Convention of National Associations of Electrical Electronic and Information Technology Engineers of Europe AISBL

E·U·R·E·L

Technological sovereignty in biomedical engineering

The focus on the human being

Issued by EUREL
Editor team from VDE DGBMT (German Society for Biomedical Engineering in the VDE); Editor: Gerald Urban, Institut für Mikrosystemtechnik – IMTEK; **Authors Core team: Kurt Becker,** APOLLON Hochschule der Gesundheitswirtschaft, Bremen; **Martin Braecklein,** Harman Digital Transformation Solutions; **Hartmut Dickhaus,** Institut für Medizinische Informatik, Universitätsklinikum Heidelberg; **Birgit Habenstein,** VDE DGBMT; **Petra Knaup,** Universitätsklinikum Heidelberg; **Andreas Melzer,** ICCAS Leipzig; **Thomas Stieglitz,** Institut für Mikrosystemtechnik - IMTEK / BrainLinks-BrainTools; **Gerald Urban,** Institut für Mikrosystemtechnik – IMTEK; **Sebastian Zaunseder,** Fachhochschule Dortmund; **With the collaboration of: Olaf Dössel,** Institut für Biomedizinische Technik KIT (ACATECH und VDE DGBMT); **Damian Dudek,** Deutsche Forschungsgemeinschaft; **Jens Haueisen,** TU Ilmenau; **David Hochmann,** FH Münster; **Frank Hufert,** Medizinische Hochschule Brandenburg; **Klaus Illgner-Fehns,** KLens GmbH (VDE ITG); **Thomas Lenarz,** Medizinische Hochschule Hannover (ACATECH und VDE DGBMT); **Arne Manzeschke,** Evangelische Hochschule Nürnberg; **Thomas Penzel,** Charité - Universitätsmedizin Berlin; **Thomas Schmitz-Rode,** RWTH Aachen (ACATECH und VDE DGBMT); **Sigurd Schuster,** Management Consulting (VDE ITG); **Ute Morgenstern,** TU Dresden (formerly); **Birgit Glasmacher,** Leibniz Universität Hannover; **Advisor: Volker Schanz,** VDE ITG

EUREL – The Convention of National Associations of Electrical Electronic and Information Technology Engineers of Europe
Square de Meeûs 35 - 1050 Brussels - Belgium
Email: eurel@eurel.org
Website: www.eurel.org

Contents

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

Executive Summary

European sovereignty of medical technologies (MT) and biomedical engineering (BME) is necessary to ensure utmost quality of healthcare, as laid out not only in the German constitution. It is important to maintain and further expand the current high medical-technical standard through thoroughly developed and mastered sovereign technologies and at the same time medical professionals trained at the highest technical level to be able to safely apply these technologies. This seems to be the only way to maintain sovereignty and shape, achieve the social and economic goals of the health care sector in the future.

The great significance of BME for health care has been demonstrated during the Corona virus pandemic. While new vaccine technologies were developed, approved, and applied very quickly, severe deficits in the pandemic management occurred to implement new technologies. Examples include the lack of uniform digitalization of the German health departments and the lack of digital networking, which consequently led to problems controlling infection rates and likely also to avoid preventable deaths in the intensive care units.

Furthermore, in the context of demographic change and an increasing proportion of people suffering from chronic diseases, we will need even more advanced biomedical technologies in the future.

In order to avoid future problems, expected as well as unexpected scenarios must be anticipated with multidisciplinary and interprofessional expertise, regulatory decisions must be prepared and made, and structural as well as technological priorities must be set. Technological sovereignty in MT and BME is a strategic prerequisite for meeting all of these challenges. This comprises technological developments and solutions as well as the organization of the interaction between the stakeholders involved.

New medical technologies and solutions for unmet clinical needs developed by BME are significantly compromised by the lack of development and enforcement of market access for new products and procedures. Occasionally, challenges within the sovereign control of certain key technologies hinder innovative, effective and efficient solutions already today. For example, we have managed the basic innovation processes, but market access is considerably complicated by bureaucratization and inhibitory regulations, especially by the Medical Device Regulation (MDR) as a key challenge of Europe’s international competitive positioning in the field of MT and BME.

The authors of this position paper, coming from a transdisciplinary scientific research and development background, propose various measures to remove the obstacles mentioned. The aim is to secure high performances in the future-relevant field of BME, to remain in a leading international position and to further develop BME to be a supporting column of the German and European economy. The

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

recommended measures are derived from the analysis of the current status of BME in Germany and Europe. In this analysis, the authors include within the purely technological aspects the human being. This is necessary and can only develop its value with the acceptance of the society by the support of the medical professionals in connection with patients. Therefore, the educational, regulatory, ethical and sustainability aspects of BME are also highlighted below

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

Core theses

I. In the future, biomedical engineering (BME) will be required in all areas of medicine to achieve the goal of individualized precision medicine. BME is therefore present in all aspects of the patient treatment pathway and their different fields of application.

II. The application fields of BME involve essential key technologies. These key technologies can be grouped in three categories: (1) biomedical microsystems and microstructure technology; (2) materials, smart materials, bio-/nanotechnologies; (3) communication technology, digitization, digitalization and application of artificial intelligence (AI), used for different key technologies depending on the application.

III. Requirements for technological sovereignty must take the value chain into account. In the context of BME, this requires comprehensive and interdisciplinary consideration: It ranges from basic research, development, and translation to market access, reimbursement, and universal application. It is essential to note, that the focus is not only set on the engineering alone, but strongly also on the human being. Therefore, the considerations along the value chain concern various domains such as education and training, qualification, regulatory as well as ethical aspects.

IV. To achieve sovereignty of medical technologies through the information technology transformation of the healthcare system (i.e. patient-centric digitalization, communication technologies, application of AI) will substantially influence the quality of healthcare and as such it needs to be resilient.

V. Data management in the healthcare sector shall comply with the strictest requirements for cyber security and must follow the FAIR principles (Findability, Accessibility, Interoperability and Reusability). EU-wide synchronized framework conditions shall ensure access to all relevant data, from mobile home care to "omics"-based systems medicine.

VI. Regulatory requirements such as the new Medical Device Regulation (MDR) have a significant impact on patient safety but also on sovereignty of medical technologies in BME. These requirements must be revised and further developed to reduce issues in the regulatory approval of medical technology and to increase the innovative strength of BME.

VII. Discrepancies between the level of sovereignty required and the level of sovereignty currently available along the value chain and patient pathway indicate an urgent need for action.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

Healthcare recommendations and requirements

Securing medical care and maintaining or expanding BME to be an economic factor requires – to a certain extent – technological sovereignty. The establishment of and significant investments in the key technologies "microsystems and microstructure technology", "materials, smart materials, bio-/nanotechnologies" as well as "communication technology, digitization, digitalization and application of AI" are just as necessary as organizational measures. Several specific recommendations are therefore given.

Securing sovereign production of biomedical technology

- Create possible ways for securing "sovereign" production and production trade secrets, management of intellectual property (IP) and quality critical components.
- Create incentives to enable the establishment of smart, flexible and dynamic warehouse solutions and a diversified supply chain.

Technological support policy requirements

- Patient-centric digitalization: Establishment of overarching networked digitalization of the entire healthcare system beyond current efforts and with nationwide consistency. In addition to the establishment of organizational and bureaucratic consistency, timely and significant investments and increased funding in future technologies such as AI research in medicine must take place.
- Develop special support programs for small and medium size enterprises (SMEs), often the "hid den champions", but suffering problems during the implementation of the Medical Device Regulation (MDR) and the application and development of standards according to the regulatory demands.
- Develop goal-oriented concepts for translation and transfer support such as regional and national translational centers and public-private partnership (PPP) models.
- Establish support models for company foundations with training and mentoring of startup companies including regulatory support, risk assessment and exit strategies.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

Knowledge management

- Ensure appropriate data availability, interoperability based on international standards, and cybersecurity considering a risk-benefit analysis for all data collected in healthcare.
- Introduction of new highly-qualified jobs and training profiles which must include intersectoral biomedical expertise among the participants.
- Promotion of the development and operation of a nationwide and EU-wide digital open-access knowledge platform on the latest technical and methodical level as the basis for sustainable interdisciplinary education and training of the required biomedical professionals.
- Prevention of "brain drain" abroad Europe through improved framework conditions, facilitation of education and long-term commitment of non-European scientists in particular.

Healthcare and regulatory requirements

- Urgent instigation of a revision and further development of the MDR through appropriate consideration of the necessary safety aspects and at the same time ensuring the competitiveness of the European medical and health technology industry.
- Stronger and earlier integration of BME competencies and of the expertise of scientific expert associations at the ministerial level for the preparation of political decisions and ministerial votes (BMG [Federal Ministry of Health Germany], BMBF [Federal Ministry of Education and Research Gemany] and BMWi [Federal Ministry for Economic Affairs and Energy Germany]).
- Establishment of a task force involving academic institutions of technical and medical disciplines, clinical medicine, the industry, medical science, self-governance in the healthcare system and politics for the development of strategies to establish sovereignty of medical technologies and BME.
- Development and testing of new and optimized procedures for launching medical technologies and healthcare applications, ranging from initial feasibility studies of innovative concepts to market access procedures and simpler and quicker ways of reimbursement.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

1 Preamble/Motivation

For Germany and the European Union, technological sovereignty is necessary to develop, shape and also to protect the population's primary care as well as the political, social and economic values, targets and priorities in consultation with each other.

In the context of demographic change with an increasing proportion of chronic diseases, technological sovereignty is a strategic prerequisite for meeting these challenges to maintain our wellbeing. Due to the diversity and complexity of the interrelations and the resulting interdependencies of biomedical engineering solutions, we have to deal with these challenges in a multidisciplinary and interprofessional way. Long-term forward-looking regulatory positioning and priority-setting are necessary in order to be able to respond appropriately to future challenges as a state within the EU and an actor in a globally networked world economy. A flexible, dynamic structural and industryal policy with the participation of stakeholders from the industry, associations, experts and researchers is needed to give valid recommendations, create incentives and make bold and clear decisions.

This means that important medical technologies need to be preserved or created in Europe so that the independence and interests of single member states, including their competitiveness, continue to be protected. This is the only way to ensure that the European and Germany's population, is provided with comprehensive supplies for healthcare in all areas as stipulated by law and to enable and secure further economic prosperity in the future.

Biomedical engineering (BME) is of particular importance in this context, since the provision of healthcare to the population is of central importance and, moreover, it is part of the constitutional law in Germany [1].

The currently achieved high level of performance can only be maintained by competent medical professionals using advanced technologies. Also, the current challenges in health, social, societal, and clinical environments of most European countries require a coordinated, complementary and joint strategy in health policy. The latter can be demonstrated, for example, by the current management of the pandemic.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

"Technological sovereignty" means to have the ability to act technologically independently and autonomously in all areas concerned in the future at the state or union level. BME is characterized by placing the focus on the human being. This requires an extension of the concept of sovereignty beyond the technological level alone to include social, societal, ethical, and also regulatory aspects.

This means that through this orientation the concept of technological sovereignty also covers the sovereignty of the human being more generally. The individual, whether healthy or not, should be able, without any obligation, to make independent decisions concerning the offered medical technology options.

The healthcare of patients is provided by medical professionals who increasingly rely on technical systems to deliver high-quality care. Modern healthcare systems can no longer be imagined without BME. The intention, however, is not to replace physicians and healthcare professionals, but rather to support and facilitate their activities and make them more effective and efficient.

BME is a multidisciplinary field at the interface of medical, biological, and engineering sciences. It has a profoundly human-centered orientation and aims towards the improvement of human healthcare concerning prevention, diagnostics, therapy, rehabilitation, and aftercare through the application of scientific and engineering means and methods. It is concerned in detail with studying and developing technology-oriented methods and instrumental engineering solutions. Without biomedical engineering, medical professionals would be less capable to provide patients with optimal care.

The authors point out the importance of BME, in particular taking into account the current geopolitical social developments, and provide recommendations for action to decision makers in politics, economy, industry and science to ensure and to further develop higher performances in future-relevant areas. This white paper has been drafted by an interdisciplinary and crossectional expert group of scientists and hence gives a scientific estimation of the current state of the art in BME.

Although the present white paper primarily focuses on the technological aspects, it is important to recognize that in medicine a purely technological orientation does not comply with society's requirements. It is therefore intended to highlight all aspects of BME and clarify how to provide the best possible medical care. In general, any individual concerned should be free to choose whether to take advantage of BME options and thus expand his/her preventive healthcare options, e.g. through personal monitoring, or support medical research by "donating personal data". Technological sovereignty at the personal level means the ability to act in a self-determined manner, well informed about the meaning of individual action in the larger health policy framework.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

1.1 Relevance of biomedical engineering

In addition to its societal meaning in healthcare, technological sovereignty is of particular importance for BME research, development and transfer: The healthcare industry, with a share of 12 % of GDP, is one of the most significant pillars of the German economy [2]. The healthcare industry (HCI), with approximately 1 million employees and 84.2 billion euros in sales, contributes 22.8 % of gross value added. Since 2007, the export volume of the HCI has increased by 56.6 billion euros to a total of 120.9 billion euros with annual growth of 5,9 %. In Germany, the BME industry (MedTech) as one of the main areas of HCI employs a total of more than 210 000 people, with over 12 000 new jobs created in the past five years. In 2019, the total sales of the MedTech sector amounted to 33.4 billion euros, with an export rate of around 65 %, which accounts for 8.4 % of total German exports [3]. The German MedTech industry is dominated by SMEs with less than 250 employees, accounting for 93% of the total, and there are approximately 13 000 microenterprises with a total of around 60 000 employees [4]. Viewed internationally, the global market for medical technologies (excluding in-vitro diagnostics) amounted to around 390 billion US dollars in 2017 [4]. With a share of 9,9 % of the global market, Germany is in second place behind the USA (38,8%). The MedTech sector is a highly dynamic sector, not only in terms of sales and the number of employees, but also regarding innovative strength. In terms of patents and world trade share, Germany is in second place behind the USA, with the majority of innovations being made in and jobs created by SMEs [5]. In general, this places the MedTech sector in the second place across the EU behind the digital communications sector, with growth of approximately 50 % over the past 10 years [6].

These facts underline the strong position of Germany, as member of the EU, in the field of BME in all sectors. In order to maintain this position of the EU and Germany and to further expand it, i.e. to not only ensure security of healthcare but also to ensure competitiveness and export strength of the MedTech industry by high innovative strength, the key technologies and production methods must be sovereignly managed and further developed in the future.

The authors of this position paper analyze and show which technologies and measures are necessary to ensure nationwide and EU-wide sovereignty and dynamic developments in biomedical engineering

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

1.2 Future challenges in healthcare

The following sections highlight key problems, deficits and foreseeable undesirable developments.

