosis (INIMS), a translational research institute at the **→ University Medical Center Hamburg-Eppendorf (UKE)**. One potential drug target identified by Friese's team is TRPM4, an ion channel in nerve cells. Chronic inflammation causes the ion channel to be hyperactive and a permanent sodium influx eventually harms and kills the neurons. Together with

Fraunhofer researcher Ole Pless

the Fraunhofer IME/ITMP ScreeningPort and biotech company → **Evotec SE**, Friese's team aims at developing a neuroprotective drug that can be taken orally. The consortium has already identified small molecules that function as effective TRPM4 inhibitors. "We have created a versatile toolbox based on iPS cell technology to test the inhibitors directly where they should act therapeutically: On human neurons," says Pless. The promising research again gained the support of the German Federal Ministry of Education and Research (BMBF) for the third successive project and received 1.2 million euros as part of a program for the validation of disease-related target structures. The aim of the project is now to learn more about TRPM4 as a possible target structure and the drug candidates in order to reduce the nerve damage specifically responsible for the progressive worsening in MS patients.

## Modelling organ systems

Another trend aims at engineering miniature organs or specialized tissues in the lab and combining them to create multi-organ systems: In the interdisciplinary research project "HiPSTAR", Fraunhofer researchers use patient-derived cells to decipher the molecular mechanisms leading to Alzheimer's disease. They have constructed an iPS cell-based model of the human blood-brain barrier (BBB) which serves as a protective but selective barricade between the sensitive brain and the blood circulation. The in-vitro model can serve as a research tool to develop drugs with brain-penetrating properties or to identify novel disease-specific targets. The BBB models are currently being validated with approved and marketed drugs and compared to conventional models. The BMBF has contributed 1.7 million euros in funding for the project. Thomas Eschenhagen and his team at the UKE and the German Center for Cardiovascular Research (DZHK) are a powerhouse of translational stem cell research in the North. They specialize in engineered heart tissues (EHTs), three-dimensional muscle constructs that can be generated from iPS cells and other stem cells. The Hamburg-based spin-off EHT Technologies GmbH with CEO Arne Hansen constructs test systems that are powerful tools for pharmacological research and drug development. The team headed by Christine Klein from the → **University Hospital Lübeck** is specialized in the stem cell-based research of Parkinson's. As partner of the European StemBANCC consortium, the researchers coordinated the formation of a bank of patient-specific iPS cell lines as a resource to study mechanisms of Parkinson's and other movement disorders, paving the way for the development of new drug targets.

## Diverse range of approaches

"iPS cells have opened doors where other technologies failed," says Lanthaler, the CEO of Evotec SE. Not only in the field of neurodegenerative disease, iPS technology provides an excellent tool for disease modelling and predicting drug efficacy. Over the last decade, Evotec has built an iPSC-based platform to meet the highest industrial standards in terms of throughput, reproducibility and robustness. Evotec's iPSC team has grown to more than 150 people. It plays an essential role in longtime alliances with strategic partners, such as Bristol Myers Squibb (formerly Celgene). "In terms of the scope of the platform and the systematic integration of the iPSC platform to all other drug discovery technologies, we are at the forefront of the whole industry," Lanthaler says. In recent years, Evotec has developed its platform to use iPSC-based cells in cell therapy approaches, e.g., in diabetes (*see page 28*). And in December 2020, Evotec and Sartorius have entered into a partnership with Curexsys GmbH, a Goettingen-based specialist in the emerging field of therapeutic exosomes. These are small vesicles which are derived from human Mesenchymal Stem Cells (MSCs). Increasing evidence suggests that exosomes can aid tissue repair and engineering vesicles could carry drugs to diseased tissue. Thus, they may represent the next generation of therapeutics in regenerative medicine.

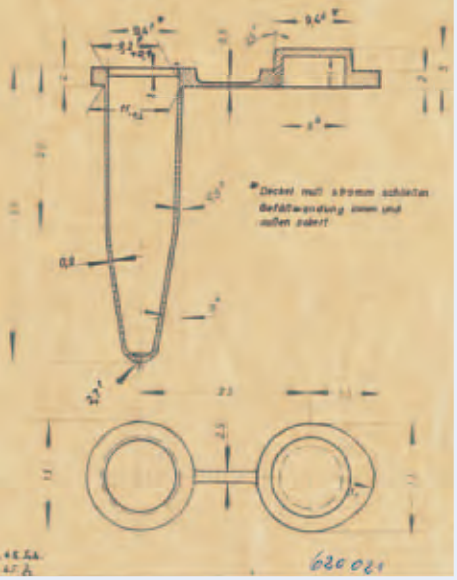
## Cell culture technology and cell logistics

Several players in the North are also providers of much-needed stem cell technologies: → **Eppendorf AG** provides bioreactors and bioprocess technology for stem cell cultivation (*see also page 26-27*). → **PerkinElmer Cellluar Technologies** produces high-content imaging systems that are used in stem cell-based screens. → **PeproTech GmbH** is a lab provider specialized in cell culture media. The Kiel-based start-up → **Cellbox Solutions GmbH** constructs portable incubators for the transportation of living cells. These high-tech boxes provide a safe environment for the transport of living cells and biological structures under laboratory conditions, e.g., at 37°C and 5% $CO_2$. The idea was born at the → **Fraunhofer Research Institution for Marine Biotechnology and Cell Technology (EMB)** in Lübeck. Founded in 2017 by Prof. Kathrin Adlkofer and currently managed by CEO Wolfgang Kintzel, today Cellbox affords 15 employees and is anticipated to grow further. Apart from stem cell research and the growing cell therapy market, the start-up also caters to the in-vitro fertilization market. pg

## STEM CELL BIOBANK

The project BONEBANK has established a German-Danish biobank and Innovation Platform for Mesenchymal Stem Cells (MSCs) in Bone Regeneration. The project combined existing expertise of the German and Danish partners in the fields of stem cell research, medical technology, trauma centres and biobank operators on both sides of the border. Within the BONEBANK project, an innovative value chain for clinical harvesting and use of MSC's during routine fracture surgeries has been developed and implemented. MSCs are isolated from the harvested bone marrow material and stored in a cross-border biobank. These cells offer a high-quality resource for the patients themselves, other patients (allogeneic use) and research facilities in universities and industry. The EU Interreg project in which Life Science Nord has been one of the project partners formally terminated in August 2020. The network partners will continue their work in the "BONEBANK Interest Group".

More information
**www.bonebank.eu**




**PURSUING A MISSION**
Dr Peter Fruhstorfer is Co-CEO and Chief Business Officer of the Eppendorf AG since 2019.

**top left:** Construction designs of the iconic Eppendorf tube (Eppi)

**top middle:** The Eppendorf production site in Oldenburg in Holstein, Germany

**top right:** A microliter system was launched in 1963

**below:** A view into cleanroom production of consumables in Oldenburg in Holstein

# IMPROVING (LAB) LIFE

**GUEST ARTICLE** Improve human living conditions – that has already been the mission of the Eppendorf founders 75 years ago. In the ongoing coronavirus pandemic, the company takes this mission very seriously, says Dr Peter Fruhstorfer, Co-CEO & Chief Business Officer of the Eppendorf AG.

**"From 2021, we will increase consumables production by almost 50 percent."**

"75 years ago, everything started on the campus of the University Medical Center Hamburg-Eppendorf (UKE). In August 1945, Dr. Heinrich Netheler und Dr. Hans Hinz began repairing defect medical devices for the UKE. Very quickly the potential of the former radar engineers became clear and together with them physicians started the development of new devices. With the new spectral line photometer, the first lab product came to market in 1949 – and became a bestseller. Following the "photometer of Eppendorf" came the revolutionary microliter piston-stroke pipette. It rang the age of precise and rapid pipetting. Hereafter, in 1963, the development of reaction vessels, known worldwide as Eppendorf tubes or "Eppis" occurred. They quickly conquered medical and scientific laboratories worldwide. Additionally, devices such as centrifuges, mixers and thermostats followed. Today, pipetting systems, centrifuges and high-tech plastic consumables for laboratory applications form the three central product groups. Apart from this, digital and automated workflow solutions are becoming increasingly important for the business.

A spirit of innovation and the will for technical advancement have now characterized our company for almost eight decades. Today, Eppendorf is a globally successful laboratory equipment manufacturer with around 4,500 employees worldwide. In close and trusting cooperation, we address the issues of the future with our partners and customers. Eppendorf is driven by the idea of enabling efficient, high-quality and sustainable lab work. Specifically, it is about accelerating laboratory processes while minimizing errors and ensuring reproducibility of even complex workflows. And all of this should go hand in hand with a significant reduction of the laboratory staff's workload. One thing is clear: this is a Herculean task for which we need digitization, the best minds and the special "spirit" that Eppendorf has.

