MEDTECH, BIOTECH & PHARMA | 2023

LSN MAGAZINE

THE INDUSTRY JOURNAL OF HAMBURG & SCHLESWIG-HOLSTEIN

LIFE SCIENCE NORD

INNOVATIVE HIV THERAPY

Provirex' genome editing approach is heading to the clinic

THE BRAINSTORMER

Christian Gerloff's plans for the University Medical Center Hamburg-Eppendorf (UKE)

ECOSYSTEM BUILDERS

How artificial intelligence applications and robotics are transforming the health industry in the North of Germany

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AstraZeneca life inspiring ideas

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OLYMPUS

→ Please find our Gold and Silver members on **page 43**.

DR JÜRGEN WALKENHORST
MANAGING DIRECTOR
LIFE SCIENCE NORD MANAGEMENT GMBH

Dear readers,

I am delighted that you are now holding the hot-off-the-press LSN Magazine 2023 in your hands. It is my first LSN Magazine since I started as Managing Director of Life Science Nord in June 2022. I am also pleased that I can give you a brief overview of the once again great topics and stories in this issue. Although AI in medicine is highly innovative, it's already an established field of research and development in the LSN region. However, it is not only the results of individual players that are remarkable, but rather the entire AI ecosystem that has emerged with research, industry and politics all working in concert. The interview with Dirk Schrödter, Head of the State Chancellery of Schleswig-Holstein and Minister of Digitalization, shows how AI in healthcare can be implemented as part of a holistic strategy incorporating politics, business, and science. The North is also in an excellent position on the research side. For instance, Stefan Fischer, Vice-President Transfer and Digitization of Lübeck University, impressively reports on how this succeeds, using the example of the KI-Med ecosystem in Lübeck. Fascinating examples express the wide range of AI applications: from high-speed protein puzzling on the DESY campus, to the use of AI-supported analytics in clinical pathology and in surgical robotics at Fraunhofer IMTE and UKSH, to additive manufacturing processes. In the North, AI has enormous potential to shape healthcare with the innovative power of the LSN cluster players. AI-based solutions, as one of the building blocks of an overall digitalization strategy, are providing the answers to many questions of the future. This issue naturally has much more to offer: Nanotechnology, high-tech devices for emergency care, bioanalytics, stem cell research, exciting start-ups, a portrait of the new UKE Managing Director... and more!

On behalf of the entire LSN team, I hope they enjoy browsing through the magazine!

Sincerely yours,

IMPRINT

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HALRIC CONSORTIUM RECEIVES EU FUNDING

➔ The Life Science Nord Cluster is one of more than 20 partners in the novel Hanseatic Life Science Research Infrastructure Consortium (HALRIC). With a total budget of 11.2 million euros, the EU Interreg project led by Lund University will strengthen cross-border research collaboration between companies, hospitals and universities in Norway, Denmark, Sweden and Northern Germany. Life science innovators will gain access to the unique research infrastructure and large-scale facilities available in the region, helping them to turn research into innovation. Other German partners include the University of Hamburg, DESY, European XFEL (pictured), EMBL, University Medical Center Hamburg-Eppendorf (UKE) and the City of Hamburg.

THE NUMBER 800

million cells grown in the lab are needed to engineer a heart muscle patch that is currently being implanted into patients with heart failure in a first-in-man clinical study entiteled BioVAT-HF-DZHK20 – the University Hospital Schleswig-Holstein (UKSH) in Lübeck is part of it.

ONCOLOGY POWERHOUSE

➔ In January 2023, the global contract research organization (CRO) Crown Bioscience, a company of JSR Life Science, announced an agreement to acquire the service business and supporting biobank of Hamburg-based Indivumed. Indivumed has an industry-leading and global reputation for the provision and analysis of clinical biospecimens. The transaction will generate two separate entities: 'Indivumed Therapeutics' and 'Indivumed Services' (then wholly-owned by Crown Bioscience). According to Hartmut Juhl, Founder and CEO of Indivumed Group, the agreement will help the company to focus on its data-analytics-driven drug and diagnostic development. "With this partnership, Crown Bioscience and Indivumed will create a powerhouse for the advancement of precision oncology. Further, it fills me with great pride that my hometown Hamburg is emerging as a leading oncology biotech location," he says. Subject to customary closing adjustments the transaction is expected to close in April 2023.

KATHARINA FEGEBANK
Second Mayor of the Free and Hanseatic City of Hamburg and Senator for Science, Research, Equality and Districts

CROSS-BORDER COOPERATION...

"... projects such as HALRIC mean we can continue our close transnational cooperation between Hamburg Metropolitan region, Greater Copenhagen and Skåne. This will help us to further position the region as a world-leading life science hub."

➔ see also page 20–21

MARINE BIOPOLYMERS FOR MEDICINE

BlueBioPol — a project which is part of the regional research alliance BlueHealthTech aims to develop medical materials made of marine biopolymers. Collagen from jellyfish or alginate from macroalgae are generally considered biocompatible and biodegradable. As building blocks for carrier materials such as hydrogels, they could enable the treatment of tissue damage caused by chronic disease. The project bundles maritime and medical competencies of the Kiel region and has received around 800,000 Euros in funding from the Federal Ministry of Education and Research (BMBF).

NEW HOME

➔ The Fraunhofer Institute for Additive Manufacturing Technologies IAPT is being expanded with a highly specialized building at its site in Hamburg-Bergedorf. The building is being erected in a sustainable design with a modular wood construction.

➔ see also page 30–33

ECOSYSTEM BUILDERS

Players from the Life Science Nord Cluster interconnect and drive the application of artificial intelligence in life science research and clinical settings forward.

SPEED PUZZLERS

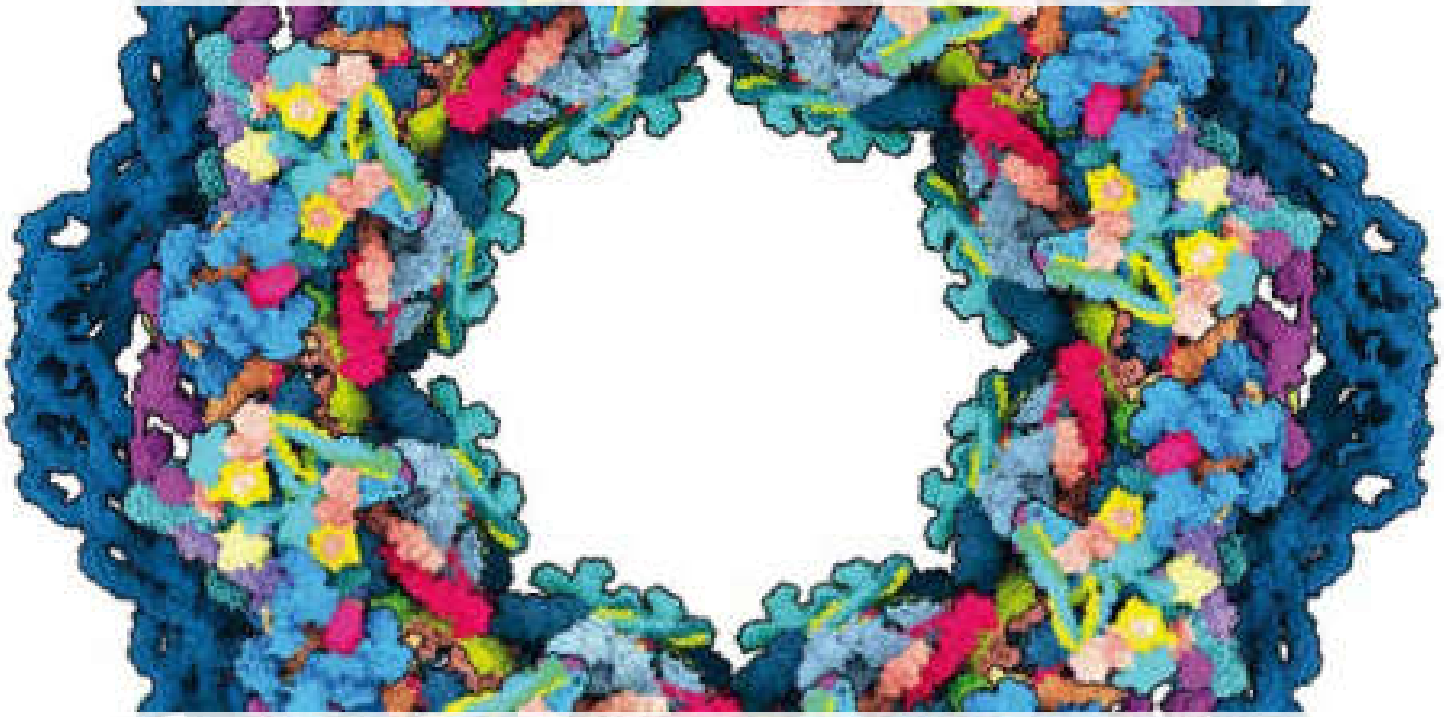
STRUCTURAL BIOLOGY The AI-based software AlphaFold2 has revolutionized the study of 3D protein structures. Players from Northern Germany are in the middle of this protein folding revolution and are involved in improving applications of the software.

For structural biologists around the world, July 2021 marked a turning point. London-based firm DeepMind – part of Google's parent company Alphabet – released an artificial intelligence (AI) tool called AlphaFold2. The deep learning algorithm can predict the 3D shape of proteins from their genetic sequence with almost pinpoint accuracy. This has transformed the studies of thousands of biologists worldwide. Researchers in the North of Germany are in the middle of this AI protein-folding revolution. One of them is Jan Kosinski, a structural bioinformatician who leads a research group at the Hamburg branch of the → **European Molecular Biology Laboratory (EMBL)**. He is also a member of the Centre for Structural Systems Biology (CSSB) at → **DESY**. Kosinski's passion is to solve tricky biomolecular puzzles – which means elucidating the accurate 3D architecture of proteins.

Figuring out the 3D shape of a giant

One structural biology masterpiece was the human nuclear pore complex which Kosinski's team solved together with Martin Beck's team from the Max Planck Institute of Biophysics and other collaborators. The nuclear pore complex (NPC) is a true molecular giant which sits on the membrane separating the nucleus from the cytoplasm. It is doughnut-shaped and works as both a gateway and a checkpoint for molecules that travel between the cytoplasm and the nucleus. For structural biologists, the human NPC is a challenging yet exciting 3D puzzle with around 30 different proteins each present in multiple copies. This amounts to around 1000 puzzle pieces.

The key to figuring out the complex's architecture was to combine several experimental and computational methods. "AlphaFold2 was a breakthrough moment for us," says Agnieszka Obarska-Kosińska, a postdoc in Beck's and Kosinski's labs who performed the molecu-



lar modelling. "Before, we didn't know anything about the structure of many of the proteins within the NPC. You cannot assemble a puzzle when you don't know what the pieces look like. But AlphaFold2, combined with other approaches, enabled us to predict those shapes." The resulting model, published in top journal "Science", was so complete and detailed that it enabled the researchers to create time-resolved molecular simulations that shed more light on how the NPC works.