- In the EU and Germany, the security of healthcare provision for the population should always be fully guaranteed. This explicitly includes any kind of emergency situation such as pandemics, disasters and unforeseeable political events.
- Demographic change and the increasing proportion of chronic diseases with more than 55 % among those at the age of 65 and above are placing an increasing burden on the healthcare system, and new technologies must support the maintenance and improvement of healthcare [7].
- The lack of clinical professionals and nursing staff leads to a significant shortage in inpatient and outpatient care. There is e.g. an estimated shortage of 307 000 nurses in 2035 in Germany [8]. This is critical as the well-being and the likelihood of survival of patients in the hospital mainly depends on the nursing sector [9].
- Reduction in the number of hospitals by 8 % and of bed spaces by 3 % in Germany during the last 10 years without being supported by digitalization and quality control measures [10].
- The very slow progress of digital transformation in the healthcare sector is not only attributable to slow implementation hardware and software, but also to the aspects of data protection. It is still associated with significant deficits in data availability, in the exchange and processing of medical data and in the transfer of medical know-how [2], [11].
- Germany's position in terms of digitization and digitalization of the healthcare system is way below the EU average level [12]. Digitization and digitalization of the healthcare systems do not on the same level and do not follow the same pace in the EU countries.
- During the past years, some branches of production in the MedTech sector were moved abroad, which resulted in a weakening of the sector and in the loss of key competences.
- The necessary translation between economy, research and product development with high specific requirements in the MedTech sector is not sufficiently supported and implies systemic innovation hurdles [13].
- The administrative (over)regulation in biomedical research for device and procedure development and medical care, which is already at a high level and is steadily increasing, significantly impedes efficient process flows and represents a central inhibition factor for the MedTech sector.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

- Further barriers affecting the procedures of market access are inadequate reimbursement levels and long-lasting decision-making processes regarding the inclusion of new processes and products in the schedule of fees.

To achieve and maintain a top position in research, development, translation and production and the urgently needed digital competence in all areas of our healthcare system and thus to become an international leader, a range of measures which are detailed in Section 6 are strongly recommended and unavoidable.

1.3 Methodology and structure of this position paper

The VDE and EUREL have published a position paper on technological sovereignty, in which it outlines an approach to the areas of information technology in which sovereign action is required and the manner of how to accomplish sovereign action [14]. This approach is used as the basis for this paper and is further developed with regard to biomedical engineering. In order to make "technological sovereignty" comprehensible, this position paper [14] interrelates several aspects as the dimensions of technological sovereignty. In modification of this methodological approach, the key technologies are defined as the first dimension of BME (see Fig. 1.1). Key technologies are those with specific properties that are indispensable for a certain field of application, where a distinction is made between cross-system key technologies such as microchip manufacturing needed for any type of application, and the key technologies that are essential for medical technologies and biomedical engineering. The second dimension that is mentioned are the application fields along the patient pathway (Fig. 1.3), and the third dimension are the sovereignty requirements. Topics such as regulatory frameworks and ethics are overarching these three dimensions.

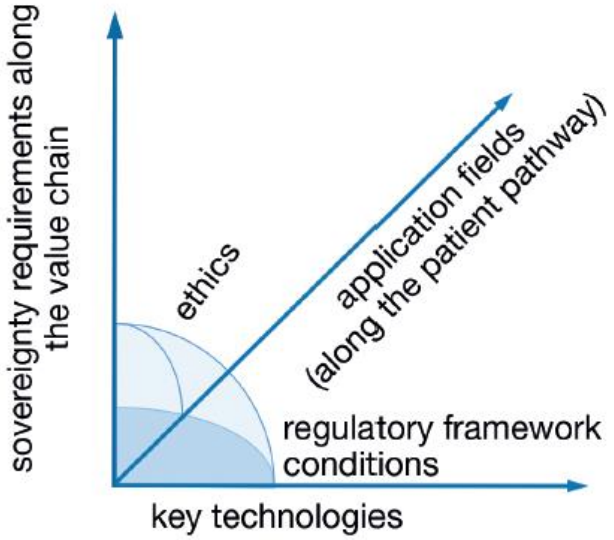

Fig. 1.1: Dimensions of technological sovereignty in BME with particular consideration of regulatory and ethical aspects.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

The requirements for technical sovereignty in BME are based on a generalized value chain (Fig. 1.2).

Fig. 1.2: Generalized value chain for methods, devices and systems.

The following criteria are used for the evaluation of the key technologies:

- National **economic performance**, which includes the aspect of basic supplies, and which covers the economic performance in the various fields of application for which the essential key technologies of biomedical engineering are relevant.
- **Innovation and future viability** of a medical technology includes the ability to innovate and develop, which forms the basis for future competitiveness.
- **Social relevance and acceptance** so that innovations are adopted by the members of a society for the benefit of the society.
- **Security** of medical technology, especially with regard to patient safety as well as data security and cybersecurity in biomedical engineering.
- **Sustainability** with regard to the evaluation of the relevance of application fields and their corresponding key technologies.

Because the focus is on biomedical engineering, the application fields are oriented towards the patient pathway illustrated in Fig. 1.3.

Fig. 1.3: Definition of the patient pathway on which this paper is based.

The patient pathway reflects chronologically various healthcare measures, the individual stations may be overlapping. Thus, diagnostics is necessary at every station of the pathway and the integration of diagnostics and interventional therapy (theragnostic) is one of the future goals in medical care. From the general formulation of the patient pathway, the key technologies can be derived.

Fig. 1.4: illustrates an example of the dependencies between the application fields and the required key technologies, based on the patient pathway. Later, requirements for sovereignty will be derived from this.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

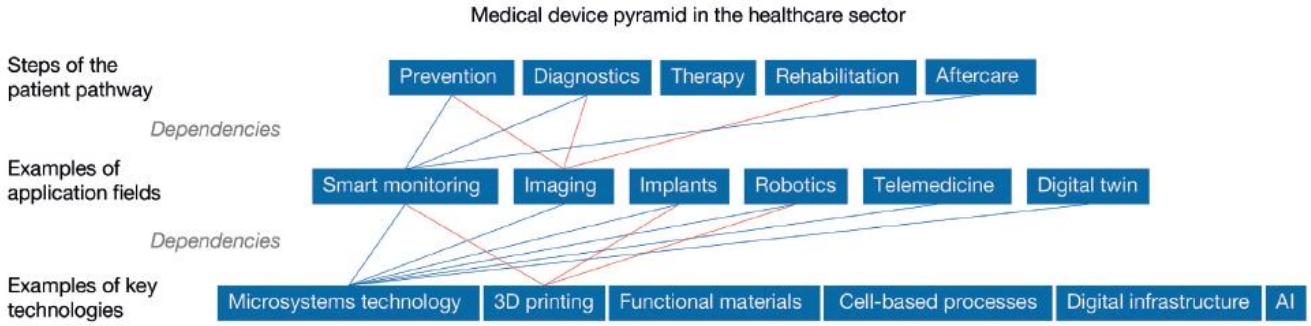

Fig. 1.4 Relationship between the key technologies and the application fields in the context of the patient pathway. The example shows the dependencies of two key technologies and two application fields.

*The fields of device safety, patie*nt protection, data security, regulatory issues, and ethical, legal and social implications (ELSI) must be particularly highlighted as essentials of the healthcare industry. Various examples such as the application of AI in medical technology, the triage problem in case of limited resources, stem-cell re*search, and human enhancement demonstrate the importance of ELSI to biomedical engineering. A holistic evaluation including these factors as further dimensions is therefore essential (Section 5).*

As a result, the application fields will be described first, with regard to a safe patient pathway (Section 2), followed by the key technologies will be defined (Section 3). Section 4 covers the evaluation criteria and provides exemplary evaluations based on the value chain. Section 5 incorporates those ELSI that are essential in the field of biomedical technology. The conclusions and recommendations are summarized in Section 6.

2 Application fields of medical technology along the patient pathway

BME and medical technologies are developed for and used in an extremely broad spectrum of patient care. This section gives examples of important application fields in the biomedical engineering sector. Modern techniques for personalized precision medicine focus entirely on highly networked digitization and digitalization in all areas of data collection and management along the patient pathway (see Fig. 1.3) thereby forming the basis for both medical care and the value chain in the industrial sector (see Fig. 1.2). The goal is to create a concept for patient-centric digitalization that is overarching all application fields.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

2.1 Digital patient-centric basic care

Overarching patient-centric digitalization is of major importance for efficient patient care in the various application fields of medical technology and can therefore be considered part of basic medical care.

The convergence of hardware and software technologies with safety- and ethics-relevant digital applications will be a future characteristic of medical technologies and BME in order to ensure the ubiquitous provision of medical care through a digitized "integrated connected health" [15] along the entire patient pathway.

This ranges from the Hospital 4.0 where basically all processes can be digitally documented and controlled, to the doctor's office or telemedicine supporting mobile care and home care, to the establishment of preventive lifestyle medicine. In the process, all systems must grow together to ensure non-bureaucratic, ubiquitous and safe medical care. This facilitates the logistical planning of the individual patient pathways in the hospital and also the networking of hospitals with different equipment to provide the patients with optimal medical care. It is the key approach to overcome the reduction of hospitals and bed spaces i.e. optimizing the bed occupancy time.

Furthermore, it is necessary to establish a digital function unit from the medical device to the medical engineering system (combination of medical devices and other products), in which all medical applications are documented to create a reasonably networked healthcare system. Meaningful steps have already been taken with the implementation of the German Digital Healthcare Act (DVG, Digitale-Versorgung-Gesetz), the Electronic Medical Record (ePA, elektronische Patientenakte) and the Digital Health Applications (DiGA, Digitale Anwendungen in Gesundheit) and Digital Care Applications (DiPA, Digitale Pflegeanwendungen). This direction must now be maintained to enable comprehensive digital networking. Harmonized European directives are still to come.

This also requires further safety and ethical measures to obtain general acceptance among the population and the sovereign control of essential key technologies (see Section 3).

A seamless networking of medical application fields, and all key technologies, is a prerequisite for developing a digital twin concept to comprehensively model patients, creating a "multidimensional medical record" and thereby predicting a temporal development that can detect pathological processes at an early stage using AI methods. This enables the adoption of biomedical-technical control loops such as closed loop or human-in-the-loop for medical purposes, in which techniques of the Internet of (Industrial) Things (IoT) are applied to create an Internet of Medical Things (IoMT).

Today, we are still a long way from this in Germany, as many systems are not yet interoperative. As a consequence, healthcare employees spend an above-average amount of time on documentation processes, which in turn is then missing for

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

direct patient care, and currently data exchange is often still done via PDF documents.

The challenges posed by the necessary overall digitization and digitalization are diverse, and there are many questions left to be answered: How to deal with ethical issues? How to obtain the necessary data for training AI processes? How to ensure data quality? How to approve AI processes according to the MDR? Section 5 and Section 6 provide answers and give recommendations concerning these questions.

The specific application fields of medical engineering and the key technologies forming the basis thereof are described below along the patient pathway that has been defined in 1.3. The example of a severely injured accident victim with a "polytrauma" shows the wide range of medical devices and systems that are involved very quickly. Some examples are illustrated in Davinci's Vitruvian Man (see Fig. 2.1). In case of a "polytrauma", diagnosis and therapy must be conducted with no delay, so that digitization and digitalization, device networking and AI to optimize diagnosis, therapy, decision-making, monitoring and stabilizing vital functions are of major importance to optimize these processes and thus save lives.

In addition to conventional osteosynthesis, joint and organ replacement or the use of stimulators is often decisive for the treatment outcome. Gene technology and "omics"-based analysis cannot be used for an accident victim. Following invasive procedures, complex and long-lasting rehabilitation is required, especially if limb replacement with prostheses was necessary.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

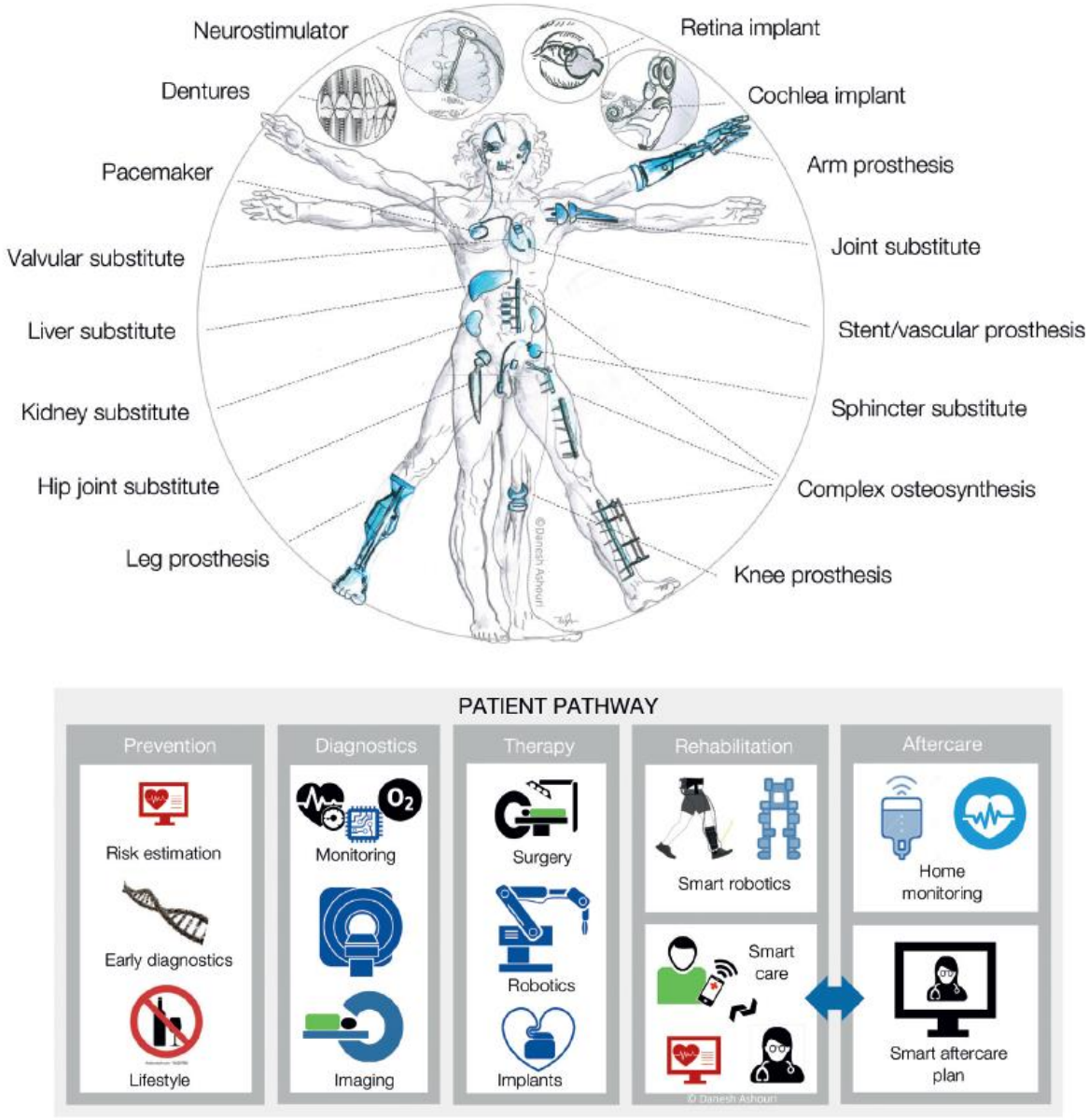

Fig. 2.1: Illustration of the application fields along the patient pathway e.g. of a polytraumatized patient, whereby these application fields are applicable for almost any disease. The necessary key technologies are detailed in Section 3.

