LSNMAGAZINE THE INDUSTRY JOURNAL OF HAMBURG & SCHLESWIG-HOLSTEIN



BLUE INNOVATION

The Kiel-based cluster BlueHealthTech combines marine sciences and innovative health technologies

MEDTECH MEETS AI

The new Fraunhofer institution IMTE in Lübeck in portrait

SMART AND PRECISE

How life science players in the North of Germany contribute to making data-driven precision medicine a reality

CLUSTER MEMBERS

Platinum



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



DR HINRICH HABECK MANAGING DIRECTOR LIFE SCIENCE NORD MANAGEMENT GMBH

Dear readers,

with our new LSN magazine, we are demonstrating that innovation, passion and collaboration have not stopped in the North over the past year. Despite the pandemic situation, all players are further implementing novel products or services – be it in the pharma, biotech or medical technology industry. What all these life science areas have in common is the growing importance of digitization for a new smart and precise medicine. But what is digital precision medicine all about? Our cover story deals with its challenges and potentials, highlighting the work of stakeholders such as AstraZeneca, Philips, Evotec, Indivumed, and Johnson & Johnson, among others.

Behind this topic, the new issue will provide further insights into Life Science Nord's activities. We will learn more about the new chairperson of our association board, Prof Dr Heike Wachenhausen, and what she is expecting to bring in. Furthermore, we are looking behind the scenes of some of cluster projects such as BlueHealthTech, MAGIA2Market and HIHeal. We will also report on recent local investments: Why Japanese manufacturer Sysmex will move its European Headquarters to Hamburg and why family-owned Nordmark in Uetersen ramped up its biomanufacturing capacities. You will also learn about the strategy of Fraunhofer IMTE. Curious to learn more about the North? We warmly welcome you to attend Deutsche Biotechnologietage 2022, the most important annual meeting of the German biotech sector, organized by BIO Deutschland and ourselves from 4th to 5th May in Hamburg.

For me personally, it is also time to say goodbye in my role as Managing Director of the Life Science Nord Management GmbH. After ten exciting and inspiring years, I will take over another position starting in Spring 2022. Stay healthy and keep on innovating!

Yours sincerely,

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CROSS RUNNERS

Digitization is a major driver of precision medicine, but dealing with it is a complex task. Pharma, biotech and medtech players in the North explore new ways of cross-sectoral collaboration.

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In an interview, Uwe Heckert, new CEO of Hamburgbased Philips GmbH, speaks about the potential of digital solutions and challenges in the sector.

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NEW BOARD OF LIFE SCIENCE NORD ASSOCIATION



→ The industry association Life Science Nord is the backbone of a strong industry region in the North. With over 270 members, it represents the interests of the life science industry in Hamburg and Schleswig-Holstein. In September 2021, the members elected the new board, with lots of newcomers such as Heike Wachenhausen as the new first chairperson → pages 38–39. On the picture from the left first row: Philipp Rostalski → pages 32–35, Britta Linnemann, Heike Wachenhausen, Janine Müller-Dodt, Karel J. Golta, from the left second row: Hinrich Habeck (Cluster manager), Dagmar C. Schneider, Martin Leucker, Volker Bahr, Christine König.

THE NUMBER



million euros from a public grant were received by Evotec to develop EVT075, a potential first-in-class immunomodulatory therapeutic against COVID-19. The funding comes from the German Federal Ministry of Education and Research.

GOLD LABEL AGAIN

→ The Life Science Nord Cluster has been awarded the "Cluster Organisation Management Excellence Gold Label" of the European Cluster Excellence Initiative for the third time in a row. "This is a great team effort from all employees of Life Science Nord Management GmbH, the Life Science Nord association, the ministries and authorities in Schleswig-Holstein and Hamburg – and of course the numerous companies and institutions based in the cluster region," comments Hinrich Habeck, Managing Director of Life Science Nord Management GmbH. To receive the Label again through recertification, a demanding audit process was carried out. Two independent experts checked the cluster man-

agement for a day based on 31 indicators. Discover some facts & figures of the Life Science Nord Cluster on → pages 20–21.



DANIEL GÜNTHER Minister-President of Federal State of Schleswig-Holstein



MEDICAL ENGINEERING ...

"... is one of the key technologies of the 21st century. The Fraunhofer Research Institution for Individualized and Cell-Based Medical Engineering IMTE at Lübeck is making a real difference to the continued growth of the healthcare sector in the region."

NEW PLATFORM FOR ROBOT-ASSISTED SURGERY IN KIEL

At the Kiel Campus of the University Hospital Schleswig-Holstein (UKSH) a new platform for robot-assisted surgery will be developed. The surgical disciplines are closely networked in minimally invasive and robot-assisted procedures under the umbrella of the Kurt Semm Center. At the end of 2021, the center has succeeded in acquiring 3.4 million euros EU funding for a lighthouse project under the title "Operation Room of the Future". The Technical Faculty of Kiel University, Vater Solution GmbH and MiE Medical Imaging Electronics GmbH are also involved.

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SMART AND PRECISE MEDICINE

Players from the Life Science Nord Cluster are making major contributions to develop smart and precise solutions for medical treatments. This special highlights their activities at many fronts.

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CROSS RUNNERS

DATA-DRIVEN INNOVATION Digitization of healthcare is a major driver of precision medicine, but the generation and usage of health data is a complex task. Pharma, biotech and medtech players in the North find their way through the challenge and explore new ways of cross-sectoral collaboration.

For Jens Nieland, health data is the most important currency in health care: "Anyone who wants to practice personalized medicine depends on the necessary data. For this reason, all stakeholders involved in a defined patient path need to develop common interfaces and standards to provide the best possible medical outcome for the individual patient and the health system in general." In his role as Medical Advisor Medical Devices DACH at \rightarrow Johnson & Johnson he is among the drivers of promoting further digitization, steadily discussing challenges and potentials as well as exploring new ways of collaboration. Topics such as connected data, interoperability, standardization and cross-sectoral exchange are on his daily agenda. His goal is to help establish a truly digital ecosystem – internally within J&J, but also in cooperation with external partners.

Moving towards patient path models

According to him past months and years demonstrated quite clearly that, "the sector boundaries between pharmaceuticals and medical technology are becoming increasingly blurred." Pharma and biotech companies are developing more targeted therapies based on new molecular insights and tools. The medical device industry is increasingly including data- and ITdriven approaches (see also the interview with Uwe Heckert, CEO of -> Philips GmbH on p. 12). At the same time, several legal framework conditions on the national level in Germany - be it in the reimbursement scheme for digital health solutions or the Federal funding of digitization of hospitals through the Krankenhauszukunftsgesetz (KHZG, Hospital Future Act) - are pushing forward ambitious plans for increased usage of digital health applications, although data privacy and data security laws are still among the strictest in Europe. Given these circumstances, the big question is how healthcare stakeholders can adapt to this situation in the

near future. For this reason, the Life Science Nord Cluster established the P.I.L.O.T. project aimed at addressing these challenges across the pharma, medtech and biotech sectors (*see details in the box, p. 9*). Nieland belongs to the active experts within this network and argues that a holistic access to health data is imperative for everything related to personalized or precise medicine. As a result, strategies will shift towards analyzing single therapies or specific medical products within their context of usage. "If we take precision medicine seriously, we will move away from purely device or product-focused sales towards patient path models that are accompanied by digital solutions," he says.

Also other large companies are taking the road towards new digital applications by using data-driven innovation. "Health data hold the potential to revolutionize healthcare and enable dynamic, learning, and sustainable health systems," emphasizes Alexander Pimperl. He heads the Data Insights & Business Intelligence team at → AstraZeneca GmbH at its German headquarters in Wedel near Hamburg. "Our mission is to leverage the power of health data and AI to enable a future of individualized healthcare, driven and informed by science and data, and aimed at substantially improving outcomes for patients and healthcare systems worldwide", he says. Among the top issues he deals with is using (new) data sources



"In bringing together data sets that normally are not connected you generate deeper wealth of real world insights."

DR ALEXANDER PIMPER DIRECTOR DATA INSIGHTS & BUSINESS INTELLIGENCE, ASTRAZENECA GMBH

PRECISION MEDICINE IN THE NORTH



The project P.I.L.O.T. led by Life Science Nord aims at building up a network addressing innovations in digitization of precision medicine approaches within Schleswig-Holstein and the cluster Life Science Nord.

The project strengthens the dialogue between researchers and industry stakeholders, physicians, regulatory agencies, and reimbursement systems and patient advocacy groups to solidify innovation pathways, close gaps and remain competitive. The project is funded by the European Regional Development Fund (ERDF) and by the federal state of Schleswig-Holstein.