The coronavirus pandemic and the enormous volume of tests are a tremendous challenge for Eppendorf. Fortunately, we are able to respond to the greatly increased demand in some product groups with the appropriate flexibility. We manufacture the products specifically requested due to the coronavirus pandemic with the highest priority and were able to produce in full at all times due to numerous, very efficient measures. This also ran and continues to run smoothly because we manufacture for the most part in Germany and could switch production quickly. Big thanks go out to our employees, who have done a lot and handled the difficult situation flexibly and responsibly. Even before the coronavirus pandemic, we had given the green light for a significant expansion of our production site in Oldenburg in Holstein, Germany, and invested disproportionately. High-quality laboratory consumables are manufactured here for customers all over the world. With the completion of two additional production halls in 2020, we have already been able to increase the production volume by more than 20 percent in 2020, and from 2021 on it will be almost 50 percent.

And we are also continuing to grow at our headquarters in the northern part of Hamburg. Two important production sites are located here, as well as a central distribution center for the worldwide supply of our customers. The growth of Eppendorf is also reflected in a steady increase in the global workforce – trend still rising. All these people live a corporate culture that is marked by a strong sense of commitment and solidarity. It is important to preserve and sustainably develop this culture. After all, our culture is an essential part of our 75-year success story, in which appreciation, empathy and reliability play a major role. That is why we invest time, money and energy to ensure that Eppendorf is and remains a place to which people enjoy coming to and where we work together and, above all, for each other." ■

**More information: www.eppendorf.com**

# POTENTIALLY GAME CHANGING THERAPY IN DIABETES

**BETA CELL REPLACEMENT THERAPY** Hamburg-based Evotec is working on a game changing therapy to cure insulin-dependent diabetes based on beta cells produced from iPS cells.

Over the past years, Evotec has built a unique platform for iPSC-based drug discovery and cell therapy covering the generation of iPS cell lines, up to cell manufacturing of various cell types for drug screening as well as GMP production of clinical material for cell therapies *(also see page 22)*. With this approach, the company is also targeting diabetes patients with human beta cells produced in islet-like clusters from a GMP-compliant iPS cell line in a scalable bioreactor format, with extensive quality control procedures.

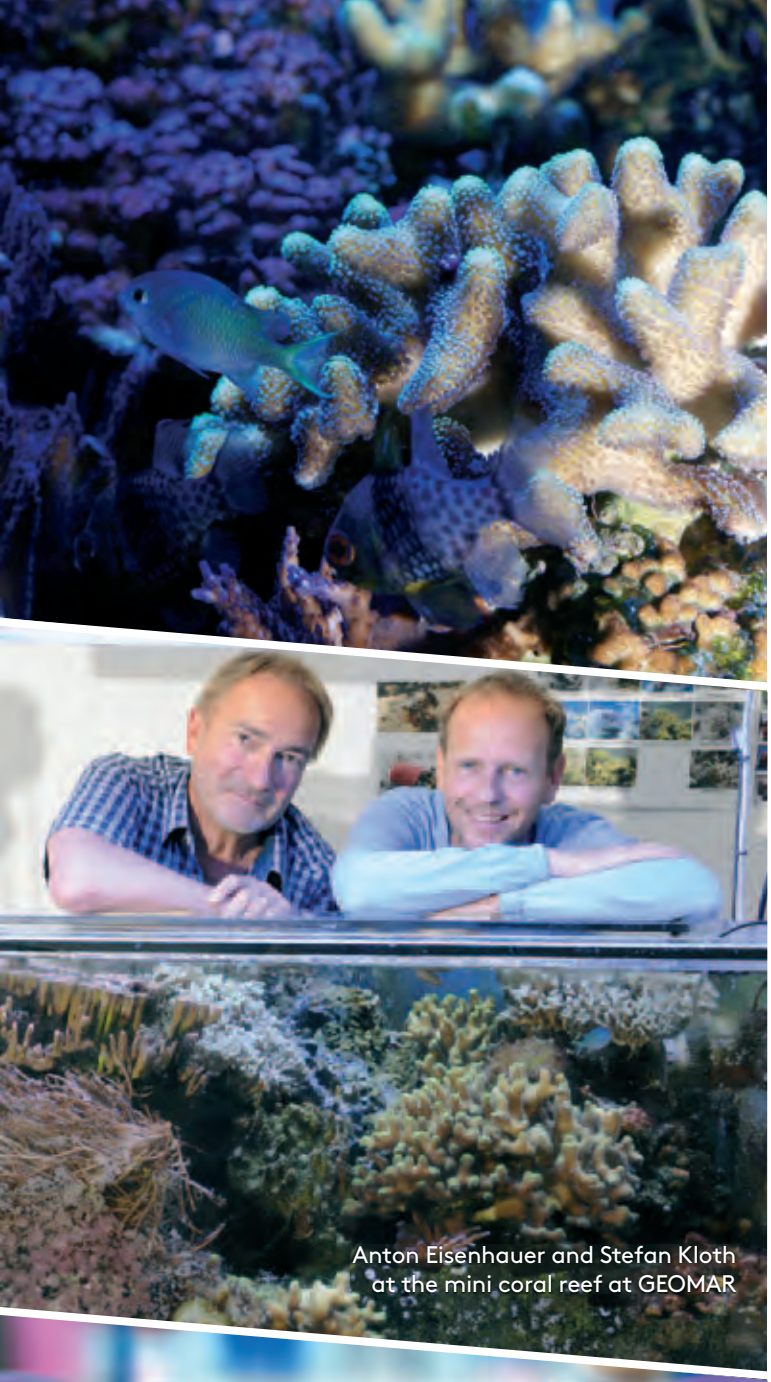
The beta cell programme has already achieved pre-clinical data demonstrating that they are functionally equivalent to primary human islets in their ability to normalise blood glucose levels in in vivo models over several months. In 2020, Evotec has regained global rights from French pharma company Sanofi to its beta cell replacement therapy and will continue the development of the beta cell programme on its own within its EVT Innovate initiative "QRbeta Therapeutics". Cord Dohrmann, Chief Scientific Officer of Evotec, underlines: "Evotec and Sanofi have developed the beta cell replacement therapy programme since 2015 in a highly productive partnership. During this time, we have made tremendous progress towards bringing a potentially game-changing treatment option to the clinic."

**"An off-the-shelf beta cell therapy product could represent a major therapeutic opportunity."**

CORD DOHRMANN
CSO, EVOTEC

In 2021, Evotec will explore the best strategic options for further long-term development and commercialisation of this approach. "An off-the-shelf beta cell therapy product has the potential to revolutionise the treatment of insulin-dependent diabetic patients and therefore could represent a major therapeutic opportunity," Dohrmann says. SW

**More information: www.evotec.com**







Anton Eisenhauer and Stefan Kloth at the mini coral reef at GEOMAR

# FROM CORALS TO BONE BIOMARKERS

**OSTEOPOROSIS TEST** Diagnostics specialist osteolabs is on the course to expansion and has closed a financing round of 1.6 million euros.

A young company in growth mode: In autumn 2020, osteolabs GmbH announced the successful validation of its OsteoTest for osteoporosis and early-stage kidney dysfunction in a clinical trial. And in December 2020, the Kiel-based start-up successfully closed a second round of financing amounting to 1.6 million euros. The capital is provided by the Seed and Start-up Fund II of Mittelständische Beteiligungsgesellschaft Kiel, Labor Dr Krause & Kollegen MVZ GmbH and SVM Verwaltungsgesellschaft mbH in Hamburg. The funds will be used for expansion in Scandinavia, the BENELUX states, Switzerland and Austria. In addition, existing laboratory capacities will be extended.

Osteolabs is one of 67 companies so far that have been actively supported by the Schleswig-Holstein Seed and Start-up Fund II on their way to entering the market. “Since the company was founded, we have been experiencing a continuous increase in orders, both from end customers and from medical practices,” says Managing Director Stefan Kloth. “This demonstrates that we are on the right track. After a successful roll-out in pharmacies throughout Germany, the OsteoTest is now also available to end consumers and can therefore be purchased not only online but also on site.”

Osteolabs is a two-year old spin-off from the GEOMAR Helmholtz Centre for Ocean Research Kiel. Geochemist and coral reef researcher Anton Eisenhauer acts as Chief Scientific Officer. He has developed a non-invasive biomarker based on a marine chemistry analysis method for calcium isotopes that only requires urine or blood for examination. The composition of different calcium isotopes is detected by sophisticated mass spectrometry methods. The osteoporosis test has been developed in cooperation with the University Medical Center Schleswig-Holstein Kiel. Whereas OsteoTest Home is based on the analysis of calcium in urine, its big brother OsteoTest Med analyzes the calcium isotope differences in urine and blood to determine the functionality of the kidney. The platform technology is unique, and it is also expected to open up further indication areas. The start-up has many ideas in the pipeline including a testing procedure for kidney stones, where calcium is deposited in the form of crystals. For this project, the team is looking for research and cooperation partners. js

**More information: www.osteolabs.de**

# HOW TO MASTER THE MDR CHALLENGE

**MEDICAL DEVICE REGULATION** How established medical technology companies, start-ups and regulatory experts in the North succeed in dealing with the new requirements of the EU Medical Device Regulation – even in uncertain times and during a pandemic. However, for many reasons a system collapse is expected for the years 2023 and 2024.

