Medical Technology in Bavaria

PROFILES
PORTRAITS
PERSPECTIVES

GLOBAL PARTNER

Editorial

Sustainable innovations ensure a better life!

The aim of all healthcare industry initiatives is the development and marketing of intelligent product and service solutions.

Bavarian medical technology has always enjoyed an international reputation and is a pioneer in a highly competitive global market.

„Medical technology in Bavaria“ provides information about new, sustainable ideas, developments and projects:

- Who supports company founders on a European level?
- Where do actors from business, science, health care and politics network to bundle resources and use synergies?
- Which goals does d.hip pursue as an innovation leader of digital applications for the optimization of health care?
- How tangible are patient-specific heart valve replicas for the preparation of heart valve surgery?
- How can high-quality wearables be used to prevent incorrect loading?
- At what point in a process or project is experience and know-how decisive?
- How important is digital image acquisition, inspection and archiving? You will learn interesting facts from research, development and application „at first hand“.

These articles will fascinate you!

Walter Fürst, Managing Director

This publication can also be found on the internet at www.media-mind.info

Masthead:

Publisher:	media mind GmbH & Co. KG Hans-Bunte-Str. 5 80992 Munich/Germany Phone: +49 (0) 89 23 55 57-3 Telefax: +49 (0) 89 23 55 57-47 E-mail: mail@media-mind.info www.media-mind.info
Managing director:	Walter Fürst, Jürgen Bauernschmitt
Design + DTP:	Jürgen Bauernschmitt
Prepress:	media mind, München
Responsible editor:	Ilse Schallwegg
Printed by:	Dgrafik+druck, München
Published annually:	1 x annually

Inhaltsverzeichnis

Bayern International

Your Key to Bavaria

Easy access to economic partners in Bavaria

Exclusively available at Bayern International, the company database „Key Technologies in Bavaria“ comes free of charge and offers free information on more than 29.000 entries of companies from all sectors.

Visit **WWW.KEYTOBAVARIA.COM**

Bavarian Ministry of Economic Affairs, Energy and Technology

Greetings

Citizens hope to benefit from the progress made in medicine. They have concerns that we are on the way to a "tech-based medicine" and that, considering the rising costs of health care, access to medical services is becoming more and more difficult thus creating a two-class society. In Germany, health expenditure per capita increased by 25% between 2010 and 2017. Patients are under the impression to be rushed through the treatment process. They want more time to be dedicated to advising them on their illness and possible treatment options.

Digitization offers many opportunities to solve the addressed problems in the interest of the citizens. For example, discussions between doctor and patient will continue being crucial but are set to change significantly. Features such as tele-consultations, telemonitoring, online coaching, etc. enable a new quality of interaction between doctor and patient. The optimization of the various processes will result in productivity gains, which in turn means that doctors can dedicate more time to consultations with patients. Many more options could be cited from all segments of healthcare that demonstrate the great potential for improvement through "digital innovation". Examples include innovations that improve the efficiency of healthcare systems in order to keep the services affordable.

Many of the innovations in the health sector are research driven. The close networking of research and industry is vital. We must continue to develop and train the ability to innovate. New training concepts – which mainly require working in transdisciplinary teams – are important supportive measures.

Hackathons are another interesting approach in this regard. Innovations shape successful economic regions. Innovations stand for growth and advanced careers. Ecosystems for innovations, such as the Leading-Edge Cluster Medical Valley, the ZOLLHOF digital business incubator, and the Digital Health and Medicine platform of the Bavarian State Government are decisive components that help foster innovations across regions. It is increasingly important that these innovations gain acceptance among the population.

Prof. Dr.-Ing. Erich R. Reinhardt

Managing Director
Medical Valley EMN e.V.

Forum MedTech Pharma e.V. – Network for Innovations in Healthcare

Healthcare is constantly gaining more attention due to the changing society and increasing technical possibilities. Meanwhile, the medical technology sector faces challenges in the fields of growing technological progress, user expectations and regulatory affairs. The aim of Forum MedTech Pharma e.V. is to support innovations in the medical care by creating a close cross-linkage between business, science and medical practice.

With more than 550 members, the Forum MedTech Pharma is one of the leading cooperation networks in Europe. A fundamental task is to provide a platform for knowledge exchange and co-operations for the entire network. This mission is based on an effective communication between all stakeholders, as well as the determination of needs, challenges and stimulations.

Forum MedTech Pharma is the German network for all actors in the healthcare sector. Individual consulting and special offers for members are part of the broad range of the organisation's profile ■

Co-operations, networking and knowledge-transfer

By offering a broad portfolio of network activities, Forum MedTech Pharma supports research institutes, companies, clinics and other actors within the healthcare market: innovation support, a knowledge database and conferences about technological developments are supporting members to attain knowledge and scout trends. Expertise in regulatory affairs, intellectual property rights and market access as well as several further education courses about medical technology are also offered. In the further development of innovations, cooperation agreements are an important factor for giving companies and research institutions a competitive edge over their rivals.

Thematic focus and projects

Forum MedTech Pharma focuses on technology and market-related topics. The technology portfolio contains the following subjects: medical imaging, minimally invasive technologies, care technologies, robotics, electronics & IT, mobile & digital health, additive manufacturing, diagnostics and biomaterials. Additionally, structural and regulatory topics addressed by the network are innovation management, R&D strategy, quality management, regulatory affairs, finances, industrial property protection as well as reimbursement and business models.

Our network shaped by diversity

The network of Forum MedTech Pharma e.V. connects more than 10,000 customers and 550 members. All the players involved with healthcare are integrated along

Technology trends such as robotics, artificial intelligence, big-data-analytics or individualized manufacturing suggest new solutions. Current approaches will be presented and discussed from May 21. – 23. 2019 at MedTech Summit together with MedtecLIVE ■

the value chain: research and development, production, clinical application as well as cost bearers and self-administration. To adopt to the high ratio of small and medium sized enterprises in the medical technology sector, all events and services suit not only big companies but also start-ups and small companies. Besides Germany, the association has members in nine other European countries, as well as in the USA, Australia, Japan and India.

20 years Forum MedTech Pharma e.V.

In the twenty years since it was founded, the Forum MedTech Pharma has welcomed about 25,000 delegates at 250 of its own expert conferences. The speakers of that conferences support the activities of the Forum MedTech Pharma with their expertise free of charge – just like the entire board of management, chaired by Prof. Dr. Thomas Armin Schildhauer.

Since the beginning, Bayern Innovativ GmbH operates the Forum MedTech Pharma via a business management contract, which is unique in Germany in terms of bringing together potential cooperation partners.

Forum MedTech Pharma e.V.

- *Independent network for innovations in medicine*
- *More than 550 members from business, science and the healthcare sector from 14 countries*
- *Various events: conferences, symposia, expert talks, workshops, company visits, trade fairs and B2B-partnering*
- *Technology and market-related topics customized to the need of the members*
- *Projects: Strategy processes and information platforms of the federal government, Cluster Medical Technology Bavaria, Pflegepraxiszentrum Nürnberg (Care Practice Centre Nuremberg) and others*

Be part of our network

You wish to expand your network? You are open minded for co-operations?

Trends and innovations in medical technology and in the healthcare sector inspire you and are relevant for you daily business? Then we are your perfect fit.

Profit from a membership at the international network Forum MedTech Pharma and a broad range of services:

- *Support regarding your innovation process – from idea to marketability*
- *Conferences, symposia, expert talks, B2B-partnering and further events*
- *Identification and direct placement of partners*
- *Funding acquisition and consulting*
- *Consulting for market approval and reimbursement*
- *Presentation of your Company and news in our network*
- *Joint stand at Medica*
- *Internationalization*

Play a part and participate with your ideas. We are looking forward to your application!

Please find more information about the membership at Forum MedTech Pharma on our website:
www.medtech-pharma.org

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#Digital Health Hub Medical Valley

Medical Valley European Metrolitan Region Nuremberg (EMN) is a leading international cluster in the field of medical technology. At Medical Valley, key players from economy, science, healthcare and politics network to combine their resources and create synergy. Medical Value by Medical Valley stands for effective and efficient solutions for optimal heathcare. As a cluster management organization, Medical Valley EMN assoc. has been in operation since 2007 and currently consists of over 200 members. In 2018, the Medical Valley EMN assoc. celebrated over ten years of existence with some 300 guests at „Medical Valley Innovation Night“ and looked back on a decade of success and excitement: In 2010 Medical Valley was the only German Leading-Edge Cluster in the field of medical technology to be awarded in the Leading-Edge Cluster Competition of the Federal Ministry of Education and Research (BMBF). Within a five-year span, R&D projects with a total capacity of over € 120 million were implemented. Since 2016 Medical Valley EMN assoc. is coordinating the „Digital Medicine/Health“ platform at the Zentrum Digitalisierung Bayern (ZD.B) as well as the Bavarian Medical Technology Cluster together with Forum MedTech Pharma. Medical Valley is also one of 12 digital hubs in Germany since 2017. Together with the Tech Incubator ZOLLHOF in Nuremberg,

Medical Valley forms the **Digital Hub in Nuremberg/Erlangen with an emphasis on Digital Health.**

de:hub
NÜRNBERG ERLANGEN
Digital Health

The federal government‘s Digital Hub Initiative aims to support the emergence of digital ecosystems in Germany. The „Hub“ idea is based on the fact that the cooperation of companies and founders in a confined space (like in Silicon Valley) promotes innovation, especially in the digital age.
Within the Digital Health Hub in Nuremberg/Erlangen, the Hub partners strive to create new structures, change processes, drive innovative business models and stimulate innovation for the health growth market through consistent digitization measures in the healthcare sector in order to improve the quality of all segments.
For more information on this topic as well as all other activities and offers from Medical Valley EMN, please visit www.medical-valley-emn.de. For information about the Digital Hub Initiative, please visit https://www.de-hub.de/. ■

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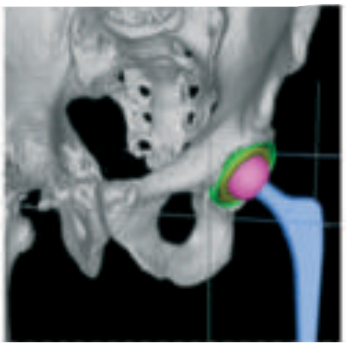
4plus
Gesellschaft für Software- und Hardwareentwicklung mbH

4 Plus GmbH - 20 Years of Experience in Medical Engineering

4 Plus GmbH represents software development in the domain of medical technology, offers solutions, products and services in the heart of the „Medical Valley" in the Nuremberg metropolitan region.
Our „Plus" is our excellent qualified and highly motivated team. We satisfy customer needs with utmost flexibility. As a service provider we help our customers to increase their competitiveness with high-quality solutions. We offer competence and excellent quality in the development of specific branch solutions and optimization of product and processes. Let us support you!

modiCAS
a 4plus company
Gesellschaft für Medizinprodukte und Automatisierung mbH

modiCAS – our Solution for Your Hospital



modiCAS 3D || plan || implants || anonymizer – We offer a very various product portfolio. This includes the software for preoperative planning of hip and knee endoprostheses. Initially only in 2D and with X-ray images, now also based on CT images. Orthopaedic and trauma surgeons now use these Application to plan three-dimensionally. "modiCAS||3D" opens up completely new perspectives on the patient and surgical preparation. We invite you to learn more about us!

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FAX: +49 (9131) 81 29 28-24 / -904
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www.4plus.de / www.modicas.de / www.modicas.blog

acad group

Innovative housing solutions – Good ideas have to be well packaged

Therefore housing solutions have to be tailored perfectly to the requirements of material as well as quality and content. Also in competition the optical design plays an important role.

acad systems – Time to Market

acad systems develops innovative housing solutions for the medical field. We produce small quantities up to 2,000 pieces, procure all purchased parts and manage the whole project – to your advantage: cost-effective solutions, high quality and a functional, innovative design.

acad prototyping – Driven by Improvement

acad prototyping produces plastic prototypes with an express injection moulding process. Quantities between 50 and 1,000 parts can be delivered within 5 to 15 working days. Applicable are all available thermoplastics, multi-component components or structured surfaces – all this is realizable.

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Active Key

Hygiene in Medical Data Input

In times of increasing multi-resistant bacteria measures to conserve purity and hygiene are gaining steam. Especially, input devices e.g. in surgery rooms, intensive care units or at doctors practices can evolve to a centre of cross contamination, due to lack of disinfection qualification.

For years, Active Key based in Pegnitz (Germany) is focussing on developing hygiene keyboards and mice for clinical application. The hygiene PC keyboard AK-C8100 ensures proper surface disinfection by wiping. Equipped with a closed contact system and together with a sanitizable Active Key pointing device, it is the best solution for the use in hygiene critical areas.

Moreover, there is a wide variety of protected and compact keyboards with or without track pad.

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www.activekey.de

About us -
„Always welcome!“

- Over 15 years of project experience
- Forsseing hardware and software solutions
- ISO 13485 certified service provider with efficient QM system

Our competences:
- Embedded Systems
- Wireless & Connectivity
- Apps & Web
- Data Mining & Predic

Our branches:
- Medical
- Security and Safety
- Mobility and automotive
- Energy

Your advantages with CDE:
- Fast reaction
- Professional project management
- Competent team
- Comprehensive documentation, EN ISO 13485, software life-cycle to ICE 62304, risk management standard IEC 14971
- Smooth hardware and software integration
- User-oriented usability
- Rounded services

Our motto: Let's talk about it!

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Corscience is an established development service provider for international medical technology companies. We provide innovative solutions for humans and are leaders in our areas of expertise as electrostimulation and monitoring, ventilation and gas analysis as

well as mobile health. Corscience is a “one stop company”, due to its wide range of medical devices and systems for use in clinical, preclinical and homecare applications as well as for clinical studies. With us, you get everything from one source:

- Comprehensive engineering services
- Module and license solutions
- Approval
- Manufacturing and logistics

Our B2B business model is in demand worldwide from medical device manufacturers. They appreciate our quality solutions and related services with a wide range of customer-specific adaptations. With Corscience, you will gain a reliable partner with individual consultation and custom work at the highest technical level.

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DiaMedCare is the first, globally active asset financing company in the healthcare sector offering novel vendor solutions for small- to midsize manufacturers of innovative diagnostics- & medical equipment. Via its specialized pay-per-use, renting and leasing solutions DiaMedCare offers the unique opportunity for hospitals & healthcare providers to replace CapEx with OpEx and to get affordable access to the latest innovations, technologies and therapies for patients.