1. **Prevention**: Promotion of a safe environment (smart cards, smart home) and mitigation of risks (including nutrition and drug abuse) based on early diagnostics and the continuous monitoring of biomarker- and model-based individual risk estimation.
2. **Diagnostics**: AI-based recognition of diseases, including monitoring, sensor systems, and imaging.
3. **Therapy**: Surgery, intervention, smart implants and AI-based decision making.
4. **Rehabilitation**: Digital/smart care and nursery.
5. **Aftercare and nursery**: Digitally networked patient monitoring, outpatient as well as home and mobile care, palliative care.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

2.2 Prevention: Application field of individual digital modelling based on biomarker monitoring

The first step is about prevention, which shall prevent accidents and diseases from occurring by the early detection of pathological processes. Individual preventive measures that are based on an individual digital model of the patient are a valuable step towards the understanding of the medical condition of the patient and provide valuable basic knowledge for the early detection of diseases and their further possible clinical treatment.

Through a patient-specific analysis of systems, biological preconditions ("omics" and biomarker analyses, see Fig. 2.2), the recording of external influences (environmental toxins, accident hazards, malnutrition and lifestyle) and the collection of physiological data using smart sensors during wellness and sports activities to create an overall view of the patient, this can be stored in the form of a virtual file and thus offers the possibility of obtaining an integrated holistic view and detect CVD such as arrhythmia at an early stage. Health education through easily accessible IT portals is an important means of preventing bad habits and subsequent organic disorders that develop from it. In the direct (IT-supported) dialog with the patient, timely advice, answers, and suggestions can be given and individual measures can be recommended. Incentives for a healthy lifestyle, promoted by those who bear the costs, can simply and directly provide help and support at this point. This means that in the future, serious diseases can thus be prevented at an early stage while staying in the familiar domestic or automotive environment by means of networked digital diagnostics or smart sensor technology with personalized dietary or sporting measures.

2.3 Diagnostics: Application field of smart monitoring systems and imaging

Meaningful diagnostics must be capable of being performed on an inpatient, outpatient and mobile basis, depending on the application. In addition to inpatient laboratory methods in a hospital, point-of-care processes for mobile or home application (e.g. SARS-CoV-2 Rapid Antigen Test) are becoming increasingly important. The use of miniaturized sensor systems that can precisely, quickly, in parallel and reproducibly record the respective biomarker (biological and physical such as ECG and blood pressure) and make it available for evaluation in digital form to complement the imaging techniques. This information on disease-specific biomarkers for diagnostic and theragnostic purposes is the basis for a personalized therapy and allows to monitor and control the therapeutic success. In the future, patient-centric systems medicine, systems biology and synthetics biology, covering all areas from "omics"-based research to the social network of the patients, will work very closely together for the benefit of the individual concerned (Fig. 2.2). Starting from gene and cell therapies to individualized implants, a precision therapy that is based, among other things, on molecular medical diagnostic tools is developing, which is distinct from today's cohort-based therapy.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

The current design and evaluation requirements for cohort-based clinical studies do not qualify for an evaluation of these individual therapies – this is where new methods for the clinical evaluation of individual therapies need to be developed (see Section 3).

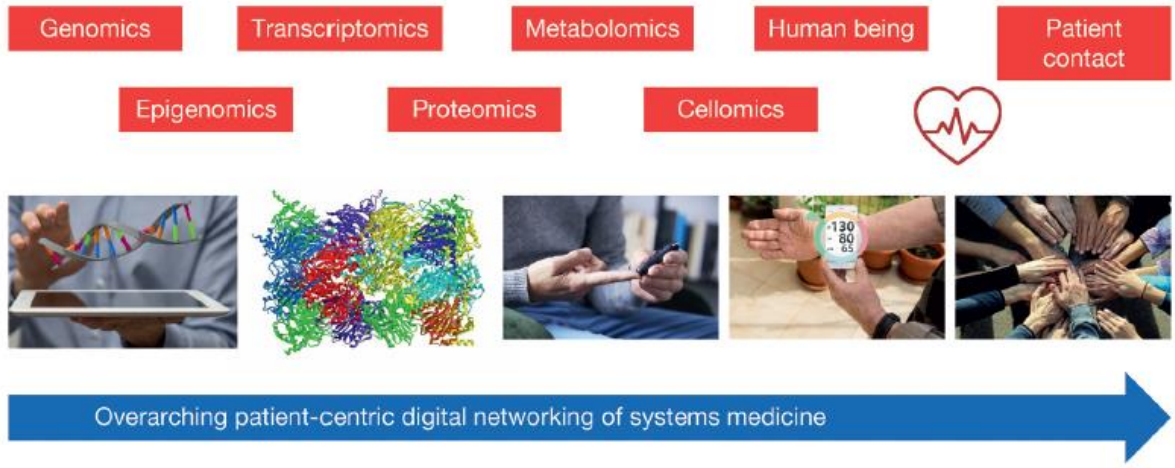

Fig 2.2: Patient-centric systems medicine from systems biology "omics"-based research to systems medicine biomarker-based techniques to patient conversation and group therapy, which must be digitally networked across the country in the future.

For ensuring comprehensive telemedical care, which is based on the documentation of all biomarkers (overarching "omics"-based research) and clinical imaging, and which is needed in the urban environment as well as in rural areas and in particular in any crisis situation, a safe and reliable collection and quick analysis of patient data must be made possible. Therefore, it is necessary to provide all the medical institutions with uniform digital equipment. In Germany, the current project called the Electronic Health Record (EHR) (elektronische Patientenakte: ePA), aims towards digitalization, can only be considered a first step along this path. When successfully realized, it is possible and desired to carry out a real-time comparison with potential previous findings included in the EHR. For example, in case of a traffic accident, ambulance and emergency services can directly collect and transmit valuable information about the medical condition of the injured or unconscious person at site by using smart sensor technology, and may receive necessary subsequent treatment options (see Fig. 2.1).

Such smart sensor systems (wearables) are also used at home, during exercise, in preventive medicine and also in clinics and rehabilitation centers. There is a current trend towards continuously monitoring multiple somatic functions to obtain a representative profile along the course of the day. Sensor technology ranges from miniaturized temperature, pressure and chemo-sensors to invasive biosensors for point-of-care diagnostics.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

Example for the application of smart monitoring and sensor systems

Full knowledge of a person's health or pathological condition is always acquired through a multimodal exchange of information, increasingly captured by microsystems engineered sensor systems and subsequently transmitted digitally. Medical monitoring systems are increasingly used everywhere, e.g. in smart watches or in hospitals, where the trend is towards ensuring complete and continuous monitoring of the relevant somatic functions along the patient pathway to relieve doctors to a large extent. Implementation of sensor technology ranges from invasive miniaturized temperature, pressure, and chemo-sensors to extremely miniaturized biosensors for point-of-care diagnostics. This is to also enable decentralized, outpatient and mobile, ubiquitous medical treatment in the future, which is of special interest in the context of prediction and early detection of diseases and for the ageing population, patients at risk, patients with chronic diseases and for regions with lack of medical care. In addition, the used sensors are an indispensable data supplier for decision proposals based on big data and AI. Over the time, this creates a digital twin of the individuum. This allows to generate individual risk profiles and make an early diagnosis [16].

2.4 Therapy: Application field of microsurgery, robotics, smart implants

In the future, personalized biomedical engineering embedded in the digital communications and data network will enable patient-specific interventions or therapies. They use patient-specific diagnostic parameters of systems medicine with regard to anatomy, physiology and biomarkers for therapeutic (theragnostics) purposes. Data acquisition via smart sensors und microanalytical systems will enable decentralized, mobile, ubiquitous medical treatment or therapy in the future, especially for the ageing population, patients at risk and patients with chronic diseases living in regions with lack of medical care.

Individual patient models can then be used to support therapeutic decisions and guidelines obtained from validated trial data for individualized therapy optimization. This includes the diagnostic insights gained in systems medicine, which can lead to individualized cell and gene therapy, organ substitution, and even smart implants.

Example for the application of robotics

Medical robotics is a fast growing field of innovative biomedical engineering. In addition to applications in laboratory medicine and rehabilitation, endoscopic robotic-assisted surgery is attracting considerable attention in urology, gynecology and increasingly in general surgery. Although the development originated in Germany [17], the market is now dominated by a US company (Intuitive Surgery). The patents, most of which are now expiring, allow European and German companies to bring new systems to market. In addition, they have made own inventions for specific fields of applications. Robotics is also increasingly being used in the field of image-guided procedures. Robotics in orthopedic surgery is experiencing something of a renaissance. A major obstacle to the clinical

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

application of true standalone robotics, e.g. in surgery, is the high regulatory hurdles in placing medical devices on the market in the EU, but also the missing acceptance by clinicians, which is often based on an insufficient understanding of the development of the systems. Simple handling (usability) of complex technical systems as well as further education through training will help to convince medical professionals of the safety, reliability and usability of robotic systems.

Example for the application of technology, including AI, for neurology

The support and substitution of somatic functions after an accident or disease by means of assistive equipment and devices is the key point of neural and rehabilitation engineering. Sensors and microprocessors in modern leg prostheses adjust the stiffness of the joints in a split second when walking. Hand prostheses are controlled by electrical signals that are recorded from still functioning muscles (EMG). According to research studies, prostheses already have the ability to "feel" through nerve stimulation. Artificial intelligence in neuroprosthetics evaluates muscular and neural signals to detect intentions ("thoughts or intents") to grasp and to initiate complex prosthesis positions bevor grasping. AI for speech recognition based on neural signals is also already well advanced.

Cardiac pacemakers, neurostimulators and cochlear implants are the state of the art. The acceptance of these medical devices does not only depend on their functionality and lifetime, but also on the safety concerned with their use. "Brain data" requires a special form of safety and privacy when AI is trained and applied. But also, compatibility with imaging techniques such as computed tomography scans or MRI diagnostics (MRI scan), which is even more sensitive from a technical perspective, shall be considered.

2.5 Rehabilitation and care: Application field of smart care and robotics

In the field of inpatient and home rehabilitation measures and care, biomedical engineering provides innovative solutions that can facilitate and improve care and relieve the burden on care takers. These measures and systems can provide patients with instructions for exercises, give background information and be motivating. Innovative solutions such as the Digital Health Applications and Digital Care Applications (German law: DiGAs according to SGB V §33a and DiPAs according to SGB XI §40a), smart nursing beds, healthcare robots, healthcare trolleys, smart exosuits or similar will facilitate inpatient and outpatient care in the future. AI-based techniques will help to identify problems early in the care process through the specific analysis of the available information and assist in identifying the most successful interventions.

The German Law on Digital Modernization of Healthcare and Nursing Care (DVPMG, Digitale-Versorgung-und-Pflege-Modernisierungs-Gesetz), which has been adopted in 2021, will also make Digital Care Applications (DiPAs) usable, similar to DiGAs. This will help to create an ecosystem within the digital healthcare sector in Germany und thus to increase sovereignty. Further steps towards this direction need to be taken consistently.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

2.6 Aftercare: Application field of home monitoring and smart aftercare

When receiving a diagnosis in the doctor's office or after discharge from the hospital or rehabilitation clinic, further monitoring measures are often required, e.g. in oncology. Therefore, the therapist will create an aftercare plan in consultation with the patients. In the event of unforeseen circumstances, either the therapist or the system may suggest corrective or optimizing action. Patient diaries, which are kept digitally by the patients themselves on their smartphones, receive a shot-term notice of these modifications and will thus enable the dynamic adjustment to the relevant health condition and provide retrospective information on the time profile of the monitored parameter. Hence, personal consultation times can also be arranged between the parties involved.

Especially for patients suffering from chronic diseases, disabled persons or elderly patients, further monitoring over a longer period of time, e.g. continuous monitoring of cardiovascular parameters, can also be useful. Remote care and telemedical concepts of remotely monitoring the health condition by means of wearables or implants are becoming more and more established. They provide patients with a high level of medical safety in their home environment. For people suffering from significantly more severe disabilities, various technical measures such as motion sensors, cameras and microphones can be used to monitor mobility. Personal motion profiles can be learned individually for people with a restricted range of motion with the aid of computers, which trigger assistive measures in the event of major deviations. Such assistive measures are already being offered commercially as modules under the term "ambient assisted living" (AAL). In addition to the reliability of these systems, the self-learning assistive strategy which flexibly adapts to the individual's needs and abilities is important. Adaptive AI methods can also be incorporated here. Important elements for this, which can be used as sovereignly as possible, are data analysis at signal and image level, decision-making, process analysis and cloud services.

Telemonitoring and the early detection of health problems will allow an early adjustment of therapy and thus prevent unnecessary hospital admissions. At the same time, the therapy may be tailored to the individual demands of the patient. For implants, but also in the case of other therapy devices, this means less doctor visits for functional testing or for the user-specific adjustment of parameters, as far as they are digitally networked. This may also incorporate a remote software upgrade or a reduction of technical failures through predictive maintenance. Overall, networked documentation is very important for that purpose. Information can be provided to those involved in the care process in a timely and transparent manner. Media disruptions and documentation mistakes can therefore be avoided, and information can be reacted more quickly. Applications that give care instructions to patients and their families can additionally bring relief.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

2.7 Future prospect and technological trends in the application fields of biomedical engineering

The progress of BME in all fields of application enables an increase in life expectancy and a better quality of life through innovative, gentle and less invasive technologies – a trend to be continued. However, an increase in more specific clinical pictures can also be expected in the future, for which an adapted needs analysis is required [18].

- Applications in neurology will grow fastest at 9,1 % p.a. over the next few years
- Antidiabetics will grow at a rate of 7,8 % p.a.
- Image-controlled techniques will grow at a rate of 5 % p.a.
- Diagnostic imaging und orthopaedic articles will grow at a rate of 3,7 % p.a.

This results in major future challenges for biomedical engineering. One basic strategy to meet these challenges is to shift from indication-specific medicine to comprehensive holistic and personalized precision medicine and networked systems medical care.