> **"We are delighted that we have left the research stage, and that our product can finally be used in clinics."**
>
> KAI FEHRS
> CQO & CO-FOUNDER, NORTHH MEDICAL

When Kai Fehrs thinks back to the summer of 2020, he is relieved that his business pushed through preparations for an audit in the autumn. The co-founder of → **northh medical** can now look back at the successful Medical Device Regulation (MDR) audit that took place during that season. "Luckily, we weren't impacted by the lockdown during the second wave. We were able to continue planning our year as usual," says Fehrs. The young company now anticipates that it will gain EU approval for its novel MRI-compatible ultrasound device in the first quarter of 2021.

## High-resolution imaging of foetal hearts

The start-up, a spin-off company from the Eppendorf University Hospital, was founded in 2017 and is based at the Health Innovation Port on the Philips campus in Hamburg. It has set itself the goal of enhancing diagnostics for congenital heart defects in prenatal testing. "Our device makes high-resolution imaging of foetal hearts available. This has previously not been possible, as current MR imaging cannot be synchronized with the foetus' heartbeat," explains Fehrs. Yet, the smart-sync technology does just that – offering gynaecologists, radiologists, and cardiologists the opportunity to better recognize congenital heart defects more in detail and to plan for a customized therapeutic approach. Once, EU MDR approval has been granted in 2021, the ultrasound device may be used in clinical routine. A milestone for the start-up. "We're delighted that we have left the research stage, and that our product can finally be used in clinics," says Fehrs. Northh medical joined forces with Reinfeld-based manufacturer Cognimed to turn the initial prototype into a medical product that is production ready. The pilot batch of ten devices is in preparation, five had already been purchased by the end of 2020.

This has also made northh medical one of the few companies in Germany to receive timely approval under the new EU MDR before the official start of the regulation. How did they manage it? "We started on time and sought out quality partners within our network," summarizes Fehrs the company's strategy. By 2018, he and his colleagues had talked with notified bodies, consultants and potential partners at MEDICA. Considering the changeover from the MDD to the new MDR, it was already evident at the time that it would be relevant to become a regular customer at a notified body to prevent capacity issues at a later date. "With that in mind, we certified our quality management system a year before we submitted our technical files. In hindsight, this proved to be the right strategy," enthuses Fehrs. In October 2019, the company's QM system was certified according to ISO-13485. A year later, the next round of ISO-13485 audit took place and the initial MDR audit for the medical device was conducted as well. This meant a lot of intensive work throughout the summer for him and his team, but their efforts were rewarded.

## Clinical evaluation based on literature

One aspect of the process that made things easier for the company was that the clinical evaluation could be done based by existing data from literature. These were gathered over the years through ongoing research collaborations with various renowned centres which were already using prototypes of the device. "The raft of publications we and our partners had under our belt were particularly advantageous here, e.g., with the UKE, the clinic in Lund, Sweden, or with the Boston Children's Hospital." These data could be used by → **NSF Prosystem** to perform a clinical evaluation without the company having to do any further clinical studies. "We were fortunate in that we could always discuss these issues here at the HIP, with Philips, and the Life Science Nord Cluster. This resulted in relatively low consulting expenses as we navigated our way through the entire MDR approval process," concludes Fehrs. On the back of this experience, his business is now on its way to achieving the next milestone: FDA approval of their product and further developing the device so that it can also be used for adults.

## System collapse expected for 2023/24

While northh medical can largely put behind it the EU MDR discussions, other medtech experts are looking to the near future with trepidation. The period between 2023 and 2024 will be the most worrying, as May 2021 will no longer mark an important deadline for most manufacturers. Although this is the date when the EU MDR will finally be effective, it is later years that will be decisive, when MDD certificates start to expire. "We

are looking forward to a veritable wave of expired MDD certificates, which will cause major issues for all notified bodies in 2023 and 2024," asserts Klaus-Dieter Ziel, managing director of → **MEDCERT GmbH** in Hamburg. His company is one of the notified bodies that were officially successful in the appointment process for MDR end of 2019. "We didn't experience much of a rush after our official MDR approval came through in 2019. Less than 5% of our customers turned to us in 2019/2020 with their MDR queries," says Ziel. These are mainly mid to large-size companies or customers with high-risk medical products. "Many customers whose MDD certificates expired in 2020, or are due to expire in 2021, are either inadequately prepared or not at all prepared," states Ziel. Instead, the postponement of the MDR by one year to 2021 pushed discussions around MDD re-certifications, early re-certifications or changing certificates.

Yet, these options were not possible forever, as Ziel goes on to emphasize. "We only accepted such applications until August 2020 and then only from our regular customers, as we would have been completely overwhelmed otherwise," remembers Ziel. Even before the surge in MDD re-certifications and certificate changes, MEDCERT GmbH was fully booked with a very high number of expiring MDD certificates in 2023/2024. Of one thing Ziel is sure: "We already postponed the problems into the future."

## Remote audits have limits

Jan-Michael Krüger who heads up Regulatory Affairs in the EMEA region for → **Olympus Surgical Technologies Europe** in Hamburg is facing a similar challenge. He also fears that they will not be finished with all their products by 2024. "We began in 2017 with a robust plan and are hopeful that we will get through it all by 2024. But if we continue at the current speed and number of employees within the notified bodies, it will be touch and go," forecasts Krüger. He goes on to underline that "the lack of resources for notified bodies combined with longer lockdowns due to the coronavirus are the main causes of the problem. These are leading to massive delays to scheduled audit activities." A bit of hope provides the fact, that by 2020, further guidelines were issued to help notified bodies carry out remote audits. Existing customers should benefit from these the most. However, for both the manufacturers and the notified bodies this option still has to be practiced more often and remains a new playing field. And further delays are to be expected.

**Jan-Michael Krüger**
General Manager Regulatory Affairs EMEA, Olympus Surgical Technologies Europe

**Klaus-Dieter Ziel**
CEO, MEDCERT GmbH

**Kai Fehrs**
CQO & Co-founder, northh medical

## Complex portfolio planning

Krüger must try to unite such uncertainty with the complex in-house portfolio planning. All products at Olympus are grouped into internal categories which are gradually being converted from MDD to the EU MDR. The category which comes first is not only determined by the risk class, but also the importance of the indication to the company and whether new products are scheduled for that area in the near future. "We want to do more than simply update current products; we also want to ensure that new products can be already certified under the new regulation. But some of our portfolio will disappear with with the end of the transition period to the MDR," admits Krüger.

To manage the entire process internally with a large volume of products, Olympus also opted for the strategy to conduct first the QM audit in accordance with the requirements of the EU MDR, and only then start scheduling further audits for the different product groups. "We managed to get that QM audit done in February 2020 before the first lockdown, which was a good foundation for our following activities," says Krüger. He believes that excellent communication with the notified bodies is the most important instrument for a smooth changeover to the EU MDR. Similarly, the expert not only views Europe as a standalone market, as it can also be seen as a guide for many international markets. "We have submitted registration dossiers based on CE mark in around 80–90% of the markets, meaning that after the torrent of EU MDR certifications, we anticipate a wave of international registration dossier updates, too." SW


Nora Mehl, Co-founder of digital health company aidhere GmbH.

# DIGITAL THERAPIES READY FOR TAKEOFF

**DIGITAL HEALTH** Among the first digital health applications reimbursed by the German standard healthcare system is an app-based therapy developed by aidhere GmbH. The start-up is housed at the Health Innovation Port in Hamburg, a start-up campus operated by Philips, the Asklepios Kliniken and further partners.

It took Germany only 15 months to develop its healthcare reimbursement system for digital therapies with the arrival of the Digital Healthcare Act [DVG]. Since October 2020, the first digital healthcare applications [DiGA] have been approved by the Federal Institute for Drugs and Medical Devices [BfArM]. These included the obesity app zanadio, developed by Hamburg-based **→ aidhere GmbH**. "We prepared specifically for this process and are delighted that we got through it so quickly," enthuses co-founder Nora Mehl. The business was only established in 2019, together with co-founders Tobias Lorenz and Henrik Emmert, and with the support of start-up financing from the Landesinvestitionsbank in Hamburg. Emmert was the initial driving force behind the company. He had spent nine years as a consultant at the Boston Consulting Group and wanted to grow his own digital health business specializing in obesity. Via the Internet he came across Nora Mehl, who had been researching obesity behaviors for the Max Planck Institute for Cognition and Neuroscience in Leipzig for some time. "I was becoming increasingly disillusioned because all of my publications ended with the realization that the results had to be transferred in a real-life setting," recalls Mehl.

