Medical Technology in Bavaria

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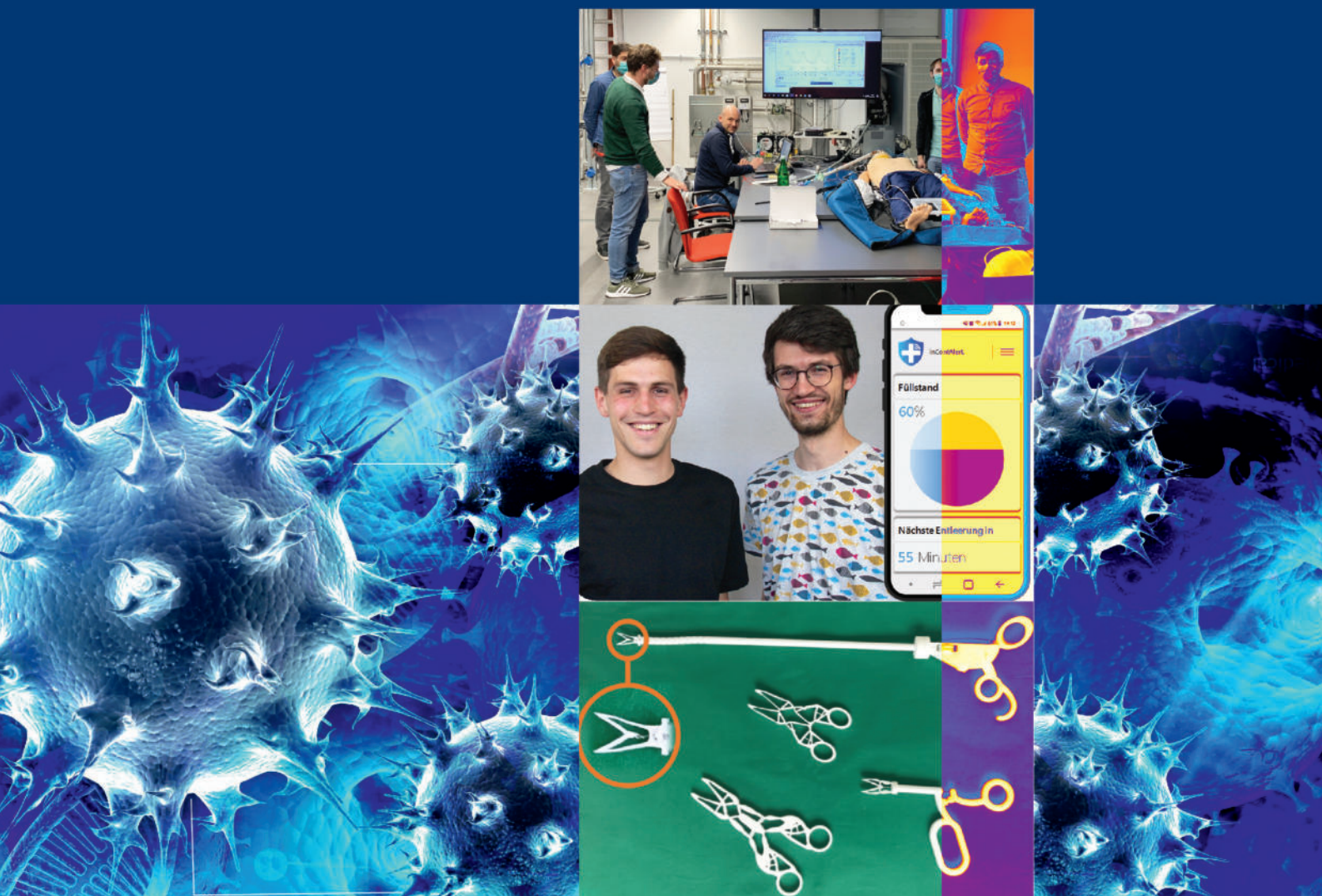

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Bavarian Ministry of Economic Affairs,
Regional Development and Energy

Editorial

"One man's joy is another man's sorrow"...

... this is one way to describe the effects of lockdown, where positive business models have made people sit up and take notice, and negative results have taken on a depressive edge.

This publication fills you in on what opportunities exist during difficult times and how you can still use funding measures to your advantage:

- How does Medical Valley promote the health economy and health care?
- Are frugal innovations more than a stopgap solution?
- What are the advantages of compliant mechanisms in instrument manufacturing?
- Why is the medical technology of the future relying on the power of digitization?
- What effects does demographic development have on social relevance?
- How do company founders pursue a career in Europe?
- What significance does knowledge sharing have for a marketable product?

The COVID-19 crisis shows how important communication is. Let's keep the future in mind!

Walter Fürst, Managing Director

This publication is also available online at
www.media-mind.info

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Make the world your home with Bayern International

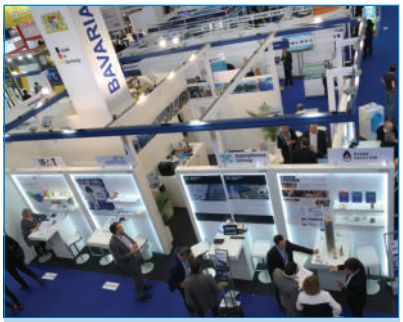
One of the central players in Bavarian foreign trade promotion is Bayern International, a company of the Free State of Bavaria. In cooperation with the Bavarian Ministry of Economic Affairs, many projects around the globe are organized every year.
Since 25 years Bayern International has supported Bavarian SMEs in their export activitis - whether in Asia, Africa or North America. True to the motto "Service for your success abroad - Off to new markets", an extensive program is available, ranging from trade fair participations to delegation trips, entrepreneur trips and delegation visits. ■

Benefit from the Bavarian Trade Fair Participation Program

Foreign trade fairs are an important distribution channel to export markets. The Bavarian Trade Fair Participation Program offers Bavarian companies a comprehensive range of services before and during the fair, financial support from the Bavarian Ministry of Economic Affairs and a turnkey trade fair booth with variable booth areas. In addition, Bayern International takes care of all organizational matters and offers support on site. ■

Political support for your export activities: Delegation trips by the Bavarian Ministry of Economic Affairs

Politics is a door opener, especially when it comes to opening up new markets. In cooperation with the Bavarian Ministry of Economic Affairs, Bayern International organizes delegation trips and takes care of all travel logistics and the organization of the business program. The focus is on the export intentions and interests of the participating companies. Small to medium-sized companies thus get the opportunity to build a network for their export activities. ■



Joint stand of Bayern International at Aquatech 2019
(Photo: Bayern International) ■

Arab Health: Business talks at the joint stand of Bayern International
(Photo: Bayern International) ■

Market entry from home: Delegation visits

The program "Bayern - Fit for Partnership" brings decision-makers from abroad to Bavaria. The delegation visits are carried out by Bayern International in cooperation with the Bavarian Ministry of Economic Affairs and combine international further training with Bavarian export promotion. This gives Bavarian companies the chance to establish promising business contacts. ■

"Key to Bavaria": Easy entry into new markets

„Key to Bavaria“ is a free of charge database containing information on Bavarian companies and institutions from 22 key sectors. It currently contains more than 32,000 entries ranging from health care and life sciences all the way to the automotive industry and cultural and creative industries. It allows potential business partners worldwide to identify interesting Bavarian products, services and technology partners. Bavarian companies and institutions can register and display their goods/services in the database free of charge. ■

Bayern International

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Greetings

Dear readers,
The coronavirus pandemic has left Bavaria's medical industry with ambivalent feelings: On one hand, many companies have been and still are economically affected by the consequences of the lockdown. On the other hand, digital services and business models experience a rapid ascent.

The sector has been engaged with digitalization for several years already!

In 2019, Medical Valley EMN e. V. and Forum MedTech Pharma e. V., together with other MedTech clusters in Germany as well as the management consultancy Econum, have therefore conducted a study called "Under the magnifying glass – implementation status of digitization in medium-sized medical technology companies". After all, it is clear that digitalization is the most important growth driver in the medical technology/healthcare sector, particularly in the context of small and medium-sized businesses.

Key findings of the study are:

- The medical technology industry expects both direct and indirect support through digitalization, e.g. better diagnoses and individual therapies and thus, a more efficient healthcare system. Data protection plays a special role here.
- Due to new technical developments, a significant growth in sales is expected on the medical technology market.
- The new technologies and digital approaches – regardless of the company size – do not only impact medical technology products. They also influence the company and its processes, methods and procedures as well as the business models.

The Free State of Bavaria and the Bavarian state government are striving to support this transformation with funding programs. In the context of Bavaria's "Hightech Agenda", which was pushed once again just last September, it was possible, for example, to set up a Department for Research and Education on AI in the field of healthcare at FAU Erlangen-Nuremberg. Furthermore, the Bavarian Ministry of Economic Affairs is consequently pursuing its funding lines for medical technology and digital health, which have been active for years. The Bavarian Cluster for Medical Technology is also consistently promoting the creation and further development of functioning network and cluster structures.

These are definitely appropriate measures, for it is certain that the digitalization will radically transform the healthcare industry and healthcare provision. Existing care structures and processes will change and generate entirely new healthcare services. Besides funding, it is therefore important that these new business models and innovations can actually be absorbed by the healthcare systems.

And there is a lot of progress going on in Germany, right now! The Digital Supply Act (DVG) and the Patient Data Protection Act (PDSG), which is currently being discussed, are opening up a new market for industrial providers of digital health applications (DiGAs). Extra-budgetary financing will shift and expand the previous sectoral supply and financing limits. Additionally, it is to be expected that the Hospital Future Act, which is currently being discussed in Parliament, will provide further innovative impetus on the inpatient care side.

In order to seize the oppurtunities outlined here, transdisciplinary cooperation and genuine teamwork on an equal level are required. And this is exactly where we as Medical Valley EMN e. V. want to contribute effectively. As a leading edge cluster for medical technology and digital health hub, Medical Valley functions on the principle of transdisciplinary networking, and thereby supports all stakeholders in the healthcare sector in generating innovations at eye level. Feel free to contact us! We look forward to exchanging with you!

Jörg Trinkwalter
Member of the Executive Board
Medical Valley EMN e. V.

Medical Valley Award – from Research to Start-Up

Since 2017 the Medical Valley Award has been offering Bavarian research teams access to funding to realize their scientific findings by starting their own enterprise. But what are the requirements for an application and what comes afterwards? In the following, Jonas Jung, Medtech engineer, project lead & techscout at Medical Valley EMN e. V. gives answers to these and further questions - maybe you will be part of the next winning team?

1. What exactly is the Medical Valley Award?

The Medical Valley Award is a pre-pre-seed funding and is explicitly directed at scientific teams at colleges, universities, university hospitals & research institutes in Bavaria. The award is sponsored by the Free State of Bavaria (Bavarian State Ministry of Economic Affairs, Regional Development and Energy).

It supports high-risk projects that show great commercialization potential and provide enormous added value for the healthcare of the future. Teams receive up to 500k Ä to implement their scientific work and findings in an entrepreneurial way.

In short, the Medical Valley Award is intended to help realize potential key technologies for the healthcare of the future and bring them to market.

2. What past challenges do you like to think back on?

Germany is not the most founder-friendly country, although we do offer a very good infrastructure and many opportunities. Of course, this is especially noticeable in the highly regulated medtech sector. Moreover, the infrastructure for start-ups at research institutes and universities in Bavaria is far from homogeneous. So, the biggest challenge for me is to find and approach the right teams that are willing to show courage and endurance. These are things you need if you want to gain a foothold in this field.

On the other hand, I also enjoy searching and encouraging potential teams to apply for MVA. You cannot always rely on the technology transfer centers here, instead you more likely have to be in an Indiana Jones state of mind ??.

3. Why should you apply for the MVA?

The Medical Valley Award has a two-stage structure and in my opinion, it has a very low entry hurdle in respect of application. At the beginning, a 5-page project outline is sufficient, which is then evaluated by our interdisciplinary 12-member jury. From the applicants, 20 potential teams are selected and invited for the pitch. I always like to take the time to give individual feedback to teams after the evaluation. I think this is a mandatory, but unfortunately it is not always offered as part of the funding context. The teams applying for the award deserve feedback, as they have already shown at the time of application that they are willing to enter unknown territories and to handle justifications. I would like to avoid hindering this spirit of the teams, as it can easily happen that some teams are basically just too advanced and would fit better into another program.

We offer all teams a wide range of services to help the applicants prepare for the pitch and to improve their strategies.

In the event of success, we will of course provide support through our network and individual guidance, so that the company is either ready to be founded or ready for follow-up financing.

4. How, where and when can one apply for the MVA?

That is very simple! At www.award.medical-valley.de you can find all information about the program and the deadlines.

5. Are there follow-up grants or programs?

Countless! However, it is not really possible to say in general which one is best. Each team is individual, and overall, all teams have a very broad spectrum - from classic medical technology to digital health. One good option, for example, is the Exist funding program as follow-up financing.

In any case, we would definitely recommend the team an individual consultation and we would be happy to assist you in every way we can.