This means that the principles for innovative future products in the field of biomedical engineering must be both medically inspired and technologically driven. However, everyone in the healthcare sector, whether patients or medical and nursing staff, clinical researchers (clinical studies), hospital operators, reimbursement institutions (both health insurance companies and pension insurance institutes) and enterprises must be viewed holistically in terms of their functions and roles (see Fig. 2.3 and Section 5) in order to become a story of success. This means to pursue an overarching systemic approach.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

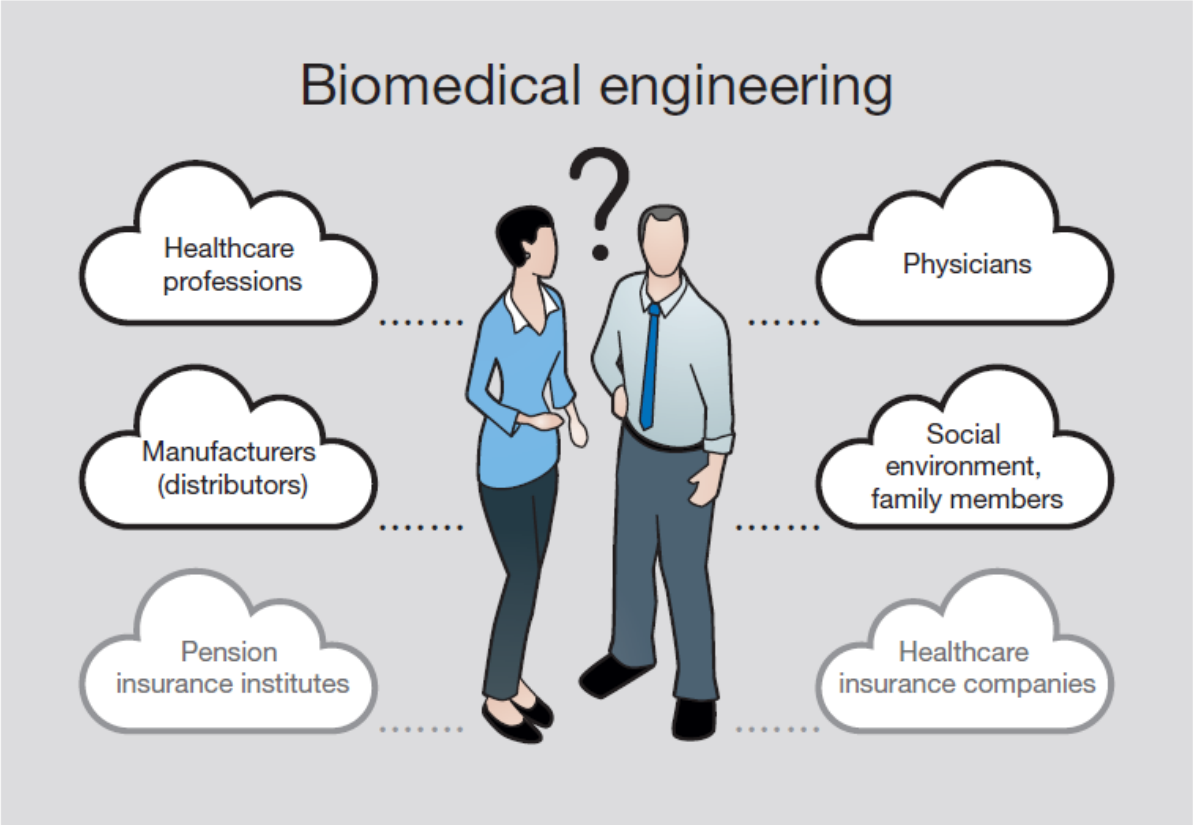

Fig. 2.3: Systemic approach: The human in the center of attention and between the conflicting priorities of the stakeholders in biomedical engineering.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

3 Key technologies in the medical application fields

This section describes both the key technologies interacting across different systems and the respective key technologies essential for biomedical engineering.

First, the key technologies of general basic medical care which must be available locally and EU-wide are described in the following. Afterwards, examples of essential cross-system key technologies are given. Finally, future challenges concerning currently used key technologies are described and a future outlook is provided.

3.1 Cross-system key technologies for basic medical care

Cross-system key technologies are all essential technologies that are needed in all fields of biomedical engineering applications. These are, for example, microelectronics and micromechanical processing technologies, standard electronic systems and components of digital communication technologies [14].

In the current pandemic, however, it also became apparent that serious problems arose not only in the high-tech area of digitalization, but also in the low-tech area. There was a lack of the simplest products and chemicals [19]. Although a planned economy of stockpiling is not expedient, in the event of a disaster, the approved institutions such as the disaster control service, the technical relief organization and the aid organizations should be equipped and topped up with all the necessary resources such as protective equipment, mobile analysis devices and intensive-care medical systems, and secondly, the armed forces should also be able to be called upon in an unbureaucratic manner. Stockpiling of essential drugs and chemical precursors should be coordinated locally in the health facilities and nationally, e.g. via the German Federal Institute for Drugs and Medical Devices (BfArM, Bundesinstitut für Arzneimittel und Medizinprodukte). Of particularly relevance is the coordination of emergency measures. They must be centrally organized nationwide and rely on overarching digitalization concepts to determine logistical flows. [20]

It is advisable to establish further basic care-relevant pharmaceutical and vaccine expertise in close cooperation with other countries of the EU and Switzerland, while also building on novel, flexible production methods for small production lots such as microsystems and micro biotechnological mini-factories .

Keeping a large stock of high-tech equipment, e.g. in large-scale imaging, automated analyzers or their spare parts, is counterproductive because the innovation-driven production cycles are too fast-moving. However, proper access to existing systems must be ensured.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

The problem of supply chain interruptions must be extensively considered: On the one hand, international regulations should be developed to protect supply chains even in periods of crisis. Their importance becomes clear using the example of rarely available raw materials. On the other hand, greater independence from international supply chains must be achieved by increasing vertical integration, bringing IP-sensitive production back to Europe and Germany or purchasing or developing own essential high-tech goods. In the case of low-tech goods for biomedical engineering such as glass or plastic articles, packaging materials, etc., a new way of smart, dynamic and predictive stockpiling must be developed. In all cases, diversification of suppliers to different locations and continents is advisable ("more than second source").

Cross-system key technologies, which are associated with high technology expenditure and/or large production volumes, can only be established within the European framework in order to ensure production sovereignty: The possibilities for data handling arising from digitization and digitalization must be significantly increased, e.g. through a standardized "EU DATA Space". Here, the GAIA-X activity is one opportunity that must be adapted and further developed to the already emerging "Internet of Medical Things" (IoMT).

As an example of the importance of basic supply in production, cardiac pacemakers provide a significant reduction in the mortality risk, and with 1 854 implantations per day, provide care to a significant number of patients [21].

Since there are currently only five essential manufacturers of implants for the treatment of arrhythmia and cardiac insufficiency worldwide (Medtronic (USA), Abbott (USA), Boston Scientific (USA), BIOTRONIK (DE) and MicroPort (China)), in the scenario of trade war or the threat thereof, as a result of which the USA and China restrict or prohibit the supply of implants to Europe, the BIOTRONIK company in the EU is the only chance of survival for 1 000 to 2 000 patients every day. Therefore, BIOTRONIK must be able to rely on a supply chain for microelectronic and chip components that is not under US and/or Chinese control.

In the field of microelectronics, production capacities in Europe are too low or do no longer exist. However, it must be questioned whether mass production or highly-complex and expensive technologies (e.g. nm-technologies), which can never be run competitively within the EU-framework, can be established, since neither the necessary capital, the necessary market access nor the associated comprehensive research and development expertise are no longer available. At this point, the EU initiative "2030 Digital Compass" should be further questioned

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

[22]. In microelectronics, building on Germany's strengths in customized chip products (ASICs), power electronics and sensor technology, chip production should be established in smaller steps, starting with small-volume, highly sensitive products, capable of being further expanded. This intelligent expansion of microelectronics expertise can thus help to slowly recover ground, even while being in tough competition, and optionally PPP may be discussed in PI-sensitive niche production areas.

Sovereignty of the production of certain medical devices should be established EU-wide, in order to demonstrate a sovereignty for action in the event of a profound trade conflict. Here are a few recommendations:

1. Identify sensitive niches of critical and IP-sensitive products and establish "key manufactures" nationally and, in the case of capital-intensive large-scale technologies, EU-wide.
2. Sovereignty in data collection, management, production and networking without excessive regulatory barriers.
3. Pandemic proofing and efficiency enhancement: Strategic initiative for remote service for medical devices.
4. Efficiency enhancements in mobile care through overarching digitization and digitalization (also see Section 3.2.1).

As accompanying measures, funding for R&D and production development in Germany and Europe should be allocated on the basis of investment and research programs such as Forschungslabore Mikroelektronik Deutschland (FORLAB) [23] and Forschungsfabrik Mikroelektronik Deutschland (FMD) [24] and supplemented with accompanying training programs. Strategic coordination between the EC and the member states are mandatory to reduce redundancies and strengthhen international competitiveness and visibility.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

3.2 Examples for the integration of key technologies that are essential in BME

The clinical application fields described in Section 2 can only be realized if the necessary key technologies are controlled. Using the example of a patient pathway of a polytraumatized patient (see Fig. 2.1), specific medical application fields have been identified and related essential key technologies defined (see Fig. 3.1).

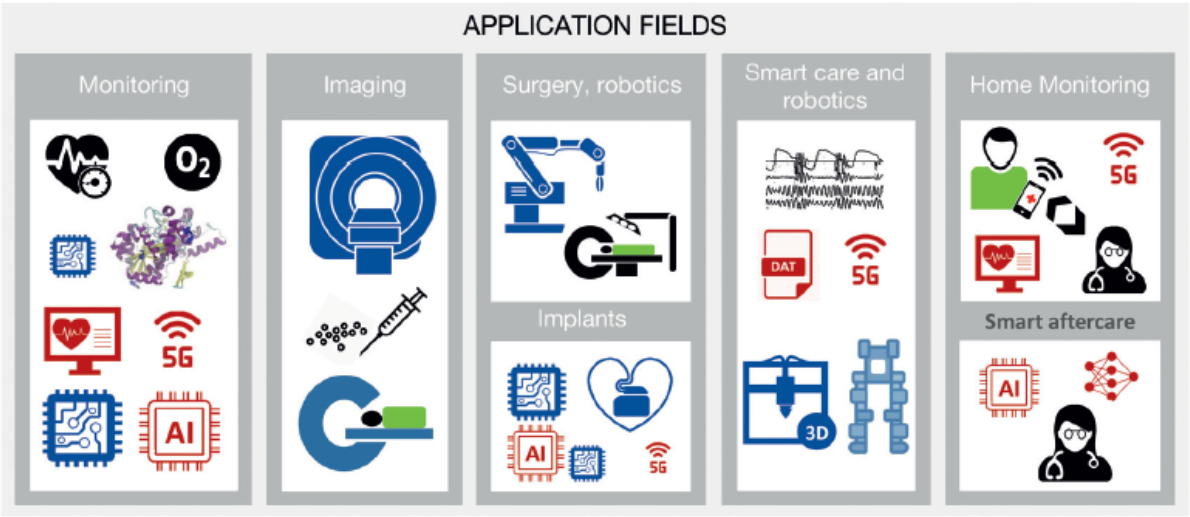

Fig 3.1: Use of essential key technologies for individual medical application fields for the patient pathway (see Fig. 2.1: Prevention, diagnostics, therapy, rehabilitation, aftercare). Microsystems and microtechnology (blue); materials, smart materials, bio-/nanotechnologies (black); networked systems technology, digital care and AI (orange). Physician/patient (green and black).

Based on the "polytrauma" example, the following application fields can be extracted, and the necessary **essential key technologies** identified, highlighted in bold:

1. Networked digital care from hospital to mobile care: The application field of integrated and digital care is important along the entire patient pathway (Fig. 3.1) and requires the following technologies: Starting with **microsystems engineering, micro-optics, smart sensor technology** (decentralized POC), **medical software, big data** solutions and analytical care with **digital networking** from home applications to Hospital 4.0, digital logistics from Hospital 4.0 to mobile care at home.
2. Smart imaging and monitoring: This application field is important from diagnostics to therapy control and requires the following key technologies: **Microelectronics, microsystems engineering, mechatronics, digital** and **AI**-based evaluation, **nanoparticle**-based imaging.
3. Robotics, microsurgery, nanotechnology- and nanobiotechnology-assisted therapies: Each surgical intervention requires smart surgical instruments, smart actuators in combination with smart sensors in navigated robotics or for theranostic closed-loop systems. For these instruments, implants, but

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

also for any biologized medical technology and theranostic closed-loop systems, **nanocoatings**, new **smart functional materials and substances** are necessary. For functionalization of instruments and implants, **nanoparticle** coatings and **biologization** of medical devices, implants and e.g. stents play an important role. For the production of medical devices and pharmaceuticals, **modular microprocesses** and, **biohybrid microreactors** will become even more important in the future for **gene and cell therapies**.

4. Smart implants: Implants play a major role in almost every therapeutic treatment, requiring **microsystem engineering, advanced materials, additive manufacturing** (3D printing), and, for active systems, **microelectronics, smart sensors, smart actuators, digital networking, biocompatible smart materials** and **nanocoatings**, and **AI**.
5. Smart care and aftercare: In the patient pathway of rehabilitation and aftercare, telemedical and prosthetic applications rely on key technologies such as **smart sensors, smart actuators, new functional and structural materials, additive manufacturing** (3D printing), **digital networking, big data** processing and **AI**, virtual therapeutics, **mechatronics**, and **microelectronics**.

From the detailed consideration of the individual technologies used in the application fields, it becomes evident that three general categories of essential key technologies for biomedical engineering can be extracted:

1. **Microsystems and micro-technology**
2. **Materials, smart materials, bio-/nanotechnologies**
3. **Networked systems engineering, digitization, digitalization and application of AI.**

These key technologies comprise a bundle of technologies, each having a similar purpose and objective. A checkerboard (see Fig. 3.2) is used to illustrate the relevance and interconnection of various key technologies in the application fields.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

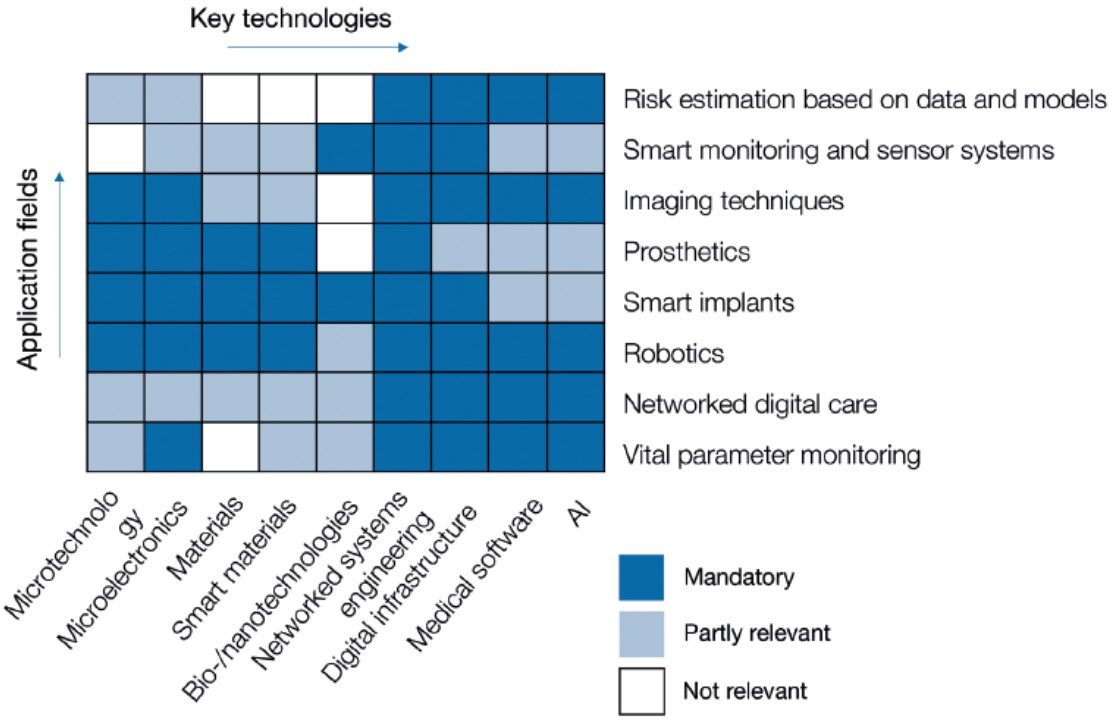

Fig. 3.2: Checkerboard to link selected application fields with key technologies. This is to assess the relevance of a key technology for achieving technological sovereignty in an application field.

3.2.1 Key technologies in the application field of networked digital care

The technological goal in this application field is to establish patient-centric, ubiquitous and integrated networking along the entire patient pathway. This networking must extend far beyond the data contained in the Electronic Health Record -EHR and cover all areas of the healthcare system. Both hardware-and software-based key technologies are therefore of importance, from prevention to aftercare.