More information: www.lifesciencenord.de and technology to develop evidence capabilities that ensure more patient insights are considered, enabling real world evidence generation and new value-based reimbursement strategies. With the Digital Healthcare Act digital health applications are getting a boost in Germany, Pimperl explains. "What is very interesting for us as an innovation-driven biopharma company is how digital healthcare solutions can help to create integrated 'healthcare ecosystems' beyond the medicine that bring benefits and support for the whole of the patient experience from prevention, diagnosis and treatment to recovery and wellness."

Digital tools and technologies can not only improve patient outcomes and bring better care along the treatment pathway, Pimperl lines out. "On the other side, they help to transform our clinical trials and make data generation more patient-oriented and efficient." Thus, they accelerate the development and approval of new therapy approaches, he points out. "They help to ensure more patient insights from the real world are considered and these generate real world evidence," Pimperl underlines.

Tapping into health data resources

In Germany, AstraZeneca is exploring different ways of data innovation. Together with Germany's largest hospital operator Helios, AstraZeneca is establishing a largely digital patient registry for heart failure – The Helios Heart Registry (H² registry). The H² registry is scientifically independent. AstraZeneca provides longterm financial support for the establishment of the registry, while



PRECISE CONTROL OF CHRONIC INFLAMMATION



The translation of precision medicine concepts for the treatment of chronic inflammatory diseases is

the mission of the Cluster of Excellence "Precision Medicine in Chronic Inflammation" (PMI). Scientists from different medical disciplines and related basic science fields are working together to significantly improve the present algorithms for the diagnosis, treatment and prevention of these diseases, taking into account the individuality of people and their environment. Their vision is to achieve complete control over the disease in more and more patients - at every stage and as early as possible. About 400 researchers from eight institutions at Kiel, Lübeck, Borstel and Plön are involved. PMI is, among others, an initiative of Kiel and Lübeck University, the University Hospital Schleswig-Holstein (UKSH) and the Research Center Borstel - Leibniz Lung Center. The Cluster is funded from 2019 to 2025 through the German Excellence Strategy.

Helios is responsible for its content, implementation and evaluation. The special thing on the H² registry is that it will provide well-structured data of high quality which are enriched with patient-reported data. "You do no longer have clinical research and care as two separate data streams – they are integrated. That is why you get a deeper wealth of real world data," Pimperl says. AstraZeneca hopes from a long-term perspective to establish register-based, randomized, controlled trials in Germany easier



"We are moving away from purely device or product-focused sales towards patient path models that are accompanied by digital solutions."



"For personalized medicine, we have to rethink the way we look at health and disease. That means: turning away from symptoms and towards a solid database."

> DR WERNER LANTHALER CEO, EVOTEC SE

and faster. Integrating different data streams is also the goal of J&J. According to Nieland, digital solutions as well as any further innovation will be developed around patient path models and value-based healthcare. Within J&J, this is for instance currently explored for use cases in oncology such as lung cancer. "Relying on surgery and medical therapies at the same time, this indication already exemplifies the interrelation of medtech and pharma interventions as well as the potential of digital support," he explains. Together with clinical partners in Germany, J&J is exploring data-driven decision pathways to support medical decision making. "Today, in clinical practice, many interfaces are not working as they should or could. Our goal is to provide smart data-driven treatment options that are able to evaluate when surgical intervention is useful, when drug therapy, but also which patient is suitable for which surgical or drug therapy," Nieland says. In another projects, the company seeks to closely work with other stakeholders in the area of wound infections to establish standardized protocols for documentation purposes. "Within the P.I.L.O.T. project we will hopefully find partners in the North to target this clinical challenge in a joint network." The collaboration with experienced hospitals such as the -> Medical Center Ham**burg-Eppendorf (UKE)** in Hamburg that are at the forefront of using digital infrastructures is key in this and other processes, he argues. "We as industry have to admit that we can learn a lot from clinics and their successful implementation strategies."

Data-driven R&D for precision medicine

Generating, harvesting and sharing data to explore multimodal treatment options - this trend is especially important for innovation drivers such as Hamburg-based biotech company → **Evotec**. "For precision medicine, we have to rethink the way we look at health and disease. That means: turning away from symptoms and towards a solid database. This is the only way to both dramatically improve the early detection of diseases and at the same time developing really effective therapeutic interventions that address the causes rather than the symptoms of a disease," explains CEO Werner Lanthaler. From his perspective, the most important thing is the integration of various state-of-the art molecular technologies such as gene and cell therapy, artificial intelligence or mRNA on a common platform and its data-driven usage. "Integrating and interconnecting data along the entire value chain of drug discovery and development is a precondition for achieving true multimodality - i.e. an openness to the therapeutic option that is really best suited. The backbone of such a platform is the constant enrichment of the database," Lanthaler points out. Evotec sees itself as a platform provider for all those state-of-the-art-technologies needed to research, develop and manufacture the precision medicine of the future. In Hamburg, among others, the internal core R&D center for induced pluripotent stem (iPS) cells has been established. It explores applications in various medical indications from neurodegenerative diseases up to heart-related diseases. For the latter, in 2021, a strategic cooperation with UKE was closed. Lanthaler: "We are pleased to see the excellent environment in our region, but are open to as many partners as possible, regardless of whether they are based in Eppendorf or Boston."

The importance of new routes of strategic collaborations is gaining momentum across the value chain. AstraZeneca, for instance, plans a so-called Datathon, trying to overcome existing data silos. "We will bring our own randomized controlled trial data in the together with claims data from a German health insurance association," says Pimperl. As a pilot format, the Datathon will be a collaborative event, with mixed teams from payers and AstraZeneca tackling different challenges. Pimperl admits it's an unconventional but highly promising way to do research. "The interesting thing is that you bring together diverse data sets and people in a 48 hours 'marathon-coding' event that normally are not connected and that may generate deeper insights to relevant medical challenges."

Jens Nieland from J&J is also convinced that research will pave the way for further implementation of precision medicine. In this context, however, he criticizes the current German legislation of being too restrictive when it comes to the usage of anonymous health data by industry stakeholders. For now, the government only allows hospitals or academic stakeholders to access health data for R&D purposes, in the future bundled via the new to be established national health data research center. Nieland: "If industry will be left out, it denies the important role we play to finally implement data-based treatment strategies in clinical practice."

REAL-TIME IMAGING FOR CLINICIANS

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With its phased-array Intravascular ultrasound (IVUS) Philips has developed a real-time-imaging tool for the use during venous and arterial interventions in clinics. Using a miniaturized ultrasound transducer mounted on the tip of a catheter, it provides a fast plug-andplay usability and precise image resolution needed for pre-procedural planning, intra-procedural guidance, and post-procedural optimization of the therapy. It is one example of how Philips is connecting medical technology competence with digital expertise to lay the ground for precision medicine in clinical practice.

"WE HAVE TO GET OUT OF SILOS"

MEDICAL TECHNOLOGY With its European headquarters located in Hamburg, medtech company Philips plays a major role in the ecosystem in the North. In June, Uwe Heckert has started as new CEO of Philips GmbH, bringing in large experience from his former leadership role in the IT industry. We spoke with him about digital solutions and current challenges in the sector.

Mr Heckert, you recently switched from the IT industry to healthcare. What surprised you the most?

UWE HECKERT In the past six months or so, I have been impressed by the commitment of everyone involved in the healthcare industry to create the best possible care for patients, especially their general willingness to grow further through the digital transformation. However, I was also surprised by the somewhat inadequate speed with which such ambitious goals are sometimes approached. Of course, an area as sensitive as health requires a particular caution, with regard to the handling of patient data, for example. Nevertheless, I would like to see a little more courage sometimes and determination to initiate the necessary changes and to follow the chosen pathway consistently.

How important is digitization for Philips? How much is your IT expertise in demand at the company?

HECKERT The value of digitization is huge – not only for Philips, but across the entire healthcare sector in terms of the quality of treatments, patient and clinical staff satisfaction, and economic efficiency. Nowadays, IT solutions are found everywhere, from devices and how they communicate with each other, to the generation and use of data, as well as the connection of clinical processes via primary systems. Digital healthcare offers enormous potential and sets the course for the future. As a healthcare company, we continue our focus on being a digital leader and help our customers to take advantage of the opportunities offered by this transformation. I am so glad when my knowledge contributes to this journey.

What do regulatory decisions in Germany such as the Hospital Future Act (KHZG) mean for your company?

HECKERT First of all, such funding programs, supplemented by initiatives as for example the electronic patient record, can definitely be understood as a commitment by political decision makers to further support the digital expansion of the healthcare sector. We expressly welcome this and take it as an important sign that we are on the right track with our strategy. At the same time, measures such as the KHZG are driving digitalization in the clinics with the available funds – even if the amount is more of a start rather than a one-off injection of funds, especially compared to other industries. However, the funds must now be used in a strategic and profitable manner. For us as a company, this means that we want to advise and support clinics in a spirit of partnership so that these digital transformation projects also bring real added value for everyone involved.



