MEDTECH, BIOTECH & PHARMA | 3/2019

LSN MAGAZINE

THE BUSINESS JOURNAL OF HAMBURG & SCHLESWIG-HOLSTEIN

LIFE SCIENCE NORD

SMART DRUG DISCOVERY

How life science companies in the North involve biomedical data and innovative technologies in the hunt for better treatments

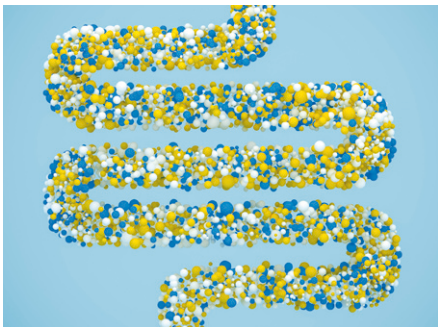
NEW AI ALLIANCE

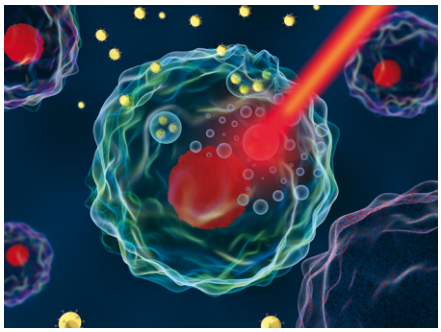
The consortium KI-SIGS connects players from the North to bring artificial intelligence into clinical application

MICROBIOME ENGINEERS

Why manufacturing microbiome-based therapeutics is a challenging task for biotechnologists

WWW.LIFESCIENCENORD.DE





SMART DRUG DISCOVERY

HOW TO PUSH THE HUNT FOR BETTER THERAPIES

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Dr Hinrich Habeck,
Managing Director
Life Science Nord Management GmbH

Dear Readers, we are excited to host one of the largest joint events for the biotech and pharma industry for the third time in Hamburg. We welcome more than 4,500 guests from all over the world to join us for a very special edition of BIO-Europe from November 11th to 13th. In addition, we are celebrating the 25th anniversary of this event series and we look forward to insightful discussions relevant to the biotech and pharma industry. Among the major topics will certainly be questions on how to address existing medical challenges, new clinical needs and demographic change which are calling for satisfactory and novel therapeutic approaches.

How can we shorten the road to a new drug? With companies such as Evotec, Eppendorf, Indivumed and Nordmark, we have strong life science players in the North that offer new ways of advancing smart drug discovery. Interested? You'll find more details of their approaches explained in this issue, but we are also pleased to meet with you at our booth in the BIO-Europe exhibition hall.

A powerful set of technologies such as stem cell technology, genome editing, or artificial intelligence is redefining efficiency and speed in drug discovery. In our special, we highlight how life science companies from the North have adopted their research and development platforms to this age of agile and smart drug discovery. The way in which academic researchers and biotechnologists are addressing the microbiome in the human gut is covered in the "Know-how" section of this magazine. Bringing artificial intelligence systematically into clinical application is the aim of a powerful public-private consortium dubbed "KI-SIGS". It is among the winners of an ambitious AI competition of the Federal government. Funded with 10 million Euro, this project is a perfect example of the power of networking in the north of Germany. The same rings true for a pioneering life science alliance made up of five partners from Hamburg and Schleswig-Holstein that is developing a portable system for the rapid on-site diagnosis of infectious diseases in the horse's stable.

Enjoy reading this edition packed with further exciting news from the Life Science Nord Cluster. Hinrich Habeck

INFECTION DIAGNOSTICS

PIONEERING POINT-OF-CARE TEST FOR THE STABLE

A life science alliance of five partners from Hamburg and Schleswig-Holstein is developing a portable system for the rapid on-site diagnosis of infectious diseases in veterinary medicine.

Outbreaks of equine herpesvirus have been a major concern for horse owners in Northern Germany in the past few years. The virus can cause severe respiratory disease and neurological disorders and it is highly contagious. Once diagnosed, the infected animals must be quarantined and tournaments have to be cancelled, resulting in substantial costs for their owners. Currently, the diagnosis of infectious diseases in veterinary medicine is time-consuming and costly: biological material is usually taken from the animal through blood samples or swabs and sent to a central laboratory for analysis. Veterinarians receive the results after about five days and only then can they initiate the appropriate measures. A consortium of five institutions and companies from Hamburg and Schleswig-Holstein named OPTOCHIP wants to greatly accelerate the process. The aim of the alliance is to develop a mobile point-of-care testing system for infectious diseases in the horse stable. "Our approach is set to take only 30 minutes from sample to result," says alliance coordinator Sabina Arndt of altona Diagnostics GmbH in Hamburg.

At the heart of the system is a disposable microfluidic chip that integrates fluorescent molecular diagnostics with optical technology based on organic light-emitting diodes (OLEDs) and organic photodiodes (OPDs). OPTOCHIP partners will receive funding of 1.1 million Euro in total for the next three years. While the partners in Schleswig-Holstein receive funding via the European Regional Development Fund (ERDF), Hamburg partners will be funded by the Hamburgische Investitions- und Förderbank (IFB). OPTOCHIP is a perfect example of how the cluster Life Science Nord enables organizations to join forces. It has accompanied the launch of the project through its innovation network "Hi-Heal". The alliance combines the expertise of the Hamburg-based companies in the fields of molecular diagnostics (altona Diagnostics) and device development (Byonoy GmbH) with the know-how of the partners in Schleswig-Holstein from the fields of plastics technology (Krämer Engineering GmbH), photonics (Christian-Albrechts-Universität zu Kiel) and microsystems technology (Fraunhofer Institute for Silicon Technology–ISIT). "After successful validation and commercialization of the test, we plan to extend its application to human diagnostics," Arndt says. pg

More information: www.wtsh.de

NORTHOPEDICS

BONE HEALTH INNOVATORS

The mission of the NORTHOPEDICS project, coordinated by Life Science Nord Management GmbH, is to establish an innovation network for the development of solutions, products, processes and services in the field of bone healing. Launched in 2016, it has grown to a lively network of 60 partners from hospitals, the scientific community and industry, which pools regional expertise and promotes interdisciplinary and intersectoral cooperation.

At the end of September, NORTHOPEDICS organized a parliamentary breakfast in the Schleswig-Holstein State Representation in Berlin. The members of parliament had the opportunity to become familiar with the activities of selected experts from hospitals, science and industry and to discuss opportunities and challenges in the development of new therapy and diagnostic solutions for musculoskeletal diseases. The aim of the event was to highlight possible structural approaches to action so that health innovations can reach patients faster. The team at Kiel-based osteolabs GmbH presented its new, radiation-free test that can be used for osteoporosis screening. The laboratory test is based on the mass spectrometric measurement of calcium isotopes in blood or urine samples. In cooperation with the University Hospital Schleswig-Holstein (UKSH) and the GEOMAR-Helmholtz Centre for Ocean Research Kiel, the method was clinically tested and validated. The financing of such clinical studies and evaluations, the number of patients required and the complexity of the regulatory framework are major challenges, especially for highly innovative small companies and startups. Clinical experts from NORTHOPEDICS underlined at the event in Berlin how beneficial cooperation between clinical science and industry is to bring about scientifically sound health innovations quickly and close to the patient. The NORTHOPEDICS project will be funded by the European Regional Development Fund (ERDF) and the Federal state of Schleswig-Holstein until 31 October 2019. The partners are keen to expand the existing network to drive innovation in bone health. pg

More info: www.lifesciencenord.de

MEDICA 2019

SHOWCASE OF NORTHERN EXPERTISE

With more than 120,000 visitors and 5,000 exhibitors, MEDICA in Düsseldorf is one of the biggest international trade fairs in the medical technology sector. As was the case in previous years, the Business Development and Technology Transfer Corporation of Schleswig-Holstein WTSH will also organize a joint booth (Hall 15/J35) in cooperation with Life Science Nord at this year's MEDICA. From 18-21 November, a dozen exhibitors from the North will showcase their newest products and services.