Medical software engineering shall be assumed a fundamental key technology here, which currently allows an added value for medical devices of more than 50 % and is usually developed by SMEs. In this context, software architectures, normative requirements and verification of conformity for medical software must be established, which cover software quality, interoperability, usability, validation, cybersecurity, test and verification procedures, risk management and the field of software lifecycle. This requires special expertise which is to be considered one of the most important key technologies of the future.

For achieving the desired goal, data availability principally has a leading role concerning the field of big data in medical applications. The use of smart sensor technology, imaging processes and advanced analytical concepts in the context of integrated connected health will generate huge data volumes. 5G and other medical engineering technologies such as mobile edge computing or campus

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

networks can provide the necessary higher data rates and lower latency times for telesurgery, for example. The goal must be a user-friendly IT infrastructure capable of being applied intuitively. Therefore, the FAIR principles (Findable, Accessible, Interoperable, Reusable) must be taken into account.

For the exchange of data, the interoperability of medical devices is of major importance. For networking, e.g. of medical devices for surgery and diagnostics, heterogeneous data formats must be avoided, and internationally harmonized interface standards for the hardware and software level (data storage, data exchange protocols, based e.g. on an extended ISO/IEEE 11073, HL7 family of standards, cloud technologies or SDC formats) should also be developed for real-time critical and safety-relevant applications. First, the interconnectivity of systems, both on the hardware and software side, through interoperability at the technical, syntactic, semantic, and organizational levels must be ensured in order to be able to complete an Electronic Health Record (EHR) and to obtain meaningful and competent findings or clinical decisions [11].

This requires the development of safe procedures for the collection, merging and labelling of data from hospital information systems (HIS) and laboratory information and management systems (LIMS) to mobile care, addressing ethical as well as legal issues of data access and automated outcome analysis. All medical service providers must be able to use these data without being prevented from doing so by restrictive regulations [25]. In addition, remote services of medical engineering devices can also be established through interoperable networking in the hospital to save costs for technicians and time. To successfully establish a digital knowledge pool comprising data sovereignty and cybersecurity, a true EU-wide digital platform, usable for medical purposes, must be further developed. A particular challenge is the application of AI and especially of machine learning for personalized medical treatments.

In the context of analysis methods for recognizing structures of medical engineering data, which are based on profound neural networks, an interoperable AI platform for the entire patient pathway must be established for care and implants up to social participation. This may lead to an "AI as a service" product to support physicians, companies, and healthcare and social service institutions, and thus also provide own AI-based products and services in the areas of health and care, as well as in social participation, as a business model. AI-based methods, however, only have the ability to support medical staff, but not to release them from their responsibility!

A prerequisite here is the sovereign availability of overarching key technologies such as microelectronics, digital components or 5G networks. Microsystems engineering, including micro-optics or smart sensors and digital networking interfaces, are essential key technologies for this application.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

3.2.2 Key technologies in the diagnostic application fields of smart imaging and monitoring

The majoritiy of application fields of biomedical imaging require micro-electronic and processing as essential key technologies, e.g. in MRI and nanotechnologies for diagnostic and therapeutic applications such as MPI (magnetic particle imaging) or hyperthermia using nanoparticles in minimally invasive tumor treatment. Based on this, image guided intervention is possible, achieving a reduction in invasiveness of therapeutic measures while increasing precision. Multimodal imaging (e.g. angiography, CT, MRI and ultrasound treatment) is increasingly combined with navigation and robotics and requires the establishment of appropriate workflows. Advanced materials and technical solutions are required for safe image guidance and effective visualization of instruments and implants, i.e in MRI.

The next generation of in-vitro diagnostics and in-vivo sensing requires integrated miniaturized biosensor systems for in-vivo applications such as catheters and implants, as well for in-vitro applications of microminiaturized and even nanotechnology systems in IVD and POC environments (infectious disease diagnostics, virus testing), and the associated supply chains. Multiplex POC and point-of-need systems, which were all manufactured using micro-technologies, have to be considered.

It is necessary to apply methods of molecular medicine in micro- and nanotechnological diagnostics to achieve an individualized overall assessment of a biological system which allows the investigation of genomics, epigenomics, transcriptomics, proteomics, metabolomics up to complete organ systems.

3.2.3 Key technologies in the therapeutic application field of microsurgery, nanotechnologyand nanobiotechnology-assisted systems

In this application field, biocompatible materials, smart materials and biological and nanotechnological processes are primarily used as key technologies. Concerning the sector of metal and ceramic materials, Germany is very well positioned and has a high level of expertise. In the future field of smart functional materials, there is a high research competence for hierarchical and living materials with sensory and actuator functionalities, but currently with only low implementation capacity.

Future fields are drug targeting, smart bandages, smart composite materials for actuators with biomimetic strategies and nanotechnological coatings for microsurgical instruments, prostheses or implants.

Organ-on-chip and human-on-chip systems are also an interesting future field for gene and cell biology applications that use key microsystems and bio-technologies: By combining microfluidic miniaturized chip-based processes, which may comprise patient-specific organoid and multi-organoid systems, drug trials can be personalized or be targeted on local cell therapies in the future.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

3.2.4 Key technologies in the application field of smart implants

The application field of "smart implants" covers both passive implants such as joint substitutes and active implants such as implantable pulse generators (IPGs) for neuro- and cardiac stimulation.

Data from imaging techniques may be applied to augment digital twin models that can be used to develop and adapt patient-specific implants for joint or dental substitutes, as well as for the recovery of bone defects in trauma surgery, reconstructive surgery and neurosurgery, using 3D printing but also conventional fabrication techniques. For individualized medical devices, 3D printing allows customization of form, structure, and function to meet individual patient needs. These devices are of particular importance due to their ability of being combined with various substances, for example with pharmaceuticals to create so-called drug-delivery implants. Advanced materials and production techniques ensure better functionality through the individual and improved adaption of (structural) biocompatibility. Integration of sensor technology in these implants and wireless data transmission of functional states (condition monitoring) by microelectronics, sensors based on microsystems technology and networking (5G, digitalization) can incorporate these implants into physiotherapeutic treatments, rehabilitation and aftercare.

Active implants to support, modulate and re-establish autonomous, sensory and motor functions related to the heart, sensory organs and the nervous system range from pacemakers and cochlear implants to computer-brain interfaces as studied in neural engineering research. Microelectronics, advanced materials for miniaturized interfaces, materials and manufacturing techniques for hermetic packages and coatings, and digital networking for remote diagnostics and therapy support are the keys to successful translational research and transition into approved medical devices. Wireless data connectivity and incorporated intelligence of these complex systems turns electrical stimulators into theranostic systems through a combination of signal recording, analysis and stimulation, which adapt to the individual patient's condition and its variations throughout the day and as the disease progresses.

Innovation and success depend on the availability of materials and substances, and of dialog-oriented and pragmatic instructions on how to transfer these systems to initial studies on humans within the scope of the MDR.

3.2.5 Key technologies in the application fields of smart care and home monitoring

Intelligent prostheses and orthoses: By using AI-based self-learning control algorithms, patients now have the chance to learn a variety of movements individually and execute them intuitively. In the field of arm prosthetics, this already allows a larger variety of grasp types and hand positions to be realized than was previously possible with conventional muscle signal (EMG) controls. In the field of leg prosthetics und orthotics, self-learning control algorithms in

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

combination with smart sensors and micro-technologies will allow optimum support for patients in all possible activities. Wearable assistive robotic systems (soft exosuits) may be seen as a further development of intelligent prostheses: Lightweight, wearable robotic systems which combine innovative design and control principles with functional garments and smart sensor technology to increase the mobility, the walking quality and the endurance of the user. Due to the low weight, the replacement of stiff structural elements by advanced functional materials, and the low energy consumption by smart actuators, these systems are perfectly suited to provide daily support for elderly or paralyzed people. Such systems can also be well used for telerehabilitation in familiar home environments.

For telemedical applications and aftercare, most of the key technologies mentioned in Section 3.2.1 also play a significant role. Another important field is the availability of relevant data to enable personalized therapy in aftercare and in the care of patients suffering from chronic diseases, which is also adapted to individual needs over time. This requires smart vital parameter sensors that record the current medical condition or measure activity as unobtrusively as possible. To ensure a high level of mobility, ubiquitous digital networking is of particular importance. Standardized data formats must be established and networking platforms need to be developed that make relevant information available to authorized persons. This is supplemented by the intelligent evaluation of the collected data making relevant statements concerning the therapy in order to achieve positive outcomes for the patients. Further key technologies include digitally supported healthcare processes and advanced digital therapeutics. Thus, patients suffering from anxiety disorders or autism may practice everyday situations in well-defined virtual environments in order to be able to draw on familiar patterns of behaviour when they actually encounter such situations. Digital therapeutics allow completely new forms of treatment for the benefit of patients.

3.3 Future challenges of the currently used key technologies and a future outlook

Germany’s predominant SME scene in biomedical engineering, which includes many “hidden champions”, relies on a proven technology mix that comprises mechatronics, mechanical micromanufacturing, microsystems engineering including optical systems, advanced materials (memory metals, innovative alloys, polymers, etc.), digitization, digitalization, and electronics system development including IT systems.

In the field of high-quality materials, semi-finished products and the precision manufacturing of products and components, Germany – and also Europe – is partly still the global market leader. The availability of medical materials is increasingly limited in Europe. Catheter materials (plastics) or implant materials such as nitinol are imported from the USA and China. Procedures of market access for new materials are also significantly complicated by the current MDR. This shows that technological sovereignty does not only depend on technological basics but also on the regulatory framework conditions. For the digital infrastructure such as

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

routers and cloud components or 5G networks, we are largely dependent on the USA and China. European initiatives (e.g. GAIA-X) should also be considered and further adapted with regard to the requirements for big data management and digital healthcare provision.

The former world center for the manufacture of surgical instruments in the Tuttlingen area (Germany), with a global market share of approximately 90 %, lost market share after a sharp decline at the beginning of the 1990s, because the OEM manufacturers, mostly family businesses with a small number of employees, were no longer able to meet fast growing demands for minimally invasive surgery, nor did they want to produce disposable instruments. As a result, production was relocated to the USA and Asia. In addition the Middle East produces cheap instruments in the simplest manner which dominate the market. However, German companies were able to continue to grow by producing high-quality instruments. Today, the Tuttlingen area is the largest medical technology cluster for innovative medical devices, surgical instruments and implant technologies in Europe, with more than 400 medical technology companies and around 8 000 employees [26].

It is also necessary to highlight the numerous OEMs in the Tuttlingen and surrounding area and the leading marketing companies in this field. Examples include one of the world's largest guide wire manufacturers or the world's leading manufacturer of nitinol implants, where the microtechnology for nitinol laser cutting has strengthened this leading position. However, production according to customer-specific needs is also considerably restricted by the current MDR.

In the pandemic, the flexibility of private industry has been recognized by the fact that it reacted quickly and purposefully, increased the vertical range of manufacture, regained lost competencies by additional purchase in order to design complex systems itself such as CMOS camera chips, and made manufacturing independent of large suppliers. This did not require large investments, and it ensured greater independence of the supply chains.

With this sound industrial base, it is also to be expected that it will be possible to recover ground in the problematic fields of microelectronics and digitalization (Section 3.1) and to build on the essential key technologies addressed in Section 3.2 if statutory regulations do not slow down the innovation performance.

3.4 Sustainable technologies in biomedical engineering

In the past, the issues of sustainability and environmental protection have played a minor role in biomedical engineering behind patient safety, patient benefit, economic efficiency, and have played no role in reimbursement systems. Meanwhile, a change in thinking can be observed. Stock quoted companies are increasingly starting to analyze and optimize their ecological footprint, as this is increasingly requested, especially from institutional investors.

Sustainability will become an important differentiator for biomedical engineering solutions. This quickly can be seen when just considering the quantities of

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

consumables in the hospital or outpatient sector. Here, considerable challenges become obvious. For hygienic reasons, single-use articles are often more convenient to protect the patients. Alternatives would be disinfection or sterilization. However, these processes are often energy-intensive or use large quantities of substances that are not very environmentally friendly. This example alone illustrates the importance and impact of sustainability in biomedical engineering and, at the same time the complexity in the conflicting fields of optimal patient care: minimal patient risk, sustainability, and economic efficiency.

Sustainable and environmentally friendly solutions must be explored, developed, tested and established.

The aim is to identify the most suitable materials and processes in development and production, i.e. those that are not only biocompatible but also environmentally safe and compatible in terms of clean production and disposal (e.g. the microplastic problem), and to promote such developments to a greater extent.

It is also important to optimize sustainability aspects already at the stage of clinical trials, up to lifecycles and the end-of-life of medical devices. Material and processing issues play as much a role as structural and process issues in healthcare. There are already useful approaches and ideas such as green and blue hospital activities [27], [28]. Similarly, telemedical solutions, for example, can sustainably reduce the necessary patient transports. This is already being discussed in other countries, for example in the USA in states like Texas.

Overall, there is still a considerable need for research in this field in order to analyze various issues and develop sustainable solutions thereof. In the field of biomedical engineering, there is basically a huge potential for achieving numerous improvements in environmental protection.

Sustainability will be a key advantage for future biomedical engineering solutions in order to contribute to improved environmental protection, but also to remain a leader in the development of innovative biomedical technology. Accordingly, a focus should be placed on the public promotion of sustainable biomedical engineering.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

4 Evaluation of sovereignty of medical technologies and biomedical engineering along the value chain

4.1 Overview

The following section evaluates examples of the key technologies "microsystems engineering and micro-technology", "materials, smart materials, bio-/nanotechnologies" and „networked infrastructure, digitization, digitalization and AI", which are essential to medical and healthcare engineering, in terms of the minimum level of sovereignty required and the level of sovereignty currently available. Such an evaluation is based on a generalized value chain (see Fig. 4.1) where different domains of biomedical engineering (vertical components in Fig. 4.1) must be taken into account (education and training, regulations and ethical aspects are of particular importance in biomedical engineering and are therefore dealt with separately in Section 5). It is important to note that these statements are examples only, which are intended to illustrate the approach to be followed and the major aspects of evaluation. In this context, SMEs and large enterprises have different requirements: For small enterprises, the unique selling point (USP) is mostly in niche applications, which sets different requirements for the supply chains and also for the employee structure and education concepts. A particular challenge for this group of enterprises is the increasingly extensive regulation in the implementation of the MDR with regard to the risk assessment and post-market surveillance that must be carried out on a regular basis. Large enterprises usually have a good staffing level and have expertise in the regulatory environment. This group of enterprises rather focuses on the respective country-specific regulations and the complex supply chains.

The development of business models for the distribution of biomedical technology products must continue to meet the highest quality standards and safety requirements, and, because it is evident, is no longer dealt with in detail, since Germany has a very high level of sovereignty in this area.