## App-based obesity therapy

With Emmert and Lorenz at her side, she took the plunge and switched to self-employment. Together, the trio developed an app-based obesity therapy that offers tailored online support to sufferers trying to change their own behaviours – based on the latest guidelines and customized for each user. "Up until now, there were few genuinely effective therapies available to people with heavy obesity and most were very costly," says Mehl. The zanadio app combines e-learning modules with fitness and food trackers. The start-up's expert panel of nutritionists, psycholo-

> **"We need excellent interfaces and must avoid island solutions at all costs."**
>
> HENNING SCHNEIDER
> CIO, ASKLEPIOS KLINIKEN

gists and sports scientists develop a bespoke program for each user based on the details they provide. The goal is to reduce their calorie intake while increasing their calorie requirements. "The program only sets targets that can actually be achieved, so it is very patient centric," emphasizes psychologist Mehl. She understands that setting realistic goals is a key factor for getting results. Since November 2020, the app can be prescribed and reimbursed as a digital healthcare application in Germany and generates first revenues for the young company. However, the BfArM approval is only a conditional on a one-year basis. A clinical trial with the University of Leipzig will run in parallel to examine how the app affects the user's quality of life, well-being and weight. "We will draw on these data with the aim of receiving final approval after a year and enter into final negotiations with health insurers," says Mehl. At the same time, the team hopes to increase awareness of the app and to collaborate with rehabilitation clinics, specialists and health insurers to establish further partnerships in the market.

## Digital health is becoming attractive

The team has garnered support from organizations such as the → **Health Innovation Port (HIP)**, where the young company has its office. This campus in Hamburg was established by → **Philips**, along with partners such as the City of Hamburg and health insurer Techniker Krankenkasse to offer start-ups the opportunity to work closely with health experts. Today, further partners such as the → **Asklepios Kliniken** are also part of the HIP. "We work with a growing number of national as well as international start-ups to support them accessing the market in Germany," says Philips representative Lukas Hoffmann, who is responsible for the start-up collaborations at the HIP. Since digital healthcare applications have become possible under the reimbursement regulations in Germany, HIP has started to offer a targeted consulting program. "We aim to help businesses make solid decisions on whether this could be a feasible route for them," says Hoffmann. According to him, the DVG has made Germany much more attractive as a digital health market. "We are increasingly receiving international enquiries from start-ups that want to sell their products here in Germany," says Hoffmann. Likewise, the new Hospital Future Act [Krankenhauszukunftsgesetz] due to come into force in Germany in 2021, will be a further milestone for digital solutions. Henning Schneider, Chief Information Officer at Asklepios Kliniken, also believes this to be true. "For the first time, the new law will allow us to claim the costs for digital structures from the Federal government and to make targeted investments. We will concentrate on solutions that can be implemented independent of a single location." Schneider is without a doubt an advocate of using platform-based approaches that network together different providers. "We need excellent interfaces and must avoid island solutions at all costs."

**HENNING SCHNEIDER** is Chief Information Officer at Asklepios Kliniken GmbH & Co KGaA since 2016. Prior to this role he was CIO of University Clinic Hamburg-Eppendorf.

## HIP offers access to global innovations

The way the HIP is organized helps Asklepios to channel and structure its collaborations with e-health start-ups. "We are bombarded with start-ups that approach us with their solutions. Everyone is interested in data available in clinics. The HIP allows us to target specific partnerships and launch pilot studies", says Schneider and emphasizes : "We are concerned with the patients and doctors for whom digital solutions must also represent improvements." He also sees a need for applications that make the admission process in hospitals more straightforward, make it safer to dispense drugs, or aid the use of mobile devices in clinical settings, such as for wound treatments. The HIP also enables Asklepios to search for innovations worldwide. "We don't need to wait for a start-up to come to us with the ideal solution, we can actively seek them out," says Schneider. SW

# GET CONNECTED TO THE TOP MEDTECH MARKETS

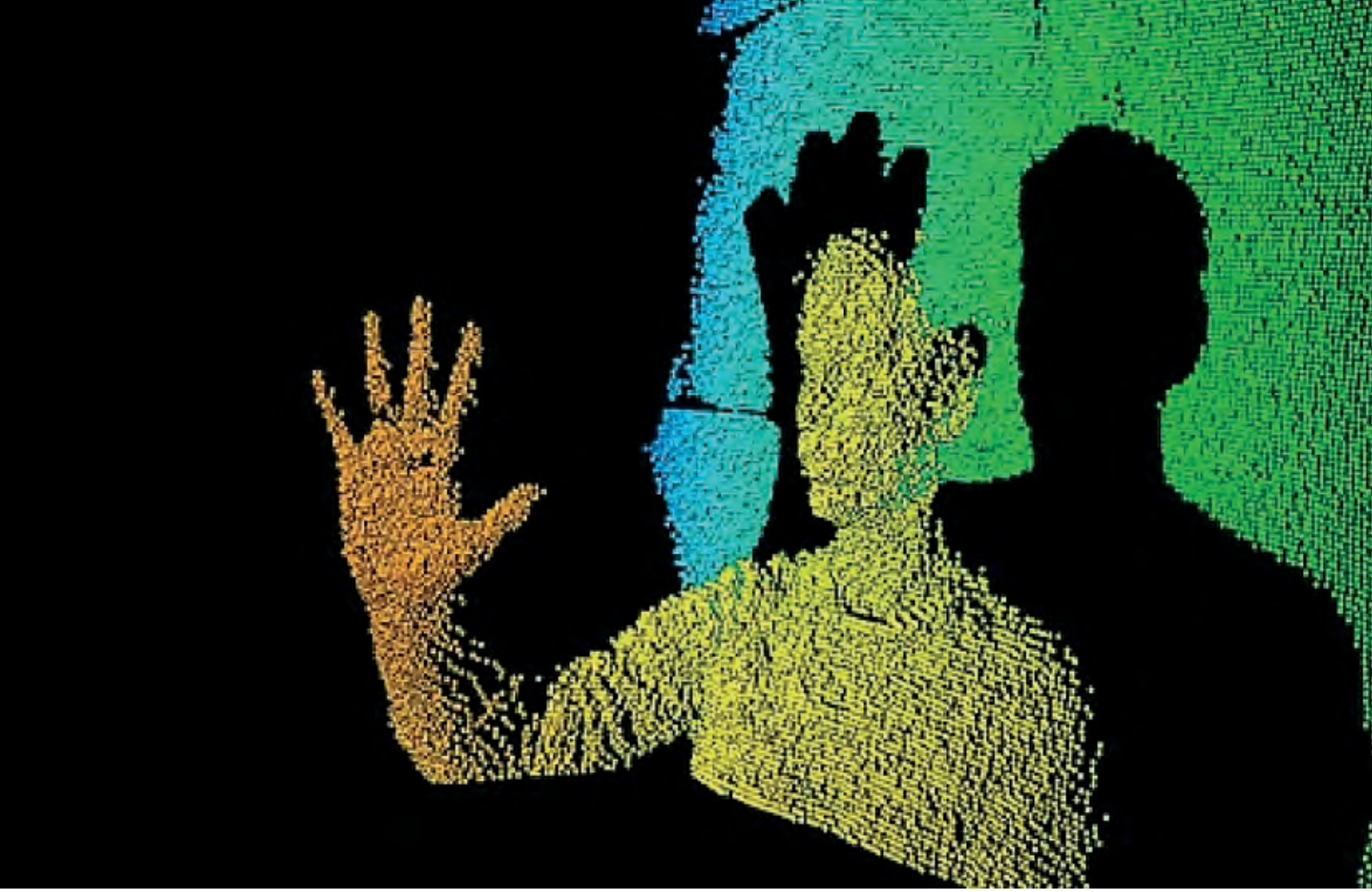
**MEDTECH ALLIANCE** Making the target markets China, USA and Japan accessible for medtech SMEs: This is the aim of the EU-funded project MAGIA. Its successor project has recently launched.

It is good news for companies and institutions from Hamburg and Schleswig-Holstein: The Life Science Nord project MAGIA (from the Italian magìa = "magic") – MedTech Alliance for Global InternAtionalization has entered its second phase. Now named MAGIA2market, over the next two years it will support SMEs in their internationalization efforts.

"For this purpose, we would like to offer delegation trips to the target markets in fall 2021 and spring 2022, but we also catalyze business matchmaking, exchange and provide knowledge via webinars," summarizes Life Science Nord project manager Sarah Niemann. "In addition to the USA and China, Japan is the latest country to join our target markets. Any companies that need advice, have an interest in finding contacts in the target regions, or have questions are warmly invited to contact us." Besides the trips, there will be a Go2Market support program that helps companies to establish contacts in the target regions. MAGIA2market focuses on business agreements, but also the initiation of joint ventures, development and collaborative partnerships. Over the past two years, the alliance of four leading European MedTech and health clusters Life Science Nord (Germany), BioPMed (Italy), Lyonbiopole (France) and BioWin (Belgium) has supported SMEs in establishing and expanding international business relations with China and the USA.