Overall, how do you rate Germany (and Hamburg) as a hub for your global corporation?

GmbH.

HECKERT Our DACH headquarters on Röntgenstrasse in Hamburg has a long tradition in the history of Philips and provides outstanding company-wide expertise in the field of component manufacturing

for imaging systems, as well as research and development. The same applies to patient monitoring at our innovative Swabian hub in Böblingen - which means that Germany, with its rich knowledge and capabilities, is of great importance for our global company. In addition, the German market itself is naturally important, particularly as it is backed by government initiatives such as the aforementioned KHZG, promoting the digitization of the local healthcare system.

"Our role has changed from merely being a device manufacturer to a solutions provider."

> UWE HECKERT CEO, PHILIPS GMBH

Philips focuses especially on MRI and CT machines. Where do you see potential for future growth and what is the role of digital solutions?

HECKERT Our role in the health technology sector has changed from being merely a device provider to a solutions provider. This means not only

do we continually develop technology for devices, but we also embed solutions in the context of a data-driven and interoperable digital infrastructure, optimizing the application, processes, image quality, and ultimately, diagnostic reliability. In radiology, for instance, AI-driven innovations offer enormous potential for digital solutions. In addition to improved and more sustainable large-scale medical devices, the use of artificial intelligence opens up opportunities for automated workflows or for algorithms that dramatically accelerate imaging exams.

In digital medicine, the boundaries between medical technology and pharmaceuticals are blurring. How do you deal with this trend at Philips?

HECKERT Health markets are generally becoming more digital and more connected, which is why all the stakeholders in the healthcare sector have to work closely together. For the medical technology and the pharmaceutical industry, for instance, this applies to the provision of joint, holistic health data sets for the development of predictive technologies. We have long been highlighting the importance of open interfaces in digitization, for instance, in order to be able to seamless-ly integrate everyone involved in a comprehensive care system. However, we have to get out of these silos and instead move closer together, across industry and national borders. This is the only way we will stay connected to other markets outside of Europe.

Which impact did or will the transition to the new EU MDR have? Did you accelerate changes internally or are there products in your portfolio that have now lost or gained in importance?

HECKERT In the early stages, Philips set up a team to implement the regulation in order to be ready for this transition period. Nevertheless, the regulation is currently leading to uncertainty within the entire medical technology industry, which we are also feeling and taking seriously. Above all, the possible loss of suppliers in light of these bureaucratic hurdles, jeopardizes the manufacturing of some products and thus harbors risk for the proven care of patients. Accordingly, we support demands, such as those made by organizations including BVMed, for practical changes to be made to the legislation.





top above: The European Headquarter of Philips in Hamburg.

left:

Philips IntelliSpace Discovery 3.0 platform enables the development and deployment of Artificial Intelligence assets in radiology.

MORE PRECISION FROM SMART DATA

The high-quality specimen in Indivumed's biobank can be regarded as a complete data set of tumor biology. Applying cutting-edge bioanalytical techniques, they are transformed into a multi-omics database. Powerful bioinformatic tools and smart algorithms are then used to extract data and to transform them into knowledge for precision oncology.

UNLOCKING THE DATA TREASURE

PRECISION ONCOLOGY In hardly any other field has the concept of personalized medicine become a clinical reality as it much as in the battle against cancer. Digitization and the advent of powerful data analytics tools such as machine learning drive this development. Here is a selection of players from the North that are leading the field.

The premise of precision oncology in the battle against cancer is to develop treatments that target the molecular and cellular characteristics of an individual's tumor. The question of where in the body a tumor originated has lost in importance, and instead treatment concepts focus on the molecular profile of cancer cells in the body. But for the dream of precision oncology to be fully realized, such therapies must "We are transforming from a technology platform provider into an Al-driven oncology biotech company."

> HARTMUT JUHL CEO, INDIVUMED

cancer patient tissues in frozen samples as well as blood samples and additional relevant clinical data. The key to highquality specimen in Indivumed's biobank was the implementation of highly standardized and stringent sample collection procedures in numerous clinics worldwide, enabling comparability and reliability of biological and clinical data across tumor entities, hospitals, and different regions.

help more people with cancer than the 5–10 percent who currently benefit. The advent of artificial intelligence and other powerful bioinformatics applications is regarded as a game changer for precision cancer medicine. These technologies help to analyze the huge and complex data sets found in large electronic health databases. Practically every drug developer is adopting smart approaches to using machine learning and big data analytics to turbocharge their R&D.

High-quality multi-omics data sets

In a world that is fueled by exponentially growing knowledge, the source and the quality of data are of major importance. Hartmut Juhl, the founder and CEO of \rightarrow **Indivumed GmbH**, sees his company as a key enabler for cancer research and the development of new therapeutics, as it has one valuable asset: a uniquely strong tumor database. "It is a powerful resource which fully deciphers the complexity of cancer biology for every patient, to understand the disease, to target the cancer according to what is available – and to develop new compounds," Juhl says.

Over the last 20 years, the Hamburg-based biobanking specialist has built up a global network of affiliated clinics that obtain Now this elaborate approach is paying off. In recent years, Indivumed has started to unlock the informative power of its biospecimen collection not only through R&D services, but by extracting a complex set of relevant biological data from it. "Our frozen material can be regarded as a complete raw data set of tumor biology", mentions Juhl. In order to transform the raw data into a multi-omics database, the Indivumed team applied a set of exceptional bioanalytical techniques such as whole-genome sequencing, phosphoproteome, proteome and transcriptome analyses. "Combined with clinical and outcome information and by applying bioinformatic tools and artificial intelligence algorithms, we are able to extract data from individual cases of cancer in a wholly unique way", he says.

To strengthen its informatics, Indivumed has recruited a team of IT specialists, bioinformaticians and data scientists. It has also entered significant partnerships with IT-driven companies or academic partners to build its digital and data analytics expertise. A recent milestone in summer 2021, Indivumed introduced nRavel, an artificial intelligence-based bioinformatics platform developed in-house to support precision cancer research. The new product marries the oncology firm's multi-omics database with machine learning and a series of powerful analytics tools. "This discovery platform enables us to routinely analyze our multi-omics datasets against virtually any issue that is currently coming up in oncology," Juhl explains. The translational cancer researcher is fascinated by its speed: "By applying nRavel, we have for example, identified a bunch of different novel drug targets for functional antibodies within a few weeks," he says. Experimental studies already showed prom"Up to 30 percent of patients receive recommendations based on their molecular tumor profile."

> CARSTEN BOKEMEYER DIRECTOR OF THE UNIVERSITY CANCER CENTER HAMBURG (UCCH)

pathology, the Hamburg-based start-up → Mindpeak GmbH has developed a deep-learning solution that recognizes and classifies breast cancer cells in tissue samples taken in a fraction of a second. In May 2021 the AI-based software received its CE-IVD mark. "This makes us the first company in Germany with such an approval in clinical routine diagnostics in pathology," says Co-founder and CEO Felix Faber.

Hamburg-based \rightarrow **FUSE-AI** is also developing intelligent solutions for radiologists to detect lesions in MRI and CT scans faster and more accurately for various indications like prostate cancer and other indications. In close collaboration with clinics in Germany and Switzerland, the company has been developing an AI-based radiological diagnostic software "prostate. carcinoma.ai" since 2019. Approval as a medical device under EU MDR as well as by the FDA is expected in mid-2022.

Oncology Center of Excellence in the North

At the University Cancer Center Hamburg (UCCH), precision oncology has become an indispensable part of daily routine. "In 2015, we introduced our molecular tumor board which comes as a new addition to our 22 interdisciplinary tumor conferences per week," says Carsten Bokemeyer, Director of the UCCH and Medical Director of the II Medical Clinic for Oncology and Hematology at the → **University Hospital Hamburg-Eppendorf**



ising data regarding the functionality of these targets, he says.

It is exciting results like these that have led Indivumed to embrace the development of new targets and early drug discovery on its own and in strategic partnerships with pharma companies. Indivumed has co-founded two biopharma companies for therapeutic development against several novel targets in 2021. "We are transitioning from being just a technology platform provider to becoming an AI-driven oncology biotech company. We utilize our own innovative power for product development, as well as collaborate with as many partners as possible, to fully unlock the tremendous value of our database for the benefit of future cancer patients," Juhl points out.