> **"AlphaFold2 was a breakthrough moment for us."**
>
> DR AGNIESZKA OBARSKA-KOSINSKA
> EMBL HAMBURG

Jan Kosinski sees three aspects that have made AlphaFold2 a game changer for his and his team's way of doing protein science. "It speeds up our work – we get a good impression of what the protein we are working on looks like within minutes instead of months or years," he says. "It makes our work easier, and finally, AlphaFold2 makes our work more fun – many technical and tedious steps are now automated so we can focus more on our biological questions!"

Since its sensational debut, AlphaFold2 has been developed further. Kosinski points out that scientists now have a better understanding of where the software works best, and in which aspects it cannot replace experimental methods. For example, while AlphaFold2 gives an idea about the structure of a protein, X-ray and high-resolution cryo-electron microscopy (cryo-EM) methods still usually give the more precise structures needed for understanding enzymatic reactions or designing drugs. DeepMind and EMBL's European Bioinformatics Institute (EMBL-EBI) have partnered to create a database for making the predictions freely available to the scientific community. The database now includes over 200 million protein models. "This means we have models for almost every catalogued protein known to science," Kosinski says. After having cracked the structural code of the NPC, his group at EMBL Hamburg is now focusing on even more difficult molecular puzzles in infection biology. "We are now using AlphaFold2 in combination with our own software to model the structures of viruses such as influenza and Lassa to map their interactions with human proteins. We have also just started a bigger project on the malaria parasite funded by the CSSB."

AI-based structural biology hotspot

Jan Kosinski is convinced that Hamburg has the potential to develop into a hotspot for AI-based structural biology. At EMBL Hamburg and CSSB, there are already a number of AI-based projects in structural biology. There is also a growing AI community at the DESY campus including researchers from other disciplines such as physics or instrumentation. "I think our potential to attract AI experts or students lies in tackling important problems in fundamental biology and questions relevant to human health." pg

Digital pathology assessment using Mindpeak's software

ZERO-CLICK PRECISION

CANCER DIAGNOSTICS Digital pathology is a major medical application using AI-powered imaging analysis. Hamburg-based Mindpeak is a global frontrunner, releasing products used in clinical practice.

The year 2022 has been outstanding for Hamburg-based → **Mindpeak** in many aspects: "We were able to release ten software products with a CE-IVD mark that are all based on our deep-learning platform," says Co-founder and CEO Felix Faber. The second highlight of the year was that Mindpeak succeeded in entering the biopharma market, winning one of the largest oncology drug developers worldwide as a customer. "Both milestones result in a 1600% increase in revenue," Faber says. Further good news is that Mindpeak's AI solutions are among the global frontrunners that are already in use in clinical routine diagnostics. One of the most promising fields of AI in clinical applications is digital pathology. AI-powered imaging analysis systems evaluate microscopic images of suspicious tissue biopsies, and trained software has learnt to distinguish tumor tissue from healthy tissue. Mindpeak's deep learning algorithms use multi-layer neural networks to analyze data, allowing pathologists to explore and extract information beyond human visual perception. "Our tools quantify cells or biomarkers and assist cancer experts in providing reliable and reproducible diagnoses. And our clients include pharma companies that want to discover and develop new biomarkers," explains Faber, who is a computer scientist by training.

Mindpeak, founded in 2018, applies a hybrid deep learning approach, where semi-supervised methods are combined with supervised methods. "A lot of work went into the first software

AI AND CANCER

Other Hamburg-based companies in the Life Science Nord cluster using AI-based approaches for precision oncology include Evotec, FUSE-AI and Indivumed.

and the platform behind it," Faber says. Developing the platform itself took about 2.5 years. The first product recognizes and classifies breast cancer cells in tissue samples taken in a fraction of a second. The software received its CE-IVD mark in May 2021. "This made us the first company in Germany with such an approval in clinical routine diagnostics in pathology," says Faber.

Working hard to develop a platform is now paying off for the product portfolio and the development pipeline. "We are now able to release algorithms much faster than before," Faber says. He reckons that one of Mindpeak's greatest assets is the algorithm analyzing the biomarker PD-L1, which is of major importance in the dynamic field of immuno-oncology. Faber says the IVDR and the limited number of Notified Bodies are major barriers now. "That is why we are likely to put only two products on the market in 2023," he adds.

Explainable AI earning the trust of users

The success of AI-based approaches relies on the quality and quantity of the data used to train the algorithm. Having access to tissue slides from partner laboratories is an important asset for Mindpeak in this respect. And there are also a limited number of customers which allow the start-up to train with their data. A network of over 30 pathologists annotate data based on rigid guidelines and create ground truth data to train the AI.

All Mindpeak products "explain" how they made a decision, allowing pathologists to understand and trust it. "We always show what the neural network detected and how it came up with the score." Faber points out that explainability is absolutely necessary to get acceptance for AI-based solutions on the market. Another special feature is what the Mindpeak team calls a zero-click solution. The system pre-processes all the cells on the whole slide with two AIs and the pathologists are presented with all the results when they open the case. "It gives you a good overview and saves a couple of seconds, which doesn't seem like much, but if you know how pathologists work, this is extremely important to the workflow." For example, Mindpeak's customer Unilabs, one of the largest European diagnostics providers, introduced its AI solution to the clinical routine to speed up breast cancer diagnosis and make it more accurate. It recently reported a 90% reduction in diagnosis time with the Mindpeak solution. "They say they are ten times faster and will now make it standard in Sweden."

The start-up is funded by the Innovationsstarter Funds Hamburg (IFH), with support from APEX Ventures, Nina Capital, Motu Ventures, and prominent angel investors. Mindpeak, with a team of 25 employees, has raised 9 million euros so far. "We want to grow our team in 2023," says Faber. Since more than two thirds of revenue come from the business in the United States, Mindpeak is going to open a Sales Office there soon. When it comes to recruiting, Felix Faber says it's helpful that data scientists and machine learning experts show interest in the healthcare market. "With our purpose-driven approach, we are able to attract talent." pg

More information:
www.mindpeak.ai

FELIX FABER is Co-Founder and CEO of Mindpeak (left). Dr Tobias Lang is Co-Founder and CTO of the Hamburg-based start-up.

"CREATING VALUE IN ECOSYSTEMS"

DIGITALIZATION OF HEALTHCARE Dirk Schrödter is Head of the State Chancellery of Schleswig-Holstein and Minister of Digitalization. His team launched the State's AI strategy and oversees its implementation. We spoke to him about how the North of Germany is transforming into an ecoystem for medical AI with international acclaim.

Minister Schrödter, you recently gave your 2019 AI strategy for Schleswig-Holstein an update. Why?

DIRK SCHRÖDTER With its own AI strategy, in 2019 the state of Schleswig-Holstein became a pioneer in Germany. We are receiving a great deal of attention, both nationally and internationally, for how we implement this regionally and how we have developed a clear profile. But we all know: The field is developing at breakneck speed, and we are keeping pace in Schleswig-Holstein. With strategy version 2.0, we are placing even greater emphasis on the applications of AI in areas where the North has clear competitive advantages. In addition to the healthcare industry, these core areas include the field of renewable energies and the blue economy. This should result in growth, value creation and jobs for our state. In total, we are providing more than 45 million euros in implementing the strategy, with further EU funding on top.

Why is the North predestined to develop an AI ecosystem in the healthcare industry?

SCHRÖDTER In Schleswig-Holstein, we already have close links between business, science and government. There is a very active and creative AI scene and the paths to government are short. We have also created good conditions in the competition for attracting the best minds to the region. We are currently filling 12 new AI professorships at universities – the North has developed appeal. The Life Science Nord cluster is an extremely important partner. This strong cluster is something like the DNA or the breeding ground on which we can build an AI-Med ecosystem.

„The strong Life Science Nord Cluster is the DNA, or the breeding ground, of the AI-Med ecosystem."

In the AI medtech ecosystem, the Lübeck area plays a prominent role as a location...

SCHRÖDTER In the Lübeck area, a truly unique network has emerged for the application of AI technologies in medical technology and the healthcare industry. It is shining so brightly, that it is already having an impact far beyond the state's borders. Here, we have initiated more intensive cooperation between research institutions and the private sector, creating very important added value for the state. We need ecosystems of this kind with many players who cross-fertilize each other and create competitive advantages for our region. We are supporting this with 4 million euros.

What role does the public-private consortium KI-SIGS play here?

SCHRÖDTER The KI-SIGS consortium, funded by the German Federal Ministry of Economic Affairs and Climate Action, brings together the most important players from medicine, the healthcare industry and AI in northern Germany and embodies the goals of our AI strategy in the best possible way: High-tech, networked, and agile – and close to clinical application. Over the past few years, a very successful network has been built up, despite the tough COVID years – that's really impressive. We want to keep this momentum going and spread the reach of the network even more broadly in the future. This includes bringing on board other German states such as Mecklenburg-Vorpommern.

How do you plan to embed the AI-Med ecosystem into the GAIA-X European data infrastructure?

SCHRÖDTER The GAIA-X-Med initiative is seeing the creation of a networked data platform to process medical data securely, in a standardized way, and efficiently. We are also investing 4 million euros in this project. GAIA-X-Med is a very important building block in our regional AI-Med ecosystem. Linking this with GAIA-X technologies is forward-looking, as it simultaneously allows us to support the European Cloud Initiative and participate in its further development, while at the same time also creating digital sovereignty.

You are funding several projects related to AI-assisted robotic systems in surgery (see p.16-19 in this issue). What potential do you see here?

SCHRÖDTER AI-assisted robotic systems in surgery open up a huge field of application. It's not just about improving healthcare. We can achieve technological leaps that enable us to become a technology exporter. In surgical robotics, we are entering an innovation gap that can bring us additional value creation. This attracts skilled workers, creates new jobs, and has many other self-reinforcing effects.

Concerning data availability: How do you intend to achieve improvements here?

SCHRÖDTER The question of data availability is absolutely central to the implementation of our AI strategy. We can no longer let health data lie unused in data silos. In recent months, we have developed the cornerstones of a state data strategy through which we want to decisively improve data provision and data availability. It is set to be adopted at the end of 2023. Data provision will become the norm here. In parallel, we are also working on the technical requirements for making data available to SMEs in a machine-readable form. We need a culture of data sharing and data use in Germany, and we want to become a digital showcase region. pg

THE SPIN DOCTOR

AI MEETS MEDTECH Lübeck has developed into a powerhouse for AI-based innovations in medicine and represents the heart of the AI-Med ecosystem in the North. How did it come about?

If you are curious about how to set up and shape a regional network for AI applications in medical technology, it is probably best to talk to Stefan Fischer. The Vice President of **→ Lübeck University**, who is responsible for digitization and tech transfer, is also known by many in the Hanseatic city as the "mastermind of the KI-Med ecosystem". At Lübeck University, Fischer is Director of the Institute for Telematics. "I had never dealt with AI as a researcher, but when the German government published its AI strategy in 2018, here in Lübeck we immediately saw the potential for our medical technology location and got going,"he says.