The overall goal of the project is, through cooperation and resource-sharing, to pave the way for the clusters' SMEs into highly relevant and interesting target markets. SMEs can already benefit from MAGIA's knowledge resources, which consist of market studies and videos, as well as from a network of strong relationships in the target countries that will be established during the project. The alliance's new website is in development and it will be launched in January 2020. pg

**For more information on international projects:**
**Please contact Sarah Niemann at**
**niemann@lifesciencenord.de**
**www.magia2market.com**



# BUILDING AN AI ECOSYSTEM

**DIGITALIZATION OF HEALTHCARE** KI-SIGS is a powerful public-private consortium that aims to bring artificial intelligence into clinical applications. The project, which receives 10 million euros in public funding, is expected to strengthen the north German medtech sector. We asked three experts involved in translation on how it can advance the idea of an AI ecosystem.

**Prof Dr Martin Leucker**
Head of UniTransferKlinik and project leader of the KI-SIGS consortium

**Dirk Schrödter**
Head of the State Chancellery of Land Schleswig-Holstein. The State Secretary launched the States' KI strategy in 2019.

**Dr Florian Neumann**
CTO of Söring GmbH, a world leader in ultrasound technology for neurosurgery. As a partner in KI-SIGS, Söring develops an intelligent aspirator.

**How important is the use of artificial intelligence for economic development in the North?**

**DIRK SCHRÖDTER** We believe AI is the technology of the future, and that's why we've included a focus on AI in our strategic framework for digitalization. The AI strategy which we launched in 2019 is to make Schleswig-Holstein competitive in this field and we want to create value for our state. This can only be achieved by bringing science and business together. We want to drive momentum so that an ecosystem for AI can develop in the North. And we want to play a leading role in the promotion of AI in Germany. To this end, we are providing more than 40 million Euro in funding, including EU funds.

**What role do medium-sized companies play here?**

**SCHRÖDTER** SMEs are the backbone of our economy and they play a key role here. They are at the heart of an AI ecosystem. We want to translate the outcomes of AI research into targeted value creation for our SMEs, ensuring their competitiveness.

**Mr. Neumann, Söring is such a medium-sized medical technology company. Do you feel adequately represented in the AI strategy for Schleswig-Holstein?**

**FLORIAN NEUMANN** We feel it represents us adequately. In addition to KI-SIGS, we have also participated in state funding programs for corporate innovation organization. They focus on how to implement AI-based solutions in companies, for example in business and quality processes. This raises exciting questions. Are we as a medium-sized company actually digitized enough? Do we generate enough data? We are also currently developing ideas on how we can use AI for the design process.

**What potential does AI have for the healthcare industry?**

**SCHRÖDTER** There is huge potential for value creation for our State in the case of AI applications in the healthcare sector. That's why we want to drive research and development in this area. Life Science Nord is a great Cluster for this. We are well positioned here and can also adapt to the strategic goals of the German government's AI strategy, in which the healthcare industry is highlighted as one of several fields of action.

**Lübeck has become a hotspot for AI research in medicine. How did this come about?**

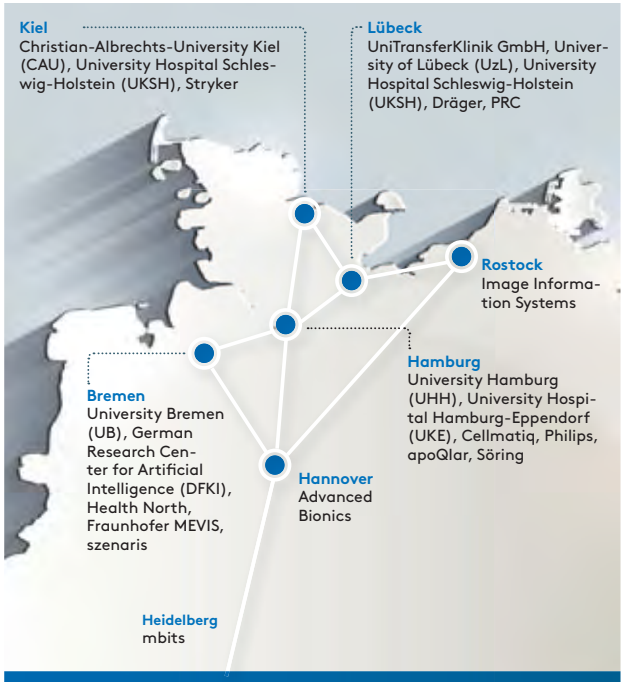
**MARTIN LEUCKER** Lübeck was originally a medical university and it has extensive expertise in this area. Computer science became a reality at the university 25 years ago, and it was increasingly grounded in neuroinformatics and bioinformatics. Imaging is one of the key areas of focus in Lübeck, and computer science has always been closely connected to medical technology. With the advent of AI, the opportunities locally have been strengthened. This has resulted in the ideal combination of computer science, medicine and medical technology.

**SCHRÖDTER** Lübeck has in fact become a major powerhouse for AI-based innovations in medicine. At the University of Lübeck, strategic advancements in technology have been recognized and clear ideas for the future have been developed at incredible speed. This has always been done in close partnership and with feedback from the government. I believe

that this is the only way to sustainably utilize our potential in Schleswig-Holstein. Lübeck has seen great development in this regard.

### How does the KI-SIGS network fit into the AI strategy for Schleswig-Holstein?

**SCHRÖDTER** KI-SIGS is outstanding in its embodiment of the goals of the AI strategy. An ecosystem of science, business and other players is emerging here in Schleswig-Holstein, extending far beyond Lübeck. High technology, networked, and agile - that's how I would like to see it. The speed alone with which all those involved got the application for KI-SIGS off the ground shows how well the collaboration is working. I think it's fair to say that KI-SIGS brings together the most important players in the fields of medicine and artificial intelligence in all of northern Germany.




**The KI-SIGS consortium**
Funded by the Federal Ministry of Economic Affairs and Energy with 10.7 million euros, it comprises 22 partners from academia, industry and hospitals.

### What is so special about the architecture of the KI-SIGS network?

**LEUCKER** Compared to the structure of traditional research projects, KI-SIGS is much larger in scope. For one thing, there are nine different innovation projects running in parallel. Information and experience are exchanged between each of these applied projects. Knowledge transfer is organized via a platform, KI Space. Within this platform, we develop general solutions, specifications and methods for the medical technology sector. We then apply these directly to the projects to see whether the solutions are viable. Our ultimate goal is to develop solutions for the entire industry. This interesting project design is only possible because of the huge scope of KI-SIGS.

### One focus of KI-SIGS is the topic of regulation. How will you approach this subject?

**LEUCKER** The question of how AI-based systems in medical technology can be developed and approved from a regulatory perspective is currently largely unanswered. In medical device development, everything is geared toward increasing patient benefit, and many quality assurance standards apply. These are completely new for the field of artificial intelligence. We are investigating this in the context of KI-SIGS. We put this directly into the applied projects and see whether the solutions are viable.

### Mr. Neumann, how important is participation in KI-SIGS for your company?

**NEUMANN** KI-SIGS is important for Söring on two levels. On the one hand, we can use the opportunity to deal with AI within our domain and create new product benefits for our customers. And we are building a bridge from our highly therapeutic perspective into diagnostics. In addition, we can further intensify and expand our ties to Lübeck. We are developing an intelligent ultrasound aspirator *(see box)*. Even in the predecessor project Ultralas, which was funded by the German Federal Ministry of Education and Research, we noticed how this collaboration inspires us. It's a lot of fun.

### What challenges do you see when it comes to data protection in AI-based medical technology solutions?

## KI-SIGS INNOVATION PROJECTS

**Intelligent Eye Diagnostics (iAuge):** A consortium of engineers, data scientists and clinicians from Lübeck, Kiel and Bremen is developing an eye imaging device based on OCT technology that patients can use at home. The AI-based system is used to support diagnosis and homecare prognostics of eye diseases like AMD or Retinopathia centralis serosa – RCS.

**Intelligent Ultrasound Aspirator:** Ultrasound aspirators made by Söring GmbH are used to resect tumor tissue in neurosurgery. One major challenge during these procedures is the detection of tumor margins in order to preserve as much healthy tissue as possible. In this KI-SIGS project, the R&D team at Söring and experts from Lübeck University use data generated during the operation combined with AI algorithms to measure and classify mechanical properties of brain tissue at the tumor site.

## MORE AI PROJECTS:

**KI#CK – Artificial Intelligence:** Run by Life Science Nord together with the University of Applied Sciences and oncampus GmbH, KI#CK is a needs-oriented qualification program for personnel working within the Life Science cluster in the state of Schleswig-Holstein. Courses are available in the LSN Academy.

**KI LAB Lübeck:** KI LAB Lübeck is a high-tech lab which provides an environment for AI activities – for research, teaching and transfer.

**SCHRÖDTER** Health data are some of the most sensitive data we have. The requirements of data protection law must be observed of course, but this does not mean that we can no longer do anything. AI is only conceivable with sufficient data. That's why we need to create a high level of trust that leads to people providing their data voluntarily. We must overcome the discrepancy between data protection and data provision.