4.2 Key technologies "microsystems engineering and micro-technology"

Microsystems engineering and micro-technology play a major role in almost every biomedical application field (see Section 2). This is a bundle of different technologies allowing the production of components in the sub-mm range down to the micrometer range, starting with classic machining centers that allow accuracies in the micrometer range, extending to the clean-room production of specific chips with structural dimensions in the micrometer range for sensors and implants.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

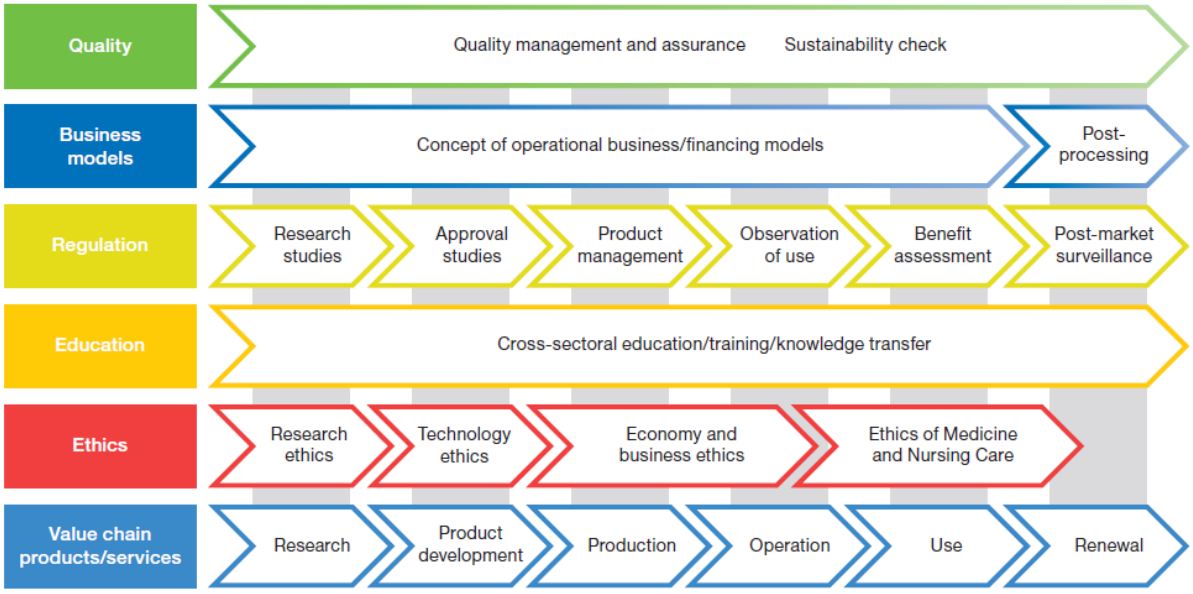

Fig.4.1: Illustration of an overarching value chain in biomedical engineering to complement the generalized value chain in Fig. 1.2.

In all of these fields, Germany is holding a leading position in the international ranking. Starting with the strong tradition in mechanical engineering, precision engineering to ASIC development and microsystems engineering where numerous leading institutions are located. Products are microsurgical devices as well as smart sensors, analytical microsystems, implants, imaging devices and partly found in robotics. Currently, the sovereign position is still very good established and is on a high level due to the introduction of new technologies such as 3D printing. A general deficit is the lack of available semi-conductor chips, which must be remedied by developing a microelectronics infrastructure across the EU and Germany.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

Value chain	Required level of sovereignty	Existing level of sovereignty	Explanations
Research and development	★★★★★	★★★★	Microtechnologies and ASIC developments concern major components of current products and are the drivers for innovation. Sovereign development is essential. This includes, in addition to mandatory training to acquire the necessary knowledge, continuing to hold intellectual property (IP), sovereign mastering of microsystems technologies, ensuring access to the necessary development tools and being able to produce prototypes and small batch series.
Production	★★★	★	It is unrealistic to make production generally sovereign. However, it should be ensured to be temporarily sovereign at least with regard to critical components of medical engineering systems. Therefore, access to raw materials and components must be secured through secure supply chains and a certain level of stockpiling. The corresponding production facilities must also be available. While the latter is the case today, the chip shortage in the pandemic clearly showed how inadequately prepared Germany/Europe is and how quickly critical supply shortages arise today due to a lack of raw materials/components.
Operation (provider, B2B)	★★★★	★★★	The operation of microtechnologies should be sovereignly managed in so far as health-critical systems are operational at all times. Maintaining the relevant systems and hence handling the microtechnology contained therein is therefore obligatory. Additional factors are beneficial, but not mandatory, such as a transparent operation and the feedback of findings from operation to the development.
Use (patient/service provider)	★★★	★★★	Sovereign use must be guaranteed, although in the case of microtechnology this must be safeguarded by the manufacturer/provider. Further aspects, e.g. transparency in use, do not play a major role here, however, educating the public about microtechnology is desired.

Table 4.1: Level of sovereignty required and level of sovereignty currently available for the key technologies microsystemsengineering and micro-technology along the value chain. The explanations are based on exemplary aspects that are relevant for the respective category. Rating scale for sovereignty: ★...very low, ★★★★★...very high

4.3 Key technologies "materials, smart materials, bio-/nanotechnologies"

Materials and substances play a major role in biomedical engineering. These are biocompatible materials for implants, materials for invasive therapeutic devices, and also materials for sterile disposable products. In all cases, high-quality grades biocompatible materials are of priority. They are also referred to as biomaterials, an overview of which can be found in [29]. The standard VDI 5701 "Biomaterials in medicine – Classification, requirements, and applications" classifies biomaterials and also defines examples of application-specific requirements for the qualification of various materials.

Future topics to be discussed here are the functionalization and biologization of materials (smart materials for sensors and actuators), primarily by the application of nanotechnologies and nanocoatings of biocompatible devices. Biological coatings in the nanometer range are also among the major future topics of this key technology.

Nanoparticles for imaging or drug release and cell-based technological approaches, e.g. for individualized tumour treatment, imply great hope for the future of personalized medical treatments. In this area of research, Germany has a leading position in all the fields mentioned. However, there is a continuously decreasing

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

number of industries producing in the biotech and chemical sector. The problem here is that large chemical companies are only interested in selling large quantities and less interested in selling specialty chemicals with only small batch sizes. For example, there are obstacles to the marketing of special materials such as polyimide, because the quantities purchased for medical devices are too small to meet the complicated regulations for marketing with the expected low sales. However, it must be noted that it is not the manufacturing companies that are responsible for tested biocompatibility of the materials, but the manufacturer of the device. Unfortunately, these problems represent a production barrier for SMEs in reality, which might be interested in selling also smaller quantities.

Processes of microsystems technology for the production of pharmaceuticals and vaccines, 3D printers for microfluidic systems and microbioreactors can be used flexibly also for smaller pharmaceutical production lots. Here, the Center for Pharmaceutical Process Engineering, among others, is conducting research on the development of miniaturized active ingredient and drug production systems for the manufacture of small, patient-specific quantities of personalized drugs [30].

Cell-based and non-cell-based productions of pharmaceuticals (microbioreactors combined with cellfree RNA-induced protein synthesis and organ-on-chip systems/human-on-chip systems) are new tools for molecular medicine which are still under development.

Among the bionanotechnologies, there are new principles for the release of drugs and molecules by special nanocarriers (such as liposomes, microbubbles, cyclodextrines) which are triggered via the external application of ultrasound, piezoelectric effects or directed EM fields. The external stimuli exhibit a high application potential. Furthermore, stem-cell therapies, protein nanocomplexes (e.g. hybrid antibodies), biologization of implants, and transfection systems must also be mentioned.

However, current procedures for marketing approval are inadequate and usually make researchers and companies to move from Germany to the USA for performing necessary studies and developments; this problem is discussed in Section 5.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

Value chain	Required level of sovereignty	Existing level of sovereignty	Explanations
Research and development	★★★★★	★★★★	Smart materials are the drivers for innovation and are also of major importance for sustainable solutions. R&D should therefore be sovereignly managed. One acute problem for innovative developments is, for example, the strict requirements of the MDR and reapproval procedures.
Production	★★★	★★★	With regard to the necessary raw materials that are not available in the country, the same applies as before: access/availability must be ensured through secure supply chains and a certain level of inventory. With regard to further processing (polymer processing, mechanical engineering, biologized materials), Germany currently has very good opportunities. However, especially for SMEs with small purchase volumes, e.g. in the area of chemicals such as polymers, ways must be found to remain sovereign in these areas in Germany and Europe.
Operation (provider, B2B)	★★★★	★★★	In particular, safety and biocompatibility of smart materials must be capable of being sovereignly tested/evaluated at any time. In the future, the circular economy should be managed sovereignly for reasons of sustainability. Besides the positive environmental effects, this can also counteract the currently critical aspects such as the availability of resources.
Use (patient/service provider)	★★★	★★★	The sovereign use must be guaranteed, but in the case of smart materials it shall be also safeguarded by the manufacturer/supplier. Further aspects, e.g. transparency in use, do not play a major role here, however, they do for the transparent communication of the safety of the materials to the patient.

Table 4.2: Level of sovereignty required and level of sovereignty currently available for the key technologies, materials, smart materials, bio-/nanotechnologies along the value chain. The explanations are based on exemplary aspects that are relevant for the respective category. Rating scale for sovereignty: ★...very low, ★★★★★...very high

4.4 Key technologies in "networked infrastructure, digitization, digitalization and AI"

As described in Section 3, a networked infrastructure, patient-centric digitalization and the application of AI are becoming increasingly important. These digital medical and health technologies, often referred to as "digital health", need to be further developed according to the motto "patient-centric digitalization". One step in this direction has been taken with the Electronic Medical Report and the associated laws, interoperable norms and standards. „Digital health" involves the integration of hardware and software and the targeted evaluation of data along the entire patient pathway. Currently, conventionally networked systems technology is sovereignly managed nationwide whereas accessibility to smart sensors, interoperable interfaces and end devices still needs to be established in many of the application fields of biomedical engineering.

As already described, one problem is the dependence on microelectronic components. Moreover, operational software and its interface infrastructure concerning computer and mobile device technology is no longer developed and produced in Europe. This leads to a nearly complete dependence on the USA or on Asian countries, as recently demonstrated by the development of the Corona warning app. This must be changed immediately in order to establish sustainable independence, since IT takes a central position for all future technologies. On the one hand, this is relevant for product development, but also for Europe's independence in any kind of crisis situation. SMEs and innovative young companies

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

have quite excellent expertise concerning medical interfaces, system application and also in the field of medical software, but support is needed in the area of highly complex documentation for the approval of medical devices and for interoperable interface integration. Here, government entities must develop cross-company digital health platforms complying with international standards and support their use with funding measures. In all cases, further development of the MDR is necessary to maintain the ability of particularly SMEs to innovate in the future.

Value chain	Required level of sovereignty	Existing level of sovereignty	Explanations
Research and development	★★★★★	★★	To achieve patient-centric digitalization, sovereign action is absolutely required in the further development of networked infrastructures, in digitalization and for the application of AI. The competence for development is largely available in Germany and Europe today, but Germany/Europe is not considered a pioneer. In addition, the strong dependence on basic electronic elements, smart devices, cloud databases and software tools from non-EU countries is already apparent today and may become extremely problematic in the future.
Production	★★★	★★	The production of specific digital medical devices is a systems technology which combines all hardware components to a complete system and adds firmware. For production, this primarily means the assembly of modules and systems, which is a well-established process. Availability of the relevant microelectronic chips and interface modules is, however, very critical. In addition, there are significant dependencies for operating systems, databases and cloud solutions as well as for software tools, which may become extremely critical. In-house production of the most basic components, secured supply chains and sufficient inventory/access must be ensured.
Operation (provider, B2B)	★★★★★	★★	Due to the importance of networked infrastructures and digitization, digitalization for the (future) healthcare system, their sovereign establishment, expansion and operation must be ensured. In order to ensure the best possible healthcare provision, manageability for the healthcare provider and protection of individual patient interests, and to create an operational framework, it is necessary to appropriately update the MDR and the data protection ordinance. Cross-national data exchangeability must also be ensured. However, this reveals deficits today. Transparency concerning the existing infrastructures or the infrastructures to be developed is as much important as the sovereignty of interfaces and of all data. It is of particular importance to establish European data platforms in order to reduce dependencies and the possible misuse of data.
Use (patient/service provider)	★★★★	★★★	Patients must be capable of deciding sovereignly about their data. They must, however, be encouraged to make the right decisions. Therefore, the complex problem of patient safety, device security and also data privacy and the associated security of supply needs to be solved. Risk-based approaches must balance innovation capability and safety. This is closely related to the required transparency: Transparency in digital processing of sensitive data and AI-based processes, which shall be no black-box systems, is important for ensuring general acceptance among the population. This is where the currently followed approaches clearly need to be further developed.

Table 4.3: Level of sovereignty required and level of sovereignty currently available for the key technologies networked infrastructure, digitization, digitalization and AI along the value chain. The explanations are based on exemplary aspects that are relevant for the respective category. Rating scale for sovereignty: ★...very low, ★★★★★...very high

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

5 The focus on the human being: Regulatory, ethical, sustainable and educational aspects of biomedical engineering

The discussion about technological sovereignty in biomedical engineering must be taken beyond the purely technological aspect and also consider its acceptance in society, the knowledge about it through education and training, and ethical aspects when used on patients. The following sections summarize key points of these issues.

5.1 Testing, evaluating and placing on the market of medical devices

The EU Medical Device Regulation (MDR) (2017/745/EU) specifies high and basically very relevant requirements for the safety, documentation and traceability of medical devices. In recent years, however, the implementation of the MDR has led to a significant decline in innovations and consequently in the marketing of new medical devices in Germany and the EU. SMEs, in particular, are only able to cope with these regulatory requirements to a limited extent, which are thus becoming restrictive. This currently poses the risk of established and well-functioning medical device to disappear because of the re-certification. According to a survey [29], almost every tenth company questioned sees the MDR as an existential threat. Devices with low sales figures or profit margins are put last in the company's order for certification, which may result in supply shortages. Many devices have been successfully established on the market for decades and must now undergo clinical testing, due to the new risk classification, for being approved under the MDR. Due to the higher classification of many medical devices, among other things, the clinical testing that will then be required will become a significant barrier to innovation. This applies in particular to surgical instruments such as a simple scalpel which must undergo clinical testing now. The aspects formulated here should be taken into account in the national elaboration of the MDR within the framework of the Medical Devices Implementation Act in order to ensure practicability. This must also be considered in view of the fact that the economic sector of medical and health technologies, and here in particular SMEs, is one of Germany's innovative fields of the future. The large potential of digital medical devices is creating new challenges. In respect of artificial intelligence and adaptive systems, the MDR is reaching its limits. Completely new processes must be identified, tested and approved here. Therefore, a pragmatic approach is indispensable. It must comprise a risk-based step-by-step approach to challenges, and the testing of various other approaches. The promotion of the scientific development of appropriate approval methods would mean a significant advantage in digital sovereignty and can result in a competitive advantage in Europe.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

This requires pragmatic and clear guidelines for implementing the MDR in biomedical engineering. This falls within the scope of the Medical Device Coordination Group (MDCG), and the DGBMT is willing to constructively support the MDCG experts with its expertise, for example in the development of the common specifications.

After all, sovereignty in market access procedures is the basic prerequisite for a competitive national and international application of European and German medical devices.

In Germany, data protection regulations have significantly slowed down digitization and digitalization of the German healthcare sector due to differing interpretations of the DSGVO (partly differing across Germany from federal state to federal state). Here, a risk-based approach, as is the case with medical interventions in the MDR, is not equally weighed. countermeasures must be taken promptly, and uniform national interpretation by the federal states must be standardized and facilitated to the extent possible.