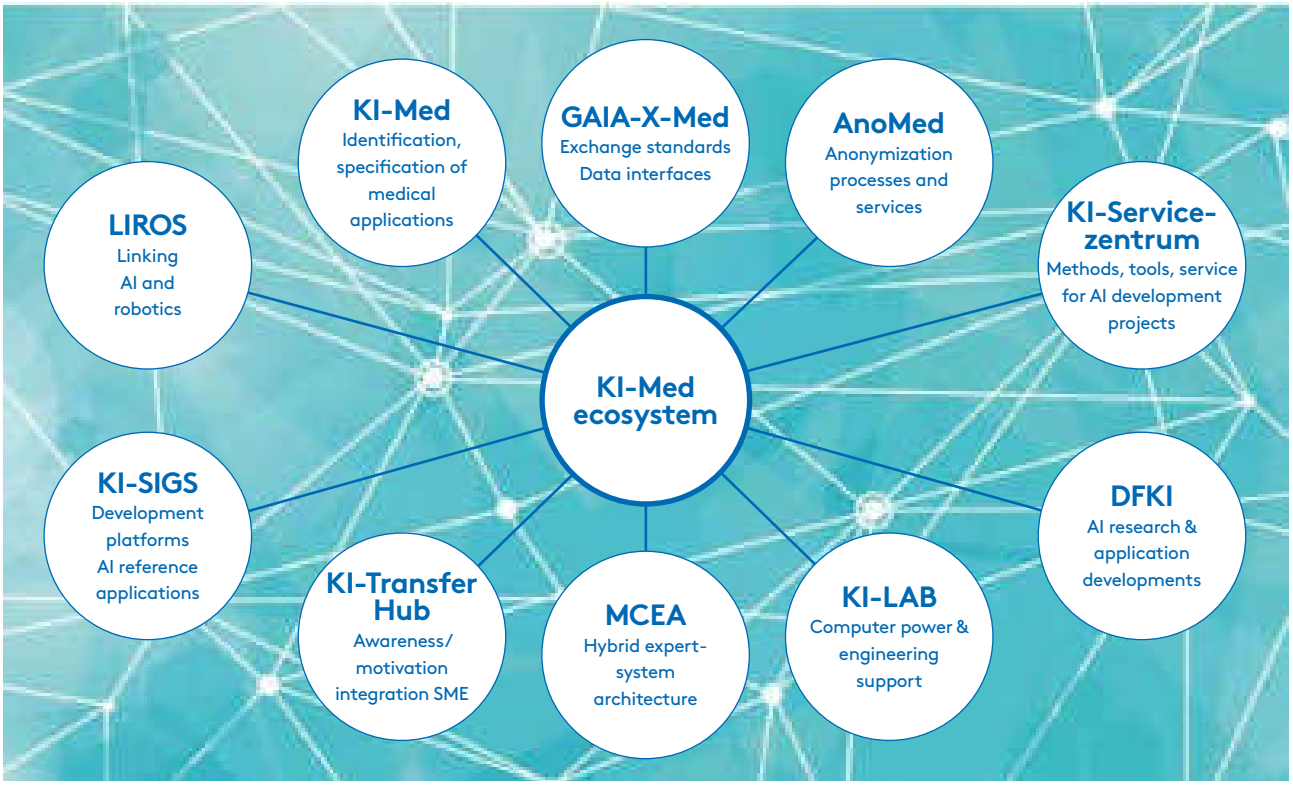
"High density of academic excellence and application partners en masse."

PROF STEFAN FISCHER
VICE PRESIDENT FOR TRANSFER AND DIGITIZATION OF LÜBECK UNIVERSITY

The initial spark

In close collaboration with the team led by Dirk Schrödter, Head of the State Chancellery of Schleswig-Holstein (see interview on page 12), Fischer and his team then got the application for the KI-SIGS (KI Space for Intelligent Health Systems) project off the ground. The project, funded by the German Federal Ministry of Economic Affairs and Climate Action to the tune of 10 million euros, was actually obtained. A huge success.

"That was the initial spark for our regional 'AI-Med ecosystem'," Fischer says. "In parallel, we tried to bring together not only the transfer but also the university's departments of computer science, engineering and medicine even more closely," Fischer says. For an ecosystem to work, it needs the whole diversity of players. And here, Lübeck can draw from a full range. In addition to the high-profile university institutes, there is the , **→ Technische Hochschule Lübeck** and the Fraunhofer institutions **→ IMTE** and **→ MEVIS**, which specialize in medical technology applications research. In addition, it has been possible to establish a branch office ot the German Center for Artificial Intelligence (DFKI) in Lübeck in recent years. "And then, of course, there are application partners en masse in the region who are potential customers for AI solutions," says Fischer. These include the Lübeck campus of the **→ University Hospital Schleswig-Holstein (UKSH)**, but also the industrial landscape, with globally active companies such **→ Euroimmun Medizinische Labordiagnostika** and Dräger or smaller and medium-sized enterprises. For start-ups, TZ Lübeck is an important incubator and there are now also ten multifunctional centers (see infographic on page 39). The funding of new AI professorships at the Lübeck University has also led to the strengthening of teaching and research of project-based AI med ecosystem development. "Even though AI professorships are currently being advertised all over the country, the excellent networking at our university is an ideal basis for getting up to speed. We are receiving good applications," Fischer underlines.



An overview of projects relevant for building up the AI-Med (KI-Med) ecosystem in the North

A perspective for KI-SIGS

As a cross-state consortium, KI-SIGS involves partners from the German states of Bremen, Hamburg and Schleswig-Holstein. "Based on the AI-Med ecosystem, project participants can access nine application projects and a four-part platform. Through input and feedback from the partners into these components of the platform, the know-how grows and thus the ecosystem should be further strengthened," says Fischer. "The cross-border collaboration has worked wonderfully so far," he adds. KI-SIGS will continue to be financed by federal funds until the end of 2023. The collaboration of current and future participants via the KI-SIGS platform components with regard to AI research and the resulting application and product developments is to be consolidated.

The KI-SIGS team headed up by Spokesman Stefan Fischer and Project Manager Martin Leucker, Head of → **UniTransferKlinik** in Lübeck, is already looking to secure for follow-up funding. The partners have developed an application concept for an KI-Med Servicezentrum, in which Mecklenburg-Vorpommern would also like to participate as a new federal state partner. The aim of the KI-Med Servicezentrum is to develop and provide standardized methods and tools as well as professional services for innovative AI development projects.

The state-funded project GAIA-X-MED creates a secure and networked data and service infrastructure using European defined interface and architecture standards as a basis for further scalable AI-Med applications. The technical exchange standards are tested and applied in six real use cases with the participation of companies and the UKSH. Speaking of data availability, the university and its AI-Med ecosystem partners have just secured a new 10-million-euro project, AnoMed, from the federal governmen. It aims to develop data anonymization techniques for medical data.

Success factors

One factor that Fischer reckons is essential for the ecosystem to thrive is the strong commitment of health care providers to collaborative projects. He also sees a need for cross-clinic integration of user experience as well as data availability to achieve broad application scenarios of medical AI applications in diverse technical and process-related application environments. And there is a need for a clear perspective for the commercialization of scalable product developments. Finally, the medical, technical, regulatory, and economic feasibility of medical AI product developments must be clarified early. "Here in Lübeck and beyond, we have created good conditions for this." pg

The LIROS operating theatre at the Fraunhofer IMTE will combine smart imaging, robotics and AI

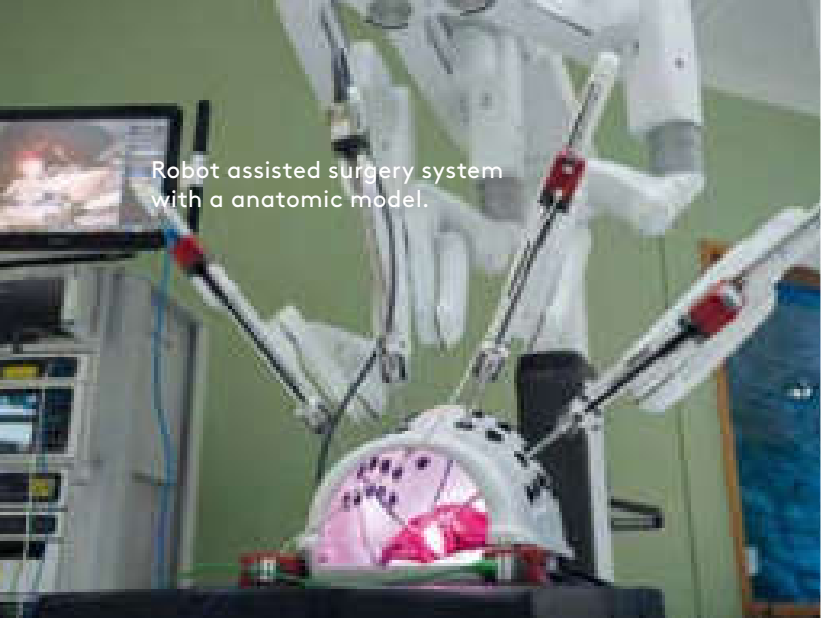
RISE OF THE ROBOTS

AUTOMATION IN SURGERY A number of highly innovative projects in the North of Germany aim at taking robot-assisted surgery to the next level – based on artificial intelligence (AI). In Lübeck and Kiel, researchers, engineers, and clinicians develop and shape the operating theatre of the future.

Robotic surgery is already with us. Instruments such as the industry-leading Da Vinci system by US tech giant Intuitive Surgical, allow surgeons to take control of multiple arms through a hand-operated console, and give them greater dexterity and vision when operating in hard-to-reach areas. But the field of robot-assisted surgical technology is in motion: Since the expiry of Intuitive's patents, new systems from a growing number of manufacturers are now increasingly entering the market. This both enables broader access to this technology and increases the pressure on manufacturers to innovate. Academic researchers, medical technologists and clinicians in Schleswig-Holstein have stepped in this dynamic field. Supported by the state government and EU funding, they want to significantly improve established robot-assisted surgical technology, developing a new generation of medical robots in an era of digitalization and artificial intelligence.

Fully functional operating theater

A visit to the Lübeck-based → **Fraunhofer Research Institution for Individualized and Cell-Based Medical Engineering IMTE**:



Robot assisted surgery system with a anatomic model.

The Kiel surgical robotics team around Thomas Meurer (left)

What currently only exists as a VR simulation will soon be reality: a fully functional operating theatre for robotic surgery. Georg Männel, group leader Training and Automation at IMTE, has brought virtual reality goggles and lets the visitor walk through an impressive simulation of the operating room and the neighboring workshop. In a matter of weeks, the real robots and all the interior equipment will move in here. The operating room is the centerpiece of LIROS, the Lübeck Innovation Hub Robotic Surgery. The project, that Männel coordinates together with engineer Svenja Ipsen, group leader Robotic intervention at IMTE, and Tobias Keck, Director of the Surgical Department at the Lübeck Campus of the → **University Hospital Schleswig-Holstein (UKSH)** was supported with 3.5 million euros by the State government of Schleswig-Holstein through REACT-EU funding (see also interview with Dirk Schrödter, page 12). "We plan to install a two-arm and a four-arm robotic system in our realistic operating theater to simulate the full range of robotic surgical procedures," says Männel. LIROS will at first be a unique research and development platform. It also serves as a medtech test laboratory for the industry. "Our goal is to facilitate technology transfer and offer students and surgeons hands-on training opportunities," says Männel. That's why the Fraunhofer researchers are closely collaborating with the team headed by Tobias Keck, and the Surgical Department at the UKSH. Keck is a strong advocate of robot-assisted surgery and has different systems in use in clinical practice. He is also committed to generating a training curriculum for robotic surgery. Since more robotic devices from different manufacturers are entering the market and smaller scale robotic systems affordable for smaller hospitals are on the rise, training will become even more important. "But LIROS is not just about robotics in surgery, it's the whole surgery process that we are trying to address. Here, we integrate many of the things we're doing at Fraunhofer IMTE and this is based on the interconnection between AI and robotics," says Philipp Rostalski, Director of Fraunhofer IMTE.