The expertise offered ranges from diagnostics and therapeutic devices in different application settings, optical systems and microscopes to hospital equipment, as well as engineering and consulting services for the medical industry. In addition, the Life Science North (LSN) cluster will provide onsite information on the "Medtech Alliance for Global InternationAlisation" (MAGIA). This project brings together four leading European medtech and health clusters to foster the internationalization of their SMEs and open gateways towards the Chinese and US medical industry markets. During the trade fair, LSN will sign a Memorandum of Understanding with the cluster Medical Alley Association from Minnesota, USA, to encourage closer collaboration between the two regions.

For anyone interested in meeting with Chinese and US MAGIA partners in Düsseldorf, please contact Sarah Niemann (niemann@lifesciencenord.de). sw

More info: www.lifesciencenord.de

NEW BOARD MEMBER

Kathrin Sabine Adlkofer, Chief Executive Officer and Founder of Lübeck-based Cellbox Solutions GmbH, was elected as one of three new members to the board of BIO Deutschland, the association of the biotechnology industry in Germany. The ten members of BIO Deutschland's board represent various segments of innovative small and medium-sized biotechnology enterprises and the industry. The new board, which will be in place for the next two years, appointed Oliver Schacht, CEO of curetis N. V., as its chairperson. Cellbox Solutions is a spin-off of the Fraunhofer Research Institute for Marine Biotechnology and Cell Technology (EMB) formed in 2017. The startup has developed high-tech incubator boxes for the transport of cell material.

More info: www.biodeutschland.org

#STEM CELL CONFERENCE

2021

will be the year when the ISSCR Annual Meeting will take place in Hamburg, co-hosted by Life Science Nord.

NETWORKING CONGRESS

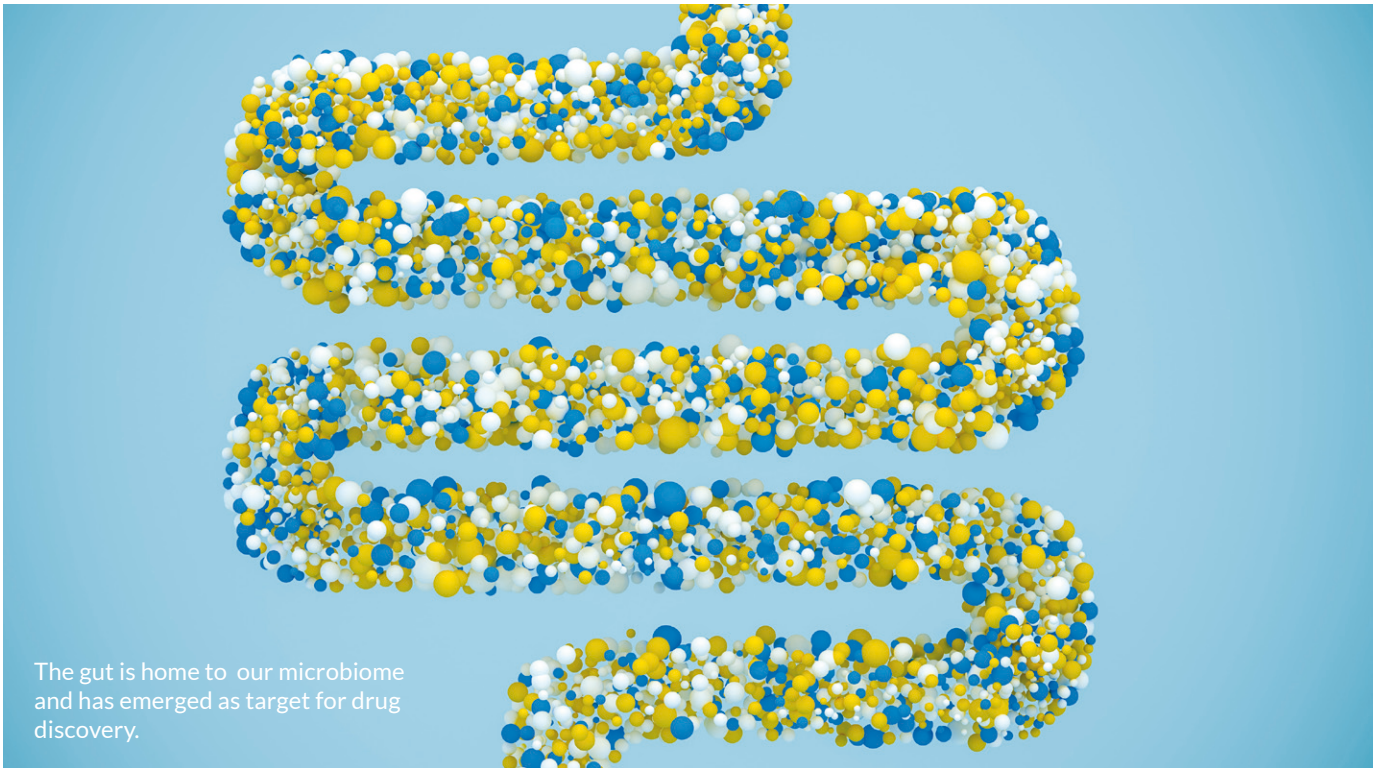
Robust networking is a central factor for comprehensive and sustainable healthcare in Schleswig-Holstein in particular. For the eleventh time, the congress "Vernetzte Gesundheit" will be dealing with the question of how cooperation between the health industry and healthcare can be shaped. The two-day congress will take place from 25–26 March 2020 at mediadocks Lübeck and it will welcome participants from all over Germany. The Ministry of Social Affairs, Health, Youth, Family and Seniors of the State Schleswig-Holstein is the organizer of the event.

More info soon on:
www.vernetzte-gesundheit.de

BACTERIAL THERAPIES

MICROBIOME ENGINEERS

Exploring microbial communities in the gut has become a hot topic in the life sciences. While biologists at Kiel University reconstruct how microbiomes interact with their host, biotech contract manufacturer Nordmark has stepped into the challenging field of producing live biotherapeutics.



The gut is home to our microbiome and has emerged as target for drug discovery.

Our bodies harbor a huge array of microorganisms both internally and externally. While bacteria are the biggest players, we also host single-celled organisms known as archaea, as well as fungi, viruses and other microbes – including viruses that attack bacteria. Together these are dubbed the human microbiota. The body's microbiome includes all the genes our microbiota contains, however colloquially the two terms are used interchangeably. Rapid advances in DNA sequencing and bioinformatics technologies in the past two decades have substantially improved our understanding of the microbial world inside our bodies. "We've come to the fascinating conclusion that life is multi-organismic – we are metaorganisms," says Thomas Bosch, a developmental biologist and head of "Kiel Life Science" (KLS) research at the Christian-Albrechts-Universität Kiel (CAU). Biologists have only started to uncover the important role of microbial communities in human physiology. Microbes help to break down the array of sugars. Other key roles of our microbes include programing our immune systems, providing nutrients for our cells and preventing colonization by harmful bacteria and viruses.

In recent years, the gut microbiome has been linked to a plethora of diseases and conditions, from diabetes to autism and anxiety to obesity. Targeting or modifying the microbiome has emerged as a hot topic in biomedical research. Bosch is convinced the microbiome provides a powerful way to approach complex diseases. He also says it is worth being cautious: many studies show correlations rather than cause and effect. "The field has to move from describing the structure of microbiomes to generating mechanistic insights on how these ecosystems work," Bosch underlines. He is convinced that basic researchers must now design experiments such that they find out how the microbiota and their host interact and communicate with each other. Bringing causality to microbiome research is at the heart

of the DFG-funded Collaborative Research Center CRC 1182 "Origin and function of Metaorganisms" at CAU. Bosch is its spokesperson. A key issue for the researchers is how the composition of an organism's microbiome forms during its unique development. To reduce complexity in their analyses, Bosch and his team use the freshwater polyp Hydra as an experimental model. The transparent animal has a tube-like body that is akin to the vertebrate intestine. And it is colonized by a simple microbiome. "The interesting thing is that we can create germ-free animals," Bosch says. "Combined with sophisticated genetic techniques, this allows us to assemble or also to deconstruct the metaorganism."