DiaMedCare has been founded by a team of highly experienced industry experts with a broad network in the healthcare & life sciences sector. With offices in Germany, Switzerland and the US, DiaMedCare provides solutions for the largest healthcare markets and enables tailored solutions for each market entry strategy. Based on the expertise in the healthcare sector, DiaMedCare is recognized by its customers as enabling, long term partner.

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EMS competence for medical technology Best EMS: EMS service provider elektron systeme

elektron systeme is the proud winner of the **senetics Innovation Award.**

This award underscores the results of steady investment into cutting-edge technologies and methods to ensure first-grade products and yield.

Electronic systems achieves its highest quality production through continuous optimization at every level. Accordance to the toughest quality standards in combination with the know-how to enable highly customized solutions are the key enabler for our medical engineering partners. Seeing a need for precise continuous inventory to improve logistics, elektron systeme started the development of the first X-ray based machine. Today the OC-SCAN®CCX X-ray scanner delivers continous and exact counts - reducing storage and material costs as well as time outside the dry pack.

Kontakt:
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Stefanie Rüdell
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For over 35 years, sepp.med gmbh, a medium-sized owner-managed enterprise, has been supporting its customers in many areas of software development and IT quality assurance and organization – especially on the rocky road to digitalization.

We are market-leaders in the German-speaking regions when it comes to development and quality assurance of software solutions in safety and business critical fields, such as in Medical Technology, Automotive, Pharmaceutical, Aviation and various other branches. Our consulting and IT engineering solutions cover the entire software lifecycle, primarily in highly regulated sectors.

Yet – no matter what branch we work in – we live by the sepp.med motto: Ensuring Quality Digitalization! Quality ensures success, our expertise ensures your success!

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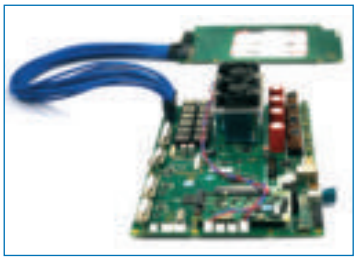
High-end electronics solutions for outstanding performance in medical technology

Solectrix considers itself an innovator and independent service provider in the development of high-end electronics solutions. With a team of qualified and specialized engineers and technicians, we develop and produce electronic assemblies and complete systems for demanding medical technology applications.



High-precision temperature control system for molecular diagnostics

Our systems and modules consist of the components electronics, software and mechanics, taking into account all specific environmental conditions. We deliver customized solutions in the field of highly integrated electronics and high-speed microprocessor assemblies with complex user interfaces and programmable logic. The device-specific component of the software is operated with associated firmware and connected to the corresponding operating systems.

Solectrix – embedding your interests.

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Cleanroom Packaging materials Protect against contamination

STRUBL is specialist for cleanroom packaging materials. We produce plastic packaging materials based on a GMP-designed cleanroom process environment. Specification, traceability, Change-Control, Monitoring guarantees products safety an protection against contamination.

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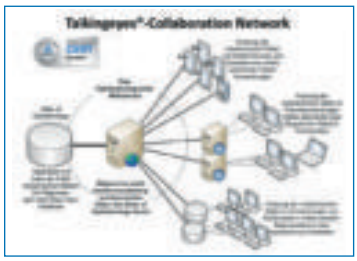
Talkingeyes-Collaboration-Network offers fully webbased telemedical applications to perform excellent eyecare. After registration medical doctors have access to following applications:



1. **Mobile Tele-Eye-Consulting** for interdisciplinary emergency units, or interdisciplinary diabetes care units, having no access to ophthalmic expertise.

2. **Home Monitoring** of IOP, visual field, and oculomotor function by VR techniques for patients with glaucoma, AMD, diabetic maculopathy, or stroke.

3. **Binocular, contrast balanced visual training program** (cDigital Vision Trainer®) for adult patients with amblyopia or for athlets, to improve their performance in stereovision.

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VTplus develops and distributes **virtual reality** simulation systems to carry out behavioural exercises and empirical research in the fields of psychotherapy, psychiatry, psychosomatics, neurology and pharmacological effectiveness as well as security research.

VTplus provides highly integrated, easy to use **VR exposure systems** with virtual environments that have been scientifically tested. VTplus VR exposure systems can be used to easily carry out behavioural exercises that would be too difficult, dangerous or time-consuming in vivo.

VTplus **VR research systems** enable data to be collected in a controlled manner and with high ecological validity. The VTplus VR simulation software supports head-mounted displays and projection systems. For individual requirements, VTplus constructs interactive virtual environments, real-time 3D models and special effects to recreate the desired real situation in highly immersive virtual reality.

The services provided by **VTplus** range from VR-laboratory concepts to the implementation of research and development projects.

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The new generation of digital microscopy

Optimised digital microscope for a smart inspection

Ultra-sharp images

Digital image acquisition, documentation and archiving are becoming more and more important in all areas of industry, especially in the medical device sector. The new EVO Cam II digital microscope combines ultra-sharp images with intuitive operation and enables smart digital inspection and documentation in production and laboratory environments.

Due to the current trends of digitization and industry 4.0, (which are becoming increasingly popular in the quality assurance of life science and medical device sector/medical technology) precise and reliable processes are expected, particularly in microscopic inspection – something that can be achieved with EVO Cam II.

New features such as Wi-Fi image transfer, customer specific overlays and the completely redesigned on-screen menu make routine work easier. In just fractions of a second, high-resolution images can be captured in outstanding detail. Parts and components can be quickly and reliably checked in the live image and documented directly if required.

An image quality of 60 fps (frames per second) enables live images to be seen without motion blur, and the optical magnification of 1.7x to 300x makes both macroscopic and microscopic viewing and capturing possible.

The new generation of EVO Cam II digital microscopes combines an intuitive and fast image capture with smart digital inspection and documentation. ■

The EVO Cam II is a fully integrated stand-alone system with internal standard software, so can be used without a PC.

Images at the touch of a button

For the professional editing and further processing of images, an optional measurement and documentation software is available, which allows 2D measurement functions and focus stacking (depth of focus module). For quick and easy recording, images can also be captured at the touch of a button and stored directly to a USB stick.

Reproducible and safe

For testing protective coatings and surfaces (especially in electronics/relevant components used in medical device technology) an optional UV ring light can be added to the digital microscope to point out specific errors that are not normally visible under standard illumination.

With the new EVO Cam II digital microscope from Vision Engineering, digital inspections, analysis and measurement tasks are reproducible and reliable.

Quality control, manufacturing, fault analysis, R&D and training are just a few of the areas where the perfect image quality of EVO Cam II is the key advantage.

www.visioneng.de/evocam2

Vision ENGINEERING

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Ensuring Quality Digitalization!

Digital and secure: When quality is a deciding factor and practical experience counts

"The biggest enemy of quality is haste," Henry Ford once stated. In Medical Technology, quality is the deciding factor, which is why it is so highly regulated. In a digital and innovation driven world, where start-ups, politics and industry are in constant competition for new ideas, regulations and quality criteria seem more of a hindrance than a help.

Medical Technology today is presented with a difficult dilemma: we are involved in projects with persistent pressure for innovation, shorter time-frames and higher quality standards, whilst products and their quality requirements are increasing in complexity. The more components there are in a medical product the greater the need to consider the interactions and interdependencies of these components during product development and quality assurance.

When dealing with complex systems, it is more advantageous for your current processes if development and quality assurance are integrated earlier and more consistently in the initial phases of a project. This is where experience and know-how gained from dedicated projects make the difference. It is crucial to find an integrated solution embedded in your general development process, from design and concept, QS and test, to aftercare operations and services.

The solution should cover all phases of the V-model: on the left branch - from requirements and architecture to design and implementation; and on the right branch - from specification and unit test execution, integration and verification tests, monitoring of field tests to installation and support of products. Individual parts of the project can be implemented through agile processes and then integrated in the so-called ‚scrum of scrums'. Our experience and knowledge of processes, methods and tools enables us to identify exactly which aspects must be considered in the developmental phases and how these can be efficiently linked to the quality assurance measures.

Validation

The manufacture of medical devices is subject to strict legal

regulations, which are intended to eliminate or reduce risks to an acceptable minimum for end users or patients. This results in stringent guidelines for the development or production processes. The challenge here is not only to meet these requirements, but also to take resource-friendly action. For the manufacturer, validation is often difficult – especially if no support is provided by the supplier. The missing documents must then be created by the manufacturer, leading to additional cost and effort. In this situation it is helpful to have a business partner who knows how to document and execute quality assurance measures in compliance to regulations, such as FDA 21 CFR 820 Quality System (QS) Regulation/Medical Device Good Manufacturing Practices.

Security

Especially in medical technology, data exchange and information are increasingly digitalized. Consequently, medical devices that communicate or are controlled via the Internet, need higher security against external attacks. Again, special know-how is required for conformity with international standards and test procedures. One should consider both the general safety aspects and security-related errors that have already been detected. Parallel to this, product-specific tests must be proactively and exploratorily secured by assessing attack scenarios and eliminating vulnerabilities.

In our projects, we cover all the core processes of the software lifecycle: from requirements engineering to concept planning, architecture development, design and coding to configuration and version management, as well as security. Development and quality assurance from a single source.

As an example, sepp.med has developed a secure, IT-based system that uses an iris scan for patient identification. The residual risk of confusing patients can be minimized by this eye scan because the iris is individual and almost tamper-proof. The medication process in the hospital can therefore be significantly optimized.

So, if you want to resolve the dilemma mentioned above and focus on a holistic and consistent approach that combines quality assurance and development skills, you can rely on the expertise of specialized IT service providers. This frees up more time for you to focus on other aspects of your business.

sepp.med has wholeheartedly dedicated itself as a IT service provider to the MedTech industry for over 35 years.

Our specialist knowledge and practical experience will give you time and quality.

sepp.med
Quality ensures success

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Medical Valley offers future oriented solutions for an optimized healthcare system

The city of Erlangen and the European Metropolitan Region of Nuremberg (EMN) have a strong association with medical technology. The EMN's strategic development statement identifies "medicine and health", a technologically significant area of expertise and growth, as particularly capable of development.

Nevertheless, competition in the health market implies a high pressure on companies. Increasingly, regions have to compete with each other for the qualified workforce. The regional economy and academia have the chance to position themselves in these spheres of activity. They are already taking advantage of this opportunity, using innovations to make healthcare provision more effective and efficient while at the same time offering dedicated people an interesting working environment.

The extraordinary concentration of companies as well as research and development organisations within the Medical Valley EMN is also proven by the numbers of employees. About 127,000 persons could be assigned to this competence field in the year 2014. With a share of 9.2 Prozent of all employees of the Metropolitan Region, about every eleventh worker is connected to the competence field "Medicine and Healthcare". In the catchment area for tertiary institutions, and in particular the Friedrich Alexander University (FAU) Erlangen-Nuremberg, there are currently 60 departments with a focus on medical technology, 20 non-university research institutions, 40 clinics and

Medical Valley Start-up and Innovation Centre in Erlangen, in the heart of the EMN ■

over 180 businesses that are enjoying economic success in medical technology. This abundance of expertise is the secret for the region's success. The region's excellent, internationally competitive credentials in medical technology's key areas are the foundation for this: electronics and microsystem technology, information and communication technology, optical technology and new materials. "Medicine and Healthcare" has been an inherent part of the strategic regional development propagated by decision makers from the economy and politics since 1998. This area of expertise has been assigned huge importance as part of the development statement produced by the European Metropolitan Region of Nuremberg under the direction of the Nuremberg Chamber of Commerce and Industry (CCI). It seeks to emphasise the development of the field of medical technology and health in the local economy and academia, and to use the potential of new technologies to increase the efficiency of the health system. The varied initiatives of regional players and the support of the Bavarian state government led to the completion in 2003 of a start-up centre, the "Innovation Centre for Medical Technology and Pharmaceuticals" – in the direct vicinity of university medical research facilities, what is now the Medical Valley Center in Erlangen. It is one of the most successful start-up centres in Germany, with over 30 companies.

Moreover the new start-up center in Forchheim created an additional offer for companies with focus on Healthcare IT.

The Nuremberg Chamber of Commerce and Industry is a founding member and has remained a shareholder of the operating company so far. The Chamber is also represented on the supervisory board of the Medical Valley Center and has been chairman for years. In this context the Medical Valley EMN e.V. was founded in 2007 to draw these activities together. The society has since than become an integral part of the EMN's overriding development strategy, and the Nuremberg CCI has been influential on the executive board from this point on.

The CCI also supports technology transfer and networking with its own advice services and offerings, such as the "Medicine and Healthcare" CCI users' club. The Nuremberg CCI is currently promoting the development initiative for a systematic operational health management (BGM), to which numerous regional companies are contributing. Moreover, the CCI Represents the interests of the regional health economy at a federal level on the "Health Economy" committee of the Association of German Chambers of Industry and Commerce.

The Medical Valley EMN e.V. currently provides support at all levels of medicinal product development, including subsidy advice, networking, events, marketing activities, training and continuing training. The Medical Valley EMN Association was named National Leading-Edge Cluster, with the claim of "Centre of Excellence for Medical Technology", in 2010. The "Medical Technology" Leading-Edge Cluster is the culmination of expertise that has grown over the years regarding healthcare provision, medicine and medical technology. The members of Medical Valley EMN e.V. are representative of how innovative medicine and healthcare are in our region, e.g. Patent applications. The current CCI report "Patents in Bavaria 2016/ 2017" credits the EMN with around 42 percent of all patents in Germany in the areas of "diagnostics".