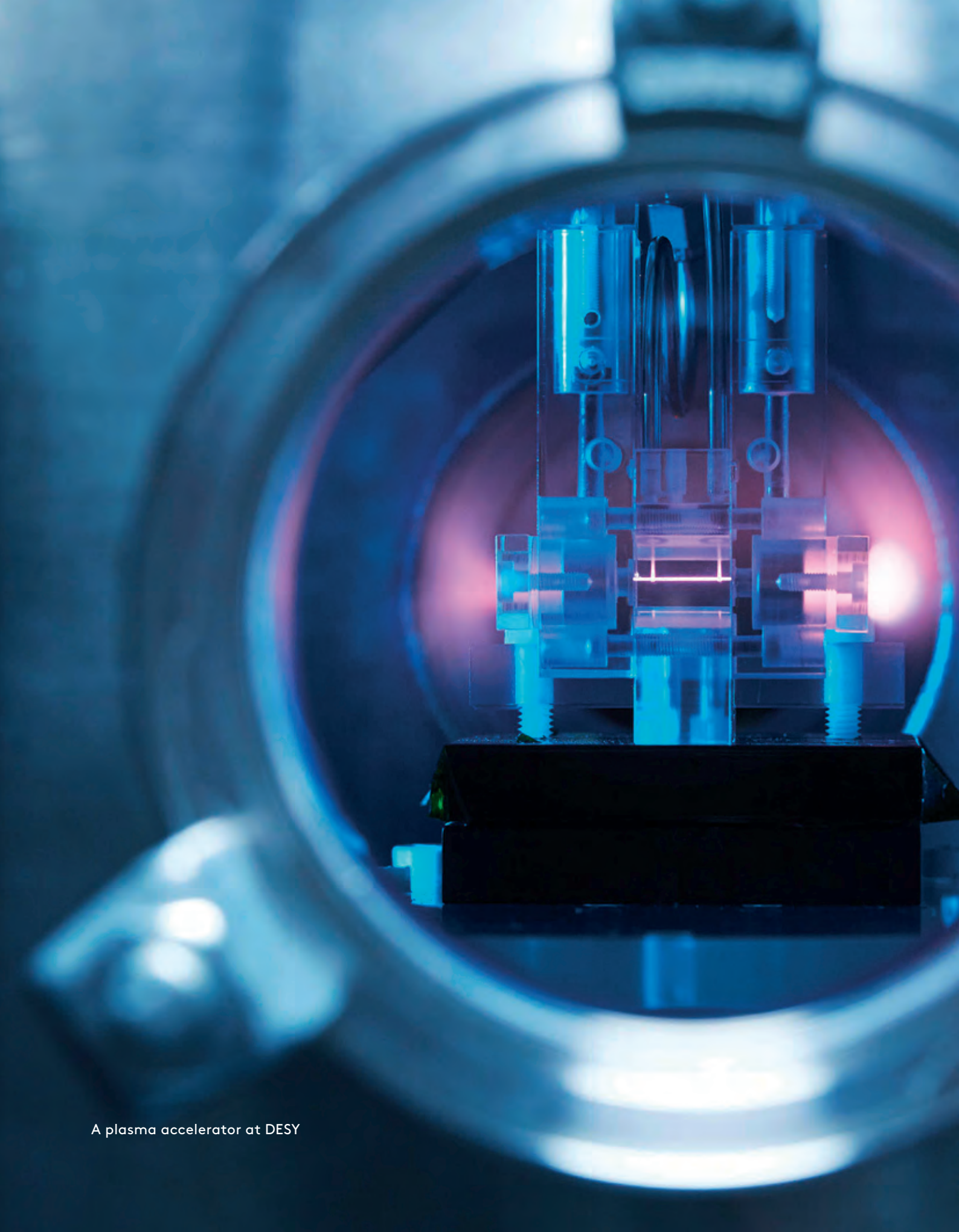
**How is the development of data ecosystems and data pools taking shape?**

**LEUCKER** We are taking two approaches to address the issue here in Lübeck. In KI Lab, funded by the Federal Ministry of Education and Research, for example, we are building an open data platform. Anyone who wants to make data available can upload it there and define the terms of use. In this way, we are creating a publicly available pool of data that SMEs can access to train their machine learning applications. However, this platform is not primarily intended for medical data. For the latter, you have to implement a completely different level of data protection. This is realized in KI-SIGS, for example, by not allowing patient data to leave the hospital domain at all. In addition, techniques such as pseudonymization and anonymization are used.

**NEUMANN** A connection to larger data pools is a basic requirement for us. In our "intelligent ultrasound aspirator" project, however, we are dealing with very specific data, such as information on tissue strength in the brain. The data are read out while the patient is being treated. We started with a laboratory data set and used it to feed the algorithms of our partners in Lübeck. We already have great results. It will be exciting when surgeons come into play and more and more disturbance variables are added.

**AI also means speed in data analysis. Have initial results already been reported in KI-SIGS projects?**

**LEUCKER** It hasn't taken long to see the first successful outcomes across all the projects. This is also the case in our applied iAuge project, in which we are developing AI-based eye diagnostics with scanners for use at home (*see box*). The question is, how stable are the solutions? We want to develop AI solutions for everyday clinical use that always work well and, of course, meet regulatory requirements. pg



A plasma accelerator at DESY

(c) DESY / Heiner Müller-Elsner

# DESTINATION DESY

**LIFE SCIENCE INNOVATION** The DESY research campus in the West of Hamburg is transforming into an innovation ecoystem and go-to-hub for young and established life science companies. And it is the nucleus of the future Science City Bahrenfeld.

As one of Germany's largest publicly funded research centres, the → **"Deutsches Elektronen-Synchrotron" (DESY)** at Hamburg-Bahrenfeld provides researchers from academia and industry a unique infrastructure to explore the world's nano-cosmos. The synchrotron radiation source PETRA III is one of the most brilliant and coherent X-ray lightsources worldwide. Another gigantic machine, the free electron laser European XFEL, has opened its doors three years ago. It is the world's most powerful X-ray source. "These machines are cameras for molecular imaging - and we at DESY are experts in taking pictures or even movies of molecules in action," explains Arik Willner, Chief Technology Officer at DESY. During the last decade, DESY has experienced a remarkable shift from particle physics focus to biomedical research and materials research. "At PETRA III, 30% of the users provided with beamtime already belong to the area of Life Sciences," Willner says. Amongst them is a recent industrial-academic cooperation of the University of Mainz, → **EMBL** and the biotech company BioNTech regarding optimizing the packaging of messenger RNA for its vaccines - amongst them the COVID-19 vaccine *(see more on COVID-19 drug research at DESY on page 8)*. "We have now maximally opened the access to our analytical infrastructure for companies," says Willner. This is just one aspect of the research and innovation strategy 2030 the DESY has marked out three years ago. "We invest a lot


(c) DESY/ Heiner Müller-Elsner

in order to create a unique innovation ecosystem on the DESY campus," says Willner, who is also Associate Director and heading DESY's Innovation and Technology Transfer department. As a major project, DESY is building a technology and start-up center– the first federal facility of its kind in Germany. The DESY Innovation Factory will be an innovation hub for new ideas, products and services, connecting scientists, start-ups and established corporations – on almost 11 000 square meters. "The DESY Innovation Factory is located in the direct vicinity of unique large-scale research and analytical facilities. Here, we can actively foster cooperation and innovation between research and application," explains Willner. The DESY Innovation Factory focuses on two topics that are of central importance for the future: New solutions for the healthcare sector, e.g. by developing promising technologies for medical imaging, and research looking into materials, which can support a circular economy. The DESY Innovation Factory will offer founders within deeptech access to highly equipped labs, workshops and offices built on the latest technologies. Other innovation related projects, as well as aspects of science industry cooperation will also benefit from the research network, the expertise of experienced specialists and the outstanding infrastructure of the campus, including the competence centers in structural biology, laser technology and DESY's nano-analytics. The total costs for construction, installation and the first three years of operation of the DESY Innovation Factory are estimated at 105.5 million euros. 90% of this is borne by the federal government, the other 10% by the City of Hamburg. The call for architectural project tender will be launched in early 2021. Construction is scheduled to begin in 2023, and the DESY Innovation Factory is set to open its doors in late 2025. DESY is responsible for planning, the construction process and the operational management for this institution.

Already opening its doors next year is another innovation center called "Start-up Labs Bahrenfeld", an incubator for young tech companies that is managed by DESY and co-financed by the City of Hamburg. "The space is already fully booked," says Willner, "and this without any promotion and marketing activities." Hamburg as a highly attractive city is a perfect recruiting machine, Willner points out. DESY is also the nucleus of the future Science City Hamburg Bahrenfeld. The vision for 2040 brings together the expansion of the DESY and of Universität Hamburg's campus in Bahrenfeld and urban development of the nearby horse racing track. "The Science City will give our innovation ecosystem another boost and will place it on the international map," Willner is convinced.