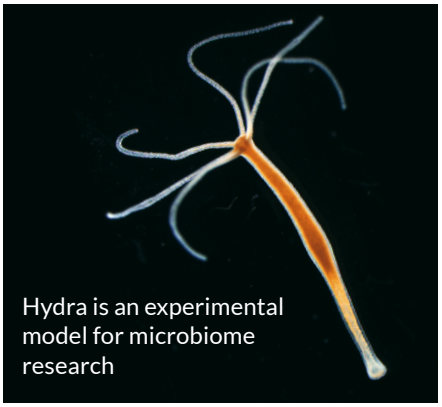
This way of microbiome engineering has, for example, generated novel insight into how bacteria and the 3,000 neurons in the simple nervous system of Hydra communicate with each other. The intact natural Hydra microbiome can play an important role in the spontaneous contractile activity of the polyp's body column. "The microbes also play a role in dysmotility of the human intestine, a disorder seen in inflammatory bowel disease or Parkinson's disease. "Thus, Hydra is a very informative model system that allows us to develop novel concepts which we can discuss with our medical colleagues here in Kiel."

Microbiome research relevant to clinical application is also part of the new Cluster of Excellence "Precision Medicine in Chronic Inflammation", a Kiel and Lübeck University cluster with partner institutions in Plön and Borstel.

Living Biotherapeutics as new modality

Influencing the function of the gut microbiome is regarded as a new frontier in pharma research and development. That is why a growing number of companies working in the microbiome field are now developing live biotherapeutics — single or multi-strain bacterial cultures that can recolonize intestines with 'beneficial' bacteria to restore the balance of the microbiome.

However, outside of their natural habitat, most gut bacteria are sensitive creatures. Being strict anaerobes they die on contact with oxygen. This is only one aspect that makes dealing with microbes as drugs so challenging. It requires specialized know-how which is scarce in the field of biopharma. Nordmark Arzneimittel GmbH & Co. KG is a biopharma company that can deliver this expertise.



Hydra is an experimental model for microbiome research

The company headquartered in Uetersen, close to Hamburg, has successfully joined the small club of manufacturers that can produce live biotherapeutics targeting the human gut microbiome. The drugmaker employs nearly 600 people and has a large biotech division specialized in the manufacturing of therapeutic proteins. Apart from supplying its own biologics pipeline, Nordmark also acts as a contract development and manufacturing organization (CDMO). "We are a fully integrated pharmaceutical company, providing service and expertise along the entire value chain," says Jan Heyland, who is responsible for research and development at Nordmark's Biotech division. "This includes process development, GMP-compliant production and formulation," he explains.

How to manufacture a microbe cocktail

Nordmark, member of the 2019 Regional Host Committee of BIO-Europe, can build on decades of expertise in microbial fermentation and cell culture processes. But bringing microbiome-based therapeutics to the clinic means navigating several tough production challenges. Unlike traditional pharmaceuticals and biomolecules, microbial-based therapeutics consist of a mix of living organisms, meaning biotechnologists must figure out how to keep their microbes alive while also considering things like product stability and shelf life. "It is a steep learning curve for all parties involved: big pharma, authorities and of course for us as biopharmaceutical contract manufacturers," Heyland underlines.

It's not only the gut bacteria species which must be cultivated under strict anaerobic conditions. "They also form spores, which can increase cross-contamination risks," Heyland says. This requires special equipment and handling to keep the microbes under anerobic conditions as well as stringent hygienic control. In addition, the biotechnologists cannot rely on standard protocols or established production platforms when cultivating their bacteria. The development of a pill including a mix of microbial species is another challenge, since the live biotherapeutics must be encapsulated and handled under oxygen-free conditions and need to be characterized in detail. Thereby, sophisticated analytic tools are needed to differentiate between closely related strains, to spot living and dead cells and to ensure a homogenic drug product.

"We are breaking new ground in many aspects," Heyland resumes. His team has successfully achieved the first milestones in microbiome engineering. Recently, Nordmark supplied an Active Biological Ingredient (API) in the form of a capsule to a partner with a view to conducting a clinical study. Although he cannot provide detailed information on the condition addressed in the study, Heyland is convinced that the therapeutic expectations within the scientific community seem to justify the efforts. "At this stage it appears that big pharmaceutical companies prefer to outsource such complex projects to specialists," he says. pg

More information:
www.nordmark-pharma.de

BIO-EUROPE Meet us! 2019

DRUG DEVELOPMENT

AGILE AND SMART DRUG DISCOVERY

How life science companies from Hamburg use complex biomedical data sets and innovative technologies to accelerate their hunt for better treatments.

In the age of agile and smart drug discovery, one should get used to different project timelines. One impressive example comes from a new drug development alliance of two Hamburg-based life science companies. In April this year, biotech company Evotec SE and oncology data specialist Indivumed GmbH teamed up to identify new therapeutic targets for the treatment of colorectal cancer. In September, the collaboration partners announced they had already achieved the first milestone: In less than three months, they were able to select three novel drug targets, analyzing a fraction of Indivumed's multi-omics cancer patient database. They will now be progressed towards first-in-class cancer therapeutics using Evotec's multimodality drug discovery and development platforms.

"This strategic collaboration is highly innovative", says Werner Lanthaler, the CEO of Evotec. "The scientific alignment is fantastic, and the local proximity of the partners is also very helpful". And Hartmut Juhl, CEO of Indivumed adds, "This partnership is extremely valuable for us. Our rapid progress shows the power of combining high-quality cancer patient data sets with bioinformatics and artificial intelligence."

"High quality biomedical data are key to applying AI"

Emerging technologies and mechanistic pharmacology

When global players from the biotech and pharma sector come together at the partnering event BIO-Europe 2019 in Hamburg (*see Info on page 10*), they meet against the backdrop of a fast-changing innovation landscape in drug development. In order to increase the success rate of drug discovery programs and decrease R&D costs, pharmaceutical companies seek to improve and accelerate every stage of the early drug discovery process. Starting with target identification and validation, and all the way towards a preclinical drug candidate with an excellent pharmacokinetics profile. To achieve these goals, drug researchers have turned to new areas in science to develop better methods and models.

To expedite research and development processes, pharmaceutical companies are increasingly turning to the concept of agility: They combine a stable backbone of core processes and capabilities with a high degree of flexibility for rapid response to change to accelerate processes. Maintaining only the most important core functions and competencies means outsourcing research-intensive programs to specialized contract research organizations (CROs) or academic labs. An increasing number of drug developers are focusing on mechanistic pharmacology and aiming at higher disease relevance. More relevant cellular systems and technologies that detect powerful multiparametric readouts have allowed researchers to focus on recreating the native biology. Increased competition and the need for speed and to do things more efficiently, especially in drug discovery, explains why artificial intelligence (AI) has started to increase in popularity. Practically every player is adopting smart approaches to use machine learning and big data analytics to turbocharge their R&D.

A dream come true

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 Indivumed, sees his company as a key enabler

MEET THE LIFE SCIENCES PLAYERS FROM THE NORTH AT BIO-EUROPE

Moin Moin: The Life Science Nord Cluster of Hamburg and Schleswig-Holstein is hosting this year's BIO-Europe for the third time from 11th to 13th November, 2019.

About BIO-Europe: With its 4,500 high-ranking guests from the international biotech and pharmaceutical sector, BIO-Europe is the largest and most significant biotech partnering conference in Europe. This year, the event will take place at Hamburg Messe, which offers the perfect conditions for effective partnering as well as the congress program and accompanying exhibition.

Evening events: The Welcome Reception on Sunday, 10th November, at the Hanseatic-style Curio-Haus and Monday night's evening reception at Kuppel Hamburg will demonstrate how tradition and innovation, old and new, can flourish side by side in Northern Germany.