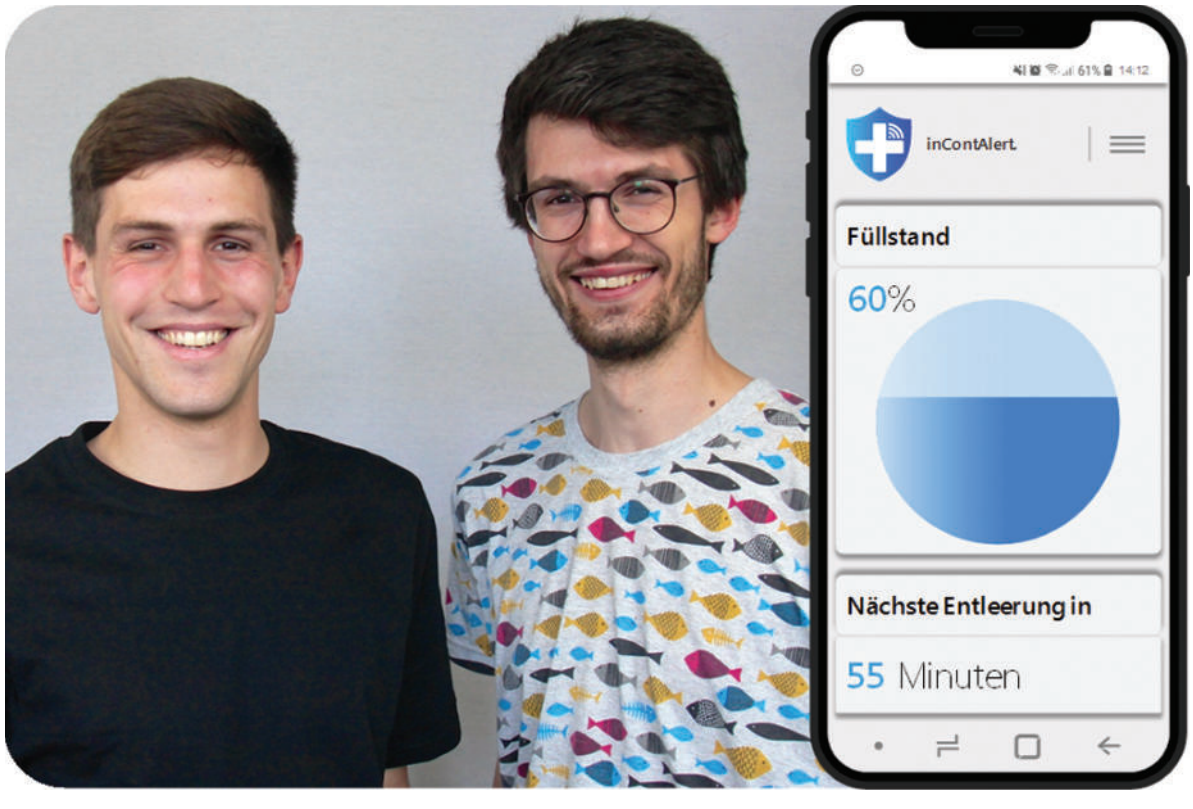
Just contact us!

Schematische Darstellung der Anbringung von inContAlert am Unterleib ■

A winning team of the Medical Valley Award 2019: inContAlert - a wearable for monitoring the filling level of the bladder of incontinence patients

inContAlert has set itself the goal of supporting people with incontinence in such a way that they can once again go through their everyday life more freely and unburdened. To this end, a wearable device has been developed that determines the filling level of the bladder and warns when it needs to be emptied. People with a neurogenic bladder dysfunction, which can be associated, for example, with paraplegia, MS, or Parkinson's disease, suffer from uncontrolled loss of urine and the harmful risks of this incontinence. Unfortunately, this suffering is still a taboo, which makes the burden of those affected even more difficult.

To ease the consequences of uncontrolled loss of urine, inserts, diapers, or urinal condoms can be worn. In some cases, however, it may not be possible to empty the bladder



Das Gründerteam um Jannik Lockl (l.) und Tristan Zürl (r.) mit einem Screenshot ihrer App ■

in a targeted manner, as the body's own controlled emptying is no longer possible due to motor-driven limitations. Accordingly, catheters are often used in such cases, but there is no knowledge about their filling level, which means that catheterization is based on time intervals or a drinking protocol. To prevent uncontrolled urine loss or harmful overfilling of the bladder, the frequency is then often too high, resulting in a significantly reduced quality of life.

A solution could be a device that determines the patient's bladder level and enables targeted emptying. inContAlert is a portable sensor system for non-invasive measurement of the bladder level that intends to fulfill this value proposition. The device alerts incontinence patients as soon as a predefined and possibly critical filling level is reached. It digitalizes the current level of the bladder and sends a warning to the user's smartphone if the level is too high. This allows, for example, assistants in nursing homes to monitor the level of the bladder and catheterize only as needed. Both unhygienic "under-catheterization" that endangers the kidneys and "over-catheterization" that causes urinary tract infections as well as wastes material could be avoided. The consequence would be reduced restrictions on the lives of those affected, a decrease in the in the use of aids and a reduction in health damage downstream.

A device like inContAlert could help with micturition management. The device consists of two components: a wearable, which is attached to the clothing at belt height with a clip, and an app that displays the fill level and the optimal time for emptying. This device can be worn for about two to three days without further medical assistance and the emptying times can be recorded. Meanwhile, the device adapts to the individual user to optimize the results. Users can then use the information about their current fill level and past emptying cycles to make their daily routines more self-determined and easier. We at inContAlert hope that this better control will help users to go through life more autonomously and carefree again.

MEDICAL VALLEY AWARD

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The Digital Health Application Center from Medical Valley and the H+ Digital Health Innovation Programme: How to realise and seize the opportunities of digitalisation in the healthcare sector.

Since 2019 dmac – Digital Health Application Center has been a substantial hub in the Medical Valley eco system where companies that work on solutions regarding the digital medicine of tomorrow can find guidance, support, and expertise. Additionally, a cross-industry programme that focuses on digital health start-ups was launched in September 2020.

Digital Health Application Center

The digital healthcare pioneers at dmac enable integration of ideas and products into healthcare and research, moderates patient-centered development and validation trials and makes technical solutions in a newly developing digital health ecosystem perceptible. Through the connection of medical and health technologies to target group-oriented provision services, an individual guidance for patients can be realized through prevention, diagnosis, therapy monitoring and care. When the Digital Healthcare Act (DVG) became effective? on December 19, 2019, dmac was able to fall back on exactly this expertise and optimally meet the increased demand for operational support in the development of digital health solutions.

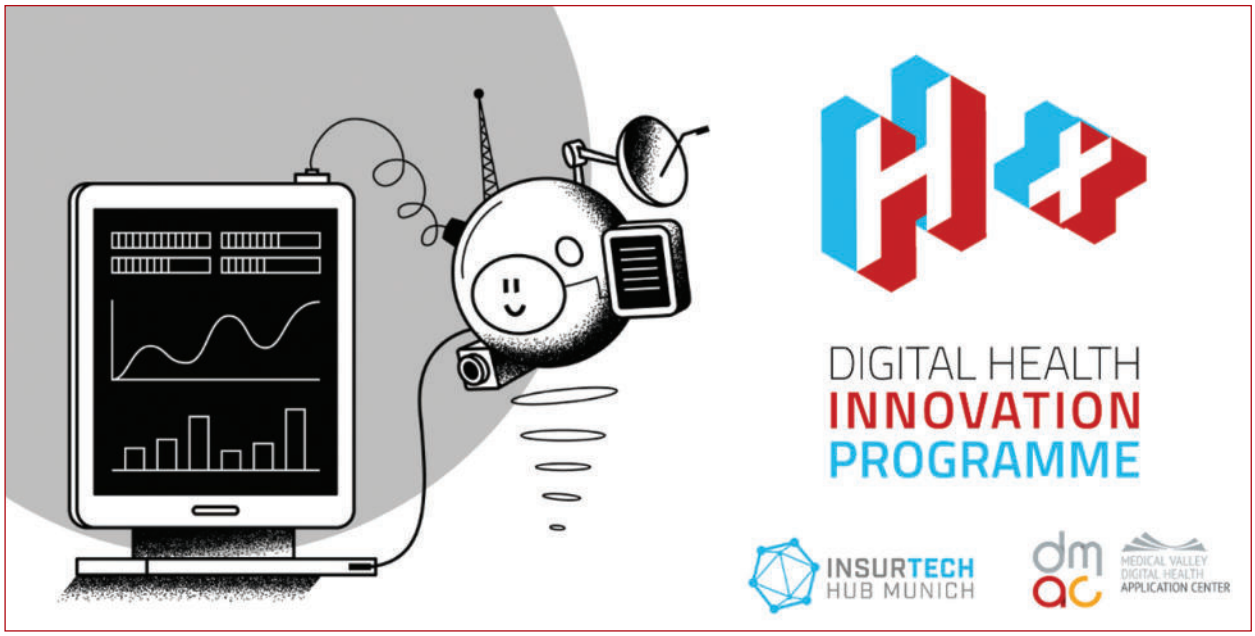
Effective support for Digital Health start-ups: the H+ Digital Health Innovation Programme

At the same time, the DVG was a perfect kick-start for the already initiated cooperation between dmac as part of the Medical Valley/Digital Health Hub and the InsurTech Hub Munich. The idea: a cross-industry programme that specifically support Digital Health start-ups that want to gain market access for their digital healthcare solution. Accordingly, the resulting H+ Digital Health Innovation Programme operates at the interface between health and insurance. It is composed of various programme points: The Business Development Weeks are primarily concerned with establishing business contacts and further developing the company's own business model. Furthermore, Business Development Weeks, a continuous curriculum with industry knowledge and entrepreneurship frameworks or specialized workshops like a "Pitch Clinic" are designed to add as much value as possible. A continuous curriculum and workshops with experts from various relevant disciplines serve to provide in-depth entrepreneurship and industry knowledge. In addition, experienced mentors support the participating startups. The entire program is designed to generate the greatest possible added value for the founders. In two "Review Events" the field of participants will be narrowed down, putting the spotlight on the most promising companies for investor meetings and a concluding "Health X Insurance. Digital Health Showcase". Due to the current situation, the H+ Programme will be accessible remotely.

"Though H+ is not specifically designed to solve COVID 19-related issues, many start-ups take into account the changing needs and wishes of patients, customers and healthcare providers."
(Marco Wendel, CEO, dmac)

Over 2000 founders in the pre-selection process

Throughout the planning and scouting phase, the two hub teams and their partners interviewed more than 2000 founders from all over the world. At the end of this process 41 startups were selected to participate in this year's H+ Digital Health Innovation Programme. The startups come from 17 different countries, more than 50 percent are based outside of Germany. Additionally, the organizers registered significantly more female participants compared to previous Innovation Programmes of the InsurTech Hub Munich. genen Innovation Programmes.



"In our innovation programmes we emphasize Internationality and Diversity: That's why this time, we are particularly very proud to welcome a very large number of female founders."
(Corine Ackermann, Startup Relations Lead, InsurTech Hub Munich)

The different topics covered by the start-ups illustrate how multifaceted the healthcare industry is: the focus ranges from prevention to diagnostics and rehabilitation. To solve their industry problems, the start-ups use valuable tools and methods from other areas, such as data analysis, IoT or artificial intelligence. The various topics demonstrate the broad variety of the healthcare sector: prevention, diagnosis and rehabilitation as well as data analytics, IoT and AI.

For the first time two Bavarian Innovation Digital Hubs join forces

The H+ Digital Health Innovation Programme is the first to combine the expertise of two Digital Hub institutions from the Digital-Hub-Initiative of the Federal Ministry for Economic Affairs and Energy. The aim of this initiative is to promote innovation in a wide range of industries. While the Digital Health Hub Nuremberg/Erlangen contributes its experience from the healthcare industry in a targeted manner, the InsurTech Hub Munich brings in an excellent know-how in promoting innovations in the insurance sector. Both hubs are also funded by the Bavarian Ministry of Economic Affairs, Regional Development and Energy. Please find news and updates online under:
https://healthplus.digital/

For more information please go to:
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Evolution like animal joints – Automatic design of compliant medical instruments using bionic structural optimization methods

Compliant mechanisms are much easier to sterilize than rigid-link-based mechanisms. Therefore, they are often used in biomedical engineering, such as the disposable compliant forceps. However, it is time consuming and inefficient to design the compliant mechanisms using empirical kinematic methods. To automate the design process, the Institute of Micro Technology and Medical Device Technology uses bionic structural optimization methods inspired by the evolutionary development of animal joints. The entire design process is performed in MATLAB using our automated design toolbox (Solid Geometry Library). In addition, the automatically designed medical instruments can be quickly printed using selective laser sintering (SLS). These instruments are available as individual parts at low cost and as disposable medical devices.