(c) DESY / R. Schaaf / Atelier Disko


(c) DESY/ Anne Gaertner


**top left:**
Research at a PETRA III beamline.

**top right:**
The innovation centre "Start-up Labs Bahrenfeld" will open its doors in 2021.

**below left:**
The DESY Innovation Factory will be constructed at two sites.

**below right:**
A view into the facility of light source PETRA III.

## X-ray technology for drug development

The latest ambitious life science project initiated by Willner's team together with the → **University of Hamburg**, is amongst the 16 finalists in the federal government's initiative "clusters4-future". The aspiring cluster Tech2Med has the ambitious goal to develop new and compact x-ray technologies for medical research to accelerate the discovery and development of new drugs. "On board of Tech2Med are leading research teams and medtech and life science companies from the region," says Willner. In close collaboration with the other cluster partners, analytical methods at light sources such as serial X-ray crystallography or x-ray fluorescence will be advanced and finetuned, so that preclinical studies of drug development can be carried out more quickly, efficiently and thereby, less expensive. The specific development of a compact "tabletop" accelerator at which these methods can be implemented. The ultimate goal is to transfer a lab-scaled accelerator with an industrial partner. Clients would be researchers from universities or R&D departments in the pharmaceutical industry. The final decision whether Tech2Med gets a multi-million euro funding over the next nine years is set to be in early 2021. "It would be a major drive to our developing life science innovation ecosystem," says Willner. pg



The Gateway49 Co-Founders Stefan Stengel (left) and Frank Schröder-Oeynhausen (middle) together with Schleswig-Holstein's Minister of Economic Affairs Bernd Buchholz (right) at the TZL Lübeck.

# TARGETED SUPPORT FOR START-UPS IN THE NORTH

**GATEWAY49 ACCELERATOR** A new infrastructure in Lübeck has been established to provide targeted support for start-ups in Schleswig-Holstein. Medtech company Dräger is among the local partners.

The Gateway49 Accelerator has put Lübeck on the start-up map. Two to three times a year, start-up teams that are in the early stages of their development can apply for a nine-month structured workshop and training program. They will not only receive financial support worth up to 30,000 euros, but also access to a broad network of coaches, mentors and established companies from Schleswig-Holstein. Ideally located at the Lübeck Technology Center (TZL), the hub has strong ties with partners such as the **→ University of Lübeck**, the **→ BioMedTec Science Campus** and the **→ Applied University of Lübeck**. "Having close connections within the region is a major benefit of our program," says Stefan Stengel, who co-founded the Gateway49 Accelerator and serves as the main contact for the team in his role as program manager.

> **"Having close connections within the region is a major benefit of our program."**
>
> DR. FRANK SCHRÖDER-OEYNHAUSEN
> CO-FOUNDER OF THE GATEWAY49 ACCELERATOR AND CEO OF TZL LÜBECK

## Positive response from founders

The first two batches, each with six teams, began in 2020. The application process for the third round runs until January 2021, and the next twelve are to be selected in the spring. "Our program has allowed us to establish ourselves on the national and international accelerator scene," asserts Frank Schröder-Oeynhausen, managing director at the TZL, who co-initiated the development of the accelerator together with Stengel. "The positive response from local founders, as well as international applicants, demonstrates that we are on the right track." In addition, the city of Lübeck is proud to be on an equal footing with larger competitors in Hamburg and elsewhere. "We can offer the start-ups our spe-

cialist help – no matter at which stage they find themselves. The close connections to local companies and dedicated coaches and mentors – founders appreciate these benefits when they choose to come to Schleswig-Holstein," says Stengel. In 2020, the coronavirus pandemic became a logistical challenge for the start-ups, but it didn't dampen local enthusiasm.

## Life sciences among the priority topics

Some teams grew from the BioMedTec Science Campus such as the first two medtech accelerator projects "ReHero" and "MobOx" (*see box on the right*). In the long-term, exchanges with the BioMedTec Science Campus and the University of Lübeck are also of high priority for the accelerator team. "In the future, we want to step up our scouting activities and search for promising start-up ideas and teams," says Stengel. Besides topics such as smart cities, logistics, nutrition and the digital economy, life sciences innovations in medical technology and digital health are right at the top of the agenda at Gateway49 – not least thanks to partners and companies such as Dräger and VisiConsult or the health insurer BARMER. Considering this, Stengel is sure to see further life science teams entering the accelerator in the third batch. "High-quality concepts and bright minds are what counts," emphasizes Stengel.

## Expert support for medtech entrepreneurs

Support from highly experienced experts can be invaluable, especially for young medtech entrepreneurs. Whether prototype development, patenting, preparing clinical studies or input on the regulatory framework under the EU Medical Device Regulation, the accelerator team offers support for all of those questions. "Our makerspace in the Fablab or our experienced regulatory experts are particularly popular," reports Stengel. "The program also forces the founders to deal with market and customer structure issues." In addition, there is ongoing regular exchange with other accelerators in Germany and northern Europe ongoing, as well as at international level. There are close ties with Silicon Valley, among others. "The Americans offer their experience in the digital economy and artificial intelligence, and we as Germans share our engineering expertise. It's a win-win situation for both sides." SW

**More information: www.gateway49.com**

## MEDTECH START-UPS IN THE GATEWAY49 ACCELERATOR

**REHERO:** The team is developing a continuous easy-to-use rehabilitation for paralyzed patients enabling independent training at home. The system consists of a sensor wristband and a software component that is able to recognize planned hand gestures. In this way it is possible to detect the intention to move even in paralyzed people, in whom no residual movement of the fingers can be detected. The system allows that existing nerve tracts are reactivated, the brain is stimulated and the training progress is increased. This has positive effect on the physical and mental condition of patients worldwide and free up financial and human resources in the health system.

**mobOx:** MobOx develops a mobile blood analysis device for use in the rescue service. The device is able to detect changes in the red blood pigment hemoglobin. The main area of application is the diagnosis of carbon monoxide (CO) poisoning in the event of fire, but also certain types of poisoning by chemicals and drugs. A particularly robust, optical measurement method is used that makes use of deep learning methods. For the first time, this enables fast, simple and reliable determination with laboratory accuracy directly on site. Further measurement parameters can be added in the future by adapting the algorithms without modifying the hardware. This opens further application areas, such as diabetes for instance.

**THOMAS F. MEYER** The renowned molecular biologist is a pioneer in infection research. Using cutting edge technologies, he has uncovered how pathogenic microbes and human cells interact during infection. The longtime Max Planck director has recently been appointed senior professor at Kiel University. Coming from Berlin with his team and a powerful toolbox in his luggage, he will further explore how microbes cause cancer.

Many of his discoveries have become textbook knowledge. His CV and list of publications are testimony of a molecular biologist who has been at the forefront of infection research throughout his career. But retirement? An option unthinkable for 68-year-old Thomas Meyer. "I am fascinated by research, and there are still many unanswered questions and hypotheses that I would like to explore." For the director emeritus of the Max Planck Institute for Infection Biology (MPIIB) in Berlin and now senior professor at Kiel University, there is no reason to leave it all behind him just as he is at the height of his research success. He recently received the Robert Koch Gold Medal in recognition of his outstanding scientific life's work. And this spring, the European Research Council (ERC) committed to an Advanced Grant of 2.5 million euros. This will allow Meyer to systematically and fundamentally investigate the role of bacterial infections in the development of cancer.

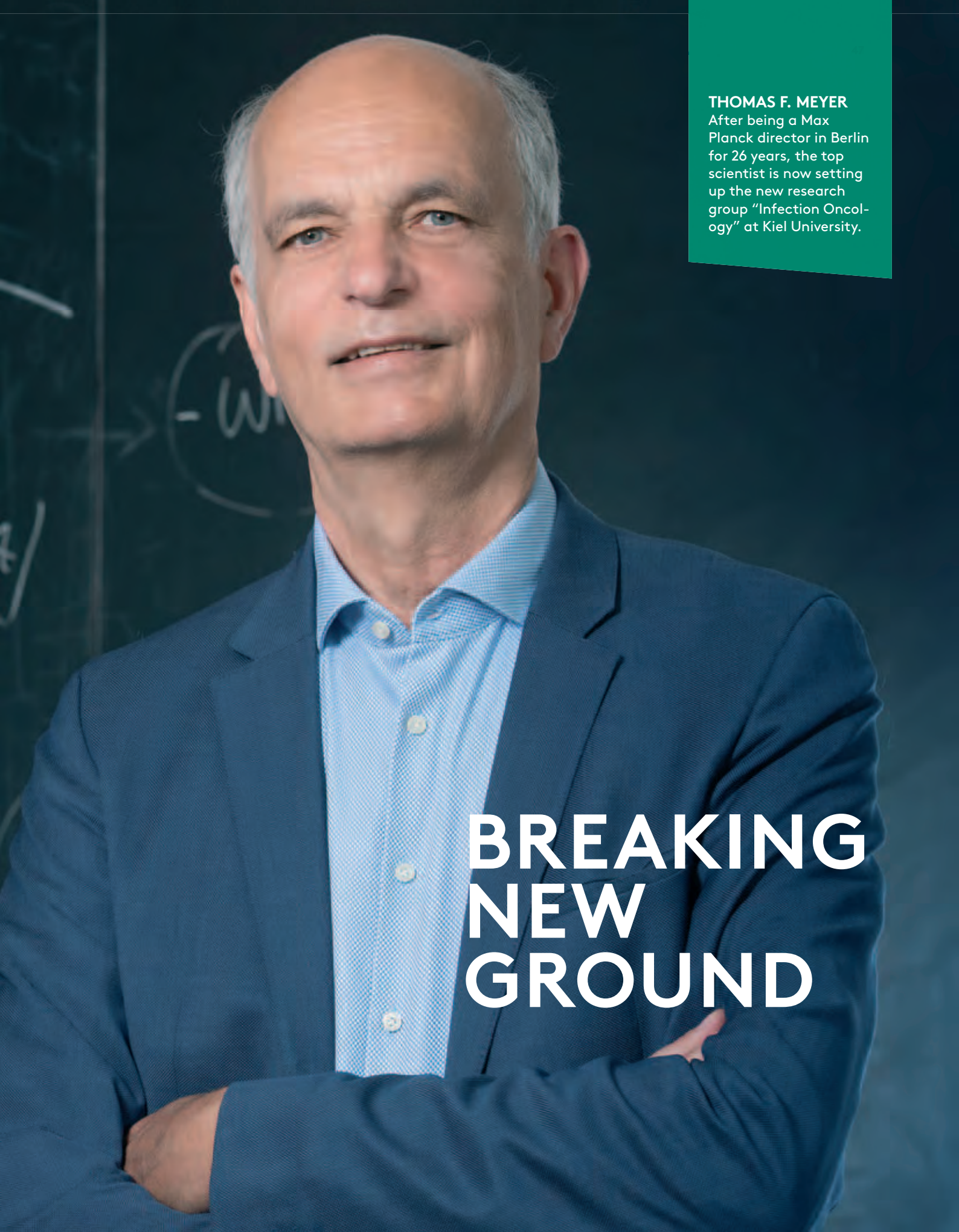
> "We provide evidence of the link between bacterial infection and cancer in humans."