Rostalski points out that process optimization and automated training evaluation will play an important role here. For example, a motion capturing system for the entire operating theatre will be used to analyze how the surgical team and the robots move and perform – and these data can be used for process and training innovation. The networking of medical technology devices and the investigation of usability aspects to increase user-friendliness and safety in the operation theatre are also in focus. Within LIROS, the Fraunhofer IMTE researchers are closely interlinked with research partners on campus especially the UKSH, → **Lübeck University,** → **Technische Hochschule Lübeck,** →

DR GEORG MÄNNEL
The Medical engineer is group leader Medical Robotics and Training at the Fraunhofer IMTE in Lübeck.

Fraunhofer Institute for Digital Medicine MEVIS and the DFKI Branch Office Lübeck. But what will the patients treated by the surgical robots look like? "Our 'patients' will be individual anatomical models and phantoms made by 3D printing at the Fraunhofer IMTE," Rostalski says (also see page 30 in this issue). They will be prepared in a room right next to the operating room. "We will really have a high-tech operating tract here at our institute, matched by a similar setup in the UKSH. This ensures a smooth transition between research and clinical practice."

Surgical assistants in Kiel

Printed or virtual models in 3D also play an important role in a robot-assisted surgery developed at the Kiel Campus of the UKSH. The project entiteled "Operation room of the Future" is like the LIROS project financed by the state government via the REACT-EU funding scheme (budget: 3.4 million euros). In Kiel the surgical disciplines are closely networked in minimally invasive and robot-assisted procedures under the umbrella of the Kurt Semm Center, which is coordinating the project. → **Kiel University** and the companies Vater Solution and → **MiE Medical Imaging Electronics** are also involved.

The OR of the future focuses on two subprojects that are expected to improve surgery in the foreseeable future: one is a so-called AI-based augmented reality solution for even more targeted and gentle tumor surgery. The developed software will help to visualize the conspicuous areas from PET-CT imaging directly in the live surgical image or provide the surgeon with a navigation aid. Augmenting the image information from computed tomography will not only provide surgeons with enhanced information about the surgical area, but also provide 3D navigation support. This procedure is expected to help identify tumor-positive lymph nodes and other tumor structures more easily during surgery. "The high-precision registration and visual overlay of 3D tumor positions from the CT into the live image supports surgeons during the operation and allows them to identify and remove tumor tissue as quickly and safely as possible. This reduces the duration of the operation and the stress on patients," explains Reinhard Koch, who is responsible for the first subproject at the Faculty of Engineering of Kiel University.

Prof Philipp Rostalski
Director Fraunhofer IMTE

Prof Reinhard Koch
Dean Faculty of Engineering Kiel University

Dr Svenja Ipsen
Group leader Robotic intervention at Fraunhofer IMTE

Prof Tobias Keck
Director Surgical Department at UKSH Lübeck

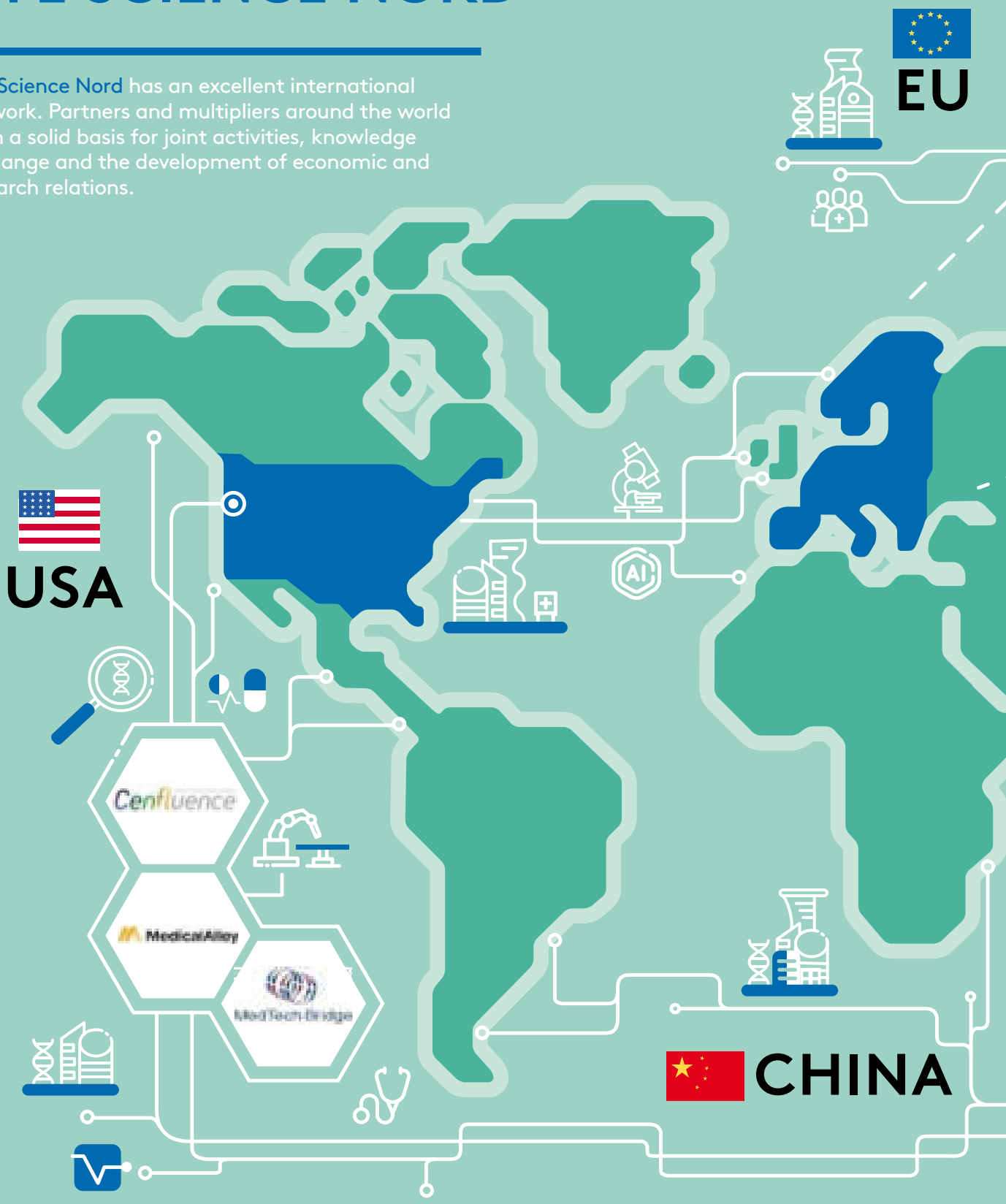
The second subproject coordinated by robotics specialist Thomas Meurer deals with the development of an AI-based robotic assistance system to optimize workflows and infection control in the OR. Until now, current surgical robots consist only of a system that is remotely controlled by the surgeon via a console. Operating room assistants support the surgeons, but work directly on the patients by hand with the necessary instruments. The technology currently being developed will enable a two-arm assistant robot. For the patients, this should make the operation more precise, infection-proof, faster and gentler. This may shorten the healing time compared to conventional open surgery procedures. Sensors and AI ensure that the two robotic arms do not interfere with each other in the process. At the same time, the surgeons' instruments, such as clamps, must remain in position during all assistance work.

A robot with open interfaces

Both research consortia in Lübeck and Kiel have decided to cooperate closely and help to make Schleswig-Holstein a key site for research and development in robotic surgery. This is exemplified by the use of an upcoming robot platform based on a novel surgical robot called Dexter, which has been developed and commercialized by Swiss company Distalmotion. The system has open interfaces and offers the experts an optimal platform for the development and testing of innovations. "We want to democratize surgical robotics and make them affordable for smaller hospitals," says Klaus Feldmann, Sales Director Germany. The connection to hospitals in North Germany is so promising that Distalmotion has opened its German office in Hamburg. Philipp Rostalski, who is also a member of the board of Life Science Nord e.V. says: "I'm convinced that the Kiel-Lübeck-Hamburg axis has enormous potential in the field of surgical robotics. There is potential for an ecosystem, which I will also try to strengthen and establish as a focus for research and development in the Life Science Nord cluster." pg

WORLDWIDE NETWORK OF LIFE SCIENCE NORD

Life Science Nord has an excellent international network. Partners and multipliers around the world form a solid basis for joint activities, knowledge exchange and the development of economic and research relations.



Medtech Cluster Alliance D-A-CH
The Alliance is an association of cluster organizations, networks and initiatives in the medical technology industry. The Alliance consists of ten German, five Austrian and one Swiss partner. It shapes an innovation and economic region with several thousand medical technology and research partners. The aim of the Alliance is to strengthen the European economic area of the D-A-CH region in terms of international competition.

CEBR
The Council of European BioRegions (CEBR) is a member-driven network of bioscience clusters and regional ecosystems across Europe, representing more than 40 members and hundreds of cluster partners around the world. Thus, CEBR represents and supports a crucial number of SMEs as well as hundreds of universities and research centers.

"All our international activities aim at being broadly positioned in the European and global core markets in order to ensure optimal visibility of our Northern German players. In parallel, we have been building resilient bridges to networks, institutions and multipliers worldwide for many years. We are looking forward to expanding existing partnerships and to establishing new ones."

Sarah Niemann,
Manager International Affairs, Life Science Nord

ANDRÉ SCHULTE
For the CEO of Weinmann Emergency, new developments of the company must meet three criteria. "They must be quickly ready for use, easy to operate and thus ultimately help the patient."

top left and right: Handmade in Germany: production at Henstedt-Ulzburg

top middle: From Hamburg into more than 120 countries: Weinmann Emergency Headquarters

below: Weinmann Emergency equipment in use at the Johanniter air rescue service

WE SIMPLIFY SAVING LIVES

GUEST ARTICLE Weinmann Emergency Medical Technology, family-owned since 1874, has developed into a world leader in a niche market. The company intends to continue growing and is committed to the North and the City of Hamburg.

Weinmann Emergency is an internationally active, family-owned medical technology company. With transportable solutions for emergency, transport and disaster medicine, it sets standards in saving lives. In close cooperation with professionals from emergency medical services, hospitals and army medical services, the employees in Hamburg develop innovative medical products for ventilation, monitoring/defibrillation and data management. Anyone who saves lives in emergency medicine, accompanies intensive care transports or provides assistance in disaster areas knows and trusts Weinmann Emergency. For almost 150 years, Weinmann Emergency has been offering customers the highest level of reliability, quality and experience.