The main advantage of the compliant mechanism over the classical mechanism is that the compliant mechanism does not require complicated assembly work. This greatly simplifies the sterilization process of medical instruments, as the contact surfaces in rigid-link-based mechanisms are difficult to sterilize. Therefore, the compliant mechanisms are often used in medical technology. For the design of classical rigid-body joint based medical mechanisms, usually the gear theory or multi-body simulation is used. However, such rigid-link-based methods for the design of compliant mechanisms are inefficient due to the monolithic continuum structure *(Fig. 1)*. Since the flexible property of compliant mechanisms is similar to that of living organisms in nature, the Institute of Micro Technology and Medical Device Technology is developing bionic methods to accelerate the design of compliant medical instruments. ■

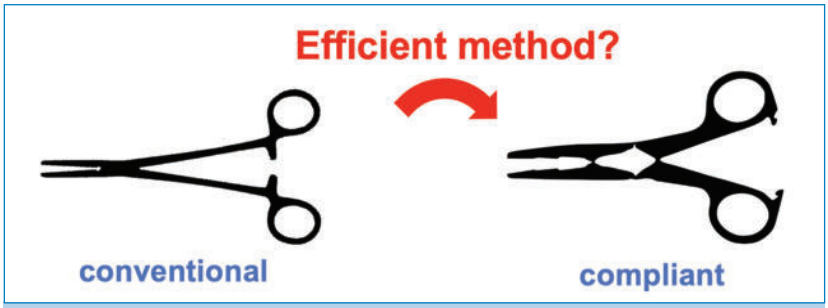

Fig. 1: *Medical forceps with conventional und compliant mechanisms.* ■

Bionic structural optimization methods

In the research, numerical optimization methods already exist, which are inspired by the biological self-optimization process. A well-known example is Computer-Aided-Optimization (CAO), which imitates the cell growth of a tree to optimize the stress distribution on the surface of a component. The method Soft-Kill-Option (SKO) on the other hand imitates the phenomenon of cell degradation of the bone, which uses lightweight structures to optimize the distribution of stress inside the component. However, the two optimization methods are limited to static structures only. Another interesting phenomenon from nature is the evolutionary development of animal joints. In contrast to the CAO and SKO methods, this occurs over a much longer period of time through natural selection and mutation *(Fig. 2)*. It would be revolutionary if the principle of the theory of evolution is also applied to the design of the mobile mechanisms. For this reason, the method "Soft Kill Option for Large Displacement (SKOLD)" is being developed at our institute in order to automatically design various me-

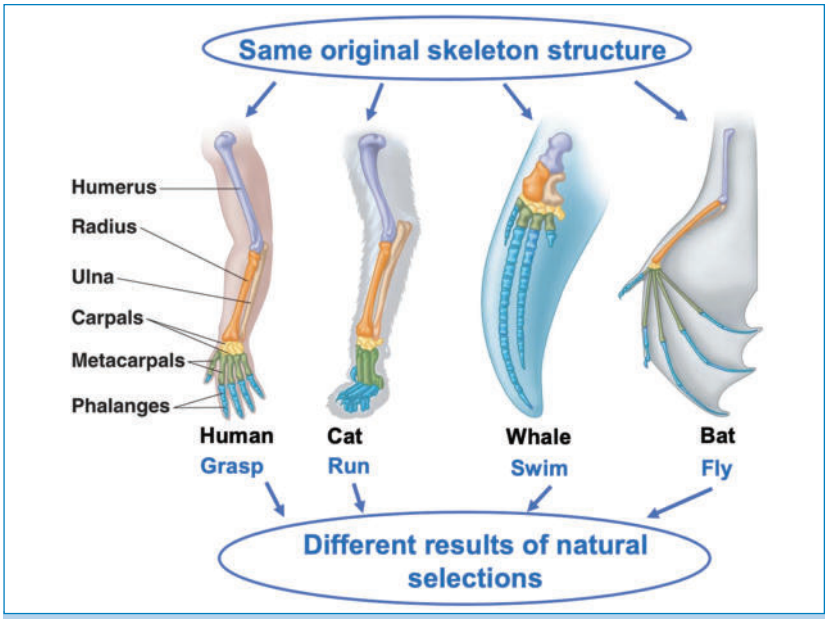

Fig. 2: *The natural selection of the hand of different animals.* ■

dical instruments according to the theory of evolution, which also incorporates the flexible property of the biological joints into the design. The SKOLD method is realized mathematically by advanced topology optimization. *Fig. 3* shows an example of the SKOLD method [1]. ■

3D printable disposable medical devices with patient-specific design

The conventional medical instruments are usually made of stainless steel. They are expensive and are therefore reusable. It is unfavorable in terms of cost and design effort to develop a metallic instrument especially for an individual patient. With the developed SKOLD method, a patient-specific instrument can be designed in a short time. In addition, the medical instruments developed in this project can be quickly 3D-printed with the biocompatible material polyamide, which are available as individual parts at low cost and as disposable medical devices *(Fig. 4)*.

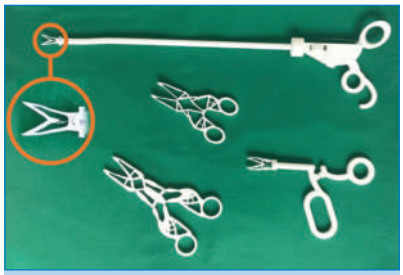

Fig. 4: *LS-printed compliant medical instruments with the function of adaptive grasping.* ■

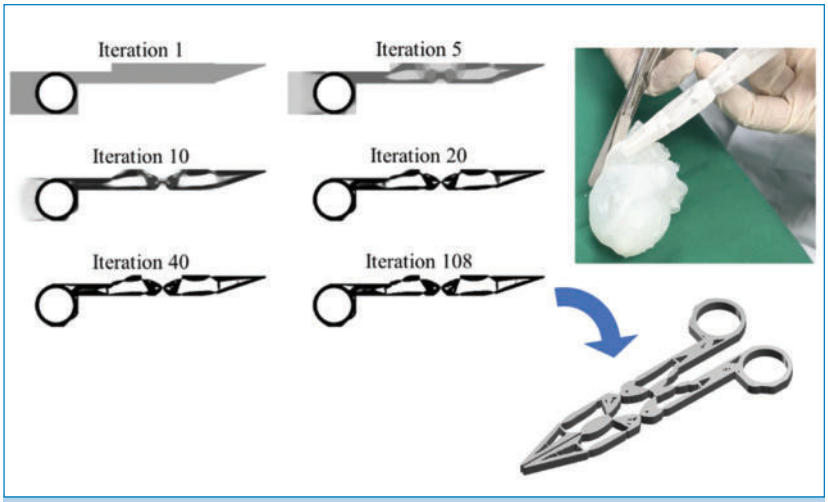

Fig. 3: *Automatic design of a compliant forceps for open surgery.* ■

Future work

The entire SKOLD method is implemented in MATLAB using our automated design toolbox (Solid Geometry Library). Since the Solid Geometry Library is easily extensible, we plan to further develop the SKOLD method in the future to create compliant medical instruments with special functions *(Fig. 4)* [2]. ■

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From vision to practice: Medical Engineering Campus in Weiden

5G - the new generation of the cellular standard is taking the existing network further. Thanks to high bandwidths and transmission rates, real-time applications such as automated and networked driving or mass networking and communication in the Internet of Things are taken to a new level. Unimagined possibilities are also opening up in the health sector.

In order to develop concepts for innovative 5G mobile communications applications, the Federal Ministry of Transportation and Infrastructure is funding six research projects across Germany. One of these highlight projects is based at the Technical University of Applied Sciences (OTH) Amberg-Weiden and deals with the health care of tomorrow. Professors Clemens Bulitta and Steffen Hamm have named their project 5G4Healthcare.

The name says it all: The aim is to find the best possible uses for 5G technology that enable real progress in prevention, diagnostics, therapy, rehabilitation or care. "With 5G4Healthcare, a platform will be created on which digital applications in rural health care scenarios can be developed, tested and evaluated in living labs (real environments) and test beds based on 5G technology," explains Prof. Dr. Steffen Hamm. So that in the end there are concrete recommendations for action for politicians, medical companies

Jetzt als Studiengang in Weiden: Physician Assistance (PA„Arztassistent“) ■

and clinics, the 15-person research team works with practical-use cases: How can the single, 81-year-old Edith, who suffers from high blood pressure and diabetes, and lives in a northern Bavarian village without public transport Local transport, benefit from telemedicine or blood sugar measurement using sensors in the future?

Using such exemplary scenarios, which added value and which effects can be realized through digital solutions in health care and which additional potential can be tapped through 5G technology are determined. To do this, the researchers investigate health economic, technical, legal and ethical questions.

Use case integrated care

A consistently digital health-based, integrated medical care approach - with both outpatient and inpatient structures - in rural areas: For example, electronic files and telemedical procedures are used that enable the availability of patient data from anywhere and specific measures for telemedical therapy and diagnostics (Implement teleconsultation. A virtual supply center, complementary to a conventional medical supply center, enables permanently available, high-quality and efficient care by experts.

Use case home care

An equally consistent digital health-based approach that explicitly addresses home care and supply in rural areas: To optimize the logistics for home-care patients, a communication platform in the form of an innovative, mobile IT collaboration tool is being set up – integrating doctor's office, pharmacy, medical supply store, nursing staff and patient/relatives. The infrastructure is supplemented by the use of assistance solutions and smart devices for a self-determined life in everyday life (Ambient Assisted Living) as well as automated solutions in patient care. The Corona crisis in particular has shown how important digital communication is, explains Dr. Clemens Bulitta. 5G can support telemedicine, and large amounts of image data can be transmitted more quickly. In addition, with a higher network capacity, many users could be active at the same time without the network becoming overloaded. In the case of urgent, sensitive data in particular, the connection must function without any problems. In addition to the possibilities, the

Digital Healthcare Management vermittelt technische, medizinische und betriebswirtschaftliche Kenntnisse■

5G4Healthcare team also wants to explore the limits of technology. Because only if possible dangers are recognized at an early stage, one can safely move from the vision to practical implementation.

In trend: Physician Assistance

For doctors practicing there, everyday life in German clinics is characterized by overtime and 24-hour shifts. A new vocation can help here: Physician Assistant. Medical assistants, as is the German name, can take on medical or administrative tasks and thus, relieve the burden of documentation tasks, organization of rounds or operating room management.

Because of the interesting and varied range of tasks, the medical assistant role, which came to Germany from the USA via the Netherlands in the 2000s, became one of the trend occupations of 2019. Students find this profession as an interesting alternative to medical studies. The OTH Amberg-Weiden is therefore the first and one of only two Bavarian universities to date to offer the bachelor's degree in Physician Assistance.

The training takes place interfacing between people, medicine, technology and the health industry and thus qualifies as best possible for the special requirements of the specialist area. The focus is on easing the burden on doctors in clinics and private practices. Graduates have the very best career opportunities. The OTH Amberg-Weiden was the first and is one of only two state universities in Bavaria where you can study the Physician Assistance degree program - without fees and without prior professional medical training.

In focus: Digital Healthcare Management

The Corona pandemic has relentlessly uncovered the backlog that Germany is recording in the area of digitization. The German healthcare system is also underdigitized in country and industry comparisons. But when so-termed P4 medicine - personalized, preventive, predictive and participatory - becomes a reality, the path to it must be consistently followed. This is impossible without digital solutions, without appropriate health policy and legal framework.

The OTH Amberg-Weiden offers the right course for the future of health care. Digital Healthcare Management imparts a profound understanding of the health system and health economic issues. The aim is an interdisciplinary education interfacing between health, business and information and communication technologies. After completing their studies, graduates are able to understand processes and complex interrelationships in the health market, evaluate (health) economics and use digital technologies based on them sensibly and effectively. ■

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www.ifmz-weiden.de

5G4Healthcare
https://www.oth-aw.de/forschen-und-kooperieren/aktuelles-in-der-forschung/5g4healthcare/aktuelles/

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https://www.oth-aw.de/studien-gaenge-und-bildungsangebote/studienangebote/bachelor-studiengaenge/physician-assistance/studium-physician-assistance/

Master:
https://www.oth-aw.de/studien gaenge-und-bildungsangebote/studienangebote/master-studien-gaenge/medizintechnik/studium-medizintechnik/

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Future healthcare with sepp.med

Tomorrow's Know-how for Future Healthcare

Future Healthcare

Future Medtech will not happen without digitalization. We can observe that – besides the real patient – the "digital twin" is increasingly gaining importance and attention. It would mean no less than a technical quantum jump if a human being could be replaced by data – like it is already done in the industrial field.

Digitalization has revolutionary potential for both the patients' therapy and the medical staff's possibilities. It can mean an important relief to the doctor and the health system.

Already today image processing algorithms reliably detect tumors and other physical transformations in the human body. Still data are hard to come by: do we possess sufficient digital knowlegde (comparative data) in order to reliably recognize every transformation in any concrete case?

MedTech development has gone through a process of constant acceleration. Meanwhile we are able to load more innovative and precise algorithms over-the-air on the treating device. Learning algorithms and BigData-Solutions will soon be able to recognize deseases which had been undisclosed so far.

But what, if the computer goes wrong? The question to be answered is "how will we manage to control selflearning algorithms?", so that we won't have to

trust them blindly. Health systems worldwide are exposed to an enormous cost pressure while quality requirements keep increasing constantly. The solution will be integrated digitalization and cross-linking: the internet of things is ready for the job! Tailor-made dataflow along clinical workflows promises more quality patient centered care and seemless scooping of service- and optimization-potential for business processes. Medical processes can be managed – we're ready for the tackle!