Together with the Forum MedTech Pharma e. V. the Medical Valley EMN e. V. manages the bavarian cluster "medical technology" until 2019. An additional strong signal for the medicine site is the planned displacement of the Bavarian State Ministry for Health and Care from Munich to Nuremberg. ■

Siemens AG, x-ray tube unit for computer tomography and angiography. Each unit is tested in a Siemens computer tomograph before it leaves the technology centre ■

Solutions for optimal and efficient healthcare from the Medical Valley EMN

Innovative medical technology is firmly rooted in our region. The interdisciplinary technologies of mechatronics, microsystem technology, optics, photonics, nanotechnology and biotechnology, concentrated in the EMN, contribute scientific know-how to medical technology. Biomedicine and bioinformatics in the Würzburg area provide the necessary supplements to interdisciplinary research and product development in the functional imaging, biomarkers and biomaterials sector. The functional textiles and nutrition sectors in Upper Franconia also provide developments. The result is a dense, extremely productive "Medical Technology Cluster" that spreads out far beyond the region and whose product portfolio and efficiency is unique within Germany. The partners of the Medical Valley EMN are furthermore international leaders in the following important medical technology product categories: computer tomography; magnetic resonance tomography; interventional imaging (imaging diagnostics); refractive laser surgery; lithotripsy; endoscopy (therapy systems); sensor technology; medicinal information systems; home care; telerehabilitation; monitoring (telemedicine); pacemakers and revision implants (high-tech implants).

The network of players in research, production and service provision strengthens and accelerates the development and implementation of new products and procedures in healthcare sector. Yet start-up centres, such as the Innovation and Start-Up Centre (IGZ) and the Medical Valley Center, are also important points of contact for start-ups, small and medium-sized businesses and academia.

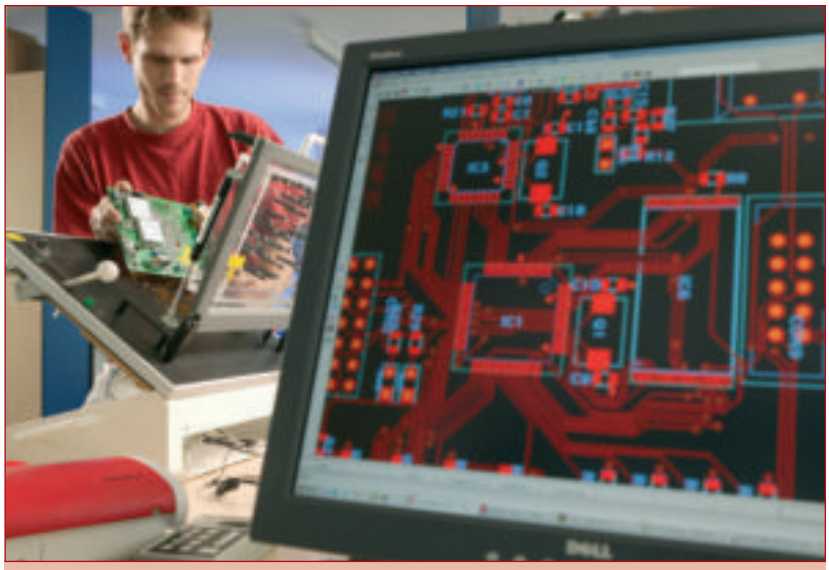
Examples of companies and their highly innovative products

But small and medium-sized businesses also provide highly innovative products: **Peter Brehm GmbH**, founded in 1981, manufactures titanium implants – hip, knee and spinal implants, jaw joints – while the instruments for inserting implants into the human body are also integral to the company's product portfolio. In the year 2014 the company was winner of the Innovation Award Bavaria. Other companies include **Corscience GmbH & Co. KG** (technologies to cardiovascular therapy and diagnosis), **Wavelight GmbH** (development and production of modern diagnostic and operations technology for correcting defective vision), **Sepp.med GmbH** (IT solutions with integrated quality assurance for complex safety applications), **ASTRUM IT GmbH** (software for the healthcare and medical technology sectors), **Bio-Gate AG** (anti-microbial products), **PAUSCH Medical GmbH** (x-ray accessories).

These, as well as numerous other companies, provide the health market with innovative products. Last but not least, as the world's biggest provider of electromedical devices, systems and equipment, **Siemens Healthineers GmbH** is a driving force in the region.

These companies further benefit from the research activities of R&D departments at universities – in particular, the FAU Erlangen-Nuremberg, the Fraunhofer Institute for Integrated Circuits (IIS) and the Fraunhofer Institute for Integrated Systems and Device Technology (IISB), as well as the Max Planck Insitute for the Science of Light. These and other institutions, such as the Diakonie Neuendettelsau, rehabilitation clinics, Rummelsberger institutions and other private clinics, not only contribute to the highest level of medical provision, but also create and test the ideas for new developments. With the Medical Valley's innovative technologies and services, the image of healthcare provision can be changed. If the new products and services can be successfully integrated into the existing healthcare system, new standards can be set for efficient healthcare provision – on an international level. ■

Peter Brehm GmbH, Weisendorf: In the year 2014 the company was winner of the Innovation Award Bavaria. The product innovation is colled "revision hip support pan". (Photo: Peter Brehm GmbH, 2018) ■



Firma Corsience GmbH & Co. KG, Erlangen: Defibrillator manufacturer in Erlangen ■

Photos: *Kurt Fuchs*
Presse-Foto-Design
91058 Erlangen
www.fuchs-foto.de

Skilled workers for the healthcare economy

Qualified young professionals are vital for the success of medical and healthcare players. The FAU and two universities for applied sciences offer degree courses in medical technology. The medical technology course at the FAU is coordinated by the Central Institute for Medical Technology (ZIMT).

The ZIMT acts as the interface between the Faculties of Engineering, Science and Medicine. Other highly specialised courses at the FAU include the Master of Health Business Administration and Integrated Life Science. The successful Medical Process Management course, created by the Faculty of Medicine, is the only one of its kind in Germany

Other programmes leading to careers in the healthcare economy, from chemical laboratory assistant, surgery mechanic, optometrist and hearing aid technician to nurse, are offered as professional training courses. Chambers in the EMN accompany and support businesses in training their employees; the publication "Health Career" is exemplary in this regard.

The region is positioned excellently to achieve its strategic goals for the future. These are: recognition worldwide as a point of reference for the medicine and healthcare sector; securing and expanding the international competitiveness of medical technology companies; accelerating knowledge and technology transfer to the greatest extent possible and increasing the attractiveness of the EMN to skilled workers. In the long term and with the support of the Nuremberg Chamber of Commerce and Industry, the EMN will become a model region for efficient and optimal healthcare provision. ■

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Start of the Digital Health Innovation Platform (d.hip)

Kick-Off Event of the Digital Health Innovation Platform

Digitization is one of the biggest growth drivers in the healthcare sector: Experts estimate the global market volume for digital health solutions for the year 2020 with over US $230 billion, compared with US $60.8 billion in the year 2013 (Source: Statista). Profiting from this growth and becoming the leader of innovation for digital applications to optimize health care – this is the goal of Digital Health Innovation Platform (d.hip).

The d.hip partners Siemens Healthineers, University Hospital Erlangen, Friedrich-Alexander-University of Erlangen-Nuremberg and Medical Valley EMN joined the d.hip consortium to implement outstanding research projects in future fields such as precision medicine, hospital management or new home care services over the next three years and make the opportunities of digitization accessible for everybody.

The launch of the Digital Health Innovation Platform was a joint kickoff event of the d.hip partners in Erlangen, in the rooms of the former Siemens Healthineers showroom on April 27, 2018. The d.hip Lab will provide over 500m² of space for project teams, start-ups, workshops and events opening September 2018.

After the first Call for Projects in June 2018, the first selected projects have started. Representatives of d.hip partners have submitted a variety of innovative ideas, from improving the care of Parkinson's patients, to optimizing breast cancer research or improving the treatment of infectious patients by means of digital solutions. A jury has selected the best projects, which will be implemented in the d.hip lab as well as directly at the d.hip partners. There are four calls per year, to which you can apply together with the d.hip partners.

In addition to the level of innovation, the projects submitted are particularly distinguishable by the great interdisciplinarity of their teams. Scientists and physicians of various fields work together with Siemens Healthineers and companies from the Medical Valley ecosystem.

Innovation through cooperation sums up an important d.hip principle. „The engaging exchange between the individual d.hip partners has created a unique opportunity to understand clinical processes and relevance, to technologically evaluate new product ideas and services and to assess their market potentials and business models at last," explains Tobias Zobel, manager of d.hip.

D.hip is complemented by a scientific program, through which junior professorships in key technology areas are to be created and international PhD students will work on projects in Erlangen.

For more information, see https://www.d-hip.de/

d.hip
DIGITAL HEALTH INNOVATION PLATFORM

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Collin Medical Line

Utmost precision, homogenous processing & high throughput.

Collin Medical Line lines are explicitly adjusted, designed and manufactured to the respective customer requirements. The entire Collin portfolio can be designed for medical lines, starting with the extruders, compounders, calenders, presses or roll mills up to complete strand and blown film lines.

Highest precision, narrow tolerances, cleanness, process accuracy, excellent cleaning handling, clean-room conformity, quick and good service and custom-made trainings for customers are a matter of course.

Medical Line Extruders

Flexible & modular, for various fields of application

Compact and modular – the Medical Line extruders from Collin. Driven by an innovative concept, the lines can be used in different ways. Therefore, different downstream equipment can be connected and numerous additional equipment and features can be realized.

Medical Line Compounders

Small & compact, ideal for pharmaceutical and medical technology

Collin compounders are used for different applications in the pharmaceutical and medical technology. Due to the compact design, the lines can easily be cleaned and guarantee extremely short material changing times.

Medical Line Presses

Practical, quiet hydraulic system & ergonomic door

Collin Medical Line presses integrate all advantages of Collin presses and are especially characterized by their quiet hydraulic system, the modern design and the vertically movable door.

Medical Line Calenders / Roll Mills

Modular & compact to the complete line

Calenders and roll mills are essential elements for prototype production in the pharmaceutical product development or for the production of tablets in any size and form.

Blown Film Lines air-cooled / water-cooled

With high quality demand versatile in use

Collin blown film lines are characterized by compact design with small floor space, easy operation and exact, reproducible movements as well as fast changes of products and parameters.

Strand Lines

Complete line from one source

What is unique about Collin strand lines is that all production steps are from one source: compounding, coextruding, take-off and cutting.

Collin has already hundreds of references worldwide as well as an existing global service network.

COLLIN
LAB & PILOT SOLUTIONS

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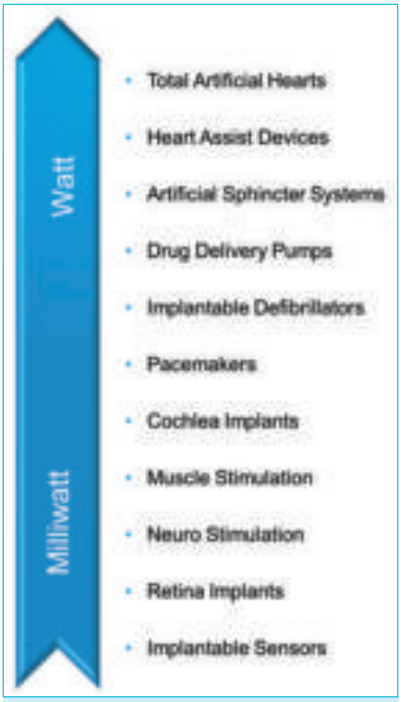
Innovative solutions for active implants and medical devices

Dualis is developing wireless energy and data transmission systems along with innovative active implants for global diseases.

Battery and wire are familiar terms that everyone can handle, in most situations anyway. In the area of active implants, however, there are good reasons to prevent an incision and cable passage through the skin and to think about alternatives in energy supply. Moreover, replacing batteries of an active implant is always associated with a revision and the associated complications.

Engineers and physicians at Dualis MedTech GmbH have been considering this issue for years and have developed the MedBase® platform in response. This allows transferring wireless energy from a few milliwatt up to about 30 watts, which makes the platform attractive for supplying numerous active implants. The range of implant applications is very wide, ranging from artificial heart systems and drug delivery pumps to small implants like neuro stimulators. MedBase® utilizes the principle of resonant inductive coupling to transfer energy wirelessly. Various secure RF communication techniques are used to control the system telemetrically, depending on the application. Because the platform has a modular design, it can be adapted to different products and their needs and can be integrated into them. The energy platform is very tolerant towards distance and displacement of the transmitter and receiver part.



Active implant application areas of MedBase® Technology ■

That is particularly critical for use in implants, because the coupling elements are always moving both inside and outside the body and cannot be precisely aligned. The implanted system heats up only slightly so that the maximum limit of 2 degrees is not exceeded in the process.

In addition to active implants, the MedBase® Platform is used in more and more external medical devices. Risks of classic cable connections such as corrosion, insulation and cleaning can be overcome with this technology, since medical devices with MedBase do not require any connections and have a completely enclosed surface. ■

Artificial Sphincter System with future oriented, technical innovations

Urinary Incontinence is one of the biggest global diseases. According to the WHO and the German Continence society, more than 200 million people are affected worldwide and around 8 million people suffer from this disease in Germany. The patients can expect help from, among other things, modern implants.

Looking back on many years of developing active medical devices and implants, Dualis is about to develop a next generation artificial sphincter system. The IWSS "implantable wireless sphincter system" will lead the way in this field. ■

Easy handling for patients

The implanted sphincter can be controlled via a smart watch or alternatively via a small remote control, making the device suitable for both men and women for the first time. Also handicapped people, people without dexterity or people with mental weaknesses can use this implant, which enormously increases the number of potential patient. The system reacts automatically to sudden changes in pres-

IWSS Sphinkter System ■

sure, whereby the patient can choose from different pressure modes via the control unit. ■

Significant improvements for physician and patient

The IWSS device will be as easy to implant as current manual systems. Once implanted, the automatic pressure adaptation controls the system pressure to ensure both continence and protection from tissue damage on the urethra. Therefore, the IWSS can remain implanted longer than existing systems. Furthermore, the system can react automatically to stress situations by increasing the pressure for a short period of time. By means of a safety system, an alarm is triggered if the implant does not open the urethra after a certain time (patient is fainting) or if the implanted battery is nearly depleted. If the alarm is ignored, the system opens automatically.

To recharge the internal battery, the patient simply positions the charger nearby the implant. The wireless recharging technique MedBase® allows a radial and axial offset from sender to receiver so that the charging process is very simple and safe.

If desired, the stored pressure values of the implant can be transmitted via radio to the attending physician and analyzed there (homecare). This allows a 24/7 care of the patient, providing both doctor and patient a completely new way of diagnosis and therapy. It is possible to detect tissue alterations or incorrectly set pressure values at an early stage and to carry out complete urodynamic examinations. The data security is, of course, guaranteed.

The system has a lifetime of ten years and is compatible with all common imaging procedures.