"We see particular growth potential in telemedicine and the digital networking of products."

ANDRÉ SCHULTE

Weinmann Emergency equipment meets the highest demands even under extreme conditions – of course in certified quality. The ventilators and products in the area of monitoring/defibrillation are just as suitable for emergency use as they are for transporting intensive care patients indoors by sea, land and air or even within hospitals. Because the products are so robust, medical services of armies and civil protection all over the world have been relying on Weinmann Emergency for decades.

Many employees at Weinmann Emergency have their own experience from rescue services, disaster control or hospitals, which they use in their daily work. However, the most important impulses for our innovative product developments come from users in the field of emergency medicine. Weinmann Emergency is in close contact with professionals from rescue services, hospitals and armies and speaks their language.

Current trends in medical technology do not stop at Weinmann Emergency. The company sees particular growth potential in telemedicine and the digital networking of products. To achieve this, the products must learn to communicate with other devices, with digital deployment documentation systems, and with platforms used by the emergency medical services, for example, for device management.

However, Weinmann Emergency focuses not only on the products, but also on the appropriate service – no product is sold without a local service partner who can carry out repairs and maintenance. A fleet of mobile service vehicles has been on the road in Germany for 20 years. This makes it possible to help German customers quickly and easily – the rolling workshop is unique. The model has already set a trend beyond Germany's borders: service vehicles are also in operation in Austria, France and Spain. International service partners are regularly trained and certified. This is a prerequisite for performing service on the life-saving devices.

Weinmann Emergency currently employs just over 300 people from its Hamburg location and intends to continue growing. "We have a great need for experts, especially in the areas of IT, digitalization and software development," says André Schulte. The move to a new company building in Hamburg Bahrenfeld is scheduled for 2026, a clear commitment to the North and the Hanseatic City of Hamburg. "Our employees are our most valuable asset," says André Schulte. To keep it that way, events and campaigns are planned with the company's own WEcommunity, in which the management is closely involved. "Regular communication and exchange at eye level with our colleagues is very important to us. The 'We' in our slogan is just as important internally as it is in our collaboration with customers and partners. We like to compare this with the work in the rescue service: alone it is difficult to save a person, together it looks quite different."

More information:
www.weinmann-emergency.com

The Provirex team (from left): Co-Founders Oliver Ahnfeld, Niklas Beschorner, Maike Voges and Jan Chemnitz.

HIV GENE-EDITING THERAPY HEADS TO THE CLINIC

MOLECULAR MEDICINE Provirex' innovative genome editing therapy enables the elimination of persistent viral genomes from infected cells. The start-up is building a therapy hub in the future Science City Hamburg Bahrenfeld.

Even though enormous advances have been made in HIV treatment, the disease is still not fully curable. Nowadays, the propagation of the virus in the body can be held in check through medication, but the viral DNA (the provirus) remains present in body cells where it integrates in the genome.

> **"The recombinase performs high precision genome surgery without any errors."**
>
> DR JAN CHEMNITZ
> CO-FOUNDER AND CEO OF PROVIREX

By translating a powerful genome editing approach into clinical application, Hamburg-based start-up → **Provirex Genome Editing Therapies** aims at revolutionizing the way HIV is treated – and even cured. The spin-off of the Leibniz Institute of Virology (LIV) is now preparing at Start-up Labs Bahrenfeld at → **DESY** for a publicly funded clinical trial at the → **University Medical Center Hamburg-Eppendorf (UKE)**. Thanks to the support of two investors in 2022, they are now building up a large space at the emerging Science City Hamburg Bahrenfeld to establish a therapy hub.

The star of Provirex' genome editing approach is a designer recombinase called Brec1. This enzyme is a programmable biomolecular scalpel that finds its target site in the genome and cuts out pieces of DNA with unparalleled precision. "Our recombinase works completely different than nucleases like CRISPR-Cas9, as it performs the complete genome surgical process without any errors or unwanted mutations left behind," says Jan Chemnitz, one of the founders and CEO of Provirex. He was part of the research team developing the technology which is based on a long-term collaboration between now retired Professor Joachim Hauber and his team at LIV and Professor Frank Buchholz at the Technical University of Dresden. The company's broad technology and patent portfolio was built up over a period of more than 15 years in the participating research institutes and exclusively licensed to the company with

the support of → **Ascenion** as a technology transfer partner. Having the recombinase technology ready for clinical application is perfectly aligned with a biopharma sector that enjoys a booming field of gene and cell therapies. But getting to this point proved to be challenging for the innovators in Hamburg. Initially, some of the scientific community was skeptical about the feasibility of the approach, and investors' interest in the clinical translation of the Brec1 technology was low. "We were ten years ahead of our time," says Oliver Ahnfeld, co-founder and CEO of Provirex.

Public funding and relentless institutional support from LIV have enabled the researchers to go on and show that the technology is safe and efficient in animals, and to prepare the groundwork for clinical trials in humans. One major milestone was a publication in the acclaimed journal "Nature Biotechnology" in 2016. In this paper, the team demonstrated that Brec1 was capable of specifically removing the provirus from the infected cells of most primary HIV-1 isolates. "It means that 94% of HIV patients can be treated with our approach," says Chemnitz. With these promising results in hand, the LIV team started fundraising and successfully applied, with the UKE, to the Federal Ministry of Education and Research (BMBF) for multi-million euros' worth of funding. The financial support would be used for a clinical trial named HIVCure. The Hamburg Senate invested another million euros for developing tools needed for the study. HIVCure, a first-in-human phase Ib/IIa clinical trial, is supposed to start recruiting at the UKE at the end of 2023. It aims to remove HIV-1 from infected subjects using gene editing of the patient's peripheral blood stem cells. "The retransplanted engineered blood stem cells build up an immune system that is now resistant to HIV," describes Chemnitz. He says Provirex also conducts research on the direct delivery of Brec1 by molecular ferries.

New investors and new headquarters

The start-up was founded in 2019 thanks to seed funding from the City of Hamburg. It received another major boost last year when venture capitalist Bioventure Management and IFB Innovationsstarter invested in the enterprise. "This investment will provide financial security for the company over the next four years and help to build a therapy hub in the future Science City Hamburg Bahrenfeld," says Ahnfeld. In 2024 the new lab, occupying an area of about 500 sqm, is due to be finished. In specially designed cleanrooms, advanced therapy medicinal products (ATMPs) will be produced, while meeting the safety standards for working with human viruses. "In the long term, we will be able to offer any type of personalized medicine for people living with HIV (PLWH) and will be among the first companies worldwide to do so," says Ahnfeld. dpd/pg

More information:
www.provirex.de

Provirex' current site at the Start-up Labs Bahrenfeld at DESY.

The illustration shows how the recombinase Brec1 cuts the HIV provirus from the genome of a T cell.

MORE LAB SPACE FOR TOP-NOTCH BIOANALYTICS

CONTRACT RESEARCH The global CRO BioAgilytix is expanding its facilities at the European headquarters in Hamburg.

Biotherapeutics – or biotechnologically produced drugs – are playing an increasingly significant role in the global pharmaceutical marketplace and account for nearly half of all new drug approvals. Their development is supported by contract research organizations (CROs) such as → **BioAgilytix Europe**, which provide pharmaceutical industry and biotech companies with bioanalytical services from early discovery to market entry.

In 2016, BioAgilytix established its European headquarters in Hamburg. Starting out with only 20 members of staff, the location has been increasingly successful and now accommodates 120 employees. Over the last year, the company made significant investments expanding the office and lab space on site. "The expansion supports our customers' growing need for large molecule bioanalysis," says Frank Horling, Managing Director of BioAgilytix Europe. The CRO has five additional laboratories worldwide: three in the United States and two in Australia. The site in Hamburg is specialized in bioanalysis for preclinical and clinical development of biotherapeutics. A team of highly experienced scientific staff and QA professionals offers services for biomarker, immunogenicity, pharmacokinetics and cell-based assays according to GLP and GMP standards.

> **"We are committed to advancing new biologic products."**
>
> DR FRANK HORLING
> GENERAL MANAGER, BIOAGILYTIX EUROPE

By almost doubling the lab space to approximately 1,200 sqm, several additional state-of-the-art technology platforms can be accommodated. New equipment for quantitative and digital PCR will expand the existing service portfolio and support the development of novel gene and cell therapies. "Our customers will benefit from the greater capacity and flexibility on site. Like them, we are committed to advancing new biologic products that can change and safe lives," says Horling. dpd

More information:
www.bioagilytix.com

Evotec's cell therapy manufacturing site in Modena

Automated iPSC-based cell screening plattform

The "Lighthouse of iPSCs" is constructed by 2024.

CELL-BASED DIABETES CURE

REGENERATIVE MEDICINE A beta cell replacement therapy jointly developed by Evotec and Sernova is progressing towards the clinic.

In type 1 diabetes, insulin producing beta cells, which are normally found in cell clusters (islets) in the pancreas, are destroyed by an errant immune system. A potentially game-changing approach relies on replacing the beta cells in the patients' body. Pluripotent stem cells allow the creation of these cells in the lab — providing an almost limitless supply of replacement cells. Hamburg-based → **Evotec** has built a unique drug discovery and cell therapy platform that is based on induced pluripotent stem cells (iPSCs). It involves the generation of various iPS cell lines and their controlled differentiation into medically relevant cell types, either for drug screening as human disease models, or for therapeutic use – including GMP production of clinical-grade material. Evotec's iPSC-based beta cell replacement program has now made big steps in bringing this innovative treatment to the clinic. In January 2023, Sernova Corp., a regenerative medicine company based in Canada, announced significant progress in its collaboration with Evotec.

Over the past years, Evotec has successfully generated an iPSC-derived product consisting of islet-like cell clusters containing a high fraction of beta cells. Under the partnership, Evotec's iPSC-derived islet-like cell clusters are combined with Sernova's implantable device called Cell Pouch. It is an implantable and scalable medical device for long-term survival and function of therapeutic cells. Evotec and Sernova aim to produce an off-the-shelf, commercially viable, ethically derived cell therapy treatment for insulin-dependent diabetes. The preclinical R&D is so promising that the jointly developed therapy is now progressing towards a first-in-human Phase 1/2 clinical trial for the treatment of patients with type 1 diabetes. The regulatory filing is slated for 2024. Cord Dohrmann, Chief Scientific Officer of Evotec, says: "The combination product is highly differentiated through the quality of the cells and the device but also the scalability of the manufacturing process of the iPSC-derived cells and therefore clearly positioned to become the best-in-class cell therapy in the field." Meanwhile, Evotec continues to expand its iPSC-based activities. The company has established a dedicated, high-quality cGMP cell therapy manufacturing site in Modena, Italy. A dedicated and growing process development and scale-up team is located at the Evotec site in Goettingen, Germany. Further, a new 12,000 m² lab building is being constructed by mid-2024 on the Hamburg-based Manfred Eigen Campus. Dubbed the "Lighthouse of iPSCs", the new space will provide room for up to 250 additional employees. pg

More information: www.evotec.com

Testing the effects of surface disinfectants on antibiotic-resistant bacteria.