Al-based cancer diagnostics

Other players in the North are unlocking the revolutionary potential of machine learning for improving clinical diagnostics in cancer medicine. In order to provide faster test results in

PROF CARSTEN BOKEMEYER

Director of the University Cancer Center Hamburg (UCCH) – Hubertus Wald Tumor Center and Medical Director of the II Medical Clinic for Oncology and Hematology at the University Hospital Hamburg-Eppendorf (UKE).



(UKE). "In 2020 among 14,500 tumor patients discussed, about 25 to 30 percent were receiving recommendations based on their molecular tumor profile. The specific molecular board is now specifically directed to patients where established therapies are no longer available or molecular therapies have already failed."

IT technology and artificial intelligence applications are also making roads here. The team led by Frank Ückert, Director of the new Institute for Applied Medical Informatics at UKE, for example, develops solutions to transform highly complex data from the molecular tumor boards into knowledge that can be used for diagnostic and therapeutic decisions.

"For our molecular tumor board patients, we have also established special consultation hours to discuss the results with them", Bokemeyer says. It is because of offers like this, but also the close integration of translational research and treatment, including the implementation of innovative early clinical studies, that German Cancer Aid has once again elected the UCCH as an Oncological Center of Excellence – one of only 14 in Germany. "This is a recognition of our intensive efforts to strengthen translational cancer research and to focus directly on the needs of our patients," says Bokemeyer.

The award as a Center of Excellence is associated with funding of three million euros. An important goal of the UCCH in the new funding period is to form a North German competence network for cancer research and medicine with the University Hospital of Schleswig-Holstein (UKSH) in Kiel and Lübeck, thus integrating these sites into a consortium with the Hamburg Top Center.

"We have already established several connections with colleagues at the Cancer Center at the University Hospital Schleswig-Holstein. Through superregional networking in the fields of translational research and clinical care, we want to be able to offer every patient in northern Germany the chance to benefit from recent innovations in cancer medicine," says Bokemeyer. "In 2024, we plan on applying to German Cancer Aid as a Northern Germany Oncology Consortium together with the Cancer Centers in Kiel and Lübeck, the UCC-SH," says Bokemeyer.

AN ECONOMIC POWERHOUSE THE NORTH IN NUMBERS

Under the umbrella of the Life Science Nord Cluster, stakeholders active in the biotechnology, pharma and medical technology sectors contribute to the economic power of the North. The cluster in numbers.

HIGH DENSITY OF EXPERTS

3%

€5bn

More than **270** companies and institutions are involved in the industry association Life Science Nord, representing more than half of the **500** companies, clinics and research institutes based in Hamburg and Schleswig-Holstein with activities in the biotechnology, pharmaceuticals and medical technology industry.

MAJOR ECONOMIC FOOTPRINT

According to the WiFor report 2020, the cluster generated a total gross value added of **€5bn** in 2018. Since 2016, a **3%** annual growth was observed.



52,800

500

270

NETWORKING IS KEY

Connecting stakeholders is among the key task of the Life Science Nord Cluster. In 2021, a total of **37** cluster events with a total audience of **1,400** participants took place – most of them virtually due to the pandemic.





2.4%

IMPORTANT PILLAR FOR HIGH-QUALIFIED JOBS

In the cluster, stakeholders in science and business provide a total of **52,800** life science related jobs, representing a **2.4%** annual growth of employee numbers since 2016 in this area.

FROM THE REGION INTO THE WORLD

Under the umbrella of the cluster, stakeholders are widely supported in their global outreach to international experts around the globe. Together with cluster partners in Belgium (Bio-Win), France (LyonBioPole) and Italy (bioPmed) Life Science Nord is coordinating the MAGIA2Market project, bringing together an ecosystem with 2,000 healthcare companies – of which 660+ medical technology players – and +50 research organizations, universities and technology centers, representing in total over 100,000 jobs. Through the MAGIA2Market project, innovative SMEs are supported to gain access to healthcare stakeholders in the three target markets USA, Japan and China. | see p. 28-29



100,000



Fraunhofer IMTE (Lübeck) | see p. 32

€12.1m funding from the state government of Schleswig-Holstein



(Kiel) | see p. 30

€15m funding by the German Federal Ministry of Education and Research (BMBF)



Evotec SE (Hamburg) | see p. 6

US\$ 500m with secondary listing and IPO on the NASDAQ stock exchange

Topas Therapeutics GmbH (Hamburg)

€40m in a series B financing round



ATTRACTIVE INVESTMENT LOCATION

In 2021, several stakeholders in the Life Science Nord area gained national and international attention with large financings.

Sources: WifOR 2020/Life Science Nord Cluster & press releases of the respective companies

SUSTAINABLE GROWTH

NEW HEADQUARTERS The Japanese In-Vitro-Diagnostics manufacturer Sysmex is massively investing into new European headquarters in Hamburg laying the ground for further growth. The relocation of 840 employees from Norderstedt is planned for 2024. The new building will span 12,300 m², offering a cross-organizational working culture within a sustainable office complex.

The relocation from Norderstedt to Hamburg is the start of a new chapter for the company in Germany. "The new building is a clear commitment to Hamburg as a place for business and technology and a visible sign of Sysmex's sustainable and steady growth in the EMEA region. We are pleased to offer our existing employees and new talent a modern and inspiring working environment in the Sustainable building technology, green roofs, intensive planting in the courtyards, protection of old trees and the creation of a biotope stand for high ecological quality.

For the new building, Sysmex Europe will also adapt to a more future-oriented and sustainable working environment. Attractive outdoor areas consisting of semi-open courtyards will surround the main building and can be used as additional meeting spaces. Sustainable building technology, green roofs, intensive planting in the courtyards, conservation of old trees and the creation of

center of the Hanseatic city," explains Alain Baverel, President & CEO of \rightarrow **Sysmex Europe GmbH**.

Built in the Hanseatic style of clinker bricks and located between the Alsterlauf and the Eppendorf Mühlenteich, Sysmex aims to offer attractive conditions for the central organization Sysmex Europe GmbH, the subsidiary Sysmex Deutschland GmbH, the affiliate Sysmex Inostics GmbH and the Sysmex RDCE (Research and Development Center Europe). "Although we are still committed to a high degree of internal autonomy within all our entities, the new office complex catering for up to 1,000 employees in total will allow us to explore even more synergies and cross-collaboration for further growth," Baverel underlines. a biotope stand for high ecological quality. Construction is scheduled to begin in the first half of 2022.

Regarding the further economic development of Sysmex Europe, Baverel is optimistic for the years to come. "We are continually growing our activities in the fields of hematology, urinalysis, hemostasis, life science, flow cytometry and essential healthcare as well as addressing the digital challenges in laboratories and clinics," he says. Within the COVID-19 business segment, the company is currently working on a tool to quickly identify the immunity status of a person to better guide prevention strategies during the pandemic. Another important area is personalized medicine which will be targeted by NGS-based liquid biopsy tools for blood-based, ultra-sensitive molecular testing in oncology.

Mr Baverel, when did the relocation project started?

BAVEREL Back in 2018, when I started as CEO of Sysmex Europe, our management in Japan requested an improvement of the building situation at the European headquarters. We examined several options and are pleased that we now found the right space in Hamburg.

What is the motivation behind this step?

BAVEREL The move seeks to bring all our four entities – the central organization Sysmex Europe GmbH, the subsidiary Sysmex Deutschland GmbH, our affiliate Sysmex Inostics GmbH and the Sysmex RDCE (Research and Development Center Europe) all under one roof to facilitate close collaboration and interaction among each of our entities and affiliates. Currently, all our employees are spread over six different buildings. To meet each other we sometimes have

to take the car even. The new location, however, will accommodate everybody and bring them much closer to each other by offering the latest technological standards for increased hybrid collaboration combined with expanded options for mobile working. We will also have enough space to present and further develop the latest digital content of our Sysmex Academy, including virtual 3D visualizations. In addition, inspired by our Japanese tradition of being close to nature, we will be surrounded by a relaxing green outdoor area and ecological biotope which is hopefully providing additional inspiration for employees and guests.

Which other opportunities does the move to Hamburg bring?

BAVEREL The new headquarters will enable our further growth strategy in the EMEA region, allowing us to easily facilitate 30 affiliate companies and communicate with more than 100 distributors. Furthermore, we will have room for expansion.



ALAIN BAVEREL

is President & CEO of Sysmex Europe GmbH, the European entity of Japanese IVD manufacturer Sysmex. Under his leadership the company will relocate its headquarters for the EMEA region from Norderstedt, Schleswig-Holstein, to the city of Hamburg.

"The new building is a clear commitment to Hamburg as a location for business and technology and a visible sign of Sysmex's sustainable and steady growth in the EMEA region."