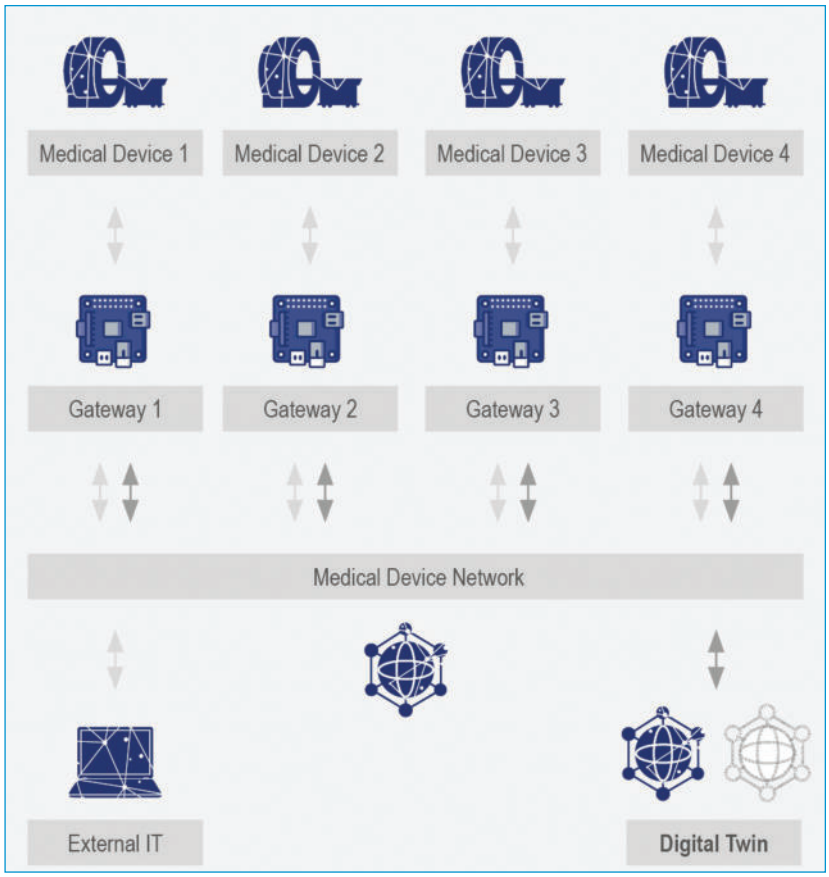
Certainly, waving good-bye to isolated solutions will bring new challenges to both producers and operators because data exchange between the medical products among each other and the adjacent IT-systems has to be most easy and safe at the same time. Most easy, in order to integrate, replace or supplement medical devices and systems without unreasonable investment in time and cost. 100% safety is mandatory as medical data are legally protected personal data and unauthorized access – e.g. to an insulin pump or diagnostic protocols – can lead to vital risks.

Healthcare digitalization promises an exciting future – come along with us into a successful future!

Let us show you 3 examples of how we see the successful way to future healthcare:

The "Digital twin" as an online-validation laboratory

Medical devices are often operated as part of an IT-network (Medical Devices Network). These kinds of networks usually connect medical devices of diverse types and producers. They don't only have to be protected from IT-risks like cyber attacks, it is equally important to guarantee reliable interaction of the connected devices in order to guarantee safe operation even after structural changes within the net or after updates.



sepp.med, in cooperation with the radiation clinic of the Friedrich-Alexander Universität Erlangen-Nürnberg, is currently envolved in a research program "Information- and Communication Technology" sponsored by the State of Bavaria. These are the sepp.med contributions:

- Construction of an online living-lab to serve as an online-validation-laboratory to safe-guard and validate the clinical processes and the technical environment of the medical-device-network.
- Creation of a "digital twin" to the medical-device-network, suitable for real-time-control of the network status as well as an early warning system. sepp.med makes use of artificial intelligence in this context.
- Real-time network-analysis in order to predict future operating conditions and to define preventive maintenance measures.
- Automatical identification of abnormal behaviour
- An additional level of intelligence uses prescriptive analysis to predict critical situations.

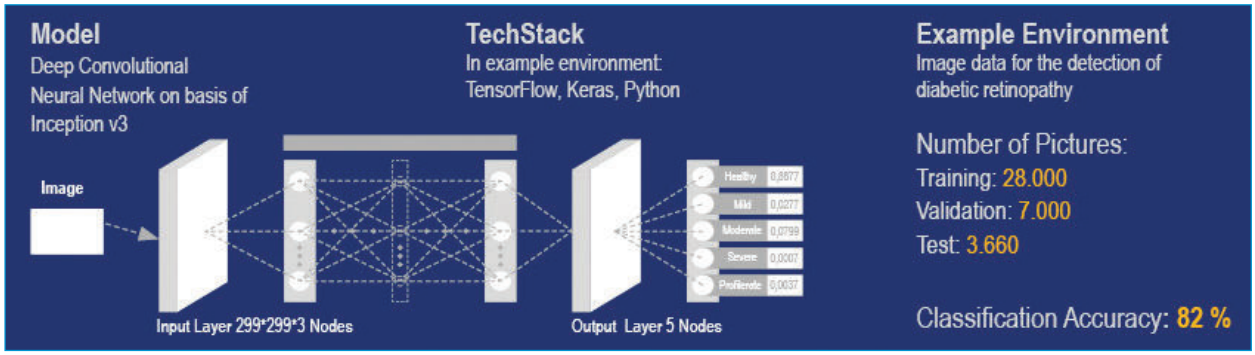
2nd opinion – safe diagnosis by digital consultation

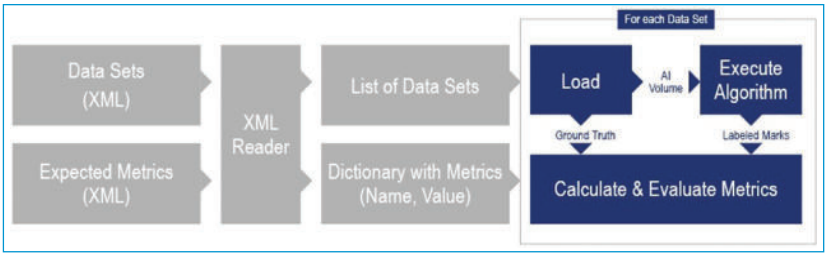
With the application "2nd opinion" sepp.med developed the web-based prototpye of an exemplary solution assisting in the image analysis of eye diseases using deep learning methods. This approach offers the specialist the possibility to have his diagnosis checked by a second opinion – the one of the algorithm.
At the same time the doctor's diagnosis can be compared with other diagnoses. Quality counts!

The sepp.med deep-learning approach:

- Separation of training-, validation- and testdata according to best practices of machine learning
- Making use of data-modelling and imaging of combinatorics in graphic flowcharts by means of MBTsuite, the automatic test case generator developed by sepp.med.
- Important: training- and validations data must be representative, normed, available and relevant!

In this model the use of MBTsuite as a test case generator will always deliver the minimum set of test data, covering any class of equivalence or limiting value. Thus you will get a new set of test data with every change you make. This increases the variance of the tests.
We control the algorithm by applying the DICE-coefficient, Hausdorff metric or execution time metric.
sepp.med works with the following test workflow.





Agile software development for medtech in combination with validation process know-how for admission to the german market or by the FDA in the USA

Agile software development makes also possible the sprint based development of medical products. Thus we can react more flexible and speedy to new ideas and requirements. Regulatory requirements are parallely checked by an inbuilt validation-consultant. This is how we prevent unnoticed changes of artefacts in retrospect. The key to successful certification is traceability.

We will take you to successful digitalization

You will find quick results compliant with standards, while your team and customer stay in good spirits. Trust in our portfolio, no matter what your upcoming challenges in future healthcare will be, we will facilitate you to meet them all. You choose the contract: overall responsibility (requirements, development and test) or selected services, agile or conventional, agile fix price or factory mode.

sepp.med will be the perfect partner for your projects!

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Central Institute of Medical Engineering (ZiMT): Medical Engineering

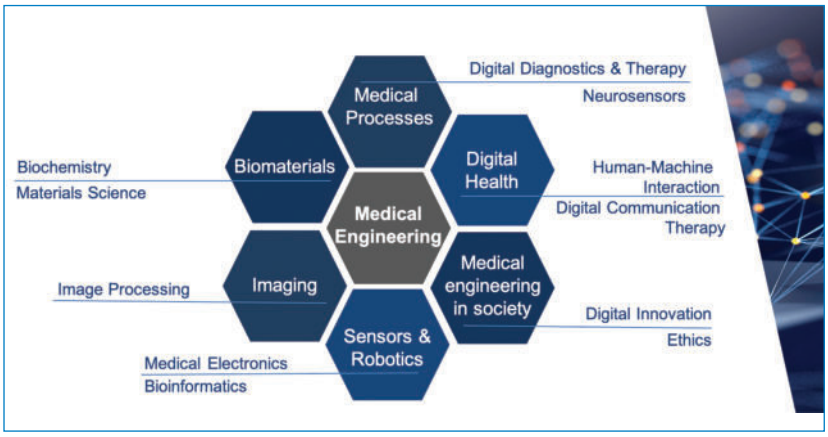
In view of demographic developments, the scientific focus on medical engineering is of the greatest social relevance and is embedded in an excellent research environment at the Friedrich-Alexander-Universität Erlangen-Nürnberg (FAU). Over 90 lecturers are active in this field at the university and have been working together in this institutional framework since the founding of the Central Institute of Medical Engineering (ZiMT) in December 2009. The aim is to further expand the research network in the priority area of medical engineering both within and outside the university and to ensure a more transparent external presentation of the highly dynamic field of medical engineering at FAU. The ZiMT acts as an interface between industry, clinic and science.

The university research and teaching activities interact closely with a high concentration of medical engineering companies within a 50-km radius that is unparalleled. Headed by Siemens Healthineers, the national excellence cluster "Medical Valley European Metropolitan Region of Nuremberg", which has been funded by the BMBF since 2010, is one of the world's strongest economic and scientifically active medical technology clusters and focuses on the prevention, diagnosis, therapy and rehabilitation of diseases elicited by demographic change.

FAU is one of the largest, research-intense and internationally oriented full universities in Germany. In addition to disciplinary excellence, cooperation across disciplinary boundaries is a particular focus at FAU, the unifying motto being "Knowledge in motion". For the second year in a row, FAU took first place in the Reuters Innovation Ranking in Germany (2nd place in Europe, 14th place worldwide). In 2020, FAU was selected as the "Health" node in the HighTech Agenda Bavaria. In the course of this, the new department "Artificial Intelligence in Biomedical Engineering (AIBE)" with 12 chairs and 4 junior professorships is currently being established at FAU (designated speaker: Prof. Eskofier). The FAU is also a "Core Partner" in the "European Institute of Innovation and Technology Health" (EIT Health), in which European institutions and industries in the field of digital health and medical engineering are networked.

The MedTech Map, a new competence map of the FAU, summarizes for medical engineering its focal points imaging, sensors and robotics, biomaterials, digital health and medical processes, as well as medical engineering in society.

The core tasks of the ZiMT thus include in particular the coordination of the competencies of the numerous member institutions as well as the bachelor and master's degree programs in medical engineering at FAU. In addition, the ZiMT offers funding structures to support interdisciplinary projects and assistance with applications at local, state, national and European levels.



ZENTRALINSTITUT FÜR MEDIZINTECHNIK

FRIEDRICH-ALEXANDER UNIVERSITÄT ERLANGEN-NÜRNBERG

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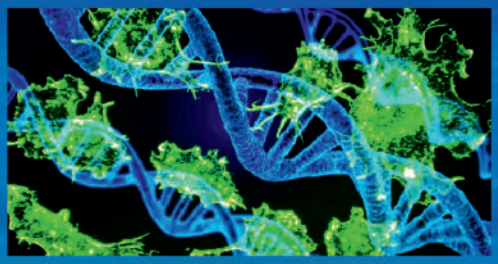

Targeted Therapies in Chronic-Inflammatory Diseases and Cancer

Advanced diagnostic methods and therapies in a new research building for the Deutsches Zentrum Immuntherapie (DZI) at the Universitätsklinikum Erlangen.

DZI, Universitätsklinikum Erlangen

Studies of the past years show that inflammatory diseases and cancer are treated with great success using immunotherapies. However, not all patients are responsive to the immunotherapeutic treatments that are currently available. Therefore, a new molecular understanding of these diseases is crucial. "The better the understanding of the immunological processes in the inflamed tissues, the more targeted the individualized therapy can be chosen. By taking the latest biophysical measurement methods and digital analytics into account, appropriate immunotherapies can be determined and prescribed for the affected patients", explains Prof. Neurath, head of Department of Medicine 1 (Gastroenterology, Pneumology and Endocrinology) of the Universitätsklinikum Erlangen, dean of the Faculty of Medicine and spokesman of DZI.

As a first step along this novel path, the Deutsches Zentrum Immuntherapie in Erlangen was founded in 2018 enabling interdisciplinary specialist consultancy and targeted immunotherapeutic treatments of patients with chronic-inflammatory diseases and cancer.

Chronic inflammations often trigger the development of cancer and control the growth of a number of malignant diseases. An early diagnosis as well as an optimized therapy are therefore of major significance.

From the left: Prof. Neurath (spokesman of DZI), Bernd Sibler (Bavarian State Minister for Science and the Arts), and Prof. Hornegger (President of FAU) during a press conference to inform about the CITABLE research concept, specific benefits for patients and the construction planning. Photographer: Michael Rabenstein/Uni-Klinikum Erlangen. ■

The second major step for DZI after opening the clinical units is now the construction of a new research building entitled "Center for Immunotherapy, Biophysics & Digital Medicine (CITABLE)" in order to combine latest immunotherapeutic strategies with innovative analytical biophysical methods and the opportunities offered by digital medicine.