Conclusion

With the future-oriented technology of the IWSS, DUALIS MedTech GmbH allows patients a comfortable handling of their disease and the physician new and innovative therapy options. IWSS is a contribution to evidence-based medicine.

Dualis is a young innovative medical engineering company that has specialized in technologies for active implants. Engineers and a heart surgeon founded Dualis MedTech GmbH in 2006 as a spin-off from the German Aerospace Center (DLR). The company is both a development contractor and supplier of its own technologies. As a development partner, Dualis tailors technologies to specific customer requirements. From the initial idea to a product ready for serial production, Dualis offers an extensive range of services and has EN ISO 13485 certification. ■

DUALIS
SPACE FOR
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Generating Prospects in the Upper Palatinate

Many have good ideas, but few drive real innovations forward. Only when ideas turn into concepts and prototypes, only when new structures or products that are ready for the market derive from an idea, something new has originated – in the best case improving our life.

Since its founding the Institute of Medical Technology (IfMZ) at the Ostbayerische Technische Hochschule (OTH) Amberg-Weiden has proven itself as a true innovation driver. Yet, the institutional name only conveys half the truth. Clemens Bulitta, Director of the institute and his team of scientists are not merely concerned with Medical Technology. Health Care Management has long become the institute's second pillar. Due to the combination of medical technology and health care management all aspects of the provision of health care can be further developed in theory and in practice.

The Weiden site focusses its research on the future of health care. No other branch of industry faces such challenges. On the one hand, the health care industry is an enormous growth market, yet the progress in medical technology and the possibilities opened through digitalization are currently only offering opportunities to some extent and at this point the potential for enterprises and employees can only be estimated. OTH Amberg-Weiden not only provides courses for new developers and highly skilled specialists, it is also generates new opportunities in the region. However, there are also considerable challenges: demographic development, increasing morbidity, economic market pressure, the population's high expectations as well as inflexible and inefficient structures are only the most acute issues.

International round table at the EDM-Workshop: „Digitalization – an Opportunity for Health Management in Rural Areas" at the OTH Amberg-Weiden. On the right: Prof. Clemens Bulitta, M.D., Director of the IfMZ. © *OTH Amberg-Weiden/Matthias Schöberl* ■

Cooperation counts

In the meantime it should have been realized, that no enterprise, no institution, no local authority can assert itself on its own in the maelstrom of change. If you want to be competitive, you must actively influence the process of change and above all cooperate. OTH Amberg-Weiden understands itself as a motor and part of this process in the Upper Palatinate. No matter how varied the demands – there is also a great variety of initiatives, networks and cooperations:

The „Health Care and Medical Technology Campus" enables a smooth transfer of knowledge and technology between applied research and industry. So far three new professorships have been created in this field.

The „Gesundheitsregionplus Nordoberpfalz" (Health Regionplus of the Northern Upper Palatinate) connects doctors, clinics, pharmacies, therapists, emergency rescue services, health insurance companies and the health offices of the districts of Neustadt an der Waldnaab, Tirschenreuth and the the city of Weiden.

The „Medical Innovation Laboratory (MIL)" set up by 2018 is a mobile experimental center not only for medical technology and health management, but which will further the development of new concepts. The project is part of the funding initiative „Innovative Hochschule" (innovative universities) that finances the universities of the Upper Palatinate's joint "TRIO"- project.

The future „Medical Valley Center Nordoberpfalz“ supports start-ups and young entrepreneurs.
The aim of the cooperation partners in the Upper Palatinate is to develop various products, process and organizational solutions for the health care of the future with a transdisciplinary approach and to transfer these directly into a measurable benefit for the local population.

Multidimensional and Interdisciplinary

With its Institute for Medical Technology, the OTH Amberg-Weiden is the main partner in all projects. Its nine professors conduct research first and foremost in the fields of hygiene, infection prevention, imaging techniques, biosignals and personalized medicine, biomechanics and implant security, human machine interface and digitalization, modeling, simulation and production in medical technology. Together with a work group of professors, scientists and engineers of various specialized backgrounds the institute offers a wide range of competencies in these special fields of medicine, molecular biology and technology.
In addition to the main pillar of medical technology, the versatile field of health care management was developed, with scientists in Weiden reviewing the entire value-added chain. Here, it is not just a question of finding a total of individual services, but of a value based health care approach, aiming at an integral service, which can be assessed by the actual, individual needs of the patient and the desired personal benefit for his or her health. Medical technology in Weiden stands for multi-dimensional thinking and interdisciplinary cooperation.

Breaking new Ground

Here, new forms of established methods as well as new types of events and formats play an increasing role. Participants of the 48

Innovative Health solutions for the region developed by the participants of the „Rural Health Hackathon“. ©Michael Reiter / https://healthcare-startups.de ■

hour “Rural Health Hackathon” for example came up with several promising ideas and concepts for rural health care provision. Some suggestions were so convincing that they were developed further into business plans and eventually into start-ups or municipal projects.
A special form of promoting young talents is the „ORTHO – Master Congress“: this event is entirely planned and realized by students of the Master of Science in Medical Technology. At the center of the 2018 conference was the potential of digitalization in endoprosthetics – from computer-assisted surgery to the manufacture of implants with a 3D printer.
In fact it is an ancient road that brings international partners together in Weiden. Even the holy roman emperors of the late middle ages and the early modern period made use of the Golden Road that connected Nuremberg and Prague. Today the “Europaregion Donau-Moldau (EDM)” (European Danube-Vltava Region) extends from Weiden to Krems, from Altötting to Jihlava: the individual regions revealing similar rural structures and therefore facing similar challenges. Together with the EDM, the IfMZ hosted a workshop with topics ranging from the use of apps in a doctor-patient-communication to big data or trend in telematics up to the application of virtual reality in therapy or smart textiles.

The Future starts Here

More and more companies in Germany and its neighboring countries are making use of the competencies of the IfMZ and its high-tech laboratories, its operation unit for training and research or the clean room (ISO-class 7 according to DIN EN ISO 14644-1), allowing hospitals and companies to make early contact with young skilled workers and become part of a growing network.
Possibilities for information and contact can be found via the following links:

Contact and Information

Institute for Medical Technology (IfMZ)
www.ifmz-weiden.de

Laboratories and Research:
https://www.oth-aw.de/forschen-und-kooperieren/in-institute/institut-fuer-medizintechnik/forschungseinrichtungen/

Degree Courses:
Bachelor:
https://www.oth-aw.de/studiengaenge-und-bildungsangebote/bachelor-studiengaenge/medizintechnik/studium-medizintechnik/

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

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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 140 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 out of six "Knowledge and Innovation Communities (KICs)" in a highly competitive process at the end of 2014. With a project volume of more than EUR 2 billion over the next ten years, 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.

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

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)*. EIT Health aims to achieve real 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. In order to successfully meet the

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

above described future challenges, an ecosystem needs to be created in which interdisciplinary innovations 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.

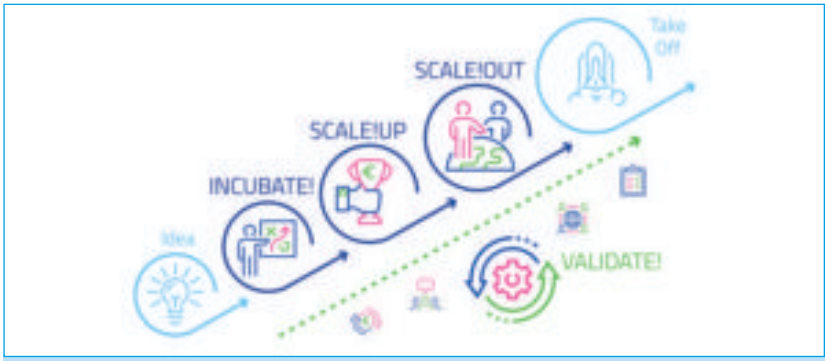

Fig. 3: *The activity lines INCUBATE!, VALIDATE! and SCALE!UP Or SCALE!OUT correspond to the maturity of the supported start-ups and their respective needs.* ■

Incubate!

The INCUBATE! Activity Line brings together entrepreneurs, intrapreneurs, start-ups and SMEs in the early stages of setting up a business. It includes various projects such as various Bootcamps, the Health Venture Lab, Smart Ageing Camp, Validation Lab and CaixaImpulse.

These are closely linked to the EIT Health Campus, the organization's education division. For example, students can participate in the 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 coun-

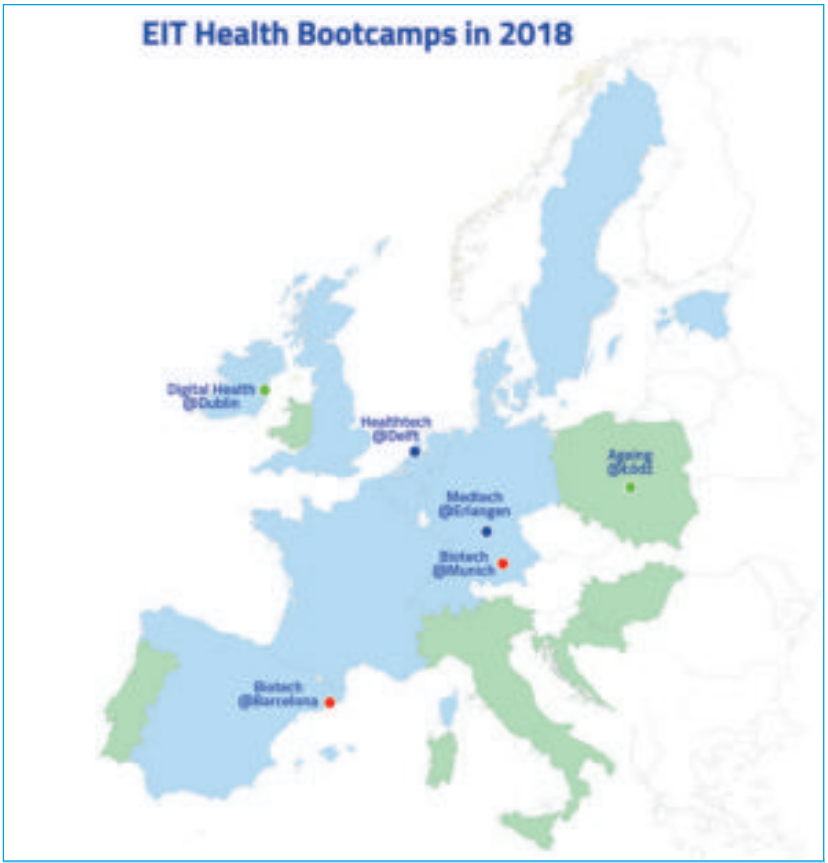

Fig. 4: *Geographical and thematic focus of the 6 boot camps* ■

tries as well as from mentors with special experience in their particular field.

The Bootcamps have been established throughout Europe due to strong demand in recent years and currently consist of 6 programs taking place in 5 different countries *(Figure 4)*. The two to three month programs 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 (with a total of €4.5 million funding, distributed as €50,000 grants to start-ups to validate their products). In addition to these programs, in 2019, the Bridgehead programm will be added. 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.

The Network of Incubators provides the basis to connect leading incubators in the currently defragmented Europe. In the coming years, the project is aimed to be an Erasmus programme for health entrepreneurs and to operate across pillars. Both the target group of start-ups and incubators will be reached and thus the programme promotes also the infrastructure of various stakeholders beyond technology projects. The programme will localise incubators, clusters and start-ups across Europe. Mapping these activities will identify both "hot zones" and regions in need of innovation and therefore serve to better understand innovation barriers in Europe. Thus, participating start-ups and SMEs can benefit from a comprehensive knowledge transfer and support in soft landings.

Scale!

The 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 EIT Health Crowdfunding Platform, GoGlobal Programmes, European Health Catapult, Product/Market Fit and Investor Network 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

Fig. 5: *After the regional pre-selection in the CLCs, an additional category specific semi-final was introduced. In addition to extensive training for pitches and business models, investors can also be better involved.* ■

the regional pre-competitions in 2017 with 174 applicants in the medtech, biotech and digital health areas, the 42 regional winners presented themselves in the newly introduced, category-specific semi-finals in Brussels, Barcelona and Heidelberg. Of the 21 semi-final winners, 9 winners were selected in the finals in London. In front of a renowned auditorium consisting of all EIT Health partner institutions prizes were handed over to the winners by the categories "Biotech", "Medtech" and "Digital Health". The prize money amounted to €135,000 in total.

The EIT Health Crowdfunding Platform provides a large number of healthcare start-ups with access to alternative seed-funding within Europe. The program serves as "mini IPO crowdfunding" and promotes the democratization of future health care. It also enables companies to benefit from interactions with crowdfunders, shareholders, ambassadors and customers.

The GoGlobal Programs give 35 teams the opportunity to explore their opportunities in global markets. Intensive one-week programs enable the company to enter into lucrative medical technology markets worldwide such as Canada, Israel, Brazil, Mainland China (Shenzhen), Hong Kong and Japan.