The new work campus 'Flow' is realized by MATRIX Immobilien GmbH and Bayerische Hausbau GmbH & Co. KG. It is located between the Alsterlauf and the Eppendorf Mühlenteich.



BIOTECH BUSINESS EXPANDED

BIOPHARMA INDUSTRY Enjoying more than 550 employees and global operations, Nordmark is a hidden champion. The family-owned pharma company is set for growth and has invested 20 million euros in order to expand its biomanufacturing capacities. Recently, a new Northern partnership has started.

→ Nordmark Pharma GmbH has a long tradition in manufacturing biological active pharmaceutical ingredients (APIs) and finished medicinal products which originate from animal sources. The main product manufactured by the company based in Uetersen, a town close to Hamburg, is the enzyme pancreatin. It is extracted from porcine pancreases and the product is distributed globally. For many years, Nordmark also operated Europe's largest snake farm. More than 600 poisonous Malayan pit vipers were kept in a building south of the company's site, and regularly milked to obtain the API Ancrod, an enzyme with antithrombotic properties. In 2019 after Ancrod delivered disappointing results in clinical phase II trials in patients with sud-

den hearing loss, management at Nordmark drew a line under the snake farm project. "We decided to invest more than 20 million euros in expanding our biotechnology business – for our own products and our contract manufacturing services," says Nordmark CEO Jörn Tonne. For ten years, the chemist has been at the helm of the family-owned pharma company which has more than 550 employees. The specialist in manufacturing biological APIs and drug products has successfully positioned itself internationally and is set for growth. Recently, the former snake farm building was transformed into a state-of-theart biotechnology center. Where once vipers lived in terrarium boxes, now flashes the stainless steel of pipework and bioreac-

NORTHERN DRUG MAKERS

Enjoying an added gross value of 1.9 billion euros and around 20,000 employees, the biotech & pharmaceuticals sector is the largest sub-sector (43%) of the Life Science Nord Cluster. Some 250 companies from the region conduct biotechnological research for medical and industrial applications.

Apart from Nordmark, which has been covered in this article, there are several other pharmaceutical giants and larger trading companies from the pharmaceutical industry operating in this region. Among others, AstraZeneca, Desitin, Medac and Richter-Helm develop and market innovative pharmaceutical products in and from Schleswig-Holstein and Hamburg.

More information: www.lifesciencenord.de tors. They are ready to house microorganisms or mammalian cell culture systems up to a scale of several hundred liters in order to manufacture biological APIs according to the standards of current Good Manufacturing Practice (cGMP). A new biomanufacturing project has now started. "In partnership with a pharma company from North Germany, we will manufacture a therapeutic protein by microbial fermentation," Tonne explains. Although he cannot provide further details on the product and the partner, he highlights that the protein produced is an API used for the treatment of cancer in children. "Our partner was looking for a new manufacturing specialist and was highly impressed by our biopharmaceutical expertise," says Tonne.

Seeking long-term partnerships

He views the new partnership as a good representation of Nordmark's new business model. "We are ready to invest in partnerships and share the risk," he says and stresses that, "For us, partnerships are always long-term." Nordmark's speciality is that it can offer support along the entire value chain, says Tonne. This includes process development, pharmaceutical development, production of clinical trial medication, regulatory support, and regular market supply. "This combination of special expertise with tailormade support for our customers has recently led to a significant increase in requests and collaboration offers," Tonne says. Apart from giving its biotech business a boost, Nordmark is busy with the digitalisation of its processes. One of the company's most important projects is to implement a manufacturing execution system in order to control and monitor production digitally. By partnering with Werum IT Solutions GmbH, Nordmark is collaborating with another player from Northern Germany. "That makes our production processes faster, safer and more efficient," says Tonne.



DR JÖRN TONNE is CEO of Nordmark Pharma GmbH in Uetersen. The company – now 95 years old – was formerly part of BASF AG and Knoll AG. Nordmark emerged from a management buyout in the year 2001.

DEALING WITH THE MDR CHALLENGE

MEDICAL DEVICE REGULATION Dealing with the new requirements of the EU's Medical Device Regulation (MDR) is a complex task. Medtech stakeholders in the North provide insights on their strategies and what they expect to be the major hurdles to come in the years 2023 and 2024.

Looking at his team these days, Jan-Michael Krüger knows that everyone has to perform like clockwork. For the General Manager Regulatory Affairs EMEA at -> Olympus Surgical Technologies Europe Olympus Surgical Technologies Europe, every task is like a small cog in a large wheel. If just one of the many parts gets out of line, everything can fall apart. "I really have to make sure we adhere to the time frames and procedures we have set," says Krüger. "Otherwise, we run the risk of missing a slot scheduled for us with the notified body."

Like Olympus, every medical technology company is still in the middle of converting to the MDR. Today, anyone who wants to approve a new medical device can no longer avoid the new regulation. Most companies however – whether large corporations such as Olympus or medium-sized companies – are primarily concerned with the recertification of their portfolio of existing products. Every single medical device must comply with the guidelines of the MDR within two or three years at the latest. "It's like a huge cleanup behind the scenes. The technical documentation, the quality management – everything has to be updated," explains Oliver P. Christ. The managing director of consulting company \rightarrow **NSF Prosystem GmbH** has his hands full. The same is true for the notified bodies which have to audit the companies

according to the MDR. By the end of 2021, a total of 25 have been approved in Europe, still too few to cope with the onslaught. For this reason, their time slots are in high demand. Anyone who was already a client before has an advantage. But Krüger knows from experience that everything is timed closely. "If we cannot keep to the schedules and agreements which we have set ourselves, we too have to join the back of the queue." At the same time, the pressure on the other side is enormous: new staff must first be trained, response times take longer sometimes, and in many cases, decisions are not made as clearly and unambiguously as the companies expect them to be. "The only thing that helps here is continuous dialog so that you can actively adapt your own schedule at all times. Also, following the specifications of the guidance documents is very helpful," says Krüger.

Time is running out for existing products

Time is running out, especially for the many existing products that are currently only on the market thanks to the extended MDD certificates. Many experts expect an extremely high wave of products that will still have to go through the re-certification process in 2023/24 – a mammoth task given the persistent staff shortage on all sides. However, even the experts cannot precisely quantify how high this wave really will be. "We ourselves only see excerpts, but the gap is still large with our customers alone. I think we still have the most critical phase ahead of us," says Christ. Overall, he perceives the companies in the North as being well positioned. Above all, the collaboration via the Regulatory Affairs working group organized by Life Science Nord works extremely well. In addition, there are discounted conditions for further training offers for members – such as the regulatory affairs study option provided on campus at the Technical University of Lübeck. All the experts agree that the greatest challenge is staff. "If even one person with expertise in regulatory affairs is leaving a small- or medium-sized company, it can lead to an existential threat," says Christ.

Portfolio cuts are foreseeable

For large companies, however, it is simply the number of tasks that is challenging: On the one hand, there are so many global markets - there are numerous other hurdles to tackle besides Europe - and on the other hand, the large number of remaining products in the portfolio, which needs to receive an updated documentation or quality assessment more or less in parallel. At Olympus, they are already preparing scenarios for the so-called blank period - meaning that the old certificate has expired, but the new one has not yet been received in order to secure business continuity and gap any potential delays in certificate availability. Overall, according to Krüger many experts say that cuts in the portfolio are foreseeable: "We expect, that the sector will not be able to keep all products in the market, and that portfolios may have to be reduced." The trend towards consolidation can already be observed, says Christ too. "It will hit economically less relevant markets with niche products, and we have to ask ourselves what that does to our patient safety and patient care." It remains to be seen whether the MDR will have a long-term positive effect here, as politicians once hoped



"We still have the most critical phase ahead of us."

OLIVER P. CHRIST GLOBAL MANAGING DIRECTOR MEDICAL DEVICES AND IVD CONSULTING EUROPE, NSF INTERNATIONAL



"We expect, that the sector will not be able to keep all products in the market, and that portfolios may have to be reduced."

> JAN-MICHAEL KRÜGER GENERAL MANAGER REGULATORY AFFAIRS, OLYMPUS SURGICAL TECHNOLOGIES EUROPE

with bringing the new regulation into effect. Because better and safer products would require adaption – with regard to their technical documentation or their intended use. "But with the MDR this means a lot more effort. Something that most companies currently prefer to avoid," says Christ. Doctors already observe with concern that medical devices with low demand in numbers – for instance in childcare or for special applications such as neurosurgery – are likely to fall through the cracks. This is now increasingly calling policy makers on the scene. At the last meeting of the Federal state's economic ministers, the request was addressed to the Federal German government to provide support in finding a solution to "avert further product portfolio adjustments, business insolvencies and supply bottlenecks for medical devices", along with recommendations that industry experts have developed together with the state government of Baden-Württemberg.