Regional Host Committee: The close-knit network of companies in the region is represented by a strong regional host committee of four industry partners – Eppendorf, Indivumed, Nordmark and Evotec – which will be hosting Monday night's evening reception. More than 20 companies and institutes are represented at our booth.

Meet us at our booth!

for cancer medicine, with its powerful tumor database as a valuable asset. Over the last 15 years, the biobanking specialist has built up a global network of affiliated clinics that obtain cancer patient tissues in frozen samples as well as blood samples.

The key to high-quality specimen in Indivumed's biobank was the introduction of highly standardized and stringent sample collection procedures. The biospecimens as a biological resource have been combined with thorough validation of medical information. "From day one, we have accurately collected the clinical information and outcome data in a far more detailed manner than any other existing clinical database," says Juhl. "This now gives us a unique basis for research and drug discovery."

Multi-omics approach delivers complex data

In recent years, Indivumed has started to unlock the informative power of parts of its biospecimen collection by extracting a complex set of biological relevant data from it. "Our frozen material can be regarded as a complete raw data set of tumor biology", mentions Juhl. In order to obtain what Juhl dubbs "molecular phenotypes", the Indivumed team applied a set of top-notch bioanalytical techniques such as whole-genome sequencing, proteome and transcriptome analyses.

"Combined with clinical and outcome information and applying bioinformatic tools and artificial intelligence algorithms, we are able to extract data from individual cancer cases in an absolutely unique way", he says. The cancer researcher is convinced that this brings his company and its customers and partners closer to the development of a true precision medicine for cancer patients.

"Having this complex and dense information is fantastic. For me as a scientist, it's a dream come true," Juhl says. "It allows drug and target discovery in a much faster way. And it also allows us to understand drug function retrospectively."

Juhl is fascinated by its speed: His team recently analyzed a cohort of cancer patients out of its multi-omics database IndivuType. "Within minutes, we were able to discover more than 30 potential targets for treatment with these complex data", Juhl explains, "lots of them have never been described before". Expanding its global cancer database reflects a change in Indivumed's business model from offering contract biobanking research services to providing comprehensive sets of cancer patient data to answer pharma R&D queries. The partnership with Evotec is only one such example.

Demand for powerful IT

It is only possible to understand this complexity through sophisticated bioinformatics and computer technology and increased storage capacity. "That is why we have recruited more than 100 people within the last year, most of them data scientists and IT specialists", Juhl explains. Indivumed has also entered into significant partnerships with IT-driven companies or academic partners to build its digital and data analytics know-how. By the end of this year, Indivumed aims to expand its database to 3,000 patient cases, each with its own multi-omics dataset. "Since we have complex multi-omics data, we can answer the same questions much faster than with genetic databases, and we require less patient numbers – and we gain deeper insight." As for smart drug discovery, it all comes down to the data quality, Juhl underlines. You need good quality, robust and structured data in order to implement AI. "The cleaner the data from the beginning, the more they correlate."

Unbiased drug discovery platform

Werner Lanthaler, the CEO of Evotec, suggests that in future the key to drug discovery will be the convergence of technologies. "Innovation and flexibility can only happen in the process of early drug development and defining target product profiles. Once you have progressed to clinical studies, you are locked in the regulatory and commercial processes," Lanthaler says.
In recent years, traditional technologies as high-throughput screening of small molecule libraries, one of Evotec's core areas of expertise, have been augmented by many other technologies that enrich the process. "Being able to provide a platform that allows these technologies to come together will be our core driver of innovation in the years to come," Lanthaler says. He describes a strategic mind-shift in the pharma development business: "You have to come from the end of the process and ask, what is the most efficient tool that leads to a drug that helps the patient?" Creating a platform that is multimodality-driven allows us to take an unbiased view on what is the most efficient tool in the drug discovery process, believes Lanthaler.

"The beauty of our approach is that we initially run many different modalities in parallel because the marginal cost in the early process is low. Then we narrow this down to the best solution with the lowest marginal cost and the highest degree of efficiency," Lanthaler explains. To get smarter in drug discovery, Evotec has integrated a bunch of powerful emerging technologies to its platform. One such disrupting technology is cellular reprogramming. Here, adult human cells are converted using a cocktail of transcription factors into induced pluripotent stem cells (iPSC). iPS cells are an indefinite source for the generation of any cell type. This gives biomedical researchers access to relevant human cell material that can even be patient specific. "iPS cells have opened doors where other technologies failed,"

says Lanthaler. Not only in the field of neurodegenerative disease, iPS technology provides an excellent tool for disease modelling and predicting drug efficacy. Over the last six years, Evotec has invested in establishing a stem cell-based drug screening platform. The aim: To industrialize iPS cell-based drug screening to the highest industrial standards in terms of throughput, reproducibility and robustness. Evotec's iPSC team has grown to more than 150 people. It plays an essential role in alliances with strategic partners, such as Celgene and Sanofi. "In terms of the scope of the platform and the systematic integration of the iPSC platform to all other drug discovery technologies, we are at the forefront of the whole industry," Lanthaler says.

Using artificial intelligence as predictive tools is key to reaching the highest degree of efficiency in drug discovery. Evotec uses AI, for example, to predict better chemistry and targets, or for selection processes in the stem cell field. "The efficiency gains are unbelievable", Lanthaler says. "Within the convergence of technologies, AI will be a bread and butter business in the years to come."

Another strategical move was this year's acquisition of Just Biotherapeutics for up to 90 million US dollars. "This has catapulted our biologics expertise and capacities to a level where we aspire to be a global technology leader", Lanthaler says. Now termed Just – Evotec Biologics, the Seattle-based team offers state-of-the-art discovery, development and manufacturing of therapeutic biomolecules. What makes their drug development especially smart is the application of machine learning-based design tools to predict and select optimal molecules for further development and for the rapid expansion of high-yielding manufacturing processes.

High-quality lab equipment key to faster R&D

Eppendorf AG, a leading life science company headquartered in Hamburg, is best known for its wide range of instruments and consumables for laboratory equipment. Since January 2019, Dr. Christian Herget is head of the Eppendorf Business Unit Consumables. He is responsible for a broad spectrum of single-use lab consumables made of plastic, such as pipette-tips, "Eppendorf" tubes or PCR plates. "Our consumables are at the epicenter of our customers' experiments, in touch with samples and reagents" specifies Herget.

Prof. Dr. Hartmut Juhl
CEO of Indivumed GmbH

Dr. Christian Herget
Head of Business Unit Consumables at Eppendorf AG

Dr. Werner Lanthaler
CEO of Evotec SE

"That's why reliability and high performance are absolutely essential here." But how can state-of-the art lab equipment make a difference to players active in pharma development? "Since both reproducibility and time-to-market are of the essence, our customers have no tolerance for experiments that need to be repeated or yield questionable results," Herget says. Applying powerful techniques such as single-cell sequencing, genome editing, or flow cytometry include highly sensitive lab procedures. "They are performed with precious samples which you cannot afford to lose. Our customers want to de-risk their R&D, and we deliver the tools to make that happen." That is why more and more customers realize that performing their experiments with reliable, high-quality devices and consumables can save significant time and money down the line, Herget underlines.

Lab work documentation becomes smart

Another trend he observes is an increased demand for end-to-end documentation of lab work – amongst other things to satisfy the regulatory authorities' growing appetite for experimental data. Digitalization has now advanced to every step of the laboratory workflow – from planning and setting-up to running the experiments.
The business unit manager details two steps as to how Eppendorf is approaching this: On the one hand, there is digitization, which means connecting your devices to a network of machines. And then there is digitalization, integration into IT systems to digitalize aspects like device management, experiment planning and documentation. This helps to improve reproducibility, efficiency and convenience of experimental procedures.