A few specific steps in the context of the regulations could boost innovative strength and competitiveness in the European Economic Area and, in addition to its strength, give Germany a model and exemplary character which "diligence" in the administrative implementation of regulations has so far prevented [18].

- Incorporate expertise from universities, (bio-)medical engineering expert societies and companies in the implementation of the MDR to ensure practicability and reduce over-bureaucratization.
- Stronger and timely involvement of technical and medical expertise and mandatory application of quality assurance methods when drafting the MDCG documents.
- Promote low-cost educational and training offers in the field of interoperable standards for medical and health technologies such as SNOMED CT, HL7, FIHR, IHE, etc.
- Promote research on certification of AI systems and draft guidelines for MDR-compliant development, especially with regard to evaluation and continuous monitoring of AI in use or calibration and validation of the AI-based decision-making ability in routine use.
- Safety of instruments and implants concerning magnetic resonance imaging: Transfer MR testing procedures and evaluations of implants to instruments, e.g. to make magnetic resonance imaging (MRI) devices and systems usable as interventional imaging modalities.
- Exemptions for research studies with respect to material-related liability: advanced materials – for example, from the field of micro- and nanotechnology – should be allowed for clinical trials on a case-by-case basis, subject to compliance with the principles of good scientific practice.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

Furthermore, we need to make properties and test results of important materials available, similar to the "material master file" that can be used for FDA market access procedures.

- Pre-clinical evaluation of medical devices: Exploiting all possibilities from digital twins to in-vitro studies, organ-on-chip systems at the molecular level. For ethical reasons, animal testing should be avoided, and 3R concepts (replacement, reduction, refinement of animal testing) should be introduced and implemented as an opportunity and not as a brake on innovation.
- Elaborate new EU-wide mechanisms for the testing of medical devices for rare diseases in research studies to enable innovations.
- Translate research results into clinical trials to evaluate the feasibility and potential of methods and products, whereby FDA principles can be adapted such as the
    - Humanitarian Device Exemption (HDE): Placing a medical device on the market without marketing authorization for rare cases for which there is no alternative treatment
    - Investigational Device Exemption (IDE): Exemptions for research systems
    - Early Feasibility Studies (EFS): Feasibility studies at an early stage of development.

Research outcomes should also be easily and uniformly transferable into clinical trials (hypothesis-driven investigator-initiated clinical trials) in Europe, independent of the country / member state in which they have been performed.

Overall, taking into account all safety-critical framework conditions, German researchers and companies should be given the opportunity to generate sustainable health-promoting and health-maintaining benefits for patients with medical and healthcare technologies developed in Germany. This goes hand in hand with the protection of intellectual property (IP) and the establishment of value chains outside the EU as well.

5.2 Professionally sound education, new forms of training and fields of occupation

Engineers, IT specialists and scientists working in the field of biomedical engineering support medical and nursing actions for the benefit of the patients and optimize techniques for an improved quality of life by using the means and methods available to them.

In this conflicting field of patients, medical staff, engineers/scientists and society, aspects of explicit interdisciplinary and interprofessional activities must be taken into account in addition to scientific-technical and information technology issues: e.g. medical-biological, psychological, social, ethical, economic, legal and safety

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

issues. In Germany, there is broad spectrum of study programs in biomedical engineering linked to the fields of engineering and science.

Currently, education and training in biomedical engineering is provided by both universities and private educational institutions and enterprises, and just like the specialist field itself, it is multi-faceted and inhomogeneous. In addition to those study programs aiming at a Bachelor's degree, a Master's degree or a Diploma degree, there is a wide variety of programs for majoring and specializing, with different designations and focuses.

While the above-mentioned occupational groups are very well-educated, there is a lack of essential education and continuing training programs for both medical and nursing professions on the one hand, and on the other hand these occupational groups often lack the willingness to deal with technological and digital issues, e.g. Germany. Although all employees of the healthcare sector use technical devices and rely on their outcomes for diagnostics and therapy control, education and training programs often lack of teaching basic knowledge in physics and technology, methodological skills and the introduction into advanced technologies so that the gap between the applicable technology options and their actual application as well as the evaluation of outcomes in the medical field of application is getting wider.

The DGBMT is willing to advise and support the respective expert associations, although structural support is necessary here. There is no comparative overview of special courses for further education, which are mostly temporarily offered and can sometimes be very cost-intensive. Educational paths as well as professional lives are currently in a state of flux. A shortage in BME skills is predicted and is already noticeable. Nationwide measures for sustainable education and support of skilled professionals are necessary: starting in kindergarten and school (including childcare and teacher education) to serious university or college education and specific further education according to professional minimum standards. Modern digital forms of e-learning/blended learning and also training and simulation supplement (meanwhile often compulsory) conventional face-to-face courses.

Digital knowledge base of biomedical engineering: Advanced knowledge that is continuously emerging from the highly innovative environment of medical engineering must be integrated faster into the different educational programs. Cooperation und coordination between universities in the different German states and the EU should also be further supported without flattening the contents of the study courses. The high demand for modern teaching and learning concepts combining e-learning and face-to-face teaching (blended learning) should be met more quickly. To ensure high quality, this must be done in a coordinated manner.

The need for lifelong learning on the job must also be supported by appropriate training offers. There is also a high demand for further education offers that better meet the requirements of the user and of the employers.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

The DGMBT recommends that existing and advanced knowledge in biomedical engineering be systematically standardized in a cross-national electronic interactive academic teaching and learning platform for education and training to promote widespread dissemination of and general interest in STEM (Science, Technology, Engineering, and Mathematics) professions and study programs.

Such a comprehensive and systematically built knowledge base with a structured and exam-relevant range of interactive e-learning modules must be developed and made available for disciplinary application and interprofessional use. Development, operation and maintenance of such a platform under an open-source license must be done in cooperation with the experts and user of these medical and health technologies.

The DGBMT as an independent organization therefore provides knowledge and resources through the technical committee "Education and Training – Biomedical Engineering in Study Programs" and has been coordinating such cooperation between the approximately 400 university teachers in the widespread field of biomedical engineering in German-speaking countries for many years. Unfortunately, these very important coordination tasks have failed so far due to insufficient financing of these educational activities.

Medical engineering in medical studies: The aim of a curriculum to be further developed is to close the gap in the teaching of modern medical technology in medical studies. The courses shall comprise several modules including the essential fields of medical engineering and their application in diagnostics, therapy and rehabilitation. Practicable suggestions have already been made for the medical curriculum (see the "Nationaler kompetenzbasierter Lernzielkatalog der Biomedizintechnik für die Studierenden der Medizin") but have not yet been efficiently integrated into the syllabus ([Biomedizinische Technik – NKLM] https://shop.vde.com/de/nationaler-kompetenzbasierter-lernzielkatalog-der-biomedizintechnik-f%C3%BCr-die-studierenden-der-medizin-bmt-nklm).

New professional fields: Medical non-physician professionals must also have medical, digital and technical skills, which must be improved with regard to acquiring higher qualifications and professional degrees and the freedom to choose concerning professional careers. These new professional fields must be supported and settled. To ensure sustainable expert activities, nationwide standardized examinations for publicly appointed, sworn experts in medical engineering must be developed.

Preservation of sovereignty by avoiding loss of knowhow and "brain drain": Excellent educational institutions and highly innovative companies ensure the establishment of advanced technologies and innovative products made in Germany on the international market. Here it becomes immediately apparent that a sufficient number of qualified specialists in every field of education who have intellectual control of these essential technologies is needed. It is very important that our first priority in Germany and Europe is to optimally support and perfectly

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

train our own young professionals. This means creating the necessary framework conditions and focusing on the attractiveness of such study courses and advertising.

5.3 Technology, technicization and its ethical relevance

For a long time, technicization has been raising the question of whether the people who design and use technology should and are allowed to realize anything they are technically able to. This genuine ethical question can neither be answered by referring to the human as a deficient being and the compulsion to compensate for his insufficient nature by technology, nor is there a technological constraint that everything that is technically possible must be done. Ethical judgements with regard to the development and use of technology are relative on the one hand, i.e. related to a certain technology in a specific socio-technical arrangement. Furthermore, they are relative to a particular societal position and the moral attitudes associated with it. Ethical judgement, on the other hand, are principled, i.e. they demand a fundamental orientation towards the morally good for the people affected by the decisions, for other living beings and environments. The ethical challenge is to relate these two perspectives (relative and principled) with each other with a reasonable effort in a reasonable amount of time, and to obtain a morally responsible assessment and implementation. Consequently, technological sovereignty also consists in integrating the ethical perspective into political, technological and entrepreneurial considerations in such a way that, throughout the entire process of the value chain and the patient pathway, the orientation towards the morally good becomes the guiding principle for action for all those involved (people) and affected (humans, other living beings, the environment).

Ethical normative questions are based on the question: “What shall we and what may we do?” They refer to specific technical artifacts in specific application scenarios. This is not about the ethical evaluation of technology as such, but about its notable or expected or avoidable effects. To think about these questions finally means deciding who and how an individual can live in society and lead his or her own life.

At the same time, it also determines how people can live together in society in their diversity. These are anything but trivial questions. When taking a closer look, it becomes apparent that existing ethical concepts will have to be revised in part as a result of biotechnological innovations. For example, with the development of artificial intelligence and autonomous robotics, the emphatic concept of targeted action will no longer be located solely with humans in the future. Something similar applies to the concept of rational decision-making, which is now beginning to be applied to AI systems as well. However, if action and decision-making are no longer attributed to humans alone, this will have far-reaching consequences for ethics itself, which until now has been based more or less exclusively on humans as rational decision-makers and agents, and will urgently require public discussion.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

For artificial intelligence [31], [32] and neurotechnology, guidelines for application [33] and governance [34] are currently being developed internationally. Some ethical concepts must be partly revised because of technological innovations. If targeted action and decision-making are no longer to be attributed to humans alone, but also to AI systems, this must be discussed intensively from an ethical point of view.

On a specific level of application, the ethical questions can be systematically arranged into the following areas, always taking into account the complex interactions:

- Changes in human self-conception (key words here are, for example: datafication, digital twin, surveillance, privacy)
- Changes in the human body (enhancement or therapy, implants, prostheses)
- Man-machine interaction (master/slave relationship, assistance, responsibility, moral actor, loss of competence).

Digitization and digitalization leads to changes in human self-perception: A person's vital parameters and data about his/her mobility, consumption or social behaviour can provide important information for prevention, diagnostics, therapy or rehabilitation of this person. In this respect, maximum data collection seems desirable. At the same time, this data is considered extremely private and sensitive, which is why data protection here stipulates spare and occasion-related collection of data. Ethically, a distinction must be made between individual and societal benefits and harms, which must be balanced against each other. Thus, for an individual person, it may seem quite useful and unproblematic to give up privacy and liberties in favour of permanent medical surveillance and thus security, whereas from a societal perspective ("How do we want to live?") this consideration may turn out quite differently. At this point, clear ethical and legal clarification is required which can then be implemented in regulations. Such clarification must be based on specific socio-technical arrangements and may not be made abstractly. At the same time, regulations must have a certain degree of generality in order to be socially effective. This dual requirement demands a careful and revocable determination. In order to make both technological sovereignty and the necessary ethical aspects tangible and practicable for the benefit of the users, appropriate structures and procedures are needed for this purpose (evaluation procedures, expanded R&D perspectives, expansion of education, training and continuing education to include social science and humanities perspectives: e.g. ethics included in engineering courses, extracurricular studies).

Technology has come to a point where it can conceive of the human body itself as a material and permanently alter the human being's physical disposition. For some people, human enhancement may seem to be an obligatory step to make the human capable of surviving under new conditions. To others, this step appears to

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

be a violation of humanity. The difficulty in this area is that even minor changes are seen as delinquent and therefore as morally reprehensible.

This makes it necessary to precisely analyse changes to the human body between therapy and enhancement and always to question when and where a grey area is entered with these changes. Since there is no defined essence of human being, it is in principle difficult to establish hard criteria according to which certain forms of enhancement are morally permitted or even required and others are definitely forbidden. Therefore, an ethical reflection of such changes must always be negotiated in a broad ethical discourse.

In the interaction with machines, humans have so far been regarded solely as acting subjects who set goals and seek and use the appropriate means to achieve them. For these self-set (free) actions, humans are attributed responsibility accordingly, which classifies them as 'moral subjects'. To the extent that machines must make 'autonomous' decisions and not only perform actions autonomously, but also combine ends and means, the question of the 'agency' of machines becomes ethically as well as legally relevant. Ethically, not only the status of machines is relevant, but also how their part in the human-machine interaction is valued. Would 'shared responsibility' correspond to 'shared decision making' and how could it be realized? In an unresolvable and indistinguishable combination of human and machine decision-making and action, who is sovereign, who is liable? However, AI at its current stage of development does not lead to entirely new aspects of responsibility. All that is needed is the adaption of testing standards to medical systems that incorporate AI. However, it is a fundamental ethical question how we humans will decide here in the future. This will determine which machines we design and which capabilities we grant them.

Ethics as an important accompanying science

The entire value chain process from research to application shall comply with ethical principles. Different domain ethics can be distinguished along this chain: Research, technical, economic and business ethics, ethics of medicine and nursing care. Despite the importance of these specialized perspectives, it may not be ignored that the ethical questions as such are general questions which can be differentiated in terms of domain ethics, but which shall not lead to a diffusion of responsibility through such a form of 'division of labor'.

Therefore, it is all about a form of "integrated research" in which ethics is an indispensable perspective alongside others and should accompany all processes in a reflexive and realistic manner. Its task is to continuously address the cardinal questions ("What does it mean to be able to live your own life as a human being?" and "How can many different people live well together in just institutions?") throughout the process and tie them back to the respective design decisions, communication and marketing strategies, and usage scenarios, thus pragmatically supporting the actors in their moral judgment to become aware of their responsibility.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

6 Recommendations for politics – Position of the VDE DGBMT & EUREL

Technological sovereignty in or for biomedical engineering is the basis for ensuring optimal healthcare and maintaining and further developing biomedical technology as an economic factor now and in the future. A SWOT diagram (see Table 6.1) provides an overview for assessing the situation of biomedical engineering in Germany and Europe.