ACCELERATOR Success Stories

The winners of the European Health Catapult in 2017 reflect the success of the Accelerator (for more information on the following examples, see https://www.europeanhealthcatapult.eu/wp-content/uploads/2018/ 02/ Catapult_2017_ Brochure.pdf):

FibriCheck by Quompium

Absolute Arrhythmia is one of the most common heart diseases. 1 in 4 people over 40 years of age is affected, resulting in 500 strokes per year in the US and Europe alone. The problem with Absolute Arrhythmia is that the first symptom often already occurs in the form of a stroke. FibriCheck was developed for an early detection of Absolute Arrhythmia. FibriCheck is an easy to use mobile app, which is available under prescription and measures the heart rhythm. The data is simultaneously forwarded to a responsible team of doctors, who can identify abnormalities and initiate respective measures. The application has already proven successful: Within 7 days, 120,000 measurements were performed with 13,000 people, of whom 600 were affected by Absolute Arrhythmia. In addition to the EIT Health Catapult Award, FibriCheck has received numerous other awards, including the Social Care Award from Vodaphone in May this year. EIT Health has been able to support FibriCheck by approach international markets, among others through its Product/Market Fit programme.

http://www.fibricheck.com

Complex Disease Detector by Hippogriff

The founders of Complex Disease Detector by Hippogriff have also taken up the challenge of heart disease, namely Coronary Artery Disease (CAD). Cardiovascular diseases, in particular CAD, are among the most frequent causes of death. As a result of narrowed coronary vessels, the blood supply to the heart is deficient, which can lead acutely to a myocardial infarction („heart attack"). The Complex Disease Detector by Hippogriff was developed in Sweden and provides a precise, non-invasive and cost-effective instrument for the early detection and diagnosis of CAD. Early detection takes place by using artificial intelligence based on standard medical data including blood tests, ECGs and demographic details. The approach has proven to be twice as precise, 10 times faster and 49 times cheaper than current early detection methods. Thus treatment costs as well as time can be saved and pain relieved by early interventions. Not only did this groundbreaking technology convince the jury at the European Health Catapult. Also the Forbes magazine has already awarded Complex Disease Detector by Hippogriff as one of the 30 most influential innovations in healthcare science.

http://hippogriff.se/index.html

Advantis Medical Imaging

Advantis Medical Imaging has developed Brainance, a web-based software solution that enables more timely, accurate and cost-effective medical imaging than current applications. The imaging can be analyzed and processed in high detail in 2D and 3D format and with 90% accurate color fiber tracking. The software also offers a simple user interface that can be linked to cloud technologies. Advantis Medical Imaging supports physicians in brain MRI examinations with state-of-the-art scientific methods to ensure precise diagnosis of diseases such as brain tumors, Alzheimer's and multiple sclerosis. Advantis Medical Imaging was one of 10 EIT Health sponsored start-ups to showcase their innovation at the MT Connect exhibition in Nuremberg this year. In addition to the large network of EIT Health, Advantis Medical Imaging benefited from pitch coaching sessions.
https://advantis.io/

SUN Bioscience

Approximately 300 children with Cystic Fibrosis are born in Germany every year, a hereditary disease that has an average life expectancy of 40 years and may severely restrict the quality of life of patients. About 50% of Cystic Fibrosis patients respond to the drug treatment. The biotechnology company SUN Bioscience has developed standardized cultures of organoids derived from stem cells. This 3D culture platform represents a promising technological solution for personalized medicine that can treat patients more effectively and with fewer side effects. The technology for the organoid culture and screening platform will be launched this year. In collaboration with leading Swiss institutions, the first clinical pilot study to determine the efficacy of cystic fibrosis treatment using organoid culture is already underway. Should clinical efficacy be proven, this technology could also revolutionize other areas (e.g. Alzheimer's disease, where only 30% of patients respond to the drug treatment). In addition to the European Health Catapult Award, SUN Bioscience received the prestigious W.A. de Vigier Award with prize money of 500,000 Swiss francs.
http://sunbioscience.ch/

LifeTag

Around 4 million people worldwide are affected by chronic inflammatory bowel diseases, and the rate of new cases is rising. Up to now, a reliable diagnosis can only be made by colonoscopy. The Portuguese biotech start-up has developed Perm1 for the early detection of a restricted intestinal function („Leaky-Gut Syndrome"). Perm1 is a capsule that is taken up orally and detects an existing leaky gut syndrome in a urine sample. Thus Perm1 is a cost-effective, non-invasive, fast and safe method to show anomalies in the intestinal function with an accuracy of 100%. LifeTag is currently in preparation for clinical trials. LifeTag not only received an award at the European Health Catapult, but also took first place last year in the EIT Health Program „Headstart/Proof of Concept" receiving the prize money of €50,000. LifeTag was also able to present its innovation to numerous relevant stakeholders at the MT Connect fair in Nuremberg this year.
http://lifetag.pt/en/index.php

Elthera

Pancreatic carcinomas and ovarian carcinomas are among the most aggressive forms of cancer, which affect around 18,600 and 7,200 people in Germany every year. In both cases, both survival and treatment options are limited. Elthera AG is a Swiss start-up working in close cooperation with experienced pharmacists and biotechnologists on innovative therapeutic approaches for aggressive types of tumours. It has developed a therapeutic antibody against the L1 cell adhesion molecule (L1CAM), a key factor in tumor progression. This antibody attaches to L1CAM and destroys it. Seed financing of 1.5 million Swiss francs has already been secured and efficacy in animals has been demonstrated this year. With this innovation, Elthera took the third place in the „Biotech" category at the European Health Catapult.
http://www.elthera.com//

Enmodes

Chronic Obstructive Pulmonary Disease (COPD) is one of the most common diseases worldwide. The World Health Organization estimates that more than 250 million people worldwide are affected by COPD. COPD patients suffer from cough, bronchitis and respiratory problems and are often very limited in their quality of life. Since the disease cannot be cured, so far, treatment has been limited to alleviating the symptoms and slowing the progression of the disease. Enmodes GmbH has set itself the task of tackling the challenges of COPD and developed the patented technology RAS-Q®. This new therapeutic approach for COPD patients incorporates a technology that supports lung function by using a compact device. No blood pump is required. This solution provides the patient with a „portable lung replacement" that greatly improves the quality of life and has a protective effect on the progression of the disease. Beyond the European Health Catapult Award, Enmodes GmbH has already received positive feedback in the USA, such as by winning the first prize at the Emerging

Fig. 6: *EIT Health participants and representatives of EIT Health supported start-ups at the MT Connect trade fair in Nuremberg in April 2018* ■

Medical Innovation Valuation Competition in Minneapolis in 2017. Thanks to the financial support of EIT Health, the concept, the prototype, proof of efficacy and initial tests on animals have been developed. Enmodes GmbH was also able to benefit from EIT Health's strong network (e.g. by participating at the MT Connect in Nuremberg this year).
http://www.enmodes.de

Mowoot

Chronic constipation affects up to 15% of the population, especially the elderly and people with neurological disorders (e.g. spinal cord injuries, multiple sclerosis or Parkinson's disease). Current treatment options include either pharmacological approaches in the form of laxatives or invasive methods using enemas. However, both are unsuitable for chronic diseases due to side effects and additional health risks for users. The medical technology start-up usMIMA has developed the medical product MOWOOT in close cooperation with the Institut Guttmann. MOWOOT is a non-pharmaceutical, non-invasive solution for chronic constipation. The portable device adopts professional massage techniques of therapists. Thus the intestinal function is activated and the quality of life as well as health of affected persons is clearly improved. In addition to the second prize in the European Health Catapult in the „Medtech" category, the product has been awarded with the „Seal of Excellence" of the European Commission/Horizon2020 since 2016.
http://www.mowoot.com

Oxford Endovascular Limited

About one in 50 people is affected by a brain aneurysm, a disease in which a weak arterial wall tears and causes massive brain haemorrhage. While about one third of the affected patients die, one third suffer from permanent brain damage. Surgical measures are highly complicated due to limited intervention possibilities. The spin-out of Oxford University Oxford Endovascular Limited has developed a flow diverter based on origami design in close cooperation between engineers and physicians. This consists of metal and takes hemodynamics in the blood vessel into account. Oxford Endovascular Limited has already proven its efficacy in animals with its unique patented technology. Initial clinical studies are in planned. To date, Oxford Endovascular Limited has received £2 million in commitments from Oxford Sciences Innovation PLC and private investors from China.
http://oxfordendovascular.com

EIT Health in the Bavarian region

Apart from its headquarters in Munich, EIT Health has a strong presence beyond the state capital. This year, EIT Health was able to enrich the MT Connect fair and MedTech Summit in Nuremberg. During these events 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, 10 start-ups supported by EIT Health presented their innovations and were able to further expand their network (*Figure 6)*, for more information see eithealth.eu/-/german-start-ups-present-innovative-solutions-during-mt-connect).

If you are an entrepreneur 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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Dr. Kurt Höller, MBA

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Medicine is becoming individualized – innovators from FB BioMed Center help companies stepping into the future

Friedrich-Baur BioMed Center gGmbH

Respecting individual differences between humans as patients, adapting medical products and therapies to natural diversity – stepping into a flexible application of products isn't a future fantasy anymore and does not require completely reinventing established solutions thanks to modern processing and manufacturing technologies.

The FB BioMed Center is a pioneer for rapid prototyping (RP) in medicine and now accompanies firms on their way into individualized production with a broad range of additive manufacturing technologies and the matching biomedical characterization. Innovative material development is supported by scientific analysis, biological testing is done in the same institute. For individual products, accordingly adaptable bioreactors are used for in vitro tissue culture systems. ■

New paths to RP lead to more flexible solutions

Additive manufacturing can be so much more than just depositing molten polymers layer by layer. Powder-bed technologies, dispense-plotting that uses liquid pastes and the integration of robotic systems enlarge the spectrum, as do laser- and illumination systems and modified building platforms. The new trend is to adapt the RP technology to the material instead of the other way round.

RP doesn't always have to be in layers. Using syringes to process pastes and slurries, the FB BioMed Center is able to process a wide range of materials, from multicomponent polymers to ceramics and

A bone model is being printed ■

hydrogels, which are even used to print living cells (bioprinting). Thanks to established data processing procedures, the team starts either with a CAD design or the conversion of medical imaging data from CT, MRI and ultrasound. ■

Tailored biological testing from bone tissue culture to cancer research

In order to test 3D printed bone and cartilage implants, bioreactors were developed that can be adapted to the sample geometry using inserts. They enable an optimized perfusion with nutrient media and thus maintain a cell culture with all relevant tissue components. The culture system for the investigation of bone substitute materials and implants is especially refined. Here, bone forming (osteoblasts) and resorbing (osteoclasts) cells are cultured singly and in coculture in a standardized protocol system – using cell lines to guarantee reproducible, comparable results. Blood vessels from fertilized hen eggs indicate vascularization capacity. For cartilage, bioreactors with mechanical stimulation have been developed. Seven different tumor cell lines are used for cancer treatment investigation. In order to reproduce realistic physiological conditions, they are bred to form 3D tumors in special carrier materials. All tissue cultures can also be realized as organoid cultures with patient cells in order to test for individual properties and medicament effects. The effect on normal healthy cells is also regarded, to minimize side effects. Especially important: reaction to low oxygen conditions is tested in a hypoxic incubator, including analysis of glucose and lactate values, an important aspect in modern physiology. This way, a broad range of individual aspects can be precisely analyzed at the FB BioMed Center. ■

Friedrich-Baur BioMed Center

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Paving the way for the digital hospital

MEDePORT – a clever software solution which benefits patients and makes clinical workflow more efficient

In times of increasing cost pressure and tight schedules, every minute counts in hospitals, doctors' surgeries and healthcare centres. e.Bavarian Health GmbH, based in Erlangen, Germany, is constantly developing its software system further to meet these demands.

In many hospitals, doctors' surgeries and healthcare centres, the workflow still resembles a time-consuming relic from the past: patient data is entered multiple times, medical histories are repeatedly recorded. As a result, precious time needed for treating patients is lost through administrative requirements such as obligatory record keeping – tasks which could be made much less time-consuming and more economical through well-designed software solutions. Informing patients prior to a procedure as required by law could also be facilitated by using "automated communication" in everyday clinical processes.

Patient communication without data integration gaps

In order to meet precisely these requirements, the Erlangenbased Bavarian software company e.Bavarian Health GmbH has developed the brand MEDePORT. It is an intelligent software system designed to provide an overview of each individual patient's communication without any data integration gaps – from a patient's initial admission, to their anamnesis and information provided to them, to treatment agreements and electronic signatures and archiving. "We want to help hospitals improve their digital information flow and thus lower their costs significantly," managing partner Angelika Balleis says.

Easily understandable 3D patient films

The multimedia platform does not only provide digital patient information sheets in up to ten different languages. e.Bavarian Health also offers medical history sheets as well as computer-animated, easily understandable 3D patient films, such as films explaining a particular examination method. "The information sheets and films are developed for each medical field by our own editorial department and a team of around 60 scientific experts made up of medical professors and head physicians." Moreover, everything is checked in detail by specialised lawyers in order to ensure that legal requirements are met.

Angelika Balleis and her team of highly-qualified staff invested more than four years to make the content fit for the digital age. MEDePORT is already being applied successfully by university clinics as well as small and medium-sized hospitals, among them the Klinikum Forchheim, whose IT infrastructure is considered a digital showpiece. e.Bavarian Health has wasted no time in developing additional functionalities – heading towards telemedicine, Artificial Intelligence and health apps.

Process managers support new users

According to Angelika Balleis, "using MEDePORT can help hospitals in Europe become significantly more efficient." Those who are only beginning to digitalise their workflow will be supported individually by experienced process managers of e.Bavarian Health. Naturally, all patient information sheets are also available on paper as a standard. ■

BAVARIANhealth
Innovative Patientenaufklärung

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Hand on the heart - Tangible, patient-specific heart valve replicas for the planning of heart valve operations

Heart valve surgery is very demanding for surgeons. So far, only ultrasound images are available for the preparation of the interventions and these only allow a rough idea of the heart valves. Only the inspection of the heart valves during the operation ensures a complete and reliable understanding, with which a mental planning of the operation can then be made at short notice. To improve the planning of heart valve operations, the Institute of Micro Technology and Medical Device Technology of the Technical University of Munich is developing tangible, patient-specific heart valve replicas. The heart valve replicas allow surgeons to understand heart valves before the operation and enable preoperative planning of the operation.

Application: *Heart valve defects*

The heart is vital to our survival. It pumps blood through our body and supplies all our organs. To perform this function, it relies on its four heart valves: the mitral valve, the aortic valve, the tricuspid valve and the pulmonary valve. The heart valves open and close, ensuring that the blood is pumped in the right direction when the heart contracts. In heart valve defects, the function of the heart valves is impaired. If a heart valve does not close completely, a part of the blood is pumped in the wrong direction. This is called heart valve regurgitation. Severe heart valve regurgitation is life-threatening and must be treated.