Regardless of which adaptions may be made in the end, some messages are already quite clear for Christ: "In any case, we will see a fewer number of products on the market, but those that are there will be better checked and controlled. In addition, the overall competence to deal with demanding regulatory requirements is increasing across the sector." In the short term, this will lead to a decline in innovation in Europe, as most of the companies will decide to go for the US market directly. In the long term, however, when Europe has established standard procedures with the MDR, it will win, Christ is convinced: "No medtech company on the world market can ignore such a wealthy market with more than 480 million consumers." According to Christ, there is also a strategic factor that can be a decisive driver of growth: "Anyone who manages to get its portfolio through the MDR will also meet the requirements of the FDA or other international markets - laying the ground for further growth, particularly in medium-sized companies." sw

EXPAND THE GLOBAL OUTREACH

MARKET ACCESS Providing targeted gateways for innovative SMEs to the attractive life science and medtech markets in China, USA and Japan is the aim of the EU-funded project MAGIA2Market. Hamburg-based company Anacyte Laboratories already benefited from the soft-landing services.

Over the past three years, the alliance of four leading European MedTech and health clusters Life Science Nord (Germany), bioPmed (Italy), Lyonbiopole (France) and BioWin (Belgium) has supported various small- and medium-sized companies (SMEs) in establishing and expanding international business relations with China and the USA. In 2020, the success of the first project MAGIA laid the ground for the successor project MAGIA2Market, which also includes Japan as an additional key market. "We catalyze business matchmaking, exchange and provide knowledge via webinars," summarizes Life Science Nord project manager Sarah Niemann and adds: "Companies that need advice, have an interest in finding contacts in the target regions, or have questions are warmly invited to contact us." Being a large network of European clusters with more than 660 medical technology players and 50 research organizations, universities and technology centers, it provides the critical mass to draw interest abroad, contributing to the alliance's main benefit - deep roots in the key markets. "We have established strong partnerships with key stakeholders in the US, China and Japan. This allows us to open doors to each market," says Niemann. Together with the company requesting support, the individual level of maturity is identified and a targeted market entry is planned accordingly.

Opening doors to potential partners

Bastian Senger, the CEO of \rightarrow **Anacyte Laboratories GmbH**, has been benefiting from the services offered by MAGIA2Market for many months. "It makes a huge difference if a well-known player such as Life Science Nord is opening the doors



"Companies that need advice, have an interest in finding contacts in the target regions, or have questions are warmly invited to contact us."



for us or providing us with connections to several players in science or industry in China, for instance, rather than we, being a small start-up company, try to approach them directly," says Senger who knows the country specifics from his previous job as consultant. "It can be quite difficult to establish trustful contacts from Europe to China, particularly during a time period with no options for in-person meetings." Since he took over the role as CEO, he gradually expanded the companies' global distribution network for the first product CellCover – a ready to use, non-toxic solution for the complete protection of RNA, DNA and protein and the cellular morphology in cells and tissues. With the growing international demand for Next-Generation-Sequencing (NGS) and liquid biopsy solutions, particularly in the field of precision oncology (*see p. 16*), Sen-

MAGIA2MARKET

MAGIA2Market started in September 2020, following the successful project "Medtech Alliance for Global InternationAlisation" (MAGIA). The overall goal of the project is to support small and medium-sized medtech companies accessing foreign markets, particularly the United States, China and Japan.

Life Science Nord represents the German cluster partner. Together with three other European Life Science clusters in France, Italy and Belgium strong partnerships in the target markets have been established. Companies interested in accessing or growing their activities there can benefit from matchmaking, delegation travels and further guidance.

More information: www.magia2market.com ger expects an attractive market for Anacyte's approach. "With our second product, currently in development, we will even be able to provide a fixative for circulating tumor cells in the blood. For the first time, this would offer the opportunity to not only locate, count and identify them, as it is currently possible with existing diagnostic tools, but also to really analyze those cells," Senger points out. This would lay the ground for the development of completely new treatment methods and therapies in oncology. To enter the Chinese market with such a further, new product would be a perfect fit for the Hamburgbased start-up. "Single-cell sequencing is widely used there, and oncology research is a significant topic. This would be the ideal starting point for us," the CEO is convinced. However, being a laboratory start-up focused on the reagent, the company would need further strategic partners - ideally active in the field of diagnostics or laboratory providers - who would be interested in investing. Senger: "In such a case, we could even think of further co-developments." With the support of Life Science Nord and MAGIA2Market, in 2021, he took part in virtual meetings and pitching sessions in which European companies and Chinese partners were able to get in touch. "We already had very promising meetings and I hope to start back with meetings in person in 2022 to establish further relationships," says Senger. For Sarah Niemann, Anacyte's journey is a great



"It makes a huge difference if a wellknown player such as Life Science Nord is opening the doors for us or providing us with connections."

> **BASTIAN SENGER,** CEO, ANACYTE LABORATORIES

example of how SMEs with an interest in international markets can benefit from the services of MAGIA2Market, which are provided free of charges due to European funding. "Despite the challenges of the pandemic, we have been able to foster market access for European SMEs in the US, China and Japan and will continue to do so. We are happy to offer guidance, but also to discuss individual challenges regarding commercialization in target countries that companies may have. We are particularly excited to not only offer continuous matchmaking and pitching opportunities, but also to carry out two matchmaking missions – a virtual one to China in March 2022, and an in-person mission to the US, which is planned for June 2022."

OCEAN-BASED INNOVATION

HEALTH TECHNOLOGIES The publicly funded BlueHealth-Tech innovation alliance combines competencies from the fields of marine research and health care in the Kiel region to improve the treatment of chronic diseases in a multiand transdisciplinary approach.

The German city of Kiel, capital of the federal state of Schleswig-Holstein, may not be a heavyweight from an industrial point of view. But it has much innovative potential to offer, particularly in the life sciences. Powerhouses include \rightarrow GEOMAR Helmholtz Centre for Ocean Research Kiel, a leading institution for marine science, the \rightarrow University Medical Center Schleswig-Holstein (UKSH), \rightarrow Kiel University and major medical technology companies such as \rightarrow Stryker Trauma GmbH.

"In the BlueHealthTech innovation alliance, we bring the region's two areas of strength together – marine sciences and

the health sector – to improve the diagnosis and treatment of chronic diseases", says Anton Eisenhauer, Alliance Coordinator and Head of Isotope Geochemistry at GEOMAR. The concept also convinced the Federal Ministry of Education and Research (BMBF) and in August 2021 it decided to support the alliance as one of 23 nationwide under its funding program "Innovation and structural change / WIR!". It will provide 15 million euros in funding over the next six years. "This decision is a huge milestone for everyone involved. Our idea, our broad regional partnership, our concept and the multitude of exciting project proposals fully convinced the jury," says Eisenhauer.

"We bring the region's two areas of strength together – marine sciences and health industry."

BLUE HEALTH TECH The alliance was established by four partners: Stryker, GEOMAR, Kiel University and USKH. BlueHealthTech has 37 members to date (see also map on p. 31) and it is open to more. The goal of the Blue-HealthTech alliance is the development and economic exploitation of innovative, biochemical agents based on marine organisms and the application of sensitive trace substance analytics from marine research to develop new approaches to the diagnosis, prevention and treatment of chronic diseases. Among the diseases the network focuses on are diabetes, cancer, osteoporosis, neurodegenerative diseases and hypertony.

Focus on translational projects

"Our vision is to be able to fight these diseases even before symptoms appear," Eisenhauer points out. "We received 26 excellent scientific proposals for inter- and transdisciplinary projects from which we will select up to seven," says Eisenhauer. He underlines the alliance would anticipate translational projects with a high technology readiness level.

The original founder of BlueHealthTech is Schönkirchen-based Stryker. "We soon recognized the potential of the interaction



between the different sectors and therefore worked towards establishing BlueHealthTech," says Nils Reimers, Project Director and Director of Global Research and Development at Stryker. "As the market leader in bone marrow nails for the treatment of fractures, we

Innovation alliance BlueHealthTech Funded by the German Federal Ministry of Education and Research with 15 million euros, it comprises partners from academia, industry and hospitals. Scholz, Chairman of the Board at UKSH said, "We recognize the potential for our patients in combining blue biotechnology, medical research and innovative therapy development for the early detection and prevention of chronic diseases. We look forward to working

pq

want to work with local partners to identify areas of innovation, launch innovative products and thus secure sustainable economic growth in the region."

In a pilot project, Stryker is working with the start-up → **osteolabs GmbH** to develop a new type of bone cement made from a mineral biomaterial. The cement is intended to enable better anchoring and stabilization of implants used in bone repair, such as femoral neck fracture care. ""The inter-disciplinary ties between research at Kiel University and the expertise of GEOMAR and UKSH in health research and application, and the knowledge of medical technology and the health care industry, creates a unique platform for successful cross-innovation," adds Carsten Schultz, Professor of Technology Management at Kiel University.