STRENGTHS	WEAKNESSES
• well-trained professionals, researchers and engineers • good industrial and transport infrastructure • high level of care for patients • to date, a highly innovative industry that is one of the international market leaders • excellent framework conditions for export • exceptionally high quality in production and manufacture	• pharmaceutical and chip manufacturing are migrating to non-European states • lacking digitization and digitalization and networking in all fields of healthcare • applied research funding only in niches, gap between basic research and product development too large, aspects of clinical-translational research underexposed • promotion of studies relevant for market access processes only possible to a very limited extent • time- and cost-intensive approval procedures for SMEs, with negative consequences • motivation for innovations has decreased significantly in the past years [35] • the overall quality of education has declined at an alarming rate in recent years, partly as a result of inadequate scientific and technical education up to the Abitur level, a lack of motivation and the lacking ability to work under pressure.
OPPORTUNITIES	**THREATS**
• high innovative performance • interest and motivation of young people for biological and "green" issues • flexible SMEs with high quality demands • increasing significance of BME to face global challenges in healthcare • the lack of human and financial resources in healthcare can be addressed through innovative BME • the age pyramid with an increase in chronical diseases raises the demand for smart biomedical solutions	• very high approval barriers for innovative technology • lack of teaching the basics in medical and care education for the technical understanding of BME • bureaucratic barriers, overregulation • too little acceptance of digitalization • complicated market access procedures for high-quality products • in the context of reimbursement, pure focus on costs while ignoring the sustainable quality aspects of BME products • overly slow decision-making process when negotiating with health insurance institutions • takeover of innovation and market leadership in BME by the large (primarily US) digital enterprises • meanwhile, other countries such as the USA offer better requirements for the approval of medical devices

Table 6.1 SWOT analysis of the Germany location with respect to biomedical engineering

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

In order to maintain a leading position with regard to research, development and production and to achieve digital competence, the identified weaknesses need to be eliminated and the risks to be mitigated, requiring the following measures, as specified:

Recommendations

- Participation in the development of value chains for the safe exchange of goods, which will also be operable in crisis situations and will assure the local and EU-wide provision of sensitive technologies.
- Further development of the MDR to ensure processes for market access in terms of improved patient safety through innovations in a timely manner and to be able to compete on the international level.
- Strengthening SMEs through special support programs also to overcome MDR-related obstacles, as they are often the "hidden champions".
- Facilitating and accelerating access to reimbursement for innovations that add value to patients or enable more efficient healthcare processes.
- Supporting and establishing comprehensive digital services along the entire patient pathway ("patient-centric digitalization") and within the entire healthcare system. Securing the required key technologies and establishing efficient regulatory processes.
- Elaborating new concepts in order to obtain sustainable expertise in the overall biomedical engineering sector based on substantial training of professionals. Establishing a comprehensive interdisciplinary digital open-access knowledge platform and modern training opportunities for lifelong learning in all medical disciplines.

Securing sovereign production of biomedical technology

- Ensuring sovereign national production of biomedical key technologies in basic care and of capital-intensive technologies in the European framework, because only multinational efforts will lead to success.
- Developing and safeguarding of production and product management of IP and quality critical components locally and across Germany to be prepared for crisis situations.
- Further developing the diversification of supply chains (from "second source" to "fourth source") also on the international level to make supply chains more redundant.
- Developing smart, flexible and dynamic warehouse solutions, e.g. through predictive and dynamic AI-supported stock-keeping, in order to optimize pricing and device availability (efficiency vs. safety/resilience).

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

Technological support policy requirements

- Patient-centric digitalization: Across the patient pathway, integral networking and digitization and digitalization in all medical fields must be established in a timely manner through relevant investments and increased subsidies for future technologies such as AI-based medical research activities.
- Bridging the gap between "old" and "new" economy: Identification and support of hidden champions to maintain and further develop all essential key technologies.
- Political support for cross-national digital healthcare approaches.
- New concepts for the support of translation and transfer across the value chain through regional, integrated incubator, accelerator and translational centers accompanied by PPP-based or bank financing models.
- Establishment of support models for company foundations in biomedical engineering, with training and mentoring of startup companies including risk assessment and exit strategies.
- Special support programs for SMEs providing support with the implementation of the MDR.

Knowledge management

- Establishment of patient sovereignty by strengthening biomedical and technical knowledge and digital skills and competencies ("literacy"). Therefore, it is necessary to know, to understand and be able to classify biomedical technology. This also promotes the acceptance concerning ethical issues among society.
- Financing, establishing and sustainably ensuring a suitable cross-national open-access data exchange platform as a knowledge base in biomedical engineering with appropriate data availability, system compatibility and portability in compliance with cybersecurity measures.
- Securing sustainable interdisciplinary education and training for the required biomedical professionals to ensure attractiveness for both national and international young professionals. Education and training must comply with high professional and methodological quality standards. Digital offers must be expanded but shall not replace necessary practical learning and practicing sessions neither in the field of engineering nor in the medical field, but shall complement them in a didactical way.
- Launch new training profiles in traditional medical professions that provide technical expertise to confidently handle the interdisciplinary connection of all measures along the patient pathway.
- Improve the inter-sectoral training in and between the sectors of biomedical engineering in order to also have an impact on medical and care professions.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

Healthcare and regulatory recommendations

- At the European level, an immediate revision and further development of the MDR must urgently take place, which adequately takes into account the necessary safety aspects and at the same time ensures the competitiveness of the European medical and health technology industry.
- Faster reimbursement procedures following efficient BME-adapted evidence-generating benefit assessments and bold testing of new procedures for reimbursement approval.
- Greater and early involvement of biomedical engineering experts and societies in policy decisions affecting biomedical engineering (GBA (Federal Joint Committee (Germany)), ministries) to incorporate technical expertise. These measures and procedures have the potential to enhance efficiency and optimize the resources used.
- better coordinated health, economic and research policies: establish a powerful strategic process in biomedical engineering with technical competencies, building on successful initiatives in the past. Support coordination between the ministries BMG, BMBF and BMWi in order to implement decisions effectively and sustainably. Biomedical engineering calls on the European funding level that focus on hardware and systems aspects as well as on first-in-human.studies.
- Formation and continuation of a roundtable and task forces of academic institutions, industry, medicine, and policy makers which work interministerially to address the challenges in technological sovereignty of all medical and related technological and educational issues.
- Processes for market access shall ensure safety and innovation. SMEs must be supported and promoted in terms of market access, innovative developments and competitiveness under rising pricing pressure.
- Creation of European database and cloud solutions and establishment of cybersecurity in healthcare which is adapted to the needs for ubiquitous and safe data availability.
- Shortening and simplification of market access and evaluation processes by involving biomedical engineering expertise.
    - technological consulting and benefit assessment when applying for NUBs (new and innovative diagnosis and treatment methods) to improve the level of reimbursement for the use of innovative medical technology.
    - when negotiating with health insurance institutions in order to provide advisory support for possibilities of accelerated and simplified reimbursement from the biomedical engineering side.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

- to enable the approval of medical devices across the EU to be competitive and powerful with regard to the FDA, e.g. through fast-track procedures for digital medical applications and procedures for small patient groups and rare diseases.

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org

7 Bibliography

1. Wissenschaftliche Dienste: Verfassung und Verwaltung, „Grundgesetzlicher Anspruch auf gesundheitliche Versorgung," 2015. [Online]. Available: https://www.bundestag.de/resource/blob/405508/4dd5bf6452b5b3b824d8de6efdad39dd/wd-3-089-15-pdf-data.pdf. [Accessed: 22-Jul-2021].
2. Bundesministeriums für Wirtschaft und Energie, „Werkstatt Digitalisierung in der Gesundheitswirtschaft," 2017. [Online]. Available: https://www.bmwi.de/Redaktion/DE/Publikationen/Wirtschaft/gesundheitswirtschaft-fakten-zahlen-2017.html. [Accessed: 22-Jul-2021].
3. Bundesverband Medizintechnologie – BVMed, „Branchenbericht Medizintechnologien 2020," 2020. [Online]. Available: https://www.bvmed.de/download/bvmed-branchenbericht-medtech.pdf. [Accessed: 22-Jul-2021].
4. Spectaris, „Die deutsche Medizintechnik-Industrie: SPECTARIS Jahrbuch 2018," 2018. [Online]. Available: https://www.spectaris.de/fileadmin/Infothek/Medizintechnik/Zahlen-Faktenund-Publikationen/SPECTARIS_Jahrbuch_2018_Final.pdf . [Accessed: 22-Jul-2021].
5. U. Marx, „Die Stunde der Ingenieure," Frankfurter Allgemeine Zeitung, 2020. [Online]. Available: https://www.faz.net/aktuell/karriere-hochschule/buero-co/corona-krise-was-geradein-der-medizintechnik-passiert-16730178.html. [Accessed: 22-Jul-2021].
6. Europäisches Patentamt, „Patentanmeldungen." [Online]. Available: https://www.epo.org/about-us/annual-reports-statistics/statistics_de.html. [Accessed: 22-Jul-2021].
7. C. Güthlin, S. Köhler, and M. Dieckelmann, „Chronisch krank sein in Deutschland. Zahlen, Fakten und Versorgungserfahrungen," 2020. [Online]. Available: http://publikationen.ub.uni-frankfurt.de/frontdoor/index/index/docId/55045/. [Accessed: 22-Jul-2021].
8. statista, „Prognostizierter Bedarf an stationären und ambulanten Pflegekräften* in Deutschland bis zum Jahr 2035," 2020. [Online]. Available: https://de.statista.com/statistik/daten/studie/172651/umfrage/bedarf-an-pflegekraeften-2025/. [Accessed: 22-Jul-2021].
9. P. G. Shekelle, „Nurse-patient ratios as a patient safety strategy: a systematic review.," Ann. Intern. Med., vol. 158, no. 5 Pt 2, pp. 404–9, Mar. 2013.
10. M. Cacace, „Krankenhausstrukturen und Steuerung der Kapazitäten in der Corona-Pandemie," Bertelsmann Stiftung, 2021. [Online]. Available: https://www.bertelsmann-stiftung.de/de/publikationen/publikation/did/krankenhausstrukturen-und-steuerung-der-kapazitaeten-in-dercorona-pandemie. [Accessed: 22-Jul-2021].
11. Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen, „Digitalisierung für Gesundheit - Ziele und Rahmenbedingungen eines dynamisch lernenden Gesundheitssystems," 2021. [Online]. Available: https://www.svr-gesundheit.de/fileadmin/Gutachten/Gutachten_2021/SVR_Gutachten_2021.pdf. [Accessed: 22-Jul-2021].
12. Bundesministerium für Wirtschaft und Energie, „Monitoring-Report Wirtschaft DIGITAL 2018 – Wirtschaftsindex DIGITAL," 2018. [Online]. Available: https://www.bmwi.de/Redaktion/DE/Publikationen/Digitale-Welt/monitoring-report-wirtschaft-digital-2018-kurzfassung.html. [Accessed: 22-Jul-2021].
13. M. Leonhard and K. Djamshidi, „MedTech: Wie Innovationen durch die Kosten des Scheiterns asymmetrisch aus Europa abgedrängt werden," Gesundheitsökonomie Qual., Jun. 2021.
14. K. Illgner, et al. „Technologische Souveränität: Vorschlag einer Methodik und Handlungsempfehlungen," VDE Positionspapier, 2020. [Online]. Available: https://shop.vde.com/de/positionspapier-technologische-souveraenitaet. [Accessed: 22-Jul-2021]. English Version: "Technological Sovereignty: Methodology and Recommendations". Available: https://www.vde.com/de/itg/publikationen/studien/vde-position-paper-technological-sovereignty

15. N. Maglaveras, V. Kilintzis, V. Koutkias, and I. Chouvarda, „Integrated care and connected health approaches leveraging personalised health through big data analytics.," Stud. Health Technol. Inform., vol. 224, pp. 117–22, 2016.
16. Becker K. (2019) Intelligentes Diagnose- und Therapiemanagementkonzept mit einem digitalen Avatar durch Integration von Vitalparametern und genomischen Daten am Beispiel des Diabetes mellitus. In: Pfannstiel M., Da-Cruz P., Mehlich H. (eds) Digitale Transformation von Dienstleistungen im Gesundheitswesen VI. Springer Gabler, Wiesbaden. https://doi.org/10.1007
17. A. Melzer, M. O. Schurr, W. Kunert, G. Buess, U. Voges, and J. U. Meyer, „Intelligent surgical instrument system ISIS. Concept and preliminary experimental application of components and prototypes.," Endosc. Surg. Allied Technol., vol. 1, no. 3, pp. 165–70, Jun. 1993.
18. Bundesverband Medizintechnologie – BVMed, „MedTech-Weltmarkt bei rund 400 Milliarden US-Dollar," 2020. [Online]. Available: https://www.bvmed.de/de/branche/aussenwirtschaft/weltmarkt. [Accessed: 22-Jul-2021].
19. K.-H. Streibich and T. Lenarz, „Resilienz und Leistungsfähigkeit des Gesundheitswesens in Krisenzeiten," acatech, 2021. [Online]. Available: https://www.acatech.de/publikation/resilienz-und-leistungsfaehigkeit-des-gesundheitswesens-in-krisenzeiten/. [Accessed: 22-Jul-2021].
20. European Commission, „COMMISSION STAFF WORKING DOCUMENT Strategic dependencies and capacities Accompanying the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Updating the 20," 2021. [Online]. Available: https://op.europa.eu/de/publication-detail/-/publication/8f76a6dd-ae95-11eb-9767-01aa75ed71a1/language-de. [Accessed: 22-Jul-2021].
21. „Global Data," 2019. [Online]. Available: https://www.globaldata.com/. [Accessed: 22-Jul-2021].
22. J.-P. Kleinhans, „The lack of semiconductor manufacturing in Europe." [Online]. Available: https://www.stiftung-nv.de/de/publikation/lack-semiconductor-manufacturing-europe. [Accessed: 22-Jul-2021].
23. „ForLab." [Online]. Available: https://www.forlab.tech/ . [Accessed: 22-Jul-2021].
24. „FMD Mikroelektronik." [Online]. Available: https://www.forschungsfabrik-mikroelektronik.de/. [Accessed: 22-Jul-2021].
25. Sachverständigenrat 3/21, Digitalisierung im Dienste der Gesundheit, Besseren Schutz von Leben und Gesundheit mit höherer Datensicherheit vereinbaren
26. „Weltzentrum der Medizintechnik." [Online]. Available: https://www.weltzentrum-der-medizintechnik.de/start. [Accessed: 22-Jul-2021].
27. „Blue Hospital – Nachhaltigkeit im Krankenhaus," VDE Positionspapier, 2011. [Online]. Available: https://shop.vde.com/de/vde-positionspapier-blue-hospital-nachhaltigkeit-im-krankenhaus-3.
28. UniTransferKlinik GmbH, „Sustainability - Green/Blue Hospital." [Online]. Available: https://www.if-krankenhaus.de/fokusthemen/facility-management-4-0/sustainabilitygreen-blue-hospital.html.
29. VDI-Fachbereich Medizintechnik, VDI 5701 – Biomaterials in medicine – Classification, requirements, and applications. 2018.
30. TU Braunschweig, „PVZ - Zentrum für Pharmaverfahrenstechnik." [Online]. Available: https://www.tu-braunschweig.de/pvz. [Accessed: 22-Jul-2021].
31. A. Carl and D. Hochmann, „MDR – Wie gut vorbereitet ist die Hilfsmittelbranche?," mt Medizintechnik, vol. 2, pp. 34–39, 2021.
32. Jessica Heesen et al. (Hrsg.), „Ethik-Briefing. Leitfaden für eine verantwortungsvolle Entwicklung und Anwendung von KI-Systemen – Whitepaper aus der Plattform Lernende Systeme, München 2020," München, 2020. [Online]. Available: https://www.acatech.de/publikation/ethik-briefing-leitfaden-fuer-eine-verantwortungsvolle-entwicklung-und-anwendung-von- kuenstlicher-intelligenz/.

33. High-Level Expert Group on AI, „Ethics guidelines for trustworthy AI," 2019. [Online]. Available: https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai. [Accessed: 22-Jul-2021].
34. IEEE, „IEEE Neuroethics Framework," 2020. [Online]. Available: http://brain.ieee.org/wp-content/uploads/sites/52/2020/03/ieee_brain_neuroethics_framework_double-sided-031920.pdf. [Accessed: 22-Jul-2021].
35. H. Garden and D. Winickoff, „Issues in neurotechnology governance," Paris, 2018.
36. BVMed-Innovationsklima-Index. [Online]. Available: https://www.bvmed.de/de/bvmed/publikationen/bvmed-newsