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Preface

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in.nrw – Innovating medical technology: a research platform to advance patient-adapted health care – the cluster "Patient Customized Engineering for Smart Cardiovascular Therapy"

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During the second half of the last century, medical technology, a joint venture of medicine, engineering, and natural sciences, became the rising star of the life sciences, attracting the attention of scientists, clinicians, students, industry, health economists, politicians, and, not to forget, patients worldwide. Many success stories to date, like cardiac pacemakers, artificial joints, organ transplantation, cochlea implant, image-guided intervention, intensive care medicine, and proton beam radiotherapy of cancer, demonstrate the ever-growing progress of this multidisciplinary branch of health science. The impact of medical technology on disease management, including prevention, diagnostics, therapy, and rehabilitation, became obvious, in short the dream of a better quality of life at affordable costs became the main motivator for the advancement of medical technology and its spreading into all facets of our daily life. Medical technology is no longer solely a matter of the science community; the socio-economic, political, and even ethical aspects are also debated. Although, sometimes, critical comments against high-tech medicine appear in the media, the benefits are clearly dominating and acknowledged by the majority of patients.

There is no other field in science that so fundamentally depends on a balanced interaction and cooperation of the main stakeholders in medical technology, the research institutes, clinics, and industry. Accordingly, the number of research groups, the investment in medical technology in hospitals, and the business volume of the medical industry are steadily growing. Additionally to the few most visible centers in biomedical engineering, like the Helmholtz-Institut für Biomedizinische Technik (RWTH Aachen), the ZiMT (Universität Erlangen), the KIT (Universität Karlsruhe), and the IMETUM (Technische Universität München), there are currently >60 academic institutes that offer degree programs in medical technology. The market of medical technology products is expanding with significant growth rates. After the USA and Japan, Germany is number three in the world market of medical products. About two-thirds of companies in medical technology are small and medium-sized enterprises. During the last 20 years, the growth rate of the sales volume of medical technology companies was about 5–6% per year. The innovative power of the medical technology industry is impressive: about 50% of the sales volume is made with products less than 2 years in the market [2].

However, with the expansion of medical technology, and the administrations, insurances, and health politics are ever more concerned on how to finance the healthcare system. Although the medical technology share of German health costs is in the order of <10%, it is essential to include at the start of any research and development (R&D) activity the cost-saving aspect and to optimize the design of a new product to be cost-efficient. Hence, a close association of research and the manufacturing process is a key criterion for creating innovative products. Accordingly, nearly all programs launched at the federal and the state levels demand the successful funding applicant to demonstrate this bilateral partnership of scientists and manufacturers. This is particularly true for the various programs initiated in North Rhine-Westphalia (NRW), like the "in.nrw – Innovating medical technology" [6], which, after run for 3 years is now finished. About 40 research and industrial teams benefitted from a 13 million Euro funding provided by the government of NRW and the European Union. The science and industrial region of Aachen won this ambitious and most challenging competition with a proposal of an integrated multi- and interdisciplinary cluster “Patient Customized Engineering”. This cluster comprises six projects, each in a field that is recognized as a most promising branch of medical technology. On the basis of a study on the position of medical technology in Germany in comparison with international approaches [2], the federal government published an action plan, medical technology 2007–2008 [3], which aims to set priorities in those areas of medical technology identified as the most innovative and associated with the three key technologies computerization, molecularization, and miniaturization.

The common thread which runs through all six projects of the cluster runs the paradigm change in medicine from standardized diagnosis and treatment concepts (*one size fits all*) toward an individualized approach, coined as *personalized medicine*. Although this term was first created some 20 years ago in the context of pharmacogenetics aiming to better match a drug to the individual genetic profile of the patient, step by step the concept has been expanded to any kind of diagnostics and treatment-related medication, method, and instrumentation. The primary goals are improving medical effectiveness and efficiency, which affect the individual patient through to the entire health-care system.

The response of medical technology to the concept of personalized medicine is precisely the title of the cluster: Patient Customized Engineering. With a share of almost 40%, cardiovascular diseases are the highest cause of mortality. The cluster underpins the urgency of this observation by focusing the research activities on this number one killer. Specifically, half out of the six projects are directly dedicated to the field of cardiac and pulmonary insufficiency, whereas the other three projects deal with image guidance and customized solutions for special applications. Following is a brief overview of all projects performed under the cluster structure.

1. Development of a telemedical rescue assistance system (TemRas) [4]: Cardiovascular disease is the most frequent category in emergency assistance. The time between the initial heart attack and medical action determines the therapeutic result. To minimize this time of first medical aid, telemedicine is the most appropriate technology which can be used. TemRas provides a real-time telemedical emergency system that broadcasts all the vital parameters, including voice and image communication to the emergency base unit. A pilot version of TemRas is now ready for application tests in five designated cities.
2. Biomonitoring in heart failure (BioMon-HF) [8]: Chronic heart failure patients urgently need overnight monitoring of vital parameters at home. Specially designed for outpatients with chronic heart failure, BioMon-HF provides an individualized telemonitoring system based on a set of external sensors.
3. Individual, integrated, and interactive assist (I^3-Assist) [9]: This innovative system addresses the treatment of patients with combined heart and lung diseases such as congenital heart disease and acute respiratory distress syndrome. The highly integrated modular I^3 system provides an individually adaptable circuit that allows it to be used short-term as a heart-lung machine and long-term for extracorporeal life support. A seamless transition between both modes and an exchange of modules during operation is possible.
4. Technical concepts for vascular electromagnetic navigated interventions (HyTher) [7]: Progress in imaging technology enables new minimally-invasive interventional methods and simultaneously enhances the safety of surgical interventions. In this project, navigation software tools interfacing with commercial navigation systems have been developed, which include registration and correction of physiological parameters and state-of-the-art three-dimensional image postprocessing.
5. Development and imaging of patient-optimized implants (Patim) [5]: This most innovative project attributed to the field of tissue engineering deals with the replacement or restoration of diseased tissue. The ongoing difficulties with translation to clinical application are addressed, in particular when developing cardiovascular implants. Molecular imaging methods are investigated to monitor processes at and around the implant.
6. Multifunctional image-guided interventions (MiGi) [1]: Magnetic resonance (MR) image guidance has several advantages over X-ray-based techniques; however, up to now, MR-opaque guidewires have been missing. With the developments of this project, this gap is now closed by using new materials (fiber-reinforced plastics). A specific technique has been developed for the manufacturing of this new type of guidewire. The performance of the new product has been investigated extensively.

This issue of the journal *Biomedical Engineering/Biomedizinische Technik* is dedicated to the work of the Aachen research cluster Patient Customized Engineering as part of the NRW program “in.nrw – Innovating medical technology” [6] and demonstrates the Aachen region as one of the strongest players in medical technology in Germany. This consortium under the leadership of Thomas

Schmitz-Rode deserves appreciation for the extraordinary success of the cluster and its significant impact on the future development of medical technology. The entire health-care system, and not least the patients, will benefit from the many achievements. The significant funding allocated to this cluster signals the strong commitment of the government of NRW to medical technology as one of the fastest-growing branches and markets worldwide. Looking at the remarkable results achieved in the rather short period of 3 years, the 40 cluster partners from clinics, R&D, and industry have been amalgamated to a network of the highest competence in medical technology, which certainly is unique in Germany. It is worth challenging all partners, the collaborating institutions, and not least the government to seek appropriate modalities to continue development of such a magnificent infrastructure.

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