In September 2020, Meyer began setting up his new research group on "Infection Oncology". The decisive factor in going to Kiel was the thematic connection to the activities here in the area of inflammatory research in the Cluster of Excellence "Precision Medicine in Chronic Inflammation" (PMI). Chronic inflammations are effectively the interface between infection and cancer. "I am highly optimistic that together we will be able to achieve important research results from these synergies right up to the development of new treatment approaches," Meyer says. "I have early been fascinated by microbiology," he recalls, "but in the early 1980s, basic research in molecular biology was far away from medicine".

That has dramatically changed with all the technological breakthroughs since then – like DNA sequencing, RNA interference, genome editing or bioinformatics. "These tools have catapulted us to the center of medicine," Meyer says. He used them to not only uncover molecular mechanisms of bacterial and viral infections. Realizing, however, that an infection always depends on two partners, the pathogen and its host, Meyer formulated the hypothesis that infectious bacteria and viruses can be eliminated by blocking functions in human cells in addition to the standard application of antibiotics or antiviral substances. Meyer's team explored the roles of host components in infection processes, thereby developing the concept of "host-directed" therapy. In addition to the use of vaccines and antibiotics, this therapeutic approach has now become a modern third pillar in the fight against pathogens.

"We then asked, 'What is the fate of a once-infected host cell'?," says Meyer. "Are the cells damaged during the event of infection? Could this be the origin of further diseases in the human body?" Soon it became clear that this opened up paths into the field of cancer research. Therefore, Meyer is now seeking a fingerprint, a genetic signature, that could prove the connection between infection and cancer. In fact, his latest research does not only underline the importance of *Helicobacter pylori* in the development of gastric cancer, it also sheds light on the effects of bacteria that damage the human genome by producing a genotoxin. Meyer and his team found that a toxin called colibactin, which is released by the gut bacterium *Escherichia coli*, causes characteristic mutations in human intestinal cells which can be detected in a subgroup of colon cancer patients years later. "Strictly-speaking, this is one of the strongest evidence provided so far for a causal link between a bacterial infection and cancer in humans," Meyer says.

In need of better models to study microbe-host-interactions, Meyer pioneered in growing organoids in the lab, stem cell-based balls of cells that mimic organs in a dish. Lung organoids provide an interesting test system for potential COVID-19 drugs. In addition, Meyer has started developing a much-needed COVID-19 vaccine that is based on a weakened strain of *Salmonella Typhi*. "It's our contribution to increase the diversity of vaccines in order to combat the current pandemic," he says. pg



**THOMAS F. MEYER**
After being a Max Planck director in Berlin for 26 years, the top scientist is now setting up the new research group "Infection Oncology" at Kiel University.

# BREAKING NEW GROUND

# YOUSEF NAZIRIZADEH, CO-FOUNDER & CEO OF BYONOY

**YOUSEF NAZIRIZADEH** is co-founder and CEO of the Hamburg-based biotech start-up Byonoy GmbH. The innovative young company has developed the world's smallest plate reader. It produces accurate and reliable results for standard 96-well plates in just five seconds.

What is so special about the Byonoy plate reader?

**YOUSEF NAZIRIZADEH** Plate readers have been a standard piece of equipment in every lab for more than 50 years, and their basic functionality has changed very little since its inception. We have broken new ground here and introduced a revolutionary step. Instead of one moving detection unit, we have installed 96 separate detection units, which is why our device can be so compact, and it can measure so quickly.

What are some recent milestones in the development of your business?

**NAZIRIZADEH** In 2020 we applied for the German Accelerator program which was co-founded by the Federal Ministry of Economic Affairs and Energy. It supports highly promising German start-ups in their efforts to access U.S. markets. We gained a lot of know-how from players and experts in the field. With this knowledge, we hope to expand quickly and more efficiently. We highly recommend other start-ups to participate in the program.

What potential do you see for your product?

**NAZIRIZADEH** Standard diagnostic tests can easily be carried out outside of laboratories, if necessary. Therefore, even in inaccessible regions like developing countries, our product can bring great benefits to people with access to a laptop only. For Absorbance 96, we anticipate high levels of adoption from in-field applications and by labs that require additional capacity or bench space flexibility.

**More information:** **www.byonoy.com**

## WE ARE ACTIVE IN THE NORTH ...

*"... as part of the publicly funded project Optochip. Here, we develop a mobile PCR-based Point-of-Care device. The first application is the diagnosis of respiratory viruses in veterinary medicine."*

## THE NUMBER 7

The Absorbance 96 is 7 times smaller than the next smallest plate reader on the market. As it is so compact, the plate reader is highly mobile, making it conceivable for use anywhere in the world.

## ABOUT ASTRAZENECA

**70,600 employees** are working for the company worldwide, of which 900 in Germany

**630m euros turnover** was generated in Germany in 2019

**www.astrazeneca.de**

# WE'RE NOT AFRAID TO DO THINGS DIFFERENTLY

**GUEST ARTICLE** AstraZeneca Germany is one of the largest research-based pharmaceutical companies in Germany and offers a location in Wedel, Schleswig-Holstein. It's a subsidiary of the British-Swedish pharmaceutical company AstraZeneca PLC with headquarters in Cambridge, UK.

"We are one of the few companies that accompany a drug throughout its entire life cycle – from research and development to production and global marketing. Our focus is on the three therapeutic areas of oncology, cardiovascular and metabolic diseases, and respiratory diseases. In addition, we conduct research in the fields of autoimmune diseases, neuroscience, and infections.

**Great Place to Work:** At AstraZeneca, we're not afraid to do things differently. We are redefining work and creating innovations, while putting patients first. We offer a dynamic and diverse workplace with excellent future prospects and opportunities to grow. With our "Great Place to Work" program, we focus on our employees' job satisfaction along with their personal and professional development.

**Committed to the environment:** All our strategic decisions are based on sustainable management and the responsible use of resources. We strive every day to ensure the sustainability of all our resources.

**Diversity and fairness:** As a signatory to the "Charta der Vielfalt" (Diversity Charter), we are dedicated to creating a work environment free of prejudice. Companies that offer equal opportunities to all individuals and not only accept differences, but encourage them, lay the foundation for new approaches and solutions. We embrace diversity and inclusion and celebrate difference!

**Your future is here:** If you are currently planning your career and looking for new opportunities, you have come to the right place. Find out more at our career site *astrazeneca.de/karriere* about next steps and vacancies. You can also apply directly online."

> **"We're always looking for exceptional candidates who want to grow as individuals and positively shape the future of the company."**
>
> DR. GUIDO HOESCH
> VICE PRESIDENT HUMAN RESOURCES,
> ASTRAZENECA GERMANY

# GET IN TOUCH WITH US!

Life Science Nord is the regional industry network for medical bechnology, biotechnology and pharma for the states of Hamburg and Schleswig-Holstein. We promote co-operation between stakeholders and are welcoming everyone who is interested in getting in touch with us!

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→ Please find more cluster members at: **www.lifesciencenord.de**

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Life Science Nord is one of the leading life science networks in Europe and covers some 500 companies, research institutes and organizations. In Hamburg and Schleswig-Holstein, pioneering lead solutions for medical devices, biotechnology and the healthcare industry are developed.

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