EFFECTIVE AGAINST OUTBREAK STRAINS

APPLIED HYGIENE Initiated by the Life Science Nord Cluster, the HIHeal consortium brings together infectious disease experts from across the North. One outcome with high impact for applied hygiene is an evaluation of disinfectants with regard to antibiotic-resistant outbreak strains isolated in the University Medical Center Hamburg-Eppendorf (UKE).

The steady rise of bacterial strains that are resistant to antibiotics poses a significant threat to humanity. Since these microbes have shown their ability to adapt to the clinical environment, one obvious question is: Are disinfectants used in routine hygienic measures still working against these bugs? "We regularly receive customer enquiries as to whether our disinfectants are also effective in the presence of MRSA or other antibiotic-resistant bacteria," says Johannes Lenz, Manager of the Microbiology and Hygiene Department at chemicals manufacturer **→ Chemische Fabrik Dr. Weigert**. Disinfectants kill bacteria through a variety of mechanisms that are completely different to antibiotic agents. "So we can always confirm efficacy of our products. However, we want to provide users with scientific proof," Lenz points out.

Clinically relevant bacterial strains

"Another question is: are the European reference bacterial strains we use for efficacy testing in the lab still reflecting what's going on in the real world?," says Florian Brill, Owner and Managing Director at **→ Dr. Brill + Partner Institute for Hygiene and Microbiology,** an independent testing laboratory based in Hamburg.

The two pressing questions on efficacy were addressed and answered by a successful joint project within the Hygiene, Infection & Health (HIHeal) network coordinated by the Life Science Nord cluster.

"The beauty of this project is that we used clinically relevant strains for the efficacy testing," says Brill. Medical microbiologist Johannes Knobloch's team at → **University Medical Center Hamburg-Eppendorf (UKE)** provided antibiotic-resistant bacteria strains that caused clinical outbreaks within the last couple of years at the UKE and other German hospitals from their collection. This club of notorious hospital germs consisted of strains from species such as *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Klebsiella pneumoniae*.

Disinfectants doing their job

In the study the effectiveness of four surface disinfectants, two agents from disinfection manufacturer → **Bode Chemie** and two agents from Dr Weigert were tested in the companies' own labs and the lab of Dr. Brill + Partner. The results were reassuring: All four surface disinfectant agents perfectly did their job and worked effectively. The researchers also did not observe any shift in the effective concentration of disinfectants. "Another conclusion is that the reference strains from European norms still represent the current clinical antibiotic resistant bacterial community," says Brill. He is convinced that the validation and generation of solid data can support and update international databases of disinfectants and several lists of disinfectants in Germany.

The project team is now writing up the results and is to publish the paper in a scientific journal. Just how interesting the data are for the scientific community became clear at the Conference of Applied Hygiene, Microbiology and Virology (CAHMV) at the end of November 2022 in Hamburg. "It was obviously the conference talk with the most questions and we had a lively debate," remembers Brill. His company is the main organizer of the annual conference.

One possible next step in the project would be including more disinfectants in the testing. "One could also imagine other testing scenarios – for example on surfaces instead of in suspension," Brill explains. He hopes to have more scientific groups and partners join the quest.

Dr Florian Brill
Owner and Managing Director Dr. Brill + Partner

Dr Johannes Lenz
Manager Microbiology and Hygiene Department at Chemische Fabrik Dr. Weigert

Juliane Worm
Director Innovation & Technologies at Life Science Nord

According to Brill, the project has also exemplified the strengths and opportunities of the HIHeal network that was established back in 2016. "By connecting different stakeholders from private industry, clinics and academia, we are able to set up joint projects which would otherwise not have been started," states Brill. His company in particular acted as a platform and intermediary between the more scientifically oriented experts in the hospitals and universities on the one hand and the private companies on the other. "Many of the industrial players are also competitors in certain areas. Normally they would not intend on joining such a project. However, under the umbrella of HIHeal, it's easier to collaborate and bring relevant experts together," he says.

In this way, the network actively helps to establish sustainable connections across the infectious disease and infection prevention ecosystem in the North. The disinfectants efficacy testing project also presented some confidentiality issues that had to be solved. "Everybody was open to solving these challenges because we were all interested in the outcome and in the science behind it," explains Brill. The collaborative spirit was also what Johannes Lenz from Dr. Weigert particularly liked about this HIHeal project: "The cooperation between disinfectant manufacturers, testing laboratories and users is a very good example of how practical solutions can be developed hand in hand."

Networking perspectives

Juliane Worm, Director Innovation & Technologies at Life Science Nord, who has been responsible for HIHeal, is not only happy with the outcome of the respective project, but also thrilled with the fruitful networking that goes on. "The HIHeal activities will receive one more year of funding from the Hamburg Department of Economics, Transport and Innovation (BWI) in 2023," Worm says. "This is great news for the many areas dealt with by this project." pg/mm

More information:
www.lifesciencenord.de

3D PRINTING MEETS MEDICINE

PRECISION MEDICINE 3D printing is profoundly shaping the future of medicine and healthcare. Researchers in the North combine artificial intelligence with state-of-the-art additive manufacturing technologies and develop bioresorbable materials and innovative bioprinting techniques to take precision medicine to the next level.

"Patients are no longer going to adapt to their treatment, but the treatment is going to adapt to them."

DR THOMAS FRIEDRICH
HEAD OF ADDITIVE MANUFACTURING AT FRAUNHOFER IMTE

In dentistry, the 3D printing revolution is already routine: patients benefit from individualized implants produced by additive manufacturing (AM) – or 3D printing – technologies. Many dental practices use their own 3D printers to manufacture dental crowns or bite splints. In the future, this technology will gradually move into clinics and enable the production of precise anatomical models and individualized surgical implants. "Nowadays, patients are well informed and demand the highest quality of care. They don't want off-the-shelf products, which don't fit their needs. I think that in the future, patients are no longer going to adapt to their treatment, the treatment is going to adapt to them," predicts Thomas Friedrich, Head of Additive Manufacturing at the → **Fraunhofer Institution for Individualized and Cell-Based Medical Engineering (IMTE)** in Lübeck.

Through a combination of their long-standing expertise in cell biology and AM, since 2020 researchers at the new institute have been working towards shaping the future of precision medicine by advancing medical products such as surgical implants. One area of focus that bridges these two competencies is research at the interface between implants and the body. "We want to understand how the surface of an implant, and its structure in particular, influence the ingrowth behavior of cells or the risk of rejection and infection. This research will help to improve the longevity of implants and reduce the need for a second operation," summarizes Friedrich. AM technologies developed at Fraunhofer IMTE allow the surface of a material to be shaped on nanometer and micrometer scale, which is ideal when it comes to studying the growth of cells or organoids.

Fraunhofer IMTE and its partner, the → **University of Lübeck**, accommodate more than twenty 3D printers, which mainly use polymers – or plastic – as a starting material. Some of these printers produce anatomical models for training medical professionals. These allow surgeons to practice challenging interventions such as the treatment of aneurysms or stroke in realistic environments, before moving on to patients. Additional printers using titanium feedstock will soon be available to enhance the study of the surface properties of titanium implants. But researchers at IMTE also look further into the future when it comes to the most suitable implant materials: "I believe that one day, no patient will want to have a foreign body implanted, if an organic, living implant that integrates seamlessly into the body were available as an alternative," says Friedrich.

Bioprinting is a budding technology that will take patient-specific implants to a completely new level. By using a patient's living cells to manufacture 3D implants such as tissues or even organs, the risk of rejection can be minimized and the long wait

PILLS FROM THE PRINTER

A team of pharmacists of the hospital pharmacy at the University Medical Center Hamburg-Eppendorf (UKE) has developed a novel process for 3D printing of medication with individual, patient specific dosage. Michael Baehr, head of the UKE hospital pharmacy, explains the potential of this innovation: "This process offers the possibility to manufacture drugs with a narrow therapeutic range individually while adjusting the required quantity and dosage. We are convinced that printing of medicines will make an important contribution to precision medicine and patient safety." Together with UKE-informaticians the team is working on improvements that will allow automation and integration into the UKE's existing digital medication process. In the future, AI might analyze movement patterns collected by wearables to calculate the individual dosage for patients with Parkinson's. The project is funded by the EU with around 650,000 euros.

for donor organs might eventually become a thing of the past. At Fraunhofer IMTE, researchers are currently developing tools for printing blood vessels.

Vascular surgeon Rouven Berndt from Kiel has already made major advances in this field. He and his team at **→ University Hospital Schleswig-Holstein (UKSH)** have developed a prototype of a 3D bioprinter to create fine blood vessels – only three to four millimeters in diameter – for use as bioartificial vessel or bypass implants. Funded by a grant from the German Heart Research Foundation, the team has investigated how the printing process and mechanical properties of the material affect its suitability for the intended application. "We have recently submitted a publication in which we demonstrate that the vessels are durable and robust enough for use as bypass implants. For a first proof-of-concept, we are now testing their performance after implantation in animals. This will also help us to understand the biodegradability of the material in vivo," summarizes Berndt.

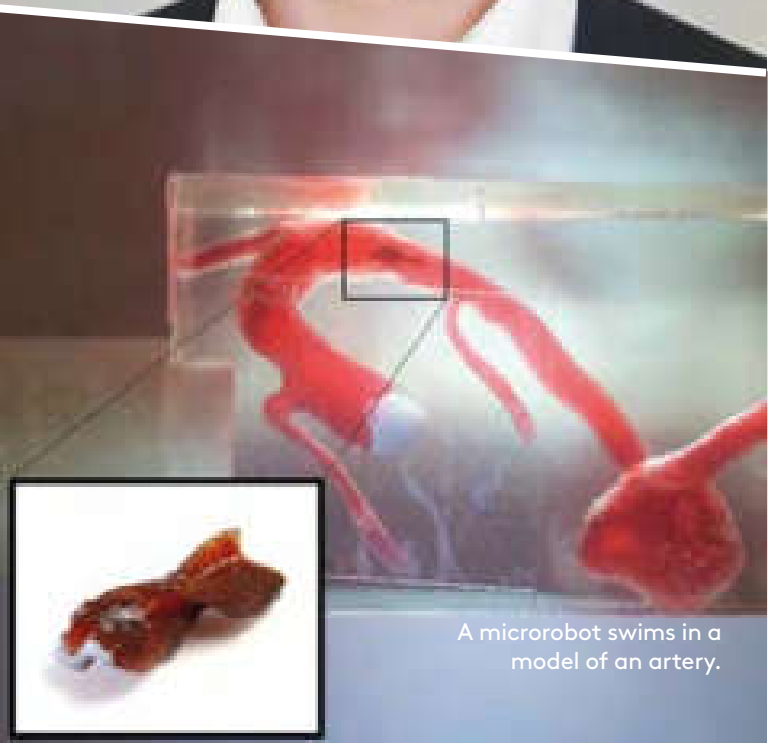
The team has patented the bioprinting strategy and the production of its own bio-ink – a gel containing brown alginate, collagens, elastin and endothelial cells – as well as the prototype of the printer. "Our next goal is industrialization of the process. Implementation according to industry standards will require a robotic platform, therefore we are currently in regular contact with a suitable industrial partner." In the future, the UKSH is going to further expand its research activities in the fields of bioprinting and tissue engineering: "Together with other research groups, we are planning to establish a core facility for tissue engineering and bioprinting to explore the opportunities for printing tissues and organs such as heart, kidney or bones," explains Berndt.