Affected heart valves can be replaced by artificial heart valves, but this requires lifelong medication. It is better for the patient if their own heart valve can be maintained. In a heart valve repair, a surgeon changes the heart valve so that it closes tightly again. He cuts out a part of the heart valve and sews the cut edges together. In preparation for the operation ultrasound images of the heart valve are available to the surgeon *(Figure 1)*. The surgeon looks at these images on a screen and imagines the heart valves in his mind. For this, he needs a good imagination and a lot of experience. However, a complete and reliable image of the heart valve is only obtained when the patient's heart valve is examined by hand and with surgical instruments during the operation. Only then, at short notice, he can plan the repair. ■

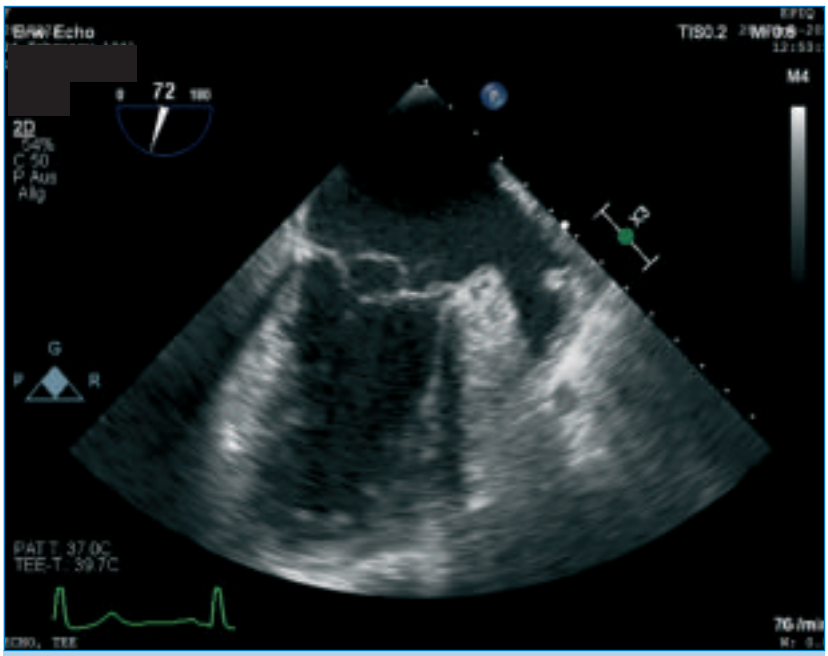

Fig. 1: *Ultrasound image of a mitral valve with regurgitation* ■

Tangible, patient-specific heart valve replicas

To improve the planning of heart valve repair, the Institute of Micro Technology and Medical Device Technology of the Technical University of Munich in cooperation with the Cardiovascular Imaging Group of the Technical University of Munich, the TOMTEC Imaging Systems GmbH, the Heart Surgery of the Ludwig-Maximilians-University of Munich and the MediClin Heart Center Lahr/Baden is developing tangible, patient-specific heart valve replicas. The heart valve replicas allow surgeons to understand heart valves before surgery and enable preoperative planning.

With the heart valve replicas, surgeons no longer have to rely on their mental interpretation of ultrasound images. The heart valve replicas make the heart valves of the patients tangible. Surgeons can take them in their hands, look at them and inspect them with their hands and surgical instruments. Thereby, they gain a clear understanding of the heart valves. Then they can plan the heart valve repair by performing it with their usual surgical techniques and instruments on the replicas. They can find the optimal repair technique in several tries. Planning no longer has to be short-term and mental.

Fig 3: *A tangible, patient-specific heart valve replica is ready for the surgeon to inspect and plan a heart valve repair* ■

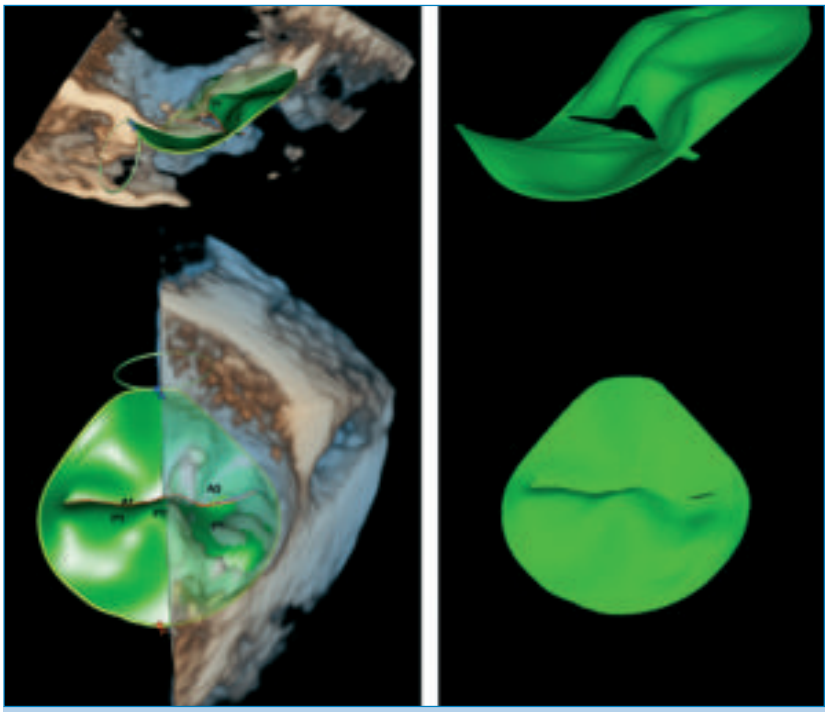

Fig. 2: *Segmentation of a heart valve from 3D ultrasound images* ■

The heart valve replicas are based on 3D ultrasound images of patients' hearts. A virtual model of the heart valve with the regurgitation is segmented from them *(Figure 2)* and then manufactured. In order for the heart valve replicas to be repaired using the usual surgical techniques, they must have mechanical properties similar to real heart valves. This can be achieved with silicone. To make silicone replicas of heart valves, molds are designed from the segmented heart valve models and manufactured with a 3D

printer. The molds are filled with colored silicone and the result is tangible, patient-specific heart valve replicas, that almost feel like real heart valves and can also be processed in this way. For processing by the surgeons, they are mounted in an alignable device *(Figure 3)*. ■

Application of heart valve replicas

Before a heart valve repair, the surgeon is given a patient-specific heart valve replica. He looks at and inspects it with his surgical instruments and gets a clear understanding of the patient's heart valve. Then he plans the repair on the replica by cutting and suturing it like in a real heart valve repair *(Figure 4)*. After successful repair on the replica *(Figure 5)*, the heart valve of the patient is repaired. The surgeon knows what to expect and how to repair the heart valve best. Since he has already performed the repair on the replica, he needs considerably less time for planning during the operation. ■

We would like to thank the Federal Ministry of Education and Research for funding this project (Support programme: „KMU-innovativ: Medizintechnik“, Contract num-

Fig. 4: *Planning of a heart valve repair on a patient-specific heart valve replica* ■

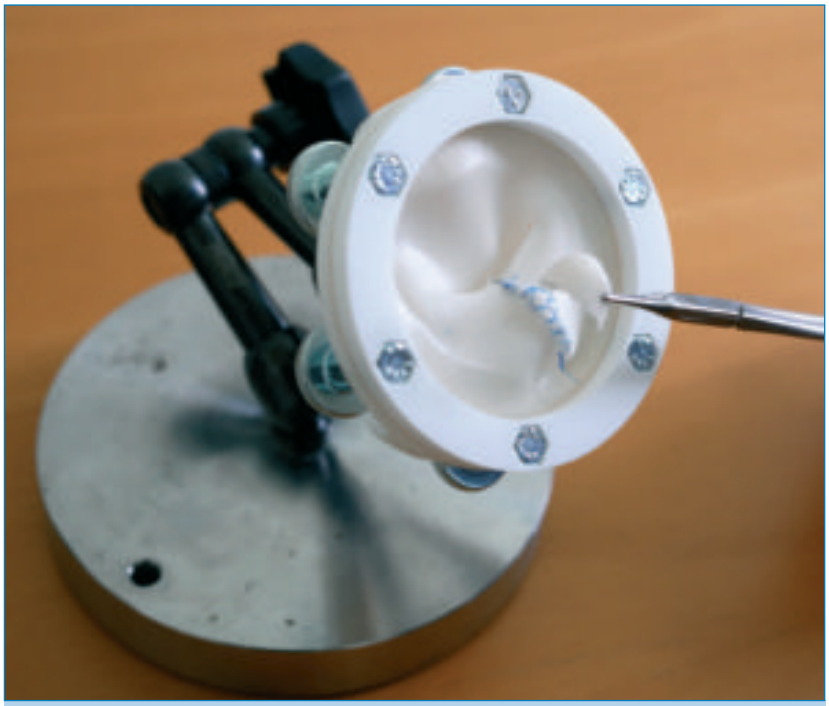

Fig. 5: *Successfully performed heart valve repair on a patient-specific heart valve replica* ■

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The development of defibrillators – a Corscience success story!

The development of defibrillators at Corscience can be traced back to preliminary work conducted by students at the Institute of Biomedical Engineering of the KIT (Karlsruhe Institute of Technology) under the supervision of Prof. Armin Bolz. Here, between 1995 and 2001, the very first steps were taken and, following the foundation of the company by Prof. Bolz and the Hamburg-based company Weinmann, these were transformed into a professional product development set-up. The founding project to be undertaken by Corscience was the development of an Automatic External Defibrillator (AED) with current-regulated pulse delivery for Weinmann. Here the current control used adapts the energy output specifically to the patient's impedance. As such, the right amount of energy is applied to all persons in need of resuscitation and, at the same time, the risk of injury to the cardiac muscle is minimised. With the conclusion of this first AED development back in 2005, Corscience laid the cornerstone to become a technology provider for defibrillation and safety-critical systems in the field of medical technology.

Corscience expanded its technology spectrum in 2007 with the "BDM65" defibrillator assembly which combined central components such as VF/VT analysis and shock delivery in an OEM component. With this, Corscience allowed its business partners to develop a defibrillator without the need for expert knowledge of this core technology on their part. ■

Development project Meducore Standard 1 for the company WEINMANN from Hamburg ■

The first professional defibrillator

The first professional defibrillator was developed between 2010 and 2013. In addition to an AED function, this device for clinical use by medical experts featured adjustable shock energies, a pacer, blood pressure measurement, a 12-channel ECG and a wide range of monitoring functions. A processor module with embedded Linux operating system which, back then, was becoming established for use in safety-critical systems was used as the basis for the display unit.

Recent Corscience developments in the field of defibrillation feature, in addition to a central defibrillator function, a range of interfaces for local and remote communication, in particular, Bluetooth, WLAN, USB, Ethernet, UMTS and LTE. These interfaces enable the mobile transfer of data for rescue services as well as monitoring both at home and in clinics.

Over the past 17 years, Corscience has completed a total of 10 developments in the area of electrostimulation. These include four AEDs for the low-end and high-end sector, three defibrillators for professional use in clinics and by rescue services as well as two OEM assemblies with ECG analysis algorithms and an external 3-chamber pacemaker. The knowledge and experience acquired over this period is applied by our engineers not only for the development of defibrillators, but also the development of life-saving and life-support systems. As a "one-stop company", Corscience offers extensive production services, including for electrostimulation. ■

Company profile

Corscience is a "one stop company", due to its wide range of medical devices and systems for use in clinical, preclinical and homecare applications as well as

for clinical studies. With us, you get everything from one source:

- **Medical device engineering:** Electronics Development, Software Development, Mechatronic, System Design, Graphical User Interfaces
- **Products and Licenses:** OEM Modules & Accessoires, OEM Interpretation Algorithms, Technology Integration Support, White Label Products
- **Manufacturing and Test Services:** Final Assembly & Inspection, Conformance Testing Services, Pilot Run & Series Production, Testsystem Design & Development, Prototype Manufacturing ■

Johannes Spallek, Head of Sales & Marketing and CEO Dr. Claudius Moor since 2016 ■

Services

Through our expertise and our extensive technical know-how, we have been able to develop products as well as module and algorithm integrations far beyond our core competencies like Heart pumps, ECMO Systems, Surgical lights, Footswitches / remote controls, Medical Software Products, Dialysis Units and many more.

Each of our OEM modules (EKG, SPO2, Gas analysis, Defibrillator) or OEM Interpretation Algorithms (HES®) is based on proven technology paired with innovative solutions and is designed to be integrated into a medical device. The modules meet the relevant medical device standards and, together with the accompanying documentation, form the foundation for a successful CE certification of your system. For easy commissioning of the modules and for testing purposes we offer comprehensive development kits. The open communication protocols will allow for easy integration, with which we will support you at any time.

Our B2B business model is in demand worldwide from medical device manufacturers. They appreciate our quality solutions and related services with a wide range of customer-specific adaptations. With Corscience, you will gain a reliable partner with individual consultation and custom work at the highest technical level.

As our customer, you will benefit from our expert know-how, our many years of experience and our detailed industry and expert knowledge. Through our extensive knowledge, our portfolio ranges from electronics, software and mechanics all the way to systems for safety-critical applications in anaesthesia equipment, life supporting systems and electronic surgery devices. ■

Core skills

- **Electrostimulation:** Defibrillation, AED, PAD, pacing, muscular stimulation Pacemakers (intracardiac, extracorporeally)
- **Ventilation:** Emergency, transport-, home- and critical care ventilation
- **Gas analysis:** Capnography, oxygen measurement, multigas analysis
- **Monitoring:** ECG devices, ECG analysis and interpretation, Vital-parameters measuring devices, Multiparameter monitors, Neurofeedback / Neurostimulation; GUI, SpO2, NiPB CO_2
- **Mobile health:** Telemedicine expenses, Transport monitors, Event-Recorders, EKG w/ UMTS, Webservers, Multiparameter monitors, Integration of interfaces like Bluetooth, Zigbee, Wifi, ANT+, GPRS, UMTS, Ethernet/HL7

As our customer, you will benefit from our expert know-how and many years of experience as a medical service provider all over the world. Through our extensive knowledge, our portfolio ranges from electronics, software and mechanics all the way to systems for safety-critical applications in in the fields of emergency care, clinical environment as well as vital signs and mobile health. The personal and individual consultation is our daily focus. ■

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Nobel laureate opens German Immunotherapy Centre (DZI) in Erlangen

Only German institution of its kind brings together specialist resources to fight cancer and inflammatory conditions

Promoting and providing a targeted approach to combating cancer and inflammatory disorders is the core mission of the new German Immunotherapy Centre (Deutsches Zentrum Immuntherapie, DZI) at Universitätsklinikum Erlangen, which was recently opened by the Nobel laureate Professor Harald zur Hausen. The only institution of its kind in Germany, its purpose is to continue and drive the establishment of specific immunotherapies for cancer and chronic inflammatory conditions, a development which has proved one of the most rapid and influential in the entire history of medicine. The uniqueness of the DZI's setting in Erlangen stems from a strong track record in clinical research, years of experience in patient care, and expertise in medical technology, science and data processing.