A direct constructional link to the DZI, focused on patient care, will enable a bi-directional translational research strategy to be implemented in a perfect manner. The physicians directly contribute their high level of expertise in research and promising research findings can directly be transferred to the patients in form of new therapies in clinical studies.

The treatment at DZI focuses on chronic-inflammatory diseases (e.g. Psoriasis, Rheumatoid Arthritis, Multiple Sclerosis, Inflammatory Bowel Disease) and cancer (e. g. Leukemia, Melanoma, Colorectal Cancer, Lung Cancer, Breast Cancer). Hotline: +49 9131 85-44944. Photographer: Michael Rabenstein/Uni-Klinikum Erlangen. ■

CITABLE will be locally supported by the Translational Research Center (TRC) as well as the new Max-Planck-Center for Physics and Medicine (MPZPM), focusing on the development of new physical measurement techniques. It also offers excellent opportunities for local cooperations with different institutions and medical device companies. ■

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Heart medicine of the future at the German Heart Center Munich

The German Heart Center Munich (DHM) is an internationally renowned hospital specializing in cardiovascular diseases and treats people of all ages with heart disease according to the latest medical findings. The practice-oriented, excellent research contributes to the further development of international guidelines, diagnostic and treatment concepts. The DHM is deeply rooted in the Technical University of Munich (TUM). An important goal is to integrate comprehensive treatment-relevant data and innovative technologies within the framework of digitalization. In this article, we would like to give an insight into our current projects, which are intended to improve the treatment of patients with cardiovascular diseases in the long term.

More information: www.dhm.mhn.de

The DigiMed Bayern executive team at the annual symposium: Dr. Thomas Huber (StMGP), Prof. Heribert Schunkert (German Heart Center), Minister of State Melanie Huml (StMGP), Prof. Horst Domdey (BioM), Dr. Jens Wiehler (BioM), Dr. Moritz von Scheidt (German Heart Center) (from left to right) ■

Personalized, digitized medicine with DigiMed Bayern

Under the scientific direction of Prof. Heribert Schunkert, Director of the Clinic for Cardiovascular Diseases at the DHM, and the project coordinator BioM Biotech Cluster Development GmbH, a renowned consortium of research and clinical patient care has received project funding of more than 20 million euros from the Bavarian State Ministry of Health and Care as part of the BAYERN-DIGITAL II master plan. The aim of DigiMed Bayern is to further improve the prognosis, prevention, diagnosis and therapy of cardiovascular diseases with a focus on coronary heart disease, heart attack and stroke. P4 medicine - predictive, preventive, personalized and participatory - is considered worldwide to be the most promising development for holistic healthcare using digital technologies from the field of Artificial Intelligence and Machine Learning, along with advances in bioinformatics and OMICs technologies (high-throughput methods for decoding genetic material, proteins and metabolism). By linking individual metabolic signatures with medical examination results and clinical studies, DigiMed Bayern enables a quantum leap in the care of patients with cardiovascular diseases. Digitalization in medicine with the necessary establishment of a new and resource-intensive infrastructure for the use of clinical data represents a major challenge for routine hospital operations. Ideally, everyone involved in the healthcare system in Bavaria should benefit directly from DigiMed Bayern in the future. The origin and course of heart attacks and strokes are of particular interest. This requires the timely transformation of a static hospital system into a dynamic, multidirectional process with constant

collection, linking and analysis of disease-relevant parameters. By identifying patterns and using learning software, Digital Medicine promises to be a key to a better understanding and more targeted prevention of atherosclerosis. In addition to the DHM, the consortium includes other renowned academic and clinical institutes of the Technische Universität München, the Ludwig-Maximilian-University, the Max-Planck-Institute for Biochemistry, the Helmholtz Centre with the Institutes of Neurogenomics and Epidemiology as well as the Leibniz Computing Centre. The project is managed by BioM, a partner that has already distinguished itself through its cluster activities and management of important programs. The implementation of P4 medicine requires constructive interaction of many different stakeholders, including patients, physicians, hospitals, health insurance companies, science and politics. Besides the active involvement of ethics, data protection and legal experts, DigiMed Bayern has a scientific advisory board that advises the participants in their scientific and patient-related activities. The advisory board consists of a group of experts from outside the project who provide independent advice. DigiMed Bayern is first of all a scientific project, which in the coming years is to make medical digitization usable for the solution of disease-relevant questions in a way never seen before and to implement it in daily clinical care. DigiMed Bayern is an important lighthouse project that is intended to contribute to the modernization of the medical and digital infrastructure and thus to the future performance of the State of Bavaria. The constant focus is on optimized and individualized patient care.

More information:
www.digimed-bayern.de

Early detection and prevention of familial hypercholesterolemia in Bavarian children — Vroni-Study

Familial hypercholesterolemia (FH) is the world's most common congenital metabolic disease, which if left untreated can cause severe cardiovascular disease at a young age. In Germany, it is assumed that there are over 270,000 carriers of the genetic defect, of which less than 1% are diagnosed. The Vroni-Study, funded by the Bavarian Ministry of Health within the framework of DigiMed Bayern, aims to implement and evaluate a nationwide screening of children aged 5-14 years for early diagnosis of FH in order to improve the diagnosis and therapy situation for patients of all age groups in Germany. The autosomal-dominant inherited lipid metabolism disorder, in which there is a massive increase in LDL cholesterol, occurs with a prevalence of about 1:250. The risk of suffering a cardiovascular event is then 5-20 times higher. Early diagnosis in childhood allows for early and effective treatment, which can reduce the risk of atherosclerosis to the level of the general population and prevent serious secondary diseases. "Our goal is to find as many patients with genetic mutations as possible and to treat them preventively," explains Prof. Heribert Schunkert, Director of the Clinic for Cardiovascular Diseases at the DHM. In Bavaria, the Vroni-Study will be used to test over 60,000 children aged 5-14 years for FH. During a regular visit to the pediatrician (KJA) 200?l capillary blood is taken and sent to the DHM for LDL cholesterol determination. If LDL values are elevated, a molecular genetic examination is performed. FH-positive tested children and their parents will be informed by the supervising KJA and if necessary referred to a specialist. In addition, the family is offered cascade screening in cooperation with the CaReHigh Register study, because behind every FH-positive child there is a sick parent and possibly other

Vroni-Study — Heart attack with 35? "WITHOUT ME!" ■

affected relatives. The combination of the collected multimodal data sets (clinical, epidemiological and molecular genetic) allows a comprehensive analysis and improvement of the diagnostic and therapeutic situation of the FH on an individual as well as general level. "The experience from the FH screening program in the Netherlands has shown that in children who tested positive, consistent therapy can reduce the risk of myocardial infarction. It is urgent that we achieve this also in Germany", says Dr. Veronika Sanin, coordinator of the Vroni-Study at the DHM.
More information: www.myvroni.de

Innovative KI-Applications - DHM-MSRM Joint Research Center

Since the beginning of this year, society has been severely affected by COVID-19. Most importantly, the health care sector felt the pressure to adapt to new circumstances quickly, to establish early warning systems and hygiene concepts, to expand lab capacities and to ensure enough ICU beds were available. Moreover, the digital, interdepartmental cooperation and implementation of a robust infrastructure has become more crucial.
In the lighthouse project "DHM-MSRM Joint Research Center", the German Heart Center Munich and the Munich School of Robotics and Machine Intelligence (MSRM) of the Technical University of Munich, joined forces in order to establish a virtual center for the future of cardiovascular health.
Information technology in the area of AI based data analysis and sensor data fusion, robotics, machine learning, augmented and virtual reality as well as image fusion is going to be developed for clinical implementation.
An international team of young scientists is supporting the renowned research groups and clinical doctors in the field of cardiovascular medicine. They are going to work on the following main topics:

- a completely digitized intensive care unit
- individual modeling of coronary arteries and congenital heart diseases
- structured exchange of digital patient data for optimized patient-centered care in cardiovascular medicine

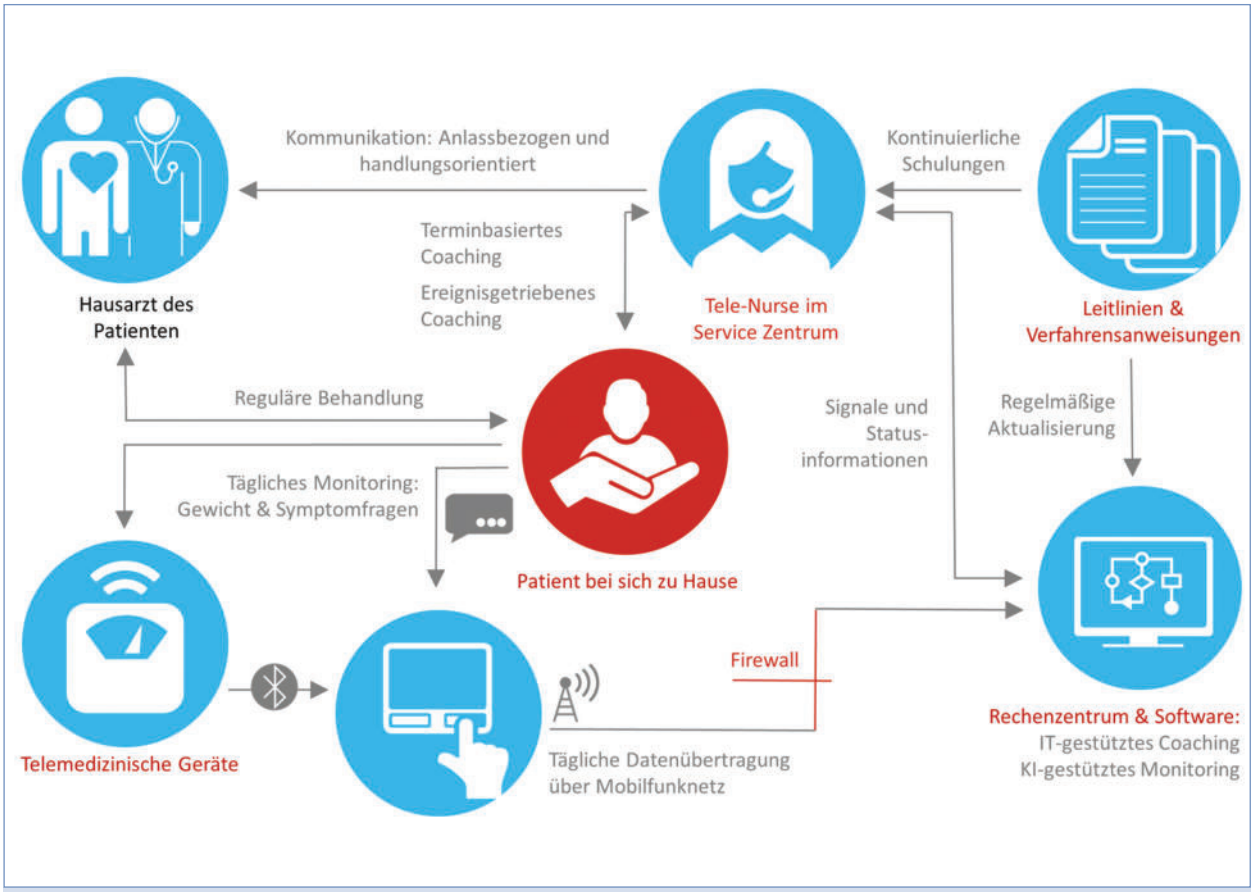
The German Heart Center is working closely together with the Munich School of Robotics and Machine Intelligence (MSRM). The MSRM serves as an integrative research center for science and technology, in order to create innovative and sustainable solutions to address the essential challenges of our time. The MSRM, led by Prof. Dr. Haddadin, offers profound expertise in the central areas of research such as robotics, perception and data science.
Within the scope of "Future of Health", the MSRM is conducting research in machine learning, data mining and analysis, virtual and augmented reality, sensor systems in robotics, as well as safe human-robot interaction, soft-robotic design and regulation. The main goal lies in the successful implementation and commercialization of these research findings in order to enhance and improve clinical care processes.

Prof. Rüdiger Lange - German Heart Center Munich

Prof. Sami Haddadin — Munich School of Robotics and Machine Intelligence

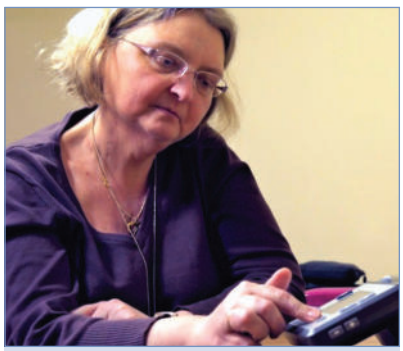
Telemedical Innovation in Heart Failure - Hedy-Hedy

Healthcare systems face the challenge of an aging population with a rising incidence and prevalence of chronic diseases. As a result, new content requirements for medical care, rising costs and scarcity of resources are emerging. One way to partially compensate for these problems is to offer telemedical services. With telemedical methods, patients can be cared for in their home environment and supported in their independence. Based on the intensive and long-standing previous experience in the field of clinical cardiology and telemedicine, the project partners HealthCare-Systems GmbH (HCSG) and the Clinic for Cardiovascular Diseases of the DHM - represented by Prof. Hengstenberg, Dr. Rosner and Dr. Knoll - have been working since 2018 on the establishment of novel telemedical services for patients with chronic heart failure, such as HedyHedy, the talking, digital health companion. Hedy's main innovation is the combination of precision medicine and telemedicine on the



Hedy-Workflow: Process of patient-centered digital care ■

one hand and the utilization of new technologies for the care of chronically ill people on the other. From the patient's perspective, Hedy is an easy-to-use app on a tablet/smartphone. By integrating multiple data (diagnoses, clinical parameters and symptoms as well as biometric measurements via tele-monitoring, psychosocial data) Hedy continuously seeks points of action that are relevant in terms of behavioral change. Of particular importance are early detection of deterioration of the disease, improvement of adherence to therapy and actions to promote health-conscious behavior. A telemedical service center has access to the data and can contact the patient and recommend further actions, such as a visit to the doctor, if Hedy has made an appropriate risk assessment. Patient care includes tele-monitoring and tele-coaching and is controlled by the medical device software mecor® developed by HCSG. The health program mecor for patients with chronic heart failure, which has been in existence by HCSG since 2016 and currently has more than 5,000 active participants, is currently being scientifically analyzed by the DHM, with regard to reducing mortality and improving quality of life. The cooperation between HCSG and DHM has already resulted in the COHIRAB study, which investigates the effect of telemedical training of heart failure patients with regard to the corona pandemic. Sub-projects of the cooperation were funded by the Bavarian Ministry of Economic Affairs (Masterplan BAYERN DIGITAL II) and the German Heart Foundation.



Studienpatientin des Telemedizinprogramms HedyHedy ■

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EIT Health Accelerator

Business start-ups at European Level

EIT Health

EIT Health is one of the largest health initiatives worldwide. It aims to promote sustainable innovations for health care and thus healthier lives and well-being for people throughout Europe. EIT Health uses the know-how of more than 150 of the most relevant organisations in the central areas of industry and research in the health care sector. The consortium was already supported by leading European research institutions, universities and industrial partners in the application phase. It was then selected by the European Institute for Innovation and Technology (EIT) under the name "EIT Health" as one of the 8 "Knowledge and Innovation Communities (KICs)" in a highly competitive process at the end of 2014. With a project volume of over EUR 2 billion, one quarter of which will be funded by Horizon2020, EIT Health will invest specifically in Europe's best entrepreneurial talent. Creative minds with ideas for the development and marketing of intelligent product and service solutions are promoted, particularly those tackling challenges linked to demographic change and the associated aging society.

The local structure of EIT Health covers the whole of Europe and connects highly innovative areas. In addition to its international headquarter in Munich, EIT Health consists of six independent regional centres, so-called "Co-Location Centres (CLCs)" based in the following cities: Heidelberg and Mannheim (for Germany), and, since the end of 2015, London (for the UK and Ireland), Stockholm (for Scandinavia), Barcelona (for Spain), Paris (for France), and Rotterdam (for Belgium and the Netherlands). A seventh company, InnoStars, integrates the innovative regions of Hungary, Poland, Portugal, Croatia, Italy and Wales *(Figure 2)*.

Fig. 1: *EIT Health headquarter in Munich (© Design Offices GmbH 2016)* ■

EIT Health aims to achieve crucial health improvements for European citizens through innovation. In this context, it has identified the following three particularly important future challenges: "Promote healthy living", "Support active ageing" and "Improve healthcare". EIT Health connects leading organisations in the fields of education, research and technology and thus bundles innovative energies in a unique way.

The EIT Health ACCELERATOR

EIT Health is based on 3 pillars: Campus, Innovation and Accelerator. The Accelerator was created to provide the best possible support to the most innovative entrepreneurs and start-ups in the healthcare sector at every stage. To successfully meet the above described future challenges, an ecosystem needs to be created in which interdisciplinary innova-

Fig. 2: *EIT Health Core Partners and Co-Location Centres (CLC)* ■

tions for the health care system can be developed. The Accelerator brings together the best entrepreneurs in healthcare and supports them in realizing their ideas in this very special market.

The EIT Health Accelerator is not an ordinary incubator, but a network that links health and medical technology clusters throughout Europe. The projects are designed to provide start-ups with the necessary know-how and tools throughout their entire development phase, adapted to their individual needs. To cover the complete supply chain for entrepreneurs, the accelerator offers a variety of programs that consist of three activity lines: "Incubate!", "Validate!" and "Scale!" *(Figure 3)*.

EIT Health does not compete with existing incubators by connecting private and semi-governmental incubators. The EIT Health Accelerator links the currently fragmented European ecosystems by offering a whole portfolio of interdisciplinary projects. Based on the positive experiences of recent years, the geographical scope of the projects in Europe will be expanded to allow that more innovative entrepreneurs benefit from the activities by EIT Health.

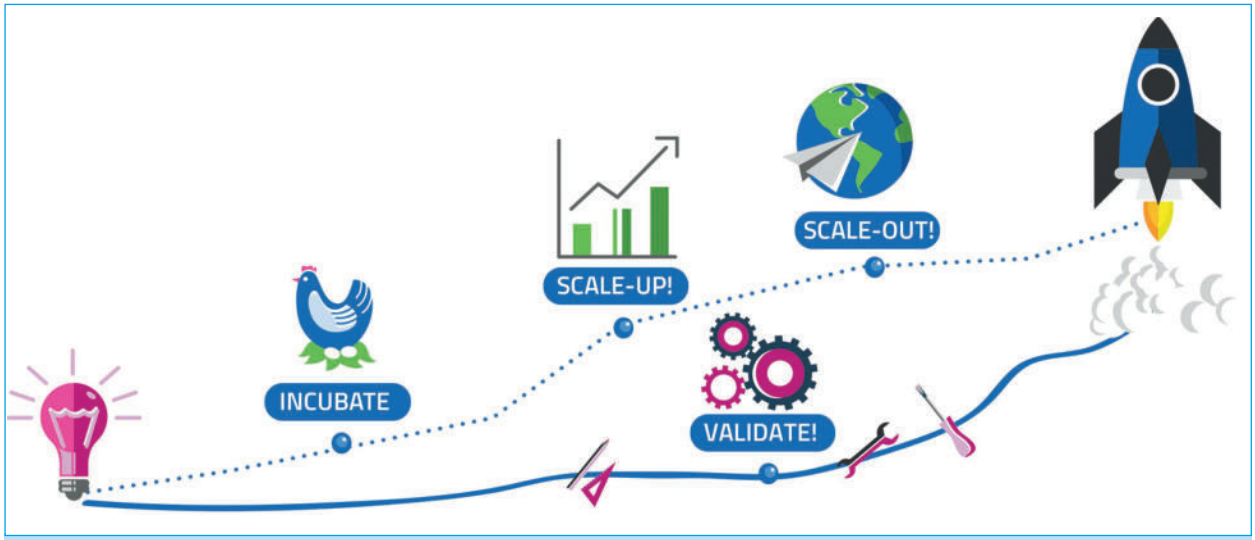


Fig. 3: *The activity lines Incubate!, Validate! and Scale-Up! Or Scale-Out! correspond to the maturity of the supported start-ups and their respective needs* ■

Incubate!

The Incubate! Activity Line brings together entrepreneurs, intrapreneurs, start-ups and SMEs in the early stages of setting up a business. The Incubate! Activity Line includes various projects targeting early stage companies such as various Bootcamps (CRAASH Bootcamp@Barcelona, Medtech Bootcamp@Erlangen, Validation Lab@Delft, penAPI@Oxford, Pa tient Innovation@Kopenhagen), the CaixaImpulse and the Start-up Meets Pharma Programmes. These are closely linked to EIT Health Campus, the organization's education division. For example, students can participate in Campus Summer Schools or e-Labs and then further develop their business ideas within the Accelerator. The connections made by entrepreneurs in this setting are extremely important, as these can learn a lot from other entrepreneurs from other countries as well as from mentors with special experience in their field.

The Bootcamps have been established throughout Europe due to strong demand in recent years and currently consist of 6 programmes taking place in 6 different countries. The two to three-month programmes strengthen ambitious entrepreneurs in the HealthTech sector in the implementation of their ideas at European level. This is done, for example, by support in developing the market potential or in determining the target groups in corresponding regions.

Validate!

The Validate! Activity Line supports start-ups, entrepreneurs, and SMEs in evaluating and validating their products or services in the health industry. The Validate! Programs run through the entire Accelerator pillar, as aspects of validation are required in each individual phase, e.g. validation of an idea, proof-of-concept, prototype or already developed product for different markets or target groups. Validate! comprises programs Living Lab and Test Beds, Mentoring and Coaching Network, and EIT Health Headstart (50,000 Euro grants to start-ups to validate their products and a strong collaboration with the Healthy Longevity Global Competition conducted by the U.S. National Academy of Medicine). The programs of the Validate! Activity Line offer direct access to common databases to all participants (Accelerator, Campus and Innovation). There they can choose their own mentors from a pool of experts or find the right Living Lab to test their product.

Scale!

DThe Scale! Activity Line helps start-ups and SMEs to take their existing business to a new level. Ultimately, the SCALE! activities will make a strong contribution to participating start-ups and SMEs to increase their turnover and increase the number of jobs they create. In this context start-ups and SMEs often face the challenges of finding the right investors, financial support for product development and the development of internationalisation strategies. The programs of the Scale! Activity lines such as European Health Catapult, Product/Market Fit and Investor Network, Gold Track Programme and Bridgehead Programme are particularly valuable for start-ups and SMEs that have already participated in other Incubate! or Validate! Activity Lines. Through business plan competitions, investor rounds, crowdfunding or GoGlobal programs, they can gain additional capital, important contacts and further input to successfully form their company. Consequently, they can gain greater visibility and reach in their home market or on international level.

The European Health Catapult is organized in cooperation with Health Axis Europe. Following regional pre-competitions in 2020 with more than 120 applicants in the Medtech, biotech and digital health areas, the 42 regional winners in the newly introduced, category specific semi-finals will present themselves this year in an online event (*Figure 4*, registration link for the event: https://www.-europeanhealthcatapult.eu/) Of the 21 semi-final winners, 9 winners will be selected in the finals during the EIT Health Summit (also as an online event in December) in front of a renowned auditorium consisting of all EIT Health partner institutions with a total prize money of 135,000 € in the categories "Biotech", "Medtech" and "Digital Health".

The Bridgehead programme aims to connect European incubators and target reimbursement and regulatory challenges in EU's fragmented healthcare market. The project has the objective of becoming an "Erasmus" programme for healthcare entrepreneurs. Start-ups will be hosted by exactly those incubators that provide the best European-wide support in terms of extensive knowledge transfer and soft-landing support. In this way, the program strengthens not only technology projects but also the infrastructure of various stakeholders. The activity locates and links incubators and clusters as well as start-ups throughout Europe and, since 2020, even on a global level. The mapping of these activities will identify both "hotzones" and regions with innovation needs, thus helping to better understand innovation barriers in Europe. Thus, participating start-ups and SMEs can benefit from a comprehensive knowledge transfer and soft-landing support in a close exchange. There are currently 17 partner institutions in the network, which have supported 90 start-ups so far, among them suc-

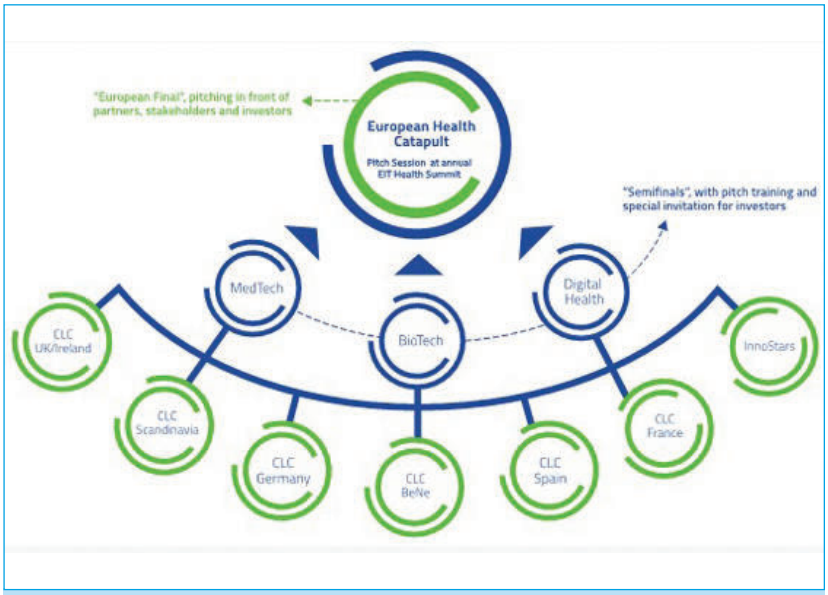


Fig. 4: *After regional pre-selections in each CLC, selected start-ups have the opportunity to present themselves to investors in the semifinals.* ■

cessful Bavarian companies like Munevo and S4DX.

Gold Track supports "high potential" start-ups and SMEs in a highly intensive and individualized programme. Based on the the successful model of the Boston-based "German Accelerator Life-Sciences (GALS)" around Christoph Lengauer selected companies with potential for massive growth will be mentored and supervised from world leading Investors and Life Science CEOs throughout one-year program. Additionally, the participants will be integrated into the EIT Health network and receive direct access to other EIT Health Accelerator programs.

ACCELERATOR Success Stories

DThe winners of the European Health Catapult in 2019 reflect the success of the Accelerator (for more information on the following examples, see https://www.europeanhealthcatapult.eu/about/):

Epihunter

is a Belgian startup which creates digital solutions that decrease the impact of epilepsy on daily life, while providing real time data and value to users, caregivers and neurologists, and in the future insurers and pharma too. The company was founded in May 2017, commercialized its first b2c product for absence epilepsy (1 in 7 with epilepsy) in August 2018 in multiple European markets. Last June this MassChallenge 2019 HealthTech finalist launched ground-breaking automated video functionality and obtained CE Class I medical device marking. Epihunter is raising funds for further geographical expansion, to start selling to neurologists, continued clinical validation & certification, and to expand their products to other types of epilepsy and neurological conditions.

https://www.epihunter.com/

Triumf Health

offers personalized approach to improve patient outcomes & empower ill children by delivering behavioral therapeutics through a mobile game. Their multi-site pilot study showed that the game was positively perceived by pediatric cancer patients, resulting in high usability & acceptability evaluations. Furthermore, the findings indicated improvement in psychological well-being & quality of life. They are now starting RCTs among various disease groups in Finland, Estonia & Singapore. Importantly, the big data from the game is analyzed for the care team; their visual dashboard helps with treatment monitoring, improves medical visit effectiveness & communication. Their seed funding round is open.

Triumf Health

https://triumf.health/

inHEART

provides the Google Maps for interventions on cardiac arrhythmias with a cloudbased service leveraging AI to transform medical images into a digital 3D map of the patient heart. This map contains key information to identify abnormal tissue at the origin of electrical disorders. As opposed to current invasive intra-operative electrical diagnostic, our technology enables non-invasive structural diagnostic from pre-operative imaging saving procedure time and cost of expensive catheters. With an international research network of more than 30 centers, our disruptive technology has been recently featured in the international recommendations for interventions on ventricular tachycardia.

https://www.inheart.fr

SparingVision

SPVN06 uses a gene therapy-based approach, independent of mutated genes. By a single subretinal injection, SPVN06 pre-

vents and stops degeneration of cones photoreceptors, first step in the disease evolution, leading to total blindness. The first clinical trial will begin in 2020. SparingVision is an agile company, a smart mix of an experimented team, a strong scientific expertise from Vision Institut (Paris), world renamed Scientific advisors and supportive investors such as Foundation Fighting Blindness (US), Fondation Voir & Entendre and Bpifrance.

http://sparingvision.com

Takis

is a Biotech Company stemming from Merck researchers (currently 20 scientists and turnover 1.8M€). TK-NEO is a patient-specific DNA-based Neoantigen Cancer Vaccine (NCV) for therapeutic vaccination in patients with advanced/metastatic solid cancers, with a 6-weeks cycle from cancer DNA sequencing to delivery, thanks to patent pending plasmid DNA production and bioinformatic pipeline. TK-NEO was proven at pre-clinical stage to completely heal a lung cancer in humanized mice in 2 months. The target is to realize a GMP DNA facility and run a Phase I Clinical Trial (investment 2 M€) before licensing to pharma for a market value of 1.5b only considering the first application to melanoma.

http://www.takisbiotech.it

uFraction8

has developed a new type of filtration technology that offers significant benefits over the incumbent technologies of pore based filters and energy intensive centrifuges.
uFraction8 is targeting the bio-manufacturing and bio-research markets where biological cell processing is particularly underserved by existing solutions.

http://www.ufraction8.com/

PKvitality

is an advanced bio-wearable company developing K'Watch, a CGM (Continuous
Glucose Monitoring) device in a smartwatch It measures glucose levels from the interstitial fluid using microneedles and biochemicals. K'Watch and its 7 patents revolutionize the CGM experience with painless microneedles, soft adhesive and an invisible CGM part. New services are brought thanks to the smartwatch embedded sensors and the power of AI. This at a fraction of present CGM cost. Rewarded by CES best of innovation awards, already expected by more than 27k patients who subscribed to the newsletter, K'Watch is in preclinical stage with excellent pig results and target to get CE mark in 2022.

www.pkvitality.com

Gasgon Medical

is a startup MedTech company based in Ireland. The company develops novel devices to reduce potential for harm and optimise clinical efficiency during delivery of intravenous (IV) medicine. Currently engaged in pre-clinical studies for a patent-pending disposable device that is effective in reducing incidence of Vascular Air Embolism (VAE). Air Embolism is a serious risk factor of every IV infusion, the most common invasive therapy in healthcare, and VAE adverse events burden healthcare with more than € 8.5bn in direct additional costs annually. Responding to poorly met clinical needs we have identified an opportunity to improve outcomes and disrupt the €11bn IV tube market. Gasgon Medical, accelerated by EIT Health, is seeking funding and partners to propel delivery to global markets.

www.gasgonmedical.com

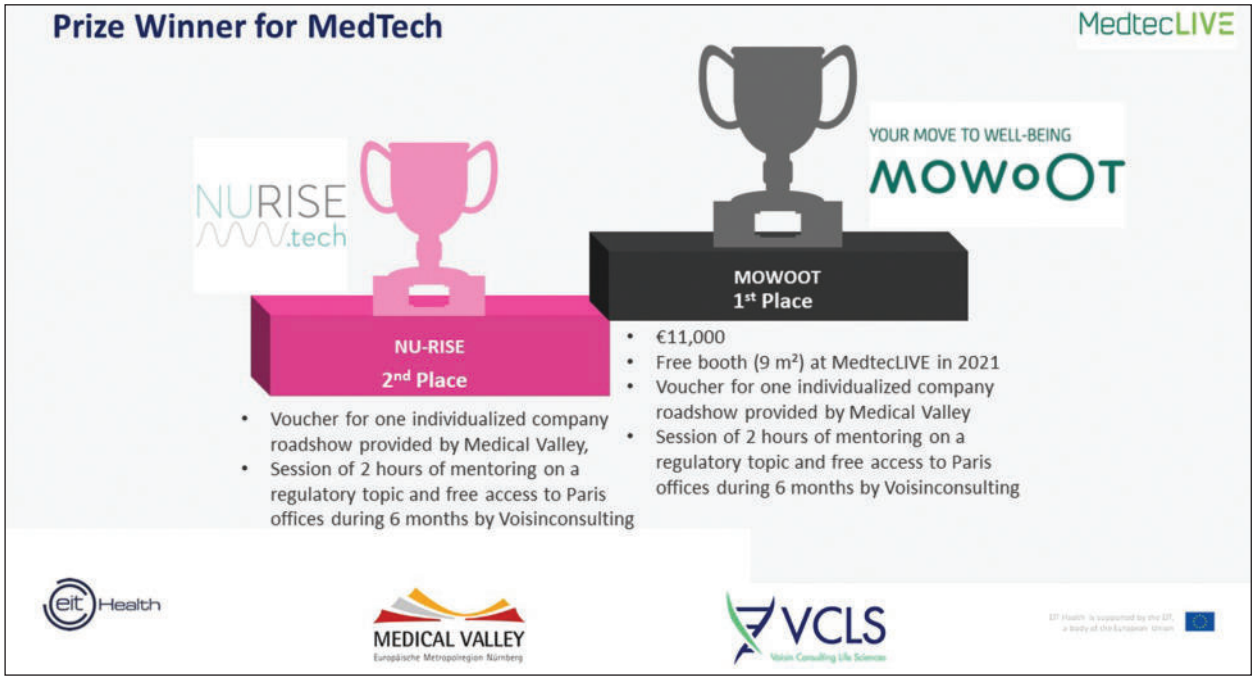
ADVITOS GmbH

(till 04/2019 "HepaWash") is an ISO13485 certified MedTech company that has developed the CE-marked and worldwide patented ADVOS device. As the only therapy worldwide offering multi-organ support within 1 single device, ADVOS is a truly disruptive technology for highly significant improval of ICU patient survival (from expected 10% to actual 35-50%) through combined extracorporeal removal of water-soluble (kidney), protein-bound (liver & kidney) toxins and CO2 (lung). With first revenues (2m€/2018) on the German market we look for 20m€ to accelerate market penetration and internationalization.

www.advitos.com

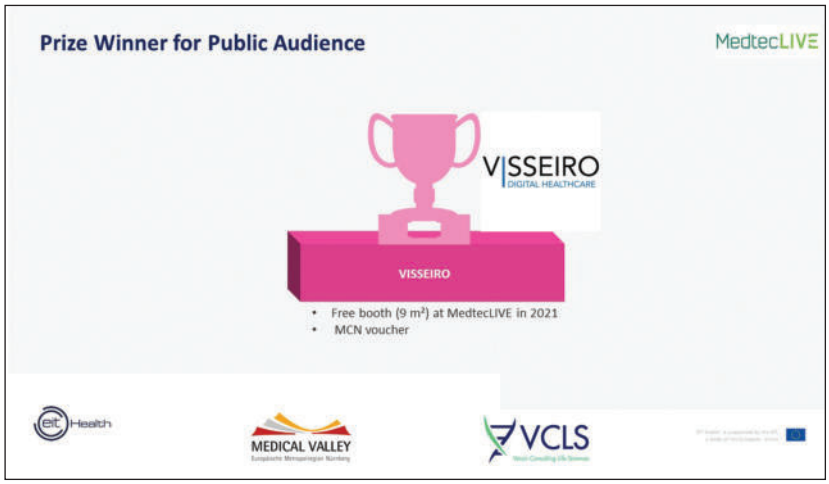
EIT Health in the Bavarian region

In addition to the headquarter in Munich, EIT Health has a strong presence beyond the state capital. In 2020, EIT Health was able to greatly enrich MedtecLIVE, where over 150 exhibitors from 13 countries presented their innovative ideas in the medical technology industry to over 1500 visitors: In addition to the active participation of leading managers from EIT Health, 11 start-ups supported by EIT Health also presented their innovations and were able to further expand their network. Two teams won a total of 21000 € prize money and other attractive prizes in the pitch competition, such as individualized support from Medical Valley in Erlangen.



MedTech 1. Platz: MOWOOT is a non-pharmaceutical, non-invasive solution for chronic constipation in the form of a portable device that mimics the colon-specific massage techniques of professional therapists. In short, the device compensates for the contractions of a healthy bowel that are reduced or absent in patients with constipation.

Digital Health 1st place: Mindpax was founded in 2015 and aims at people suffering from schizophrenia or a bipolar disorder. Mindpax has developed a personalized e-health platform with an app that continuously records the development of the disease via a wearable. By monitoring comprehensive data on activity, sleep, mood and external events that may affect the patient's health status, Mindpax is able to improve the learning process in dealing with psychiatric disorders and to ensure relapse prevention.



If you are a company founder and are also interested in support from EIT Health, please contact the Director of Business Creation directly kurt.hoeller@eithealth.eu) or visit our website www.eithealth.eu/accelerator

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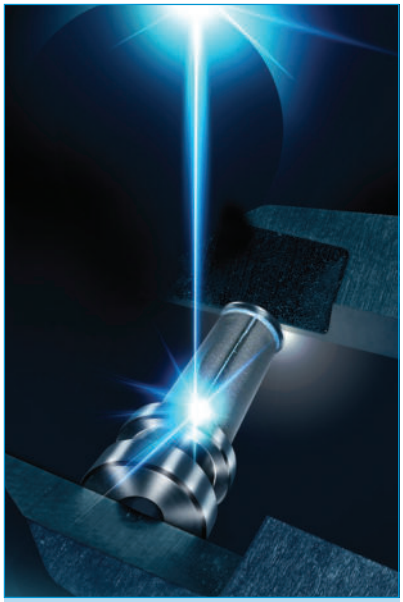
Intelligent Filter System for Medical Device and Pharma Industries

A key part of processing within the medical device industry is the purification of fluids. Filter systems are avoiding the contamination with particles and enable a sufficiant cleanness. Due to this, filter systems are a integral part of medical devices as well as of production processes.

Miniaturized Filter Device, microfilter GmbH ■



Micro-Laser Welding Process, microfilter GmbH ■

Filtration Systems and Cartridges, microfilter GmbH ■

However, filter systems are constantly contaminated during operation and block after a certain time. This can lead to a shutdown periode of single machines or even the whole production facility. To enable a reliable predication of the filter's degree of contamination, microfilter GmbH is developing the intelligent filter analysis system (FAS). The device is working on behalf of special sensors and based on network technology as well as intelligent software algorithms. This allows for a robust determination of the degree of contamination as well as a prediction of the remaining periode to operate the filter system before a change is required.

microfilter GmbH is an innovative company focusing on the production of pressure filtration systems and filter cartridges. The company was founded in 1973 and provides filter systems for liquides and gases in large scale production or custom-built devices. The company is customer orientated, this enables for a wide range of appications and filtration systems provided. Filter systems are as well provided for pharmaceutical and medical device appliances. For this field, the production faces high requirements on quality, reliability and performance. By means of innovative welding techniques, e.g. the micro-laser welding, microfilter GmbH provides miniaturized filter systems for dental applications. These filters are not bigger then 3 – 4 mm and provide the highest standard of quality. With the same technology, microfilter manufactures filter systems for the analysis of blood in diagnostics. The filter systems are protecting the micro gear pumps as well as the micro valves and avoid blocking. For the filtration of

gases, the so called „inline filter“ is provided for resparatory protective devices.
A major adventage of the microwelding is the direct heat-sealing of the fabric with the solid parts of the filtration cartridge. Due to the little amount of heat introduced to the fabric, the texture is not destroyed. The filter does not require any gluing and is absolute dense.