Bone implants made by AI

Artificial intelligence (AI) is gradually transforming the health care sector and combined with 3D printing, it might revolutionize the way patient-specific implants are produced. With experts in AM and AI working under one roof, the **→ Fraunhofer Research Institution for Additive Manufacturing Technologies (IAPT)** is the perfect place to merge both technologies. In 2021, Fraunhofer IAPT researchers entered a collaboration with medical experts at the **→ University Medical Center Hamburg Eppendorf (UKE)** and **→ Helmut Schmidt University (HSU)**, to develop an AI-based, fully automated process for designing and producing personalized implants. Their project DigiMed pursues three main goals: "With the use of AI algorithms, we want to speed up the production of 3D printed implants, while lowering costs and improving implant quality," summarizes Phillip Gromzig, project leader of DigiMed at Fraunhofer IAPT. By now the team has significantly reduced production time for implants, which will save valuable time for accident victims: "Conventional 3D printed implants are designed manually and

Magnesium alloy as starting material for 3D printing.

Fraunhofer researcher Phillip Gromzig



A microrobot swims in a model of an artery.

manufactured by external service providers who must ship the product to the clinic. By using AI, optimizing manufacturing, and combining all these processes under one roof, we have decreased production time from nine to three days," summarizes Gromzig. So far, the collaboration team has focused on the production of orbital implants. These wafer-thin titanium plates are used to treat injuries of the eye socket. In the future, many other bone injuries could be treated using the AI-based workflow developed at Fraunhofer IAPT, and the team has shown that it can be integrated in hospitals or enterprises. "We have demonstrated that the implants are safe and produced in line with the current Medical Device Regulation (MDR). However, legal barriers remain, as it is not yet certain who is liable should AI make a mistake," says Gromzig. Two AI-algorithms are at the heart of the DigiMed workflow: one analyzing CT scans of a patient's anatomy and the other designing the virtual implant. "This technology could cause a paradigm shift in the production of personalized implants, with great added value for patients, whose time in hospital will be shortened significantly. Therefore, our next goal is to bring the workflow into the clinic," adds Gromzig.

Magnesium – biomaterial of the future

Further improvements for patients with bone injuries can be expected of research into highly innovative, bioresorbable implant materials like magnesium. Down the corridor at Fraunhofer IAPT, Kevin Janzen is working on a novel 3D printing process using magnesium alloys as a starting material. "Unlike titanium, magnesium has the advantage that it decomposes inside the body. Therefore, bone implants don't have to be removed in a second operation," explains Janzen. For project BioMag3D, the engineers optimize the process of sinter-based Additive Manufacturing of magnesium, in which printed parts undergo a heat treatment.

"One advantage of this technology is that it allows us to build hollow structures into the implant. These help us to control the rate of degradation and thereby aid the healing process," adds the mechanical engineer. But using magnesium also has its downsides. Firstly, its chemical properties complicate 3D printing and secondly, hydrogen gas builds up as the implants decompose. To tackle these issues, the Fraunhofer researchers are closely collaborating with engineers at the **→ Helmholtz-Zentrum hereon** in Geesthacht to optimize the properties of the feedstock. Within the next three years, the team will test the properties of their implants in petri dishes, before *in vivo* experiments take place. Janzen estimates that it will take at least ten years until the first 3D printed magnesium implants produced with this method enter the clinic: "Our technology is still very new, but we are in regular contact with medical staff at the UKE and the BG Hospital Hamburg to develop implants for the treatment of complicated bone fractures of the arm," explains Janzen. dpd

The technology enables the imaging of cancer biomarkers in the blood in many colors.

TUMOR BIOMARKER TRACKERS

LIQUID BIOPSY A Fraunhofer team has developed a sensitive method based on nanoparticles for detecting biomolecular traces of breast cancer in the bloodstream in real-time. The approach could give a boost to the field of liquid biopsy.

When a tumor forms in the body, a tiny number of cancer cells or their products such as proteins and DNA, enter the bloodstream. There are various advantages to detecting these biomolecular traces and cells circulating in this bodily fluid compared to performing a classical biopsy of tumor tissue. Most importantly, the liquid biopsy approach is less invasive, since only a small amount of the patient's blood needs to be drawn. Furthermore, the findings are available within a matter of hours, meaning that the process can be adapted based upon current information about the status of the patient at any given time during their treatment. "We expect that with liquid biopsy, medical staff would be able to determine whether a treatment is successful, as well as find early-stage breast cancers more quickly and in a gentler manner, which is of great advantage to the patient," explains nanomaterials expert Neus Feliu Torres. Since 2020, Feliu Torres has been leading the working group "Nanocellular Interactions" at the Center for Applied Nanotechnology (CAN), a research division of the **→ Fraunhofer Institute for Applied Polymer Research (IAP)** in Hamburg. With her team, she combines liquid biopsy with nanotechnology to improve the sensitivity and specificity of this emerging diagnostic approach.

In the LIBIMEDOTS project the team is working together with researchers at the University of Hamburg and the **→ University Medical Center Hamburg-Eppendorf (UKE)** (with liquid biopsy pioneer Klaus Pantel on board) and the Spanish University Rovira i Virgili. The purpose of this collaboration is to work on detecting, gathering, and examining biomarkers of breast cancer in the blood-

LIQUID BIOPSY HOTSPOT

The Life Science Nord Cluster, and here in particular the Hamburg region, represents a highly active region in the area of liquid biopsy approaches for cancer diagnostics. A recent publication of the biotechnology sector association BIO Deutschland identifies the folllowing players with important research and development activities in the field:

- Asklepios Tumorzentrum Hamburg
- Fraunhofer IAP/CAN
- Indivumed
- Medical Center Hamburg-Eppendorf (UKE)

More information:
www.biodeutschland.org

stream. The Fraunhofer researchers use magnetic nanoparticles that help to detect and target the tumor cells. They can then dock onto the cancerous cells or their cell products and be concentrated in a magnetic field, thus allowing the tumor cells to be closely examined. The second step of the procedure consists of decorating those cells with a wide range of fluorescent particles that are also specialized to target specific cell types. The fluorescence and its patterns can then be measured and analyzed to detect what type and degree of cancer the patient has. Liquid biopsy has been studied for years now and many labs are making progress in the cancer field. However, the FDA-approved method currently on the market is using only a limited amount of one or two fluorophore markers. "What sets our project apart is that we are testing a wide range of different kinds of fluorescent particles. This allows for multiplexing, meaning that different fluorescence signals can be detected simultaneously," says Feliu Torres.

Nanoparticles as signal enhancer

She points out that the use of nanoparticles is especially valuable for signal enhancement. The team is designing a variety of distinct particles with the capability to bind with specific types of tumor. This will improve the sensitivity, specificity, and speed of the detection process, as well as making it more cost-effective. Although focusing on the detection of breast and prostate cancer, the project is aiming to expand their particles' abilities to detecting any cancer that releases biomarkers into the blood stream. But cancer doesn't have to be the limit, says Feliu Torres. "Our particles could be widely used in medicine, as a diagnostic system, but also as a drug delivery agent," the bionanotechnologist says. She hopes to find more collaboration partners from the industry. "Our particles can be of service in many more nanomedical applications." mm

DR NEUS FELIU TORRES leads a working group at the Fraunhofer Center for Applied Nanotechnology CAN in Hamburg. Born in Spain, she received her doctorate from the Karolinska Institute in Stockholm.

CHRISTIAN GERLOFF Brain imaging specialist Christian Gerloff has taken on the top job as Medical Director of the University Medical Center Hamburg-Eppendorf (UKE). He is keen on shaping the future of one of the most modern hospitals in Europe with more than 14,000 employees. His major aims include driving forward the process of digitalization and the future development of the campus. He also aims to promote the concept of artificial intelligence (AI)-assisted medicine.

Christian Gerloff has put up a huge digital whiteboard right next to his desk in his newly occupied office. "This is a smart brainstorming tool, in front of which you can put heads together or graphically access and shape organizational charts and timelines," Gerloff says. At the push of a button, all your ideas are saved and can be shared as an image file. "Working that way is attractive to me."

Shaping the future of the dynamic UKE campus, making the University Medical Center attractive for the people who work and study here and making the most of the opportunities offered by digitalization. These are the primary goals the 59-year-old Gerloff has set himself in his new position as Medical Director of the UKE and Chairman of the Executive Board. As such, he is at the helm of one of the most modern hospitals in Europe with more than 14,000 employees. A hospital that he knows well and whose dynamics he appreciates: Since 2006, Gerloff has been Director of the Department of Neurology and Director of the Head and Neurocenter. He is also experienced in the management of the UKE, having been its Vice Medical Director since 2013.

> "The UKE is driving modern university medicine forward. We are aiming for new frontiers both digitally and structurally."

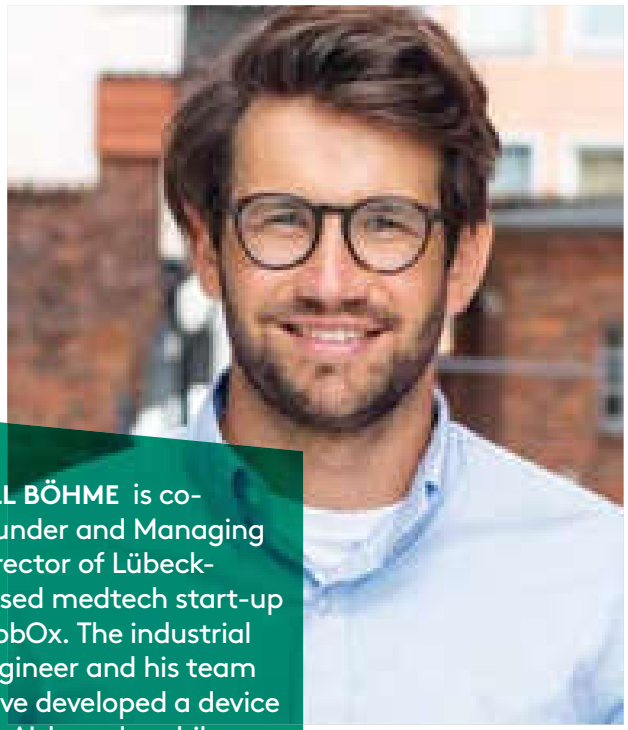
After studying medicine in Freiburg and Vienna, Gerloff initially wanted to become a trauma surgeon, but then became enthusiastic about neurology while doing his doctoral thesis and during his residency at the University Hospital in Tübingen. Gerloff's career was boosted during his three years as a postdoc at the National Institutes of Health (NIH) in Bethesda, where he focused on brain imaging and systems neuroscience: "I particularly appreciated the patient-oriented research there, it was a very productive time," Gerloff recalls. After several years as a Senior Attending in Tübingen, where he became a specialist in the diagnosis and treatment of strokes, Gerloff joined the UKE in 2006 as a W3-professor, focusing on brain imaging and neurostimulation. "I am a clinician with heart and soul and enjoy working with patients," says Gerloff. Since he's been in Hamburg, he's been particularly keen to drive forward medical translation. In this regard, he describes the WAKE-UP study as a highlight of his career. In 2018 the results of this large European research consortium revolutionized the treatment of stroke patients with unknown time since symptom onset. "This was super interdisciplinary teamwork and something like winning the champions league in stroke medicine: the international treatment guidelines were changed in a very short time," Gerloff says. To this day, he remains fascinated by how dynamic and adaptable the adult brain is. "This plastic potential opens up opportunities for us to explore new therapeutic avenues," he says. Moreover, we have modern methods that help us understand these complex networks in the brain, he adds. This is also true for applications of AI. For example, his team recently used 2.5 million data points to train an AI algorithm that can be used as a warning system in intensive care units in the future: By analyzing complex data, the system can detect impending cerebral pressure crises and sound the alarm hours in advance. A demonstrator already exists. In addition to such early warning systems in intensive care, AI assistance systems could also help with suspected diagnoses during initial diagnostics, believes Gerloff. AI could also help optimize workflows and patient pathways in the hospital.