German Immunotherapy Centre (DZI)

‚Ten years ago, a diagnosis of malignant melanoma was pretty much a death sentence', recalls Professor Georg Schett, spokesperson for the DZI and director of Universitätsklinikum Erlangen's Department of Medicine 3 – Rheumatology and Immunology. ‚These days, chances of remission are 50 to 60 percent. This improvement is primarily down to the extremely rapid developments in modern immunotherapies that have taken place in recent years.' Medicine is already working towards new targets; as Professor Markus Neurath, also a DZI spokesperson and director of Universitätsklinikum Erlangen's Department of Medicine 1 – Gastroenterology, Pneumology and Endocrinology, explains, the establishment of the DZI supplies opti-

At the opening ceremony for the German Immunotherapy Centre (DZI) at Universitätsklinikum Erlangen (from left): Prof. Dr. Dr. h. c. Jürgen Schüttler (Dean, Faculty of Medicine, FAU Erlangen-Nürnberg), Prof. Dr. Dr. h. c. mult. Harald zur Hausen (professor emeritus, German Cancer Research Center, Heidelberg), Prof. Dr. med. univ. Georg Schett (spokesperson, DZI), Prof. Dr. Markus Neurath (spokesperson, DZI), Prof. Dr. Joachim Hornegger (president, FAU Erlangen-Nürnberg) and Prof. Dr. Dr. h. c. Heinrich Iro (Medical Director, Universitätsklinikum Erlangen).
Image: Michael Rabenstein/Universitätsklinikum Erlangen ■

The DZI's two spokespersons, Prof. Dr. med. univ. Georg Schett (right) and Prof. Dr. Markus Neurath, in one of the new centre's immunology labs.
Image: Michael Rabenstein, Universitätsklinikum Erlangen ■

mum conditions for their attainment: ‚Research in immunology to date has given us the ammunition we need to effectively combat cancer and chronic inflammatory diseases. But we now want to be able to make precise decisions as to which therapy is most suited to which patient. That's the core objective of modern precision medicine.' Professor Heinrich Iro, Medical Director at Universitätsklinikum Erlangen, is acutely aware of the opportunity presented by the DZI's unique situation in Germany: ‚We have the chance here to act as a beacon far beyond our geographical location, drawing patients and ambitious researchers alike.' ■

Erlangen leading on interdisciplinary collaboration

The key feature of the DZI is that it draws on several departments across Universitätsklinikum Erlangen including the Departments of Obstetrics and Gynaecology, Neurology and Dermatology and the two participating Departments of Medicine. Nobel laureate Professor zur Hausen is full of praise for the new centre: ‚What stands out about Universitätsklinikum Erlangen is its truly interdisciplinary approach to conditions such as chronic inflammatory diseases. The establishment of the DZI is a significant initiative advancing us towards the diagnostic and therapeutic procedures of the future.' The DZI is based within Universitätsklinikum Erlangen's Centre of Internal Medicine (INZ), where it occupies premises of around one thousand square metres. In the neighbouring Translational Research Centre, opened in 2014, DZI researchers will work in close clinical cooperation with the DZI's outpatient clinics to develop and carry out clinical studies on therapies for cancers and chronic inflammatory disorders. ■

Open to patients

The DZI will act as a direct point of contact for patients, who can approach its specialists without a referral in order to obtain information and, if required, a second opinion on their condition. The DZI has set up hotlines which patients can call on +49 9131 8540333 (for patients with chronic inflammatory diseases) or +49 9131 8544944 (for cancer patients) from Monday to Friday between 8:00 a.m. and 12:00 noon. ■

Find out more:
www.dzi.live

The DZI is situated in Universitätsklinikum Erlangen's Centre of Internal Medicine (INZ).
Image: Universitätsklinikum Erlangen ■

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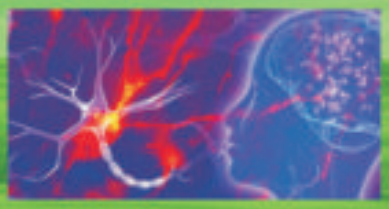


„Our network is ready to be incorporated into standard healthcare“

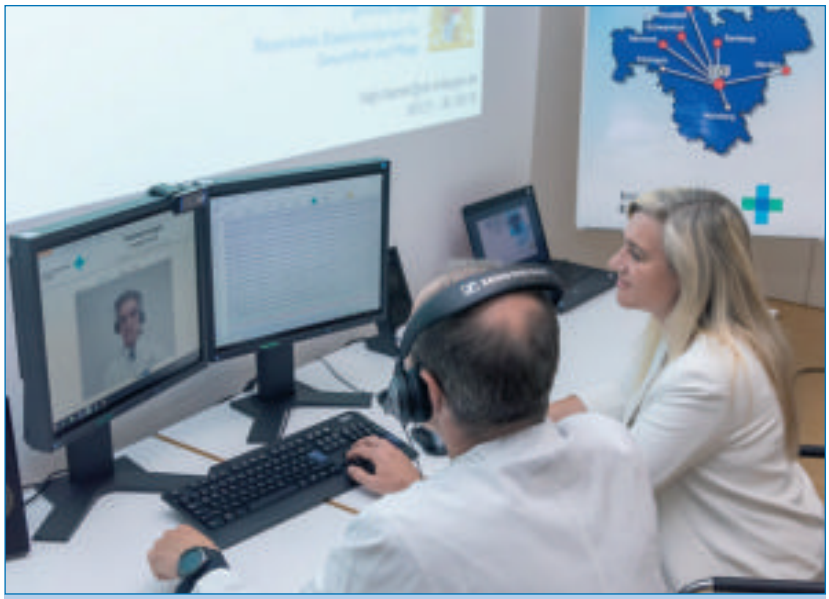
Project funded by Bavarian State Ministry for Health and Care completed successfully – statutory health insurance providers to assess future funding

Professor Hajo Hamer, Director of the Epilepsy Centre at the Department of Neurology, Universitätsklinikum Erlangen (Head of Department: Prof. Stefan Schwab), has good news. ‚After a funded six-year pilot phase, the Telemedical Network for Epilepsy in Bavaria (TelEp) is ready to be incorporated into the standard healthcare system‘, Hamer, who acts as TelEp‘s coordinator, has announced. ‚Now we need Germany‘s statutory health insurance providers to continue funding the project from 2019‘, he continued. A presentation attended by Melanie Huml, Bavarian State Minister of Health, alongside representatives of the TelEp network and health insurers, explained the successes achieved by the network and provided a live demonstration of a telemedical case conference. The presentation‘s key message: In the future, an optimum strategy for the provision of high-quality healthcare which can reach the entire population will include telemedical solutions. And, as State Minister Melanie Huml pointed out: ‚This is an area in which Bavaria now has the opportunity to be a pioneer in Germany.‘ Statutory health insurers have committed to taking a positive approach to considering future funding for the project.

Netzwerk für Epilepsie

An epileptic seizure or a series of seizures will often call for speedy and effective treatment if life-threatening complications are to be prevented. ‚The earlier treatment is initiated, the greater its chances of success. Epilepsy is a complex and multi-faceted condition, however, and the expertise needed to diagnose it accurately and treat it as effectively as possible is frequently found in only a handful of specialist centres which provide supra-regional services‘, explained Prof. Hamer. This situation inspired the foundation in 2012 of the Telemedical Network for Epilepsy in Bavaria (TelEp) with over 500,000 euros in funding from the former Ba-

Hoping for a continuation of the successful Telemedical Network on Epilepsy in Bavaria (from left): Dr. Albrecht Bender (Managing Director of Universitätsklinikum Erlangen), Melanie Huml (Bavarian State Minister of Health and Care), and Prof. Dr. Hajo Hamer (Director of Epilepsy Centre, Universitätsklinikum Erlangen).
Image: Michael Rabenstein/Universitätsklinikum Erlangen ■



Prof. Hamer (Director of Epilepsy Centre, Universitätsklinikum Erlangen) shows Melanie Huml (Bavarian State Minister of Health and Care) how a telemedical case conference works: The patient's physician connects to Universitätsklinikum Erlangen by video link to discuss the results of the EEG with Prof. Hamer. ■

varian State Ministry of the Environment and Public Health. The first member of the network, based at Universitätsklinikum Erlangen's Epilepsy Centre, was the Leopoldina hospital in Schweinfurt; it has been joined over the years by hospitals and specialist medical practices in the Bavarian towns of Nuremberg, Bamberg, Weiden, Bad Neustadt, Markt Werneck and Kitzingen.

The project's pilot phase saw well over 100 telemedical case conferences held, with experts assessing EEG recordings, images and in some cases a video of the patient. State Minister Melanie Huml emphasised the network's purpose and significance: ‚Epilepsy is a frightening and worrying condition for patients and their families. It's important that people are not left to deal with it alone. We need to make sure that local doctors and their patients have access to the knowledge and expertise held and developed in specialist epilepsy centres.' As Dr. Roland Roth from a neurological group practice in Nuremberg confirmed, the network's members found that the telemedical case conferences both speeded up the diagnostic and treatment process considerably and improved its quality. Dr. Mario Giraldo-Velasquez from the Department of Neurology at the hospital in Bamberg observed that the network has been ‚fantastic' for its member institutions: ‚I recently treated a lorry driver with suspected epilepsy and had to decide the fate of his career with just an EEG to help me. It was extremely reassuring to be able to discuss the finding with a specialist.' ■

Health insurers to assess future funding and feasibility of telemedicine in standard healthcare

So what's next for this successful project? The pilot phase reaches its conclusion in October 2018. Its impressive record includes a demonstrably lower rate of seizure reoccurrence among patients assessed telemedically than among those not included in TelEp, and a surveyed satisfaction rate of 98 percent after six months. To continue this success story, TelEp now needs permanent funding, ideally by means of inclusion in the catalogue of standard methods covered by German statutory health insurers. Melanie Huml expressed the value she places on a continuation of TelEp by offering time-limited funding for a period of transition while Germany's statutory health insurers reach a decision on funding. She commented: ‚The North Bavarian telemedical network for stroke, STENO, has shown that it is possible to transition from a pilot project to a standard healthcare programme recognised by statutory health insurers.' Huml added that it was now up to the insurers to give the green light for the project to be incorporated into standard healthcare.

Udo Schulz from the statutory health insurer Techniker Krankenkasse indicated the prospect of a positive assessment for the network: ‚I don't see us letting go of such a successful project.' The insurers now plan to scrutinise the project's findings and take a decision on its future funding. ■

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Bioelectronic sensors: Innovative systems for medicine, hygiene and environmental protection

In our smartphone, in our car, at home, at the office: electronic sensors are omnipresent in our daily lives - without them, most machines and devices would not work at all. By contrast, in the field of medical and environmental technology, electronic sensors and the intelligent systems they enable could be used far more extensively and bring much-needed progress - many developments are ready for use.

For more than 20 years we have been designing systems for medicine, care, hygiene and environmental protection based on electronic sensors. What they have in common is to bring decisive advantages to the user, i.e. the patient or the person in need of care (or in the case of environmental protection, nature). In the following, we would like to introduce some promising developments and outline the path from a simple sensor to complex intelligent systems.

From sensors to biohybrid systems

How does a tumour react to a particular drug? What impact do pollutants have on aquatic plants? How well does a bone fracture heal? For physicians and biologists, it is essential, in many situations, to know exactly how cells and tissues behave. Only then can they decide how to proceed in each particular situation. Therefore, the multi-parametric sensor chips *(Fig. 1)*, which have been developed over decades of research, continually improved and produced using different technologies, can provide the crucial information. They can „eavesdrop“ on living cells, because cells and tissues react sensitively if their physiological conditions change. This means that, with the help of our chips, cells can be used as indicators.

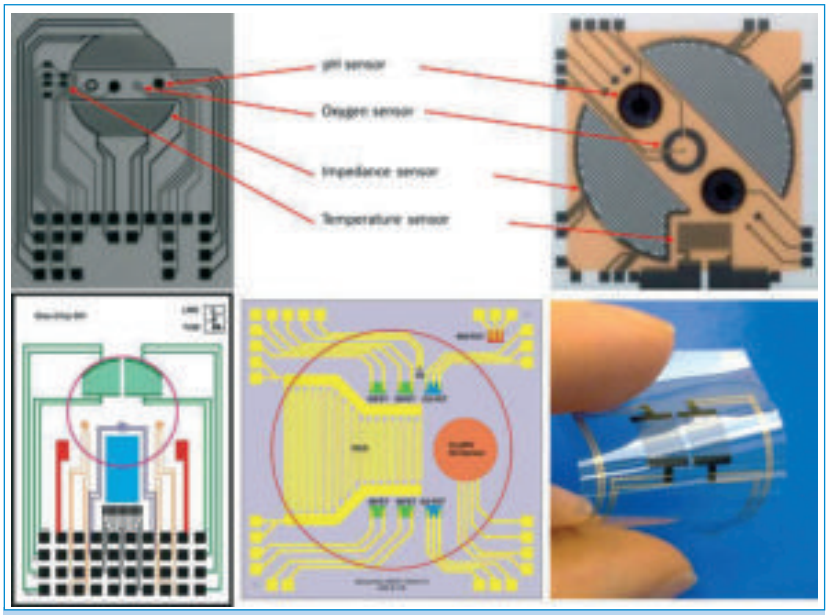

Fig. 1: *Selection of various multiparametric sensor chips and sensors: glass chip specially designed for microscopic and other optical applications (top left and bottom), silicon chip (center bottom), ceramic chip (top right) and sensors printed on film (bottom right).* ■

Such a multi-parametric sensor chip can determine parameters such as pH, temperature, oxygen content, impedance, ion concentration and the presence and concentration of selected substances in a single operation. To be able to measure the reactions of cells to a wide variety of influences, the cells are cultured directly on the sensor chip, creating a biohybrid system of living cells and electronic sensor. A small reaction chamber is placed on the chip, resulting in a lab-on-chip *(Fig. 2)* - we called it BioChip or Cellristor®. It can be used to determine the content of pollutants in liquids, for example. For this purpose, on the sensors plant cells are cultured that react sensitively to such pollutants and subsequently change their metabolism. The resulting change in the pH level and the oxygen content in the cells‘ environment is detected by the sensors. A lab-on-chip can also be used to test the effectiveness of drugs. In this case, animal