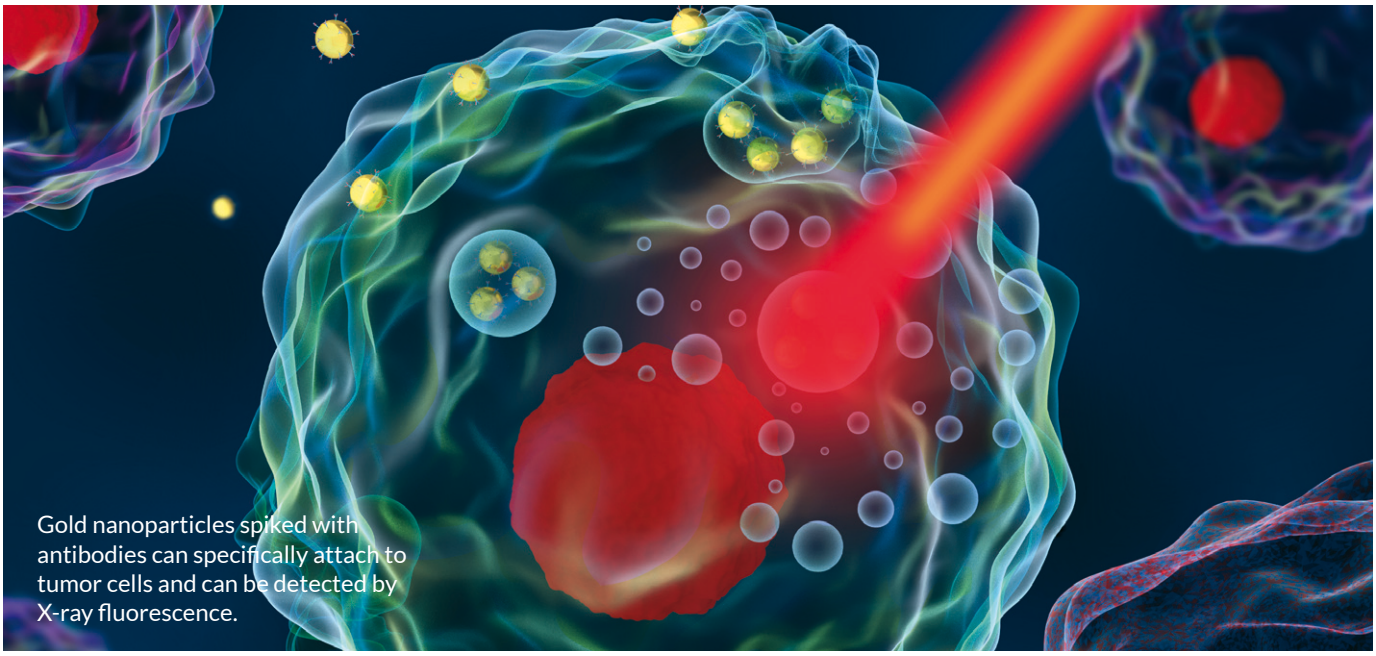
"For consumables, we support lab digitalization by barcoding them with unique identifiers." Agility and sustainability are two key pillars of Eppendorf's future-orientated initiative "be Eppendorf 2021". It aims at making the company fit for global and accelerated growth. It comes not only with a recruitment offensive but also a fundamental cultural change, Herget explains. The aim is to purposefully change and strengthen the way in which more than 3,000 Eppendorf employees around the world collaborate. "To us, establishing agile methods and processes means developing innovative products faster and in closer cooperation with our customers."

pg

DESY SPIN-OFF

PRECISION X-RAY IMAGING TO TRACK MEDICAL DRUGS

The Hamburg-based startup axiom insights GmbH aims at introducing precision X-ray fluorescence imaging to set new standards in pharma R&D.



Gold nanoparticles spiked with antibodies can specifically attach to tumor cells and can be detected by X-ray fluorescence.

It is a precision imaging technique that can detect the tiniest tumors and track medical drugs in living organisms, and it is set to revolutionize the field of pharmacokinetics in pharmaceutical research and development.

The method named X-ray fluorescence imaging (XFI) is very powerful: "It enables us to look so deeply into living organisms that the path which drugs can take will be made visible throughout the entire body," says Marc Jopek. He is the CEO of the Hamburg-based startup axiom insights. The spin-off of German Electron Synchrotron DESY aims to translate XFI into a gold-standard method for pharmacokinetic research. The new method has been developed by a research team headed by Florian Grüner, a professor at the Department of Physics at the University of Hamburg. In a project performed at DESY's X-ray source PETRA-III synchrotron, they succeeded in drastically reducing the XFI-background signal using a sophisticated computer algorithm. The research study is published in the journal "Scientific Reports". For the detection of XFI signals, small gold nanoparticles are covered with tumor biomarkers or drug molecules. After injecting the nanoparticles into the living organism, the particles travel through the body to dock on an existing tumor or on the drug target. When scanning the patient with an X-ray beam the width of a hair, the gold particles start to illuminate and emit characteristic X-ray signals recorded by a special detector. "It is not only possible to visualize how the particle travels, but the technology also allows detection of their local amount, destination, and retention time. These are important parameters for the pharmacokinetic drug research to perform dose finding studies and toxicology, which do not exist in these details today," underlines Jopek.

The X-ray examination is gentler in terms of radiation exposure than other techniques such as PET. "Our aim is to offer a product and services for the pharmaceutical industry, biotech companies and scientific research institutes," Jopek explains. Further R&D is needed to standardize the method. The team plans to apply the technique in preclinical studies over the coming months. . The DESY spin-off team will present its technology in the start-up slam session at BIO-Europe 2019 in Hamburg. js

More information:
www.axiom-insights.com

PHILIPS

SMART PATIENT MONITORS

More than 1,200 portable IntelliVue patient monitors from Philips will be in use at the University Hospital Schleswig-Holstein (UKSH) by the end of 2020. This will support fast and efficient clinical decision making.

"To provide patients with the best possible care, we need a complete overview of their general state of health at all times. Ideally, this should be independent of location," explains Norbert Weiler, Clinic for Anaesthesiology and Operative Intensive Care Medicine at UKSH Kiel. „Modern technology and advancing digitalization make this increasingly possible nowadays, and in addition to supply, they also improve the work processes for hospital teams," continued Weiler.

Embedded in a modern database server concept, the new patient monitors from Philips seamlessly monitor predefined vital parameters, which are easily transferred to clinical systems for documentation and analysis. The IntelliVue patient monitoring system can be quickly and flexibly adapted to a wide range of clinical requirements and allows connection to third-party devices. The monitors can be adapted to a patient's requirements in just a few steps. The data collected in this way support clinical decision-making and are also incorporated into a hospital alarm management system that immediately alerts the relevant medical decision-makers in critical situations, e.g. via mobile devices. The Kiel campus will soon be connected to the network for the new patient monitoring system. Installation at the Lübeck campus will begin a few weeks later and is expected to be completed by the end of the year. The main system will be installed across campuses over the next one and a half years and accompanied by a unique training concept over the entire period. „It is crucial to take users on this journey and familiarize them with possible uses of the technology," emphasizes Marcus Bataryk, Business Group Manager Monitoring, Analytics and Therapeutic Care at Philips GmbH Market DACH. „After all, innovative technology can only contribute to better healthcare if people are aware of its capabilities and use them in everyday clinical practice."

By the end of 2020, around 1,400 people will receive separate training and be made fit for use in medical technology and IT training courses, on dialogue days or with the help of personal contact persons on site. External service providers are also involved. In order to ensure smooth operations, a concept has been developed which includes remote service, virtualization and 24/7 availability. sw

More information:
www.philips.de

NSF PROSYSTEM

A FOCUS ON MEDTECH INDUSTRY CHALLENGES

NSF PROSYSTEM GmbH, celebrated its 20th anniversary and its first two years as part of NSF International with an expert panel.