His team uses strategic foresight methods including scenario analysis of the demands of the health care market to develop technology roadmaps. These indicate future fields of innovation with high potential for projects with local partners in Kiel. Jens together in this interdisciplinary consortium."

PROF ANTON

EISENHAUER, Coordinator of BlueHealth-Tech and Professor of Marine Isotope Geochemistry at GEOMAR.

The future of medical engineering: combining smart imaging, robotics and AI

OPERATING ROOM OF THE FUTURE



MEDTECH TRANSLATION With its strong link to the University of Lübeck and combining know-how in medical engineering and health science, the new Fraunhofer Research Institution IMTE focuses on the integrated development of innovative medical devices for diagnostics and therapy.

Up to now, research in the new building on the grounds of the Hanse Innovation Campus Lübeck has focused on cell technology and marine food resources. Soon autonomous robots will take over: An innovation hub for surgical robotics is being created at the -> Fraunhofer Research Institution for Individualized and Cell-Based Medical Engineering IMTE. "We will construct a fully functional operating theater to simulate operations executed by smart surgical robots," says Svenja Ipsen. The engineer leads a 3.7 million euros project called Lübeck Innovation Hub Robotic Surgery (LIROS). "No humans will be treated here, but we will mirror exactly what is happening in the clinic." LIROS is only one of numerous exciting projects at the Fraunhofer IMTE. The institute emerged from the Fraunhofer Research Institution for Marine Biotechnology and Cell Technology EMB as a result of strategic realignment and restructuring measures in December 2020. In order to maximize synergies and opportunities, Fraunhofer - one of Germany's top research organizations - is stepping up its long-standing collaboration



with the \rightarrow **University of Lübeck** and its institutes for both medical engineering and electrical engineering in medicine. Its research focus is on developing innovative, personalized medical devices for diagnostic and treatment applications. With expertise in biosensor technology, cell technology, imaging, magnetic methods, and mechatronics, in combination with interdisciplinary cross-sectional topics such as additive manufacturing, artificial intelligence, systems engineering and regulatory affairs, IMTE offers a unique service portfolio for the health industry. For this, 13 additional groups were incorporated under the umbrella of the IMTE.

Individualized health technologies

"The integrated approach Fraunhofer IMTE is taking to address issues and research projects concerning individualized medical engineering, from basic research to the construction of the device, is paving the way for the transfer of personalized instrumentation into hospitals and industry," says Philipp Rostalski. The electrical engineer is one of the IMTE directors. Together with physicist Thorsten Buzug he oversees the restructuring of the Fraunhofer Research Institution toward individualized health technologies. "We aim to establish instrumentation-, software- and cell-based medical technology that will drive the development of individualized medical devices and personalized systems solutions," Buzug underlines. The new research institution is systematically aligning its services and developments with the process of getting approval for medical products and supports the translation into the market. It is actively contributing to translation into clinical trials and the commercialization of personalized medical engineering.

Apart from the Fraunhofer-Gesellschaft, the state of Schleswig-Holstein and the European Union provide substantial funding for the development of the Fraunhofer IMTE. It is contributing an initial 12.1 million euros for the first three years. Another 28 million euros have been announced for the upcoming European Regional Development Fund (ERDF) period from 2023–2026. Visiting the new institution last summer, Minister-President of Schleswig-Holstein Daniel Günther said, "Medical engineering is one of the key technologies of the 21st century. Fraunhofer IMTE is making a real difference to the continued growth of the healthcare sector here in the region. With Fraunhofer IMTE in Lübeck, a second Fraunhofer Institute in Schleswig-Holstein would be a great benefit for us. The state is behind this venture and therefore lending its support. We are confident that the Fraunhofer IMTE will act as a catalyst for many novel healthcare and life science applications!"



SCIENCE & TRANSLATION | LSN MAGAZINE 35



top left: Robot-assisted surgery system.

top middle: Dr Svenja Ipsen and Prof Matthias Gräser

top right:

A tomographic scanner based on Magnet Particle Imaging for intensive care stations.

below middle:

A microrobot swims in a model of an artery.

below right:

IMTE building on the Lübeck University campus.

Matthias Gräser is the driving force behind the implementation of such cutting-edge technologies. Funded by a Fraunhofer Attract grant worth 1.7 million euros, he is developing a human-sized scanner based on a tomographic real-time imaging technology called Magnetic Particle Imaging (MPI). It is based on weak magnetic fields and determines the distribution of magnetic nanoparticles in the body. "We're developing a mobile device that can be used as an imager in intensive care stroke units to monitor the perfusion of the brain," Gräser says. Magnetic Particle Imaging is also used to visualize another spectacular device being developed at the Fraunhofer IMTE: microrobots. Smaller than a grain of rice, they will be able to navigate through the body like submarines in the vasculature. The magnetic microrobots can be used to treat blocked blood vessels or aneurysms or to deliver drugs directly to a tumor. Recently, an IMTE research team succeeded in steering such a microrobot through a 3D-printed model of the middle human cerebral artery. "Additive manufacturing allows us to create realistic anatomical models that we can use to simulate a surgical intervention," says Svenja Ipsen. Such models will be used in the surgical innovation hub at IMTE. The researchers will also make use of virtual and augmented reality and digital twins. "We want to make our surgical robots more intelligent and autonomous, while making future procedures safer and more effective at the same time," says Ipsen.







TOWARDS EFFECTIVE HYGIENE STRATEGIES IN CLINICS

HIHEAL Initiated by the Life Science Nord Cluster, infectious diseases experts in the North are working together under the umbrella of the HIHeal network. Among other things, they evaluate both the effectiveness of disinfectants with regard to the most recent antibiotic-resistant strains and the validity of reference strains.

Efficacy testing of disinfectants is a key prerequisite for successful hygiene measures in a clinical environment. Bringing together many stakeholders, the Hygiene, Infection & Health (HIHeal) network provides the ideal starting point in the Life Science Nord cluster for joint projects. Coordinated by analytical experts from \rightarrow **Dr. Brill + Partner GmbH Institute for Hygiene and Microbiology**, clinicians from the \rightarrow **Medical Center Hamburg-Eppendorf (UKE)** and the disinfectants specialists \rightarrow **Bode Chemie** and \rightarrow **Dr. Weigert** are evaluating the relevance of clinically isolated antibiotic-resistant bacteria and the effectiveness of surface disinfectants on these bugs. "In clinical settings, we have seen several new antibiotic-resistant strains occurring in recent years. Against this background, we want to explore if the current European reference strains are still a valid for testing the efficacy of available disinfectants and if existing products fabricated by

players in the North can combat the most recent antibiotic-resistant strains," explains Florian Brill, Owner and Managing Director at Dr. Brill + Partner. Although detailed data will only be published during 2022, initial results tend towards a positive outcome for both issues – the reference strains from European norms still seem to reflect the current clinical antibiotic resistant bacterial community and the products are still working effectively.

Regardless of the specific outcome of the project, according to Brill, the project exemplifies the opportunities provided by the HIHeal network established back in 2016. "By connecting different stakeholders from the private industry, clinics and academica, we are able to set up joint projects which would otherwise not have been started," states Brill. His company in particular acts as a platform and intermediary between the more scientific oriented experts in the hospitals and universities on the one hand and the companies on the other hand. "Many of the industrial players are also competitors in certain areas. Normally they would not intend 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.

More info: www.hiheal.de



PRINT YOUR BYPASS

BIOPRINTING Tissue engineers at Kiel have developed a novel 3D cell printer to construct fine blood vessels for individualized bypass implants.

A glimmer of hope for bypass patients: Together with a team of scientists, vascular surgeon Rouven Berndt from Kiel succeeded in developing the prototype of a novel 3D bioprinter to create fine blood vessels that are robust and durable enough to use them for bypass implants. For his research project the senior physician at the Clinic for Cardiovascular Surgery at the -> University Hospital Schleswig-Holstein (UKSH), Kiel Campus, receives a grant by the German Heart Research Foundation, among other funding.

Bypass operations are now routine procedures; every year, heart surgeons in Germany perform around 45,000 bypasses. The problem is that in about 20 percent of patients who require bypass surgery, there are no suitable endogenous vessels available. Against this background, Rouven Berndt, together with a team of physicians, biologists and engineers from the Technical Universities in Kiel and Hamburg, has developed the prototype of a 3D bioprinter.

The platform is based on the inkjet technique: A mix of cells and a hydrogel – the bio-ink – is dispensed through fine nozzles in the form of minute droplets. "Our home-brew bio-ink is based on brown alginate and various human collagen structures," says Berndt. To print a bypass, it only takes two cell types that can readily be isolated from a patient's blood. "The print head we designed can print a tube from living endothelial and muscle cells," he says. Endothelial cells line the vessels from the inside. The overlying muscle cells ensure that vessels can contract and dilate. These are important properties that ensure bypasses last a long time and remain open. "The tubes we printed have the required thin vessel wall and a diameter of four to six millimeters," Berndt explains.

The creation of comparatively small artificial vascular grafts in particular is a Holy Grail in cardiovascular surgery because most materials do not appear suitable and premature occlusion can occur. In experimental studies, the printed vessels from Kiel have already proven themselves. Initial results will soon be published in scientific journals and a patent is filed. The prototype of the bioprinter is now to be industrially manufactured. This is because existing commercially available bio-printers are not capable, for example, of producing vascular grafts in the overall length of 30 to 40 centimeters that is often required for bypasses and vascular protheses.

HEIKE WACHENHAUSEN

After her legal studies in Göttingen, she spent several years as a consultant in commercial law firms in Düsseldorf and Bonn as well as in the legal department of Novartis Pharma in Basel. In 2011, she started her own law business in Lübeck.

PASSIONATE & FORWARD THINKING

HEIKE WACHENHAUSEN As a lawyer specializing in regulatory affairs for the pharmaceutical and medtech industry, Heike Wachenhausen is well-known in the North for her passionate work and straightforward thinking. In September 2021, she was elected as honorary chairperson of the industry association Life Science Nord. In her new role, she especially wants to be a strong voice with regard to new local or national legislation relevant for the health sector.

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When Heike Wachenhausen gets something in her mind, she does it. Straightforward and always looking ahead, that's her philosophy in life. "I can make up my mind and I am a quick decision-maker," says the 53-year-old lawyer. The decision to take on the honorary chairpersonship of the Life Science Nord association was not difficult for her either. "We as women, in particular, have to accept responsibility when it is offered to us." Working with the former chairman Mathias Kraas, Olympus Surgical Technologies Europe, Wachenhausen spent several years in the cluster's Regulatory Affairs working group which she helped to set up ten years ago. It would never have occurred to her to take on the job of chairing the organization one day. "In 2020, I was in the process of rethinking some of my existing tasks and jobs: an honorary professorship in Marburg, work on a commentary in the field of regulatory affairs. I

handed them over to younger colleagues and wanted to have more time for myself, my private life and new challenges," she recalls.

In a career spanning more than 20 years at the University of Göttingen, several business law consultancies and the pharma industry, she finally founded her own business law firm in Lübeck ten years ago – with other female lawyers. Today, the

firm is one of the top addresses for regulatory affairs advice in the field of pharmaceuticals and medical products. Companies from both sectors are included among her clients, and the EU Medical Device Regulation in particular has generated a surge of further inquiries in recent years. "The fact that I would get back to a new voluntary job so quickly in autumn 2021 came as a surprise to me, too. Mathias Kraas asked me whether I had really thought about it carefully. But making a difference at the interface between life sciences and policy making appealed to me and I thought it would be great to change something myself."

It goes without saying that Wachenhausen will not only want to fill her new position on paper. She is a woman of action, for whom no mountain is too high, no journey too far. She may face challenges in her private life as a passionate hiker or in her career, but none that cannot be mastered. Wachenhausen has already climbed glaciers high in the mountains (such as the Himalayas) and conquered 21,000 meters altitude in a fiveweeks-journey by foot from Munich to Venice (in summer 2021) with her husband.

Now she wants to bring her passion for tackling things into the Life Science Nord Cluster. "I would like the cluster to become even more of a driving force for new projects and legislative proposals – both at regional and national level. I want us to be perceived as a lighthouse in the North, with our own opinion and a strong, competent voice," says Wachenhausen. Many topics that need to be addressed under the umbrella of the healthcare industry and life sciences are already going through her mind: climate change, sustainability, and digitization. At the same

> time, a close connection to the Life Science Nord members and their demands are important to her as well. "Of course, we will need to focus on our strengths and should not get lost in too many general challenges," she points out.

> Down-to-earth thinking and focus are qualities she learned at home as she was the first one in her family to study at university. "When I was 17 years old, I

decided to go for legal studies after school. It was maybe a bit naive at the time, but I made it all the way through and never regretted taking that step." Today, although Wachenhausen does not originate come from the region - she grew up on a farm near Kassel - she is increasingly rooted in the North. Above all, the link between local stakeholders and fostering young talents has been on her agenda for a long time. Since 2017 Wachenhausen has been honorary professor in the applied natural sciences department at the Technical University of Lübeck and she was instrumental in setting up the regulatory affairs master's course for which the second class finished its studies at the end of 2021. She believes educating the next generation will be key for the North. "We need close collaboration between industry, business, authorities, and universities because finding qualified employees is currently among one of the greatest challenges facing us."

"Making a difference at the

interface of life sciences

and policy making

appealed to me."

BRUNO CHILIAN, CO-FOUNDER & CEO OF TRI



(left) is co-founder and CEO of the Hamburgbased biotech startup TRI Thinking Research Instruments GmbH. Together with data scientist Johannes Bauer (right), the physicist has developed the platform VAIDR to analyze cell culture systems. Mr Chilian, what exactly did you develop and what is unique about your products?

BRUNO CHILIAN VAIDR is an all-in-one-solution for cell culture imaging and AI-based image analysis. We developed both the imaging hardware and the software. The systems consist of an automated brightfield microscope and our software, which runs on a high-performance machine learning computer. All of this is integrated into two boxes.

What is your mission?

CHILIAN Our systems make data acquisition and management easy, fast and safe, and they put AI-based routine image analysis in the hands of lab researchers. We unlock the potential of state-of-the-art machine learning for people and applications that don't normally have access to it.

Could you tell us about some recent milestones in the growth of your business?

CHILIAN We recently placed three of our systems at renowned cell research labs in academia and industry. Several of our partners are based in Hamburg, e.g., at the UKE (Profs. Cuello and Fehse), Evotec and acCELLerate. Additionally, we just filed a patent for our non-invasive bioreactor cell culture imager, which is suitable for imaging 3D cell aggregates.

More information: www.vaidr.de

WE ARE ACTIVE IN THE NORTH ...

"... because of its vibrant community and its emerging life sciences AI ecosystem. Our goal is to bring the power of AI to biomedical research applications."

THE NUMBER



cell culture images labelled by an expert are already enough to train the machine learning algorithm developed by the TRI team.



RANKING FAMILY & WORK IN MEDTECH

TOP 1 EUROIMMUN Medizinische Labordiagnostika TOP 2: Sysmex Europe TOP 3: Löwenstein Medical Technology

HOW MEDTECH COMPANIES BALANCE FAMILY AND WORK

EMPLOYER RANKING Companies from the Life Science Nord Cluster have reached first to third place ranking of the most family-friendly companies in the "Medical Technology" category in Germany. The ranking was conducted by job evaluation portal kununu and women's magazine Freundin among German and Austrian companies.

With the corona pandemic still ongoing, 2022 will also be affected by the crisis. For numerous employees, this means mastering the balancing act between home office and home schooling, between family and work. For employers, the family-conscious staff policy has therefore gained in importance. On a regular basis, the job evaluation portal kununu and German women's magazine Freundin select employers who offer the best work-life balance strategy. most family-friendly employers. Finally, 600 German companies found their way in the ranking, distributed in over 30 industry sectors. In the medical technology industry, Northern employers clearly stood out and gained top evaluations: EUROIMMUN Medizinische Labordiagnostika AG, headquartered in Lübeck, reached the first place, followed by Sysmex Europe GmbH, based in Norderstedt, on the second place, Hamburg-based Löwenstein Medical Technology as third winner and Drägerwerk AG & Co. KGaA in Lübeck on the sixth place.

Attractive jobs & high quality of life

Interested to work in Northern Germany? If you are searching for attractive positions in the life science industry, don't miss to take a look at the Life Science Nord (LNS) job exchange platform. Numerous job offers and exciting challenges from up to

> 280 companies – start-ups, SMEs and large corporations – active in pharma, biotech and medtech can be found.

More information about Northern companies & jobs: www.lifesciencenord.de

Northern firms in Top 10

A total of 1,400 companies in Germany and around 300 in Austria were selected according to a defined catalog of criteria to participate in the ranking for the Northern companies active in medical technology clearly stood out and gained top evaluation in the ranking.

GET IN TOUCH WITH US!

Life Science Nord is the regional industry network for medical technology, 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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 \rightarrow Please find more cluster members at: **www.lifesciencenord.de**



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