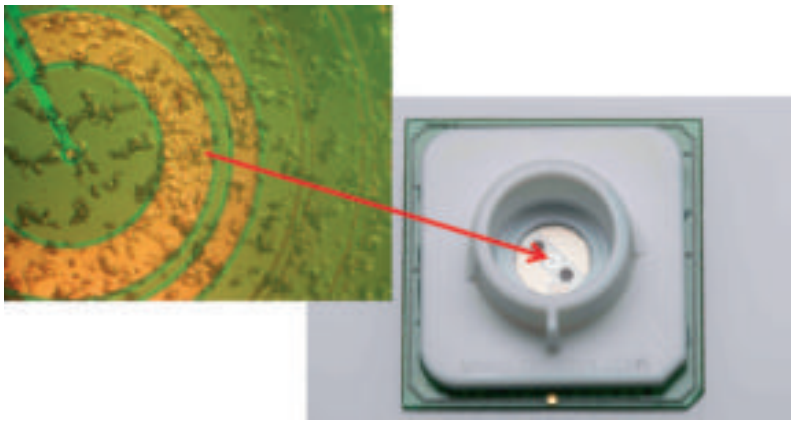

Fig. 2: *Sensor chip with attached reaction chamber (lab-on-chip; right). Cells grow directly on the sensor (biohybrid system; left).* ■

or human cells are cultured on the sensors. When the drug is poured into the reaction chamber on the chip, the cells show a physiological response – and that's exactly what the electronic sensor can capture and relay to a computer. [8]

Mobile mini-lab

To be able to carry out such tests outside the laboratory, we developed an easy to operate portable device. As it is a miniaturized laboratory, we called it microLa *(Fig. 3)*. It can be used in food control, to determine the pollutant content of fruit, for example. For this purpose, a biochip is used on which yeast cells are cultured.
These react sensitively to fungicides, such as those sprayed on fruit. The microLa is simply taken to a fruit and vegetable producer's warehouse, for instance, where the yeast cells' vitality is checked after a sample of the food (and, with it, possibly the pollutant) has been added. The microLa shows the results on a display, but it can also transmit them to a database, which collects the values. Experiments have already shown that living cells are actually suitable signal converters for food tests. [7]

Automatic water monitoring

Biohybrid sensor chips can also be used to monitor the water quality of rivers, lakes or wastewater. For this purpose, green algae are cultured on the chips, which increase or decrease their rate of photosynthesis with increasing or decreasing nutrient supply or pollutants in the water. The sensors measure a resulting change in physiological pollutant-specific patterns. For permanent monitoring of rivers, we use these biochips in small devices placed on the bank, which automatically take water samples at regular intervals via a hose system. To monitor surface waters, we place the chips in buoys that float on the water surface and are equipped with solar cells for power supply - here, too, regular sampling takes place fully automatically via a fluidic system *(Fig. 4)*. In both cases, the water quality data measured by the sensors are sent to a database where they are available for evaluation. In 2008, we received the E.ON Bayern Environmental Award for our water quality monitoring systems. [5] [6]

A ray of hope for cancer patients

For tailor-made, personalized tumour therapy, however, it is not enough to use individual biohybrid sensor chips: here, enormous test series have to be carried out in a short time. That is why we have designed a system with the so-called intelligent multiwell plate in its heart *(Fig. 5)*. In each of its 24 reaction chambers, there is a multiparametric sensor array - each chamber is, so to speak, its own lab-on-chip.
The test uses biopsy or histopathological material from the patient, which is cultured in every chamber of the plate, directly on the sensors. The intelligent multiwell plate is then inserted into the Intelligent Microplate Reader (IMR), which is equipped with a powerful pipetting robot and a process microscope *(Fig. 5)*. In a single step, 24 different active ingredients or 24 different concentrations of an active ingredient can be filled in the 24 reaction chambers. In each chamber, the sensors measure changes in oxygen concentration, pH and electrical conductivity in the vicinity of the tumour tissue - that is, the cells' reactions to the substances. The microscope automatically

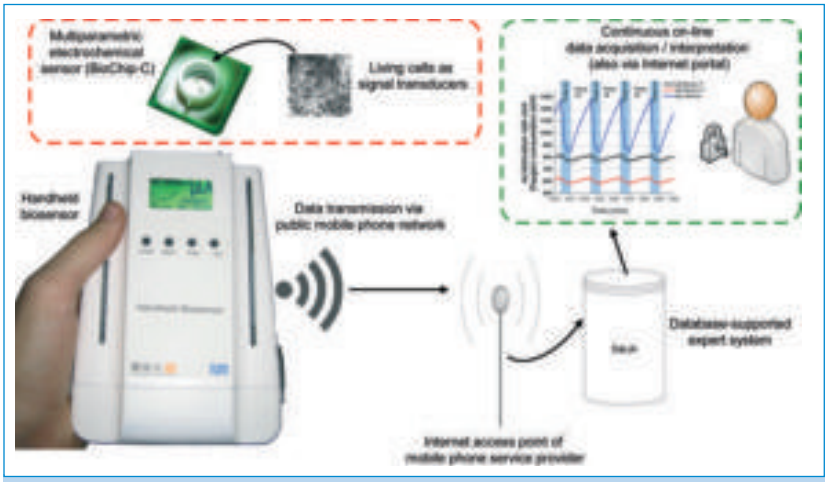

Fig. 3: *Functional diagram of the mobile biosensor system microLa (µLa) to use with cellristors, e.g. for food control or toxicity tests.* ■

Fig. 4: *Water monitoring with the help of biohybrid sensor chips: in a device on the bank of a river (left) and in a buoy for use in a lake (right).* ■

detects morphological changes in the cells. On the basis of the collected data, a computer then evaluates the tumor's chemosensitivity to the tested substances. [3] [4] [9]

The IMR could soon bring tremendous improvements to cancer treatment. Thanks to the test, doctors could know which chemotherapeutic is ideal for a given patient, and in which concentration – already before the treatment. As a result, the chemotherapy's chances of success can be drastically increased and side effects minimized. Moreover, the Intelligent Microplate Reader can be used for drug testing in general and thereby replace animal testing.

Tumour treatment with minimal side effects

The next level of personalization would then be the acquisition of physiological data directly in the human body - not only in cancer medicine, but also in the monitoring of transplants. For this, we developed intelligent implants that are about the size of a sugar cube. They can, for example, be used directly on tumors that cannot be surgically removed. As soon as the tumour grows, the sensor on the implant's surface measures the decreasing oxygen concentration in the surrounding tissue, whereupon a chemotherapeutic agent is delivered directly into the tumour, out of the small drug reservoir in the implant (*Fig. 6*). Such a closed-loop system allows a very rapid medicative response to changes in the tumour as well as a very high local drug concentration exactly where it is actually needed.

Severe side effects are thereby avoided and the organism is spared; the patient's quality of life during therapy is significantly less impaired than with usual chemotherapies today. However, it is also possible to use tank-free systems. In this case, electrochemical signals are conducted to the tissues that, according to literature and our own work, promise to be therapeutically useful. [1] [2]

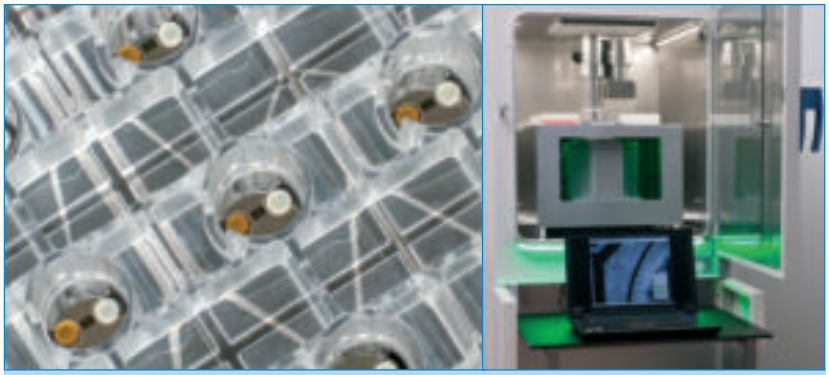

Fig 5: *Section of the intelligent multiwell plate: all reaction chambers contain sensors to measure the pH level, the concentration of dissolved oxygen and the impedance (left). Intelligent Microplate Reader (IMR) with a pipetting robot at the top, a process microscope in the middle and a computer for evaluation at the bottom (right).* ■

Stop teeth grinding

The smart dental splint SensoBite, used to diagnose and treat bruxism (teeth grinding), also works as a closed-loop system *(Fig. 7)*. It is based on a conventional dental splint individually adapted to the patient, in which a piezoelectric sensor, a radio transmitter and a power supply are integrated. The sensor measures the (mostly nocturnal) grinding activities. The measured data is then sent wirelessly to a receiver unit located next to the bed or under the pillow. Thanks to a USB interface, the stored data may be transferred to the physician's computer from time to time. The intensity and the points in time at which the grinding occurs allow conclusions about its causes to be made. [11] [12]

In addition to the diagnostic application of the system, an immediate tactile (vibration) or acoustic biofeedback is possible via the receiver unit. In the long term, this stimulus leads to a conditioning of the patient and a reduction in bruxism activity.

Maintain adequate healthcare

Demographic change, shortage of doctors, tight budgets - to maintain nationwide care, patients will in future have to measure their vital signs themselves. That's why we used our expertise in sensor technology to develop a handy, mobile, all-in-one medical device: it's like a doctor in the pocket. Every day, the patient inserts his finger into an integrated cuff - here, sensors measure blood pressure, temperature, pulse, oxygen saturation of the blood and hydration. The blood sugar value is determined by a drop of blood on a measuring strip.

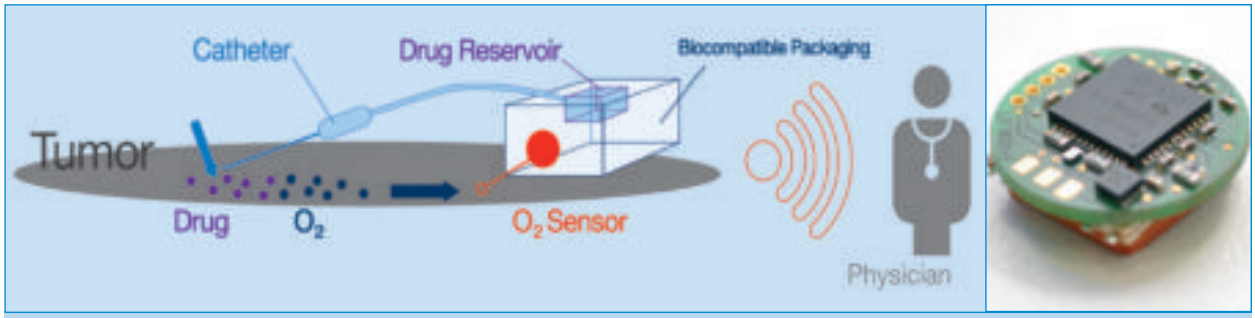

Fig. 6: *Functional principle of the intelligent implant as a closed-loop system (left); Intelligent implant in the open position (right).* ■

If the patient agrees, the all-in-one medical device automatically transmits all values to a database via mobile radio, using the telemedicine system COMES®, developed in recent years. The physician has access to his patients' data at all times - he is immediately alerted in case of suspicious values and can intervene. In emergencies, a service center can step in as well. COMES® can also send the patient automatic alerts and suggest individual measures, on the basis of the measured values. [10]

The great advantage of the all-in-one medical device is that it is handy and easy to use. It easily fits in the pocket and can therefore be used anywhere, by the patient but also by a nursing service. In cooperation with Prof. Dipl.-Ing. Axel Michael Thallemer of the National University of Singapore, we are currently developing a new generation of the device, which should be even handier and have a particularly appealing design *(Fig. 8)*.

Outlook

Electronic and, above all, biohybrid sensors make it possible to conceive intelligent systems for medicine, biology, environmental technology and hygiene. From today's perspective, the number of conceivable applications is almost infinite - the examples presented here should only be the beginning of a long series. They can significantly improve our health and make the everyday life of sick, elderly and disabled people more comfortable. They can relieve doctors, nurses, therapists, clinics and health insurers and, thanks to better networking, mitigate the shortage of doctors and the care crisis. They can make our healthcare system easier and cheaper, improve environmental protection and avoid animal testing.

Some of the developments shown are already available on the market, others have a foreseeable market maturity. Our Steinbeis Transfer Center is currently working with our partner company BioChip Systems GmbH to facilitate the transfer from research to industry for many of these systems. However, financing (for instance of clinical trials and certifications), is often a major hurdle before the market launch. It would be desirable if efficient funding structures could speed this up in the future, so that the great benefits of intelligent systems could come into effect more quickly.

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Fig 7: *Intelligent dental splint SensoBite with sensor and electronics (bottom) and receiver and vibration unit (top). [11] [12]* ■

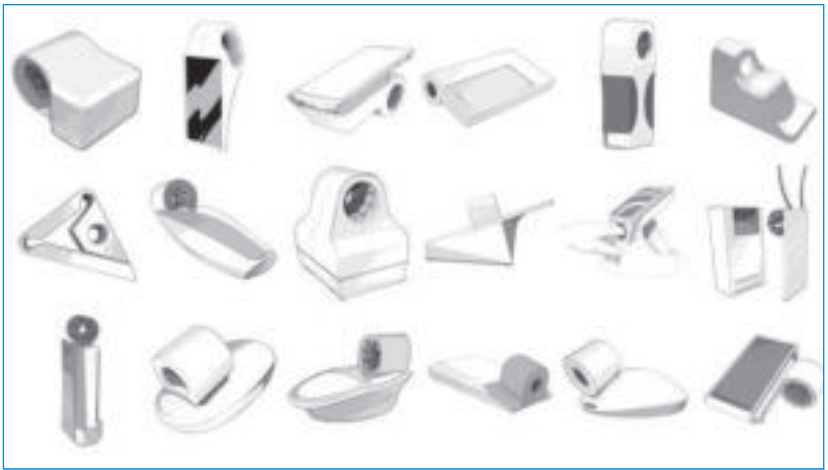

Fig. 8: *Design studies for a new generation of the all-in-one medical device, the sensor cuff being the noticeable common feature of all designs (design studies by Prof. Dipl.-Ing. Axel Michael Thallemer, Division of Industrial Design, National University of Singapore).* ■

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Further references and illustrations on
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