The event also served as a starting point for the company's use of the NSF International name in its communications and offices. The NSF International Expert Panel was held on 1 October 2019 and brought together industry leaders to discuss regulatory challenges in the medical device industry. "There are two powerful forces driving medical device innovation which both have a global impact: digital technology and regulatory change," said Oliver Christ, Executive Vice President of NSF PROSYSTEM GmbH. Workshop discussions included a five-year forecast on EU Medical Device Regulation, the needs of a truly digital hospital, the future of artificial intelligence in medicine, and ways in which digital giants like Microsoft, Google, Amazon and Apple are moving to radically change the healthcare market by 2025.

Founded 75 years ago, NSF is committed to improving and protecting human health and safety worldwide. NSF International is a Pan American Health Organization/World Health Organization (WHO) Collaborating Center on Food Safety, Water Quality and Indoor Environment. "For 75 years, NSF International has been at the vanguard of protecting and improving human health. Likewise, since 1999, PROSYSTEM has been a thought leader in biomedical engineering," said Christ. "In our two years together, we've witnessed the medical device industry begin to shift its focus from repair to prevention. That shift is going to accelerate as tech giants seek – and create – opportunities in the healthcare marketplace and regulatory bodies adapt to the impact of rapidly developing technology on patient safety." Over the past year, NSF International has strategically invested in European regulatory training in support of that public health mission. In 2018, NSF opened a new Hamburg training center in anticipation of a rise in the demand for regulatory education ahead of the deadline for the European Union Medical Device Regulation (EU MDR) 2017/745 on May 26 2020 and the In Vitro Diagnostic Medical Devices Regulation (EU IVDR) 2017/746 which will fully enter into force in 2022. sw

More information:
www.nsf-prosystem.com

LIFE SCIENCES IN KOBE (JAPAN)

EPICENTER FOR BIOMEDICAL RESEARCH

Data & Facts

Focal areas:
Medical devices, biopharma, regenerative medicine and cell therapy

Important Centers:
Institute of Biomedical Research and Innovation (IBRI), Translational Research Center for Medical Innovation (TRI), Research and Development Center for Cell Therapy (RDC), RIKEN for Biosystems Dynamics Research

Cluster management:
Center for Cluster Development and Coordination (CCD)

Further information:
www.fbri-kobe.org/kbic/english/

From conception to one of the world's leading biomedical hubs: Within 20 years, the Kobe Biomedical Innovation Cluster (KBIC) has transformed the city's Port Island, shaken by the Great Hanshin earthquake, to a first-class life sciences campus. A long-term partner for LSN, one of KBIC's key aims is to bring stem cell therapies forward.

The conversion of adult cells into induced pluripotent stem cells (iPS cells) is a groundbreaking technology developed by Nobel laureate Shinya Yamanaka. iPS cells can be differentiated into any kind of cell – opening new avenues for the field of drug discovery and regenerative medicine. The clinical application of stem cell-based therapies has become a national priority for Japan. And the Kobe Biomedical Innovation Cluster (KBIC) is at the forefront of this new wave of stem cell therapy: In a first-of-its-kind clinical study, a KBIC-based research team transplanted retinal cells derived from iPS cells into patients with age-related macular degeneration, an eye disease. Researchers expect to see other stem cell-based therapies used in clinical practice soon for knee cartilage injuries, vocal cord scarring and blood vessel obstructions in the legs.

Founded after the 1995 earthquake that devastated the region and with an ambitious plan to revitalize the urban area, KBIC now performs some of the most cutting-edge medical research in the world. About 360 research centers, specialized hospitals, companies and universities are housed in a unique science campus on Port Island off Kobe. KBIC contains facilities that cater to the entire range of medical research and development, from basic research to clinical applications and mass production.

Ecoystem of healthcare innovation

Unlike the life science hubs of North America, Europe or elsewhere in the Asia Pacific region, KBIC did not grow around existing academic institutions and infrastructure.

A biotechnology area designed to unite fundamental research with clinical applications of regenerative treatments and medical devices is at the heart of the campus. On one side of this scientific core lie state-of-the-art medical facilities that can accommodate around 1,500 patients, allowing clinicians to run large clinical trials while promoting new systems for routine care. In contrast, the other side of the core contains buildings devoted to computational modelling. One of them is home to the Kei computer, the world's highest performance supercomputer, which accelerates drug discovery by running complex simulations.

Promoting international alliances

The central pillar of the cluster is the Foundation for Biomedical Research and Innovation at Kobe (FBRI). Launched in March 2000, its mission is to promote advanced clinical research, next-generation healthcare systems and collaboration among KBIC entities. President of the foundation is immuno-oncologist Tasuku Honjo, who was awarded the Nobel Prize in Physiology or Medicine last year. In 2018, FBRI was relaunched with an increased focus on providing business support to strengthen public–private–academia partnerships and to promote international alliances.

The cluster Life Science Nord has been tied to KBIC by a long-standing relationship. Between 2014 and 2017, the FBRI and LSN joined forces as part of the Regional Industry-Tie-Up program, which resulted in a fruitful collaboration. For example, in the field of translational neuroscience the Fraunhofer Research Institution for Marine Biotechnology and Cell Technology (EMB) in Lübeck is collaborating with a team of biomedical researchers at Kobe, addressing dementia. The use of stem cell technologies for drug discovery has now come into the focus of a new alliance that emerged at a joint Stem Cell Symposium in August 29 in Kobe when a delegation from North Germany, accompanying the First Mayor of Hamburg, Peter Tschentscher, visited the KBIC (*see interview on the right*). The symposium, with talks given by stem cell experts from Kobe and Hamburg, underlined the new opportunities of stem cell-based drug screening and highlighted the huge potential of exchanging expertise in stem cell technologies. pg

For more information on collaboration with Kobe and other international projects, please contact Sarah Niemann at niemann@lifesciencenord.de

LIFE SCIENCES IN KOBE

"TRANSLATION MODEL CLUSTER"

Takeyuki Sato is Director of the Center for Cluster Development and Coordination (CCD) at the Foundation for Biomedical Research and Innovation in Kobe. A specialist in regulatory affairs, he is leading the CCD strategy to foster support for industrialization and international cooperation in the healthcare sector.

How has KBIC become a forerunner for the introduction of regenerative medicine to clinics?

Sato: KBIC has been promoting "translational research" since the launch of the project. Based on its success and as the first of its kind KBIC has become a model cluster in Japan. As a result, the cluster has developed into a dense concentration of research centers, medical institutes and companies. Riken, the largest national research institute, broke ground as the key organization to promote stem cell therapy with its very first KBIC project. Clinical trials using fibroblasts from third-party donors, which Dr. Masayo Takahashi has been working on, are heading towards clinical application. Additionally, KBIC is one of the few organizations located outside of the US to manufacture investigational drugs for use in clinical trials of Kymriah, the world's first approved CAR-T cell therapy.

Were there any opportunities for cooperation that emerged at the Stem Cell Symposium with the German delegation in August?

Sato: The cooperation between LSN, Dr. Taguchi of FBRI and Prof. Clausen of Fraunhofer IME-Screening Port saw the launch of an international joint research venture. In this collaborative project lead by Dr. Taguchi, regenerative medicine for cerebral infarction using stem cells is expected to be applied to a large-scale candidate drug search system. The system is managed by Fraunhofer IME Laboratory with the aim of developing an innovative drug for dementia.

Can you name some KBIC projects that aim to develop next-gen healthcare?

Sato: In order to develop cell therapy, we will promote various collaborations and global business development. The world's most powerful supercomputer "Fugaku" is scheduled to start operation in 2021. It offers 100 times the performance of the previous supercomputer "Kei" and will be used for drug discovery. As for medical technology, we encourage the development of innovative devices in the field such as robotic surgery.

Where do you see further opportunities for life sciences companies from Northern Germany to cooperate with KBIC institutions?