In the coming months, three large new buildings – the Heart Center, the Martini-Klinik and Research Campus II – will be completed as part of the UKE Future Plan 2050. "Here, it is important to link campus development with the optimization of processes." Concerning data availability, he points out that it is crucial that ways are found for different healthcare providers to pull together on data flow and data presence. "This is also where we need to find constructive solutions with data privacy regulators," he says. "In this regard, I would like to see more tailwind," says the passionate sailor. "The hope is that the digital transformation ushers in a new era that changes the way we do medicine." pg

THE BRAIN-STORMER

PROF CHRISTIAN GERLOFF
In January 2023, the brain imaging specialist started his job as Medical Director of the University Medical Center Hamburg-Eppendorf (UKE)

TILL BÖHME, CO-FOUNDER OF MOBOX



TILL BÖHME is co-founder and Managing Director of Lübeck-based medtech start-up mobOx. The industrial engineer and his team have developed a device for AI-based mobile blood analysis that delivers results within 30 seconds.

What makes mobOx's technology for blood analysis stand out?

TILL BÖHME We developed a novel AI-based optical sensor that makes our mobile device particularly robust in varying environmental conditions. The device measures blood gases accurately across a wide temperature range. In addition, only 20 microliters are required to determine up to 14 blood parameters within 30 seconds. This combination of features makes our system unique and opens new areas of application.

When will your product be available?

BÖHME The launch onto the European market is scheduled for 2024. Currently, we are looking for investors to support the next stages such as ramping up serial production. Trials with our prototypes will begin in 2023 – first in a lab and later in a clinical setting. In the final phase, the device will be tested in emergency ambulances.

What potential do you see in your technology?

BÖHME We are planning to extend the range of blood parameters to include, for instance, the measurement of electrolytes. Due to the small amounts of blood needed for one analysis, the device is ideal for use in neonatology. In the future, mobOx might also be used by general practitioners or doctors in developing countries.

More information:
www.mobox.health

WE ARE ACTIVE IN THE NORTH ...

"... because we are in close proximity to our collaborators whom we can reach within a short walking distance."

THE NUMBER 20

The mobOx handheld device needs only 20 microliters of blood – about one drop – to accurately determine blood gases and perform a full CO-oximetry, making it ideal for mobile blood analysis.

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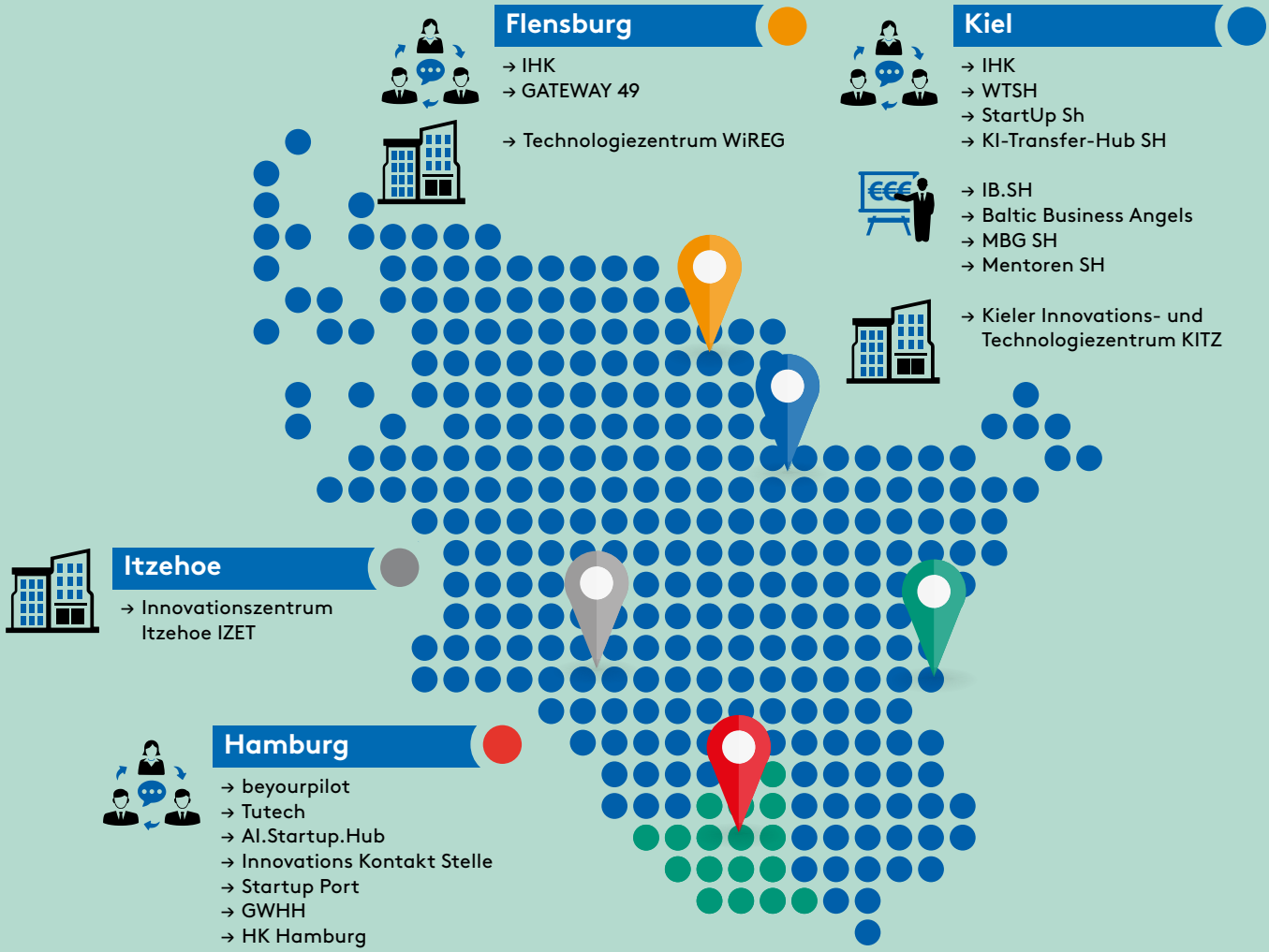

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REACHING TOP SCORES IN EMPLOYER AWARDS

AWARDS & RANKINGS Last year, three member companies of Life Science Nord were recognized for their efforts in employee support and for showing responsibility as regional employers.

In times of skilled labor shortages it is more important than ever to retain talent in the region and to invest in employee satisfaction. Northern companies continue to show an outstanding commitment to the region and to their employees, which is reflected in recent awards and top rankings.

Promoting fairness and gender equality

A broad range of evaluation criteria including employee management and investment in jobs in our region qualified President of → **DMG Chemisch-Pharmazeutische Fabrik**, Wolfgang Mühlbauer, to receive the "Family Entrepreneur of the Year Award" from German lobby association DIE FAMILIENUNTERNEHMER. The family-owned business DMG, which produces dental materials for worldwide markets, is standing up for "made in Hamburg" and invested heavily in its local production site. Promoting fairness and gender equality in the workplace are integral parts of DMG's corporate culture. A family service agency offers employees support with childcare and caring for relatives, as well as advice in difficult life situations. Flexible working hours and the option of working from home further contribute to the family-friendly work environment. Women make up more than 50% of staff including in the management team. In 2020 the Hamburg-Lurup based company already received the "Hamburg's Best Employers" award, which is based on the results of employee and manager surveys.

Balancing family and work

Two other medtech companies are repeatedly recognized as top employers by supporting their staff in balancing family responsibilities and work. The job evaluation portal kununu and the German women's magazine Freundin regularly select employers who offer the best work-life balance strategy. In the "Medical Technology" category → **EUROIMMUN Medizinische Labordiagnostika**, headquartered in Lübeck, achieved first place, followed in second place by → **Sysmex Europe**, based in Norderstedt.

More information:
www.dmg-dental.com
www.euroimmun.de
www.sysmex-europe.com

FAMILY BUSINESS AWARD

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FAMILY & WORK RANKING

TOP 1 EUROIMMUN
TOP 2 Sysmex Europe

ABOUT ALLERGOPHARMA

350 employees are working for the company

400+ authorized preparations for allergen immunotherapy

PHARMA INNOVATION MADE IN GERMANY

GUEST ARTICLE Since its foundation in 1969 Allergopharma has specialized in the development, production and commercialization of medical drugs for the diagnosis and treatment of allergic diseases.

Specific allergy immunotherapy is aiming to reduce allergic symptoms like allergic rhinitis and conjunctivitis and prevent and treat allergic asthma. Allergopharma is a global leader in the field of allergy therapeutics. More than 330 scientists, technicians and marketing experts at the headquarters in Reinbek near Hamburg are constantly working on improving life and health of allergic patients. Allergopharma's products are approved and available in several European countries and in Asia.

Committed to people: At Allergopharma people are the focus of everything we do. "Allergies do significantly reduce quality of life of patients. This is why we are striving to make high quality sterile drugs available to improve patients' health," says Dr Christoph Willers, CEO of Allergopharma.

Professional Opportunity: We offer experienced professionals and outstanding top talents various opportunities to proof their excellence and achieve targets beyond the regular perspective. By offering an exciting and innovative work environment and best-in-class training programs Allergopharma will kick-start your career in the pharmaceutical industry.

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More information:
wwww.allergopharma.de/karriere

GET IN TOUCH WITH US!

Life Science Nord is the regional industry network for medical technology, biotechnology and pharma for the federal 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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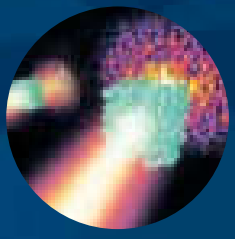

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innovation.desy.de

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