Filtration in Industrial Plants

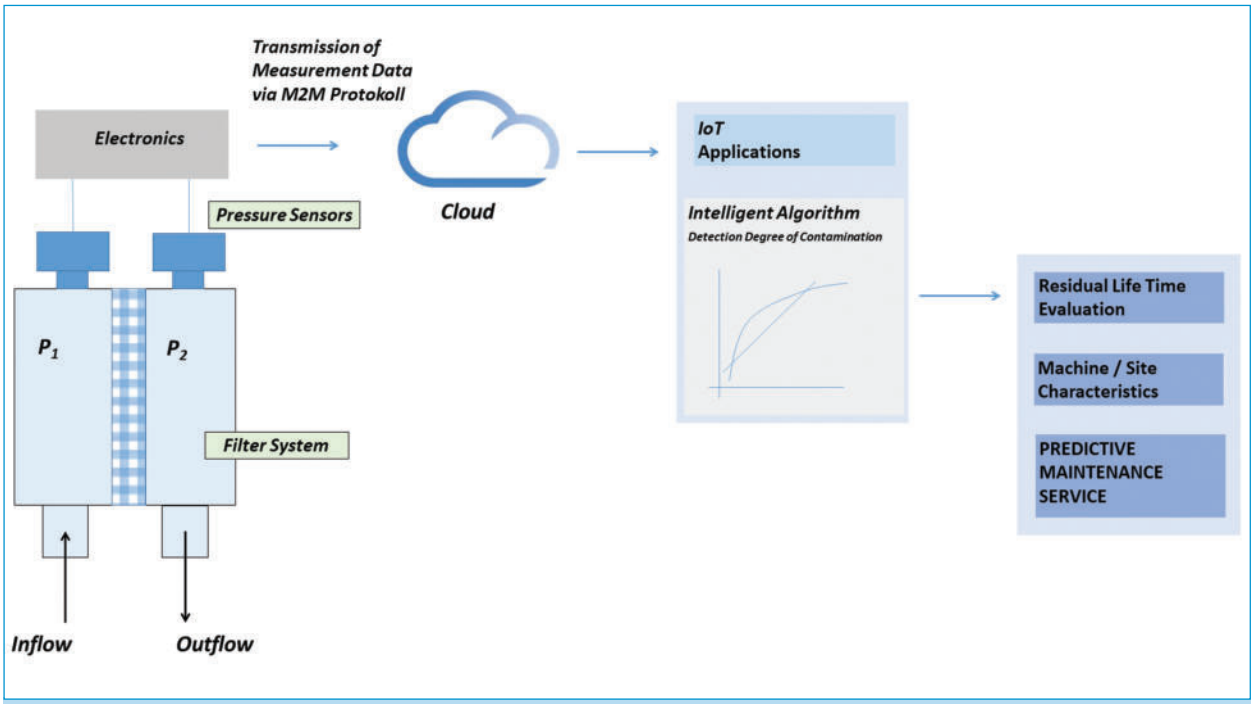
Filtration systems ensure the purification in industrial plants and machines. They serve as prefiltration units for the seperation of solid particles from sugar syrup, as ventilation filter for tanks or sterile filter for the removal of organic contaminants. In many cases, there are several types of filters used in a production site. Only a reliable filtration system can assure a maximum of process safety. The permanent contamination leads to a plugging of the filtration units. Costy shutdown periods can be avoided in case the status of the filter and his remaining operational time could be estimated.

Intelligent Filter Analysis System

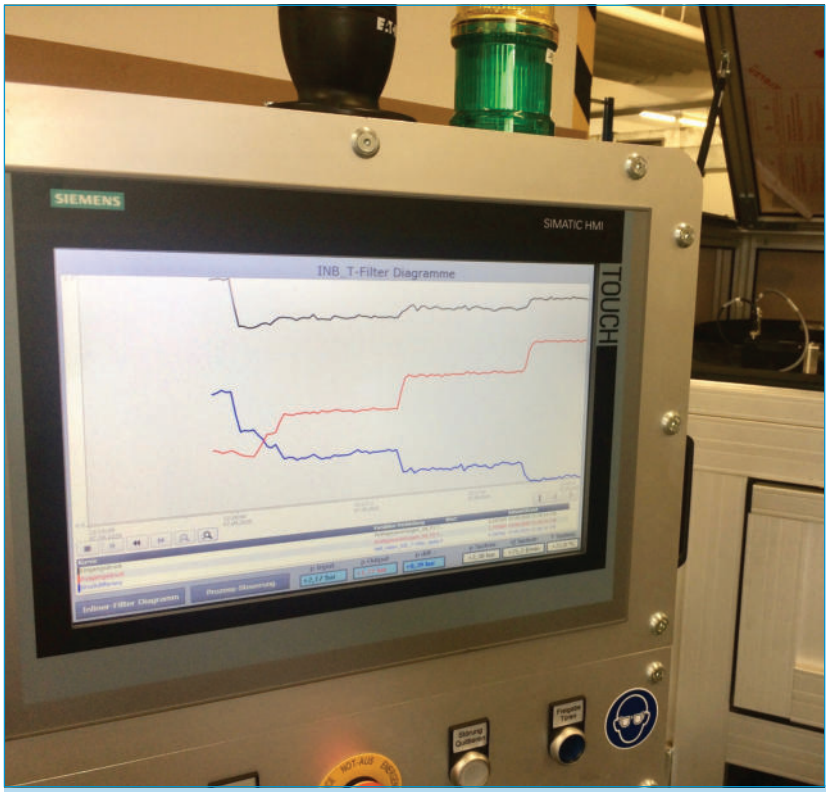
In contrast to established solutions the intelligent filter analysis system is able to detect the deficiency of the filter unit a couple of days or weeks in advance. An additional innovative feature is the way of connecting to the „Internet of Things“. This follows the idea of „Industry 4.0“. The filter is connected to the local network and provides data via machine-to-machine (M2M) protocol. The Internet of Things allows for examples suppliers to monitor the status of filters and provide service or replacement parts in time. This allows for service before the plant shuts down and enables new business models, e.g. Filter-as-a-Service. With this model, the operator of a facility purchases a subscrition for service assuring a permanent functioning filter systems within his application.

Analysis of Fluidmechanics and Intelligent Software

In future, required parameters of different filters and fluids can be used for parametrization of the software. The intelligent algorithm provides a comparison between the typical behavior of the filter system and the actual measured values. On this base, a grapfh of the residual life time is calculated, providing a non-linear characteristics. With parameters like temperature, viscosity and an error estimation the valuation of remaining life time of the filter can be calculated.
Based on this model and the intelligent algorithm, a predictive maintainance service can be provided to avoid shut down periods. The permanent collection of filter and fluidmechanical data allows for optimization of the filter model (Big Data), with the evaluation of disturbance values an optimization of the facility can be performed.
The development of the filter analysis system was founded by the German Federal Ministry of Economic Affairs and Energy (ZIM) since 2017. The further development of the system is conducted. To obtain a robust analysis system, multiple measurements are performed at the test bench as a next step.



Principle of the intelligent filter analysis system with connection to a cloud ■



Testbench to investigate the degree of contamination in filter systems Hochschule der Bayerischen Wirtschaft, Munich ■

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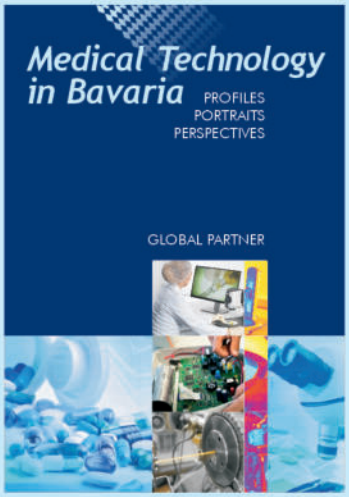

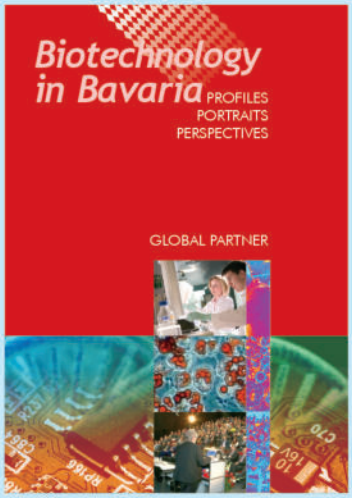

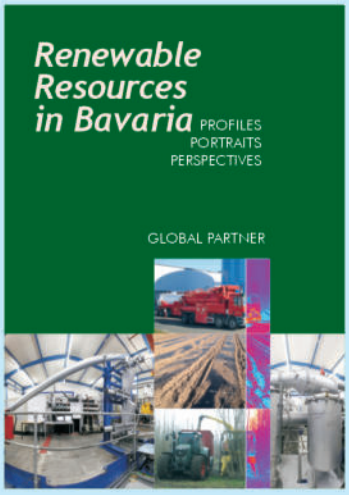

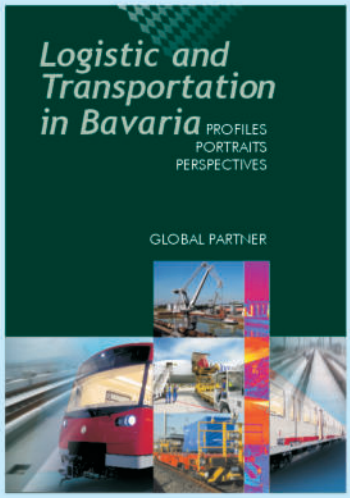

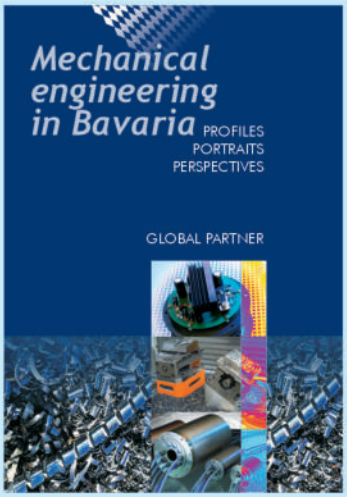

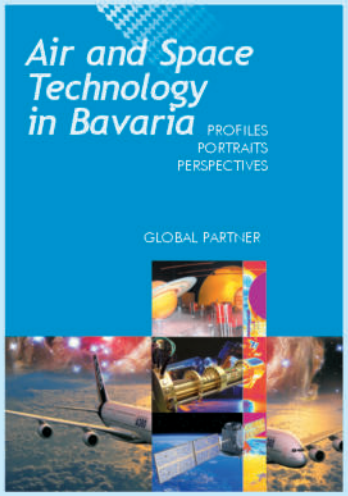

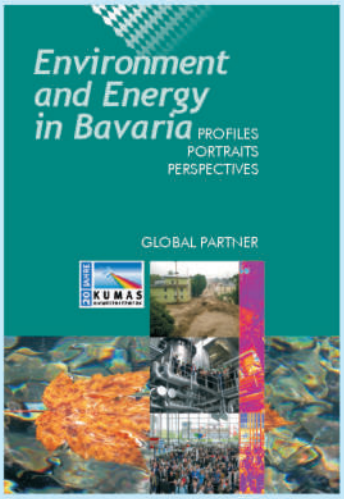

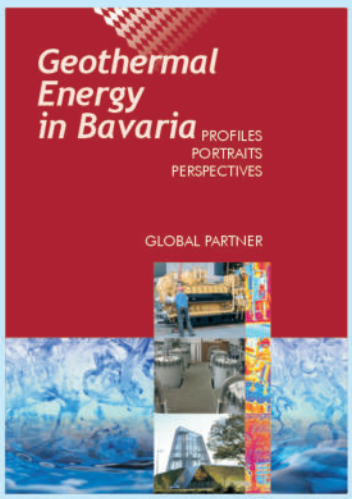

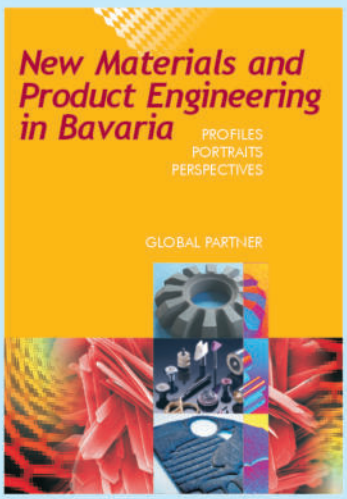

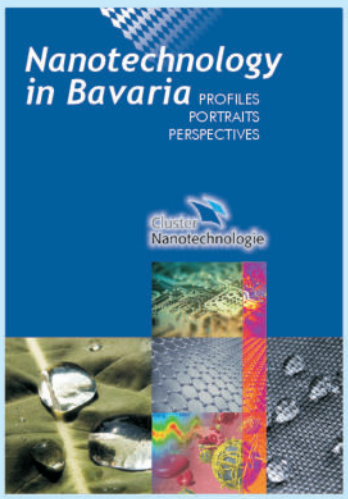

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