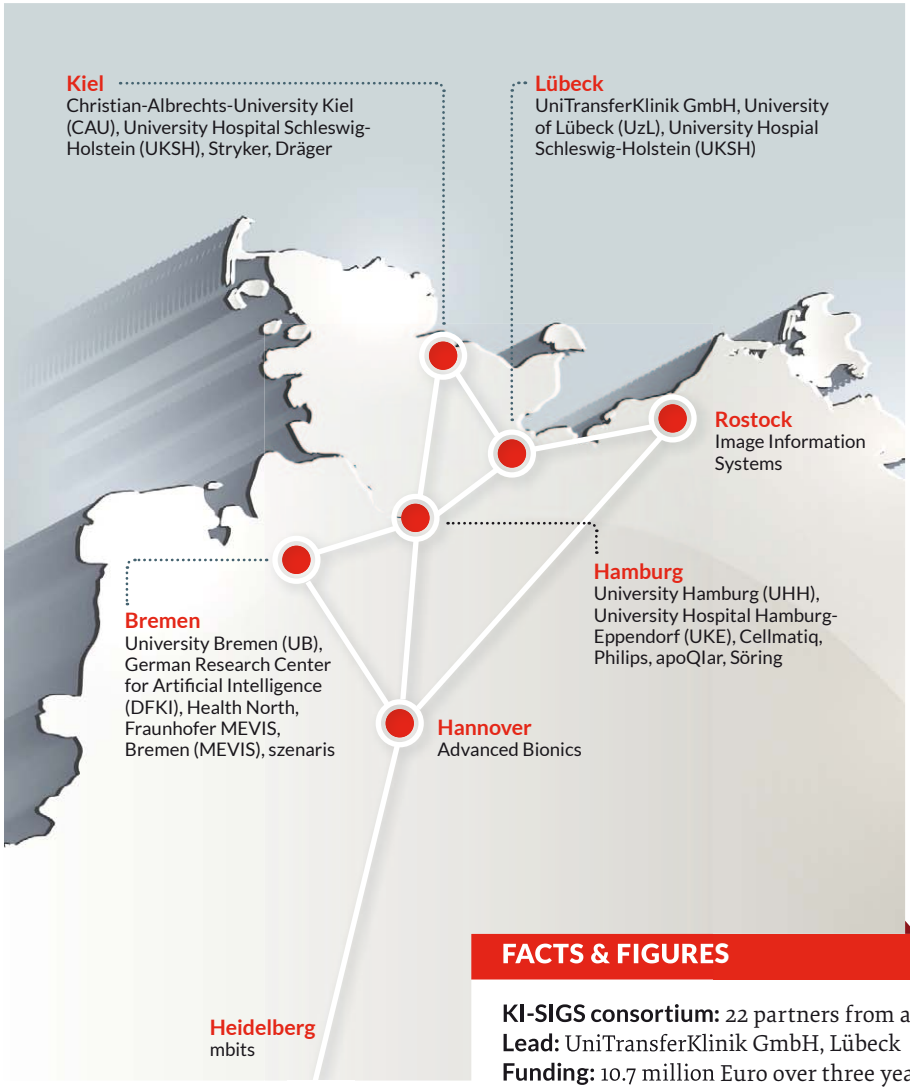
Sato: We predict further collaboration with Fraunhofer IME in Northern Germany will accelerate our joint projects. The Stem Cell Symposium with the German delegation on August 29 was a great opportunity for this. We will promote our cooperation in various ways so that both parties can work together to plan future activities for companies and organizations in Germany and Japan.

More information: www.fbri-kobe.org/kbic/english/

KI-SIGS

AI ALLIANCE DRIVES DIGITAL MEDICINE

A powerful public-private consortium aims to systematically bring artificial intelligence into clinical application. The project, which received 10 million Euro in funding, is expected to strengthen the competitiveness of the north German medtech sector.



Artificial intelligence (AI) could well prove to be a driving force for the north German healthcare industry. In the national AI innovation competition, the Federal Ministry for Economic Affairs and Energy has decided to support a consortium of research and business partners from the states of Schleswig-Holstein, Hamburg and Bremen who aim to introduce AI systematically into medical technology. Subject to the approval of the German Bundestag for the upcoming budget, a good 10 million Euro in funding should flow into the North.

"AI will have a lasting impact on the business models of many industries. Our vision in this climate is to boost the competitiveness of the north German medtech sector internationally," says Stefan Fischer, who is Vice President for Transfer and Digitization at the University of Lübeck and spokesman for the award-winning consortium. The project is named "KI-SIGS", which stands for "KI-Space für intelligente Gesundheitssysteme" (AI space for intelligent health systems). In the nationwide AI innovation competition, a total of 16 projects from various industries were selected for funding, including two more from the health sector, with which KI-SIGS aims to cooperate over time.

Interdisciplinary innovation platform

The consortium currently comprises 22 organizations, including the universities of Lübeck, Kiel, Hamburg and Bremen, the German Research Center for Artificial Intelligence and the Fraunhofer Institute for Digital Medicine in Bremen, the university hospitals of Schleswig-Holstein and Hamburg, as well as a dozen large and small medical

FACTS & FIGURES

KI-SIGS consortium: 22 partners from academia, industry and hospitals
Lead: UniTransferKlinik GmbH, Lübeck
Funding: 10.7 million Euro over three years
Total project volume: 15.3 million Euro
Kick-off: April 2020

More information: ki-sigs.de

technology companies. "The North is one of the top locations for artificial intelligence in healthcare," comments Claudia Schmidtke, member of the German Bundestag and health committee as well as patient representative of the Federal Government. Schmidtke is a heart surgeon who happens to be a native of Northern Germany.

KI-SIGS has two essential elements at its core. On the one hand, it is about building – and consolidating – a comprehensive platform with four different components: First, it will provide interoperable medical data, storage space or algorithms via an IT infrastructure and ensure technical communication between the project partners.

Secondly, the platform is also conceived as a content network, in which the partners collaborate on an interdisciplinary basis via virtual media, workshops or advanced training courses and present results to the public and other stakeholders.

Thirdly, developers and companies will be supported in regulatory matters regarding product approval, which are highly complex especially for technologies with self-learning software. Last but not least, it is planned to discuss ethical aspects of the ongoing introduction of AI into medicine.

Stefan Fischer coordinates KI-SIGS.

Making AI ready for the market

In contrast, the second element will see several concrete AI-based innovations introduced within the framework of KI-SIGS, with the individual partners both benefiting from the common platform and developing it further through their respective inputs. One example is an intelligent X-ray assistant, in which a 3D camera system captures the relevant body parts of the patient before the scan and then uses AI to give position recommendations for an optimal image. The approach also known as "smart scanning" is intended to increase the quality and informative value of the images and avoid unnecessary repetition due to poor scans. The project is carried out in cooperation between the University Medical Center Schleswig-Holstein and two globally active SMEs (Image Information Systems, Pattern Recognition Company). Altogether, a total of nine such development projects are to be implemented, ranging from AI-based individual fitting of hearing aids to intelligent surgical ultrasound instruments for the resection of brain and liver tumors to AI-assisted movement training in aftercare.

"On an international scale, we are already good in Germany when it comes to basic AI research, but we still have some catching up to do in terms of transfer to specific applications," comments Stefan Fischer. KI-SIGS therefore has a specific goal to bring the technologies involved to market maturity as widely as possible.

In addition, the state of Schleswig-Holstein has signaled its intention to provide financial support for further projects in the KI-SIGS sector in order to make the initiative a success for the entire North German medtech industry, Fischer adds. If everything goes according to plan, KI-SIGS will officially launch in April 2020. ml

HIHEAL

TOWARDS SMARTER INFECTION CONTROL

How can we improve prevention measures with the help of digital solutions to fight infectious diseases? A gathering of experts on smart infection control and an action day on hand hygiene are just two events in the HIHeal network calendar in 2020.

Hand hygiene is a key topic of the HIHeal network.

How will powerful technologies like artificial intelligence and machine learning impact our efforts to combat infectious diseases efficiently? How will hospital workflows change? How do big data analytical techniques transform infection diagnostics? In future, digital solutions will offer plenty of opportunities to improve healthcare processes in diagnostic and therapeutic settings. Opportunities and challenges in this field will be in highlighted at the event known as "Smart Infection Control 2020", where experts from hospitals, research institutes and companies will convene. The event planned for early next year will be jointly organized by the "e-health network health economy Hamburg" and the "Hygiene, Infection & Health" (HIHeal) project which brings together regional companies, scientific institutions, hospitals and funding agencies in Hamburg working in the fields of hygiene and infections. Other important areas that will come into the spotlight of HIHeal activities within the next year are hand- and water hygiene. World Hand Hygiene Day takes place on the 5th of May 2020 and will be marked by a specific HIHeal event around that date. "All three main topics will be accompanied by discussion groups and workshops," says Juliane Worm of Life Science Nord Management GmbH, coordinator of the network. "Through stronger networking, synergies can be optimally used to counter current challenges in the healthcare system more efficiently." Another major aim will be to strengthen the HIHeal network's international ties. sw

More information: www.hiheal.de

FOUR BUSINESS QUESTIONS TO

JOANA GIL, CO-FOUNDER & CEO LIGNOPURE

Biotechnologist Joana Gil is co-founder and CEO of Hamburg-based startup LignoPure. The spin-off project from the Institute of Thermal Separation processes at Hamburg University of Technology aims at using lignin, an abundant biopolymer extracted from wood or straw, as a biodegradable component in cosmetics and other consumer goods.

What is your approach to utilize lignin?
Lignin is a highly abundant by-product in paper mills, but it is mostly burned there. Modern biorefineries focus on the chemical conversion of lignin into liquid basic chemicals. However, LignoPure lignin can be obtained in its original structure, in the form of powder. We increase the value of this underutilized material by using tailor-made lignin particles as ingredients for a wide spectrum of products. Our team´s know-how is in lignin extraction, particle engineering and product development.

What kind of products do you deal with?
Our lignins can be used to produce microbeads for care products, biobased foams for construction, adhesives tapes and composites for plastic- or rubber-like and plastic substitutes. Each of these products requires a different lignin with unique properties in order to maximize its performance.

Are there applications for your lignin products in the healthcare sector?
It's something about which we are very excited and proud. We have developed lignin-based microbeads and beads for body scrubs and shower gels. They are 100 % biobased and due to their composition, they will not make it as far as the sea, but rather will decompose during wastewater treatment! This year we are also starting to develop a lignin-based sun blocker. Lignin can also be used for the treatment of traveler diarrhea and food or alcohol intoxication. We have produced a tablet dosage form based on LignoPure lignin and together with pharmaceutical and nutraceutical companies we are now assessing the feasibility of using our lignin in this type of product. We know that it will take several years for it to be market ready as a health product, but we envisage ourselves as pioneers in the use of lignin for the life sciences.

What are the next steps in the development of your business?
In 2020, with the financial support of the InnoRampUp program, we will perform the industrial proof of concept for our business model. Our team of four aims to have a consolidated client database and to fine-tune our service offering. We plan to obtain product certifications required for commercialization and dedicate considerable time to R&D to improve our product and service portfolio. ih

More information: www.lignopure.de

THE NORTH STANDS FOR ...

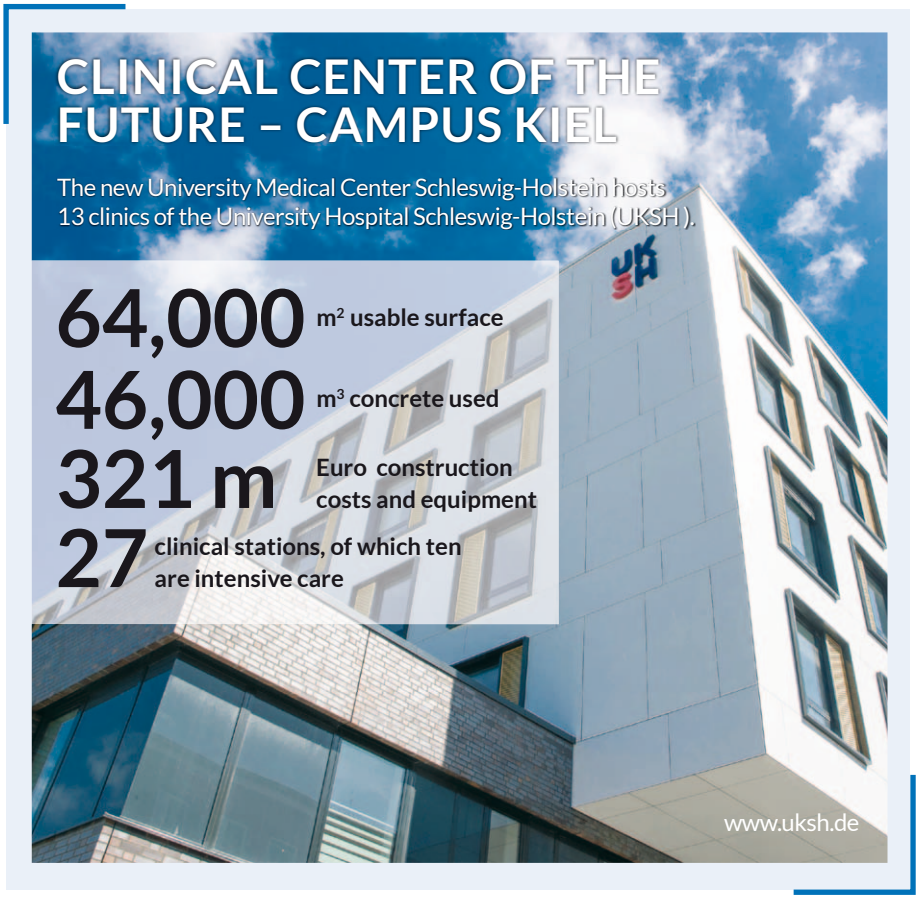
"... a well-known hotspot for startups in logistics, e-commerce, and media in the Hamburg region. But it has also the infrastructure, industries and strategic location for more technological and chemical-based startups – which we need to attract."

THE NUMBER

98

percent of the biopolymer lignin produced in industry is burned to drive internal processes instead of further valorizing it. This gives LignoPure the opportunity to develop more biobased alternatives from those lignins.

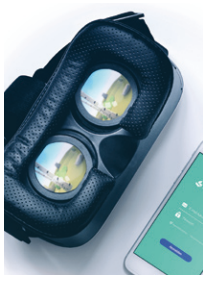
IN NUMBERS



INTRODUCING ...

Ibrahim Alkatout & Johannes Ackermann from the Clinic for Gynaecology and Obstetrics of the University Hospital Schleswig-Holstein (UKSH) were honored with this year's Hans Frangenheim Prize of the Arbeitsgemeinschaft Gynäkologische Endoskopie (AGE). The prize worth 1,500 Euro goes to an endoscopic training concept on a specially prepared body donor. The Hans Frangenheim Prize is awarded for innovative clinical and experimental work in the field of gynaecological laparoscopy. Professor Alkatout heads the Kiel School of Gynaecological Endoscopy, one of the first training centers in Germany to be certified by the AGE. pg

More info: www.uksh.de



Sympatient, a Hamburg-based startup specialized in the digital therapy of anxiety disorders, is the winner of the 2019 Hamburger Gründerpreis. The startup was co-founded in 2017 by the brothers Christian and Julian Angern and Benedikt Reinke. The Sympatient team develops virtual reality (VR) solutions for psychotherapy. Their products run on VR-headsets in combination with smartphone apps and they address anxieties such as the the fear of flying and other phobias as well as stress management. The Hamburger Gründerpreis is an initiative of Hamburger Sparkasse and local newspaper Hamburger Abendblatt. pg

More info: www. sympatient.com

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PUBLISHER

Life Science Nord Management GmbH
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PRINT: Druckerei Siepmann GmbH, Hamburg. Printed on EU Ecolabel certified paper.

Life Science Nord Magazine for Medtech, Biotech und Pharma is published three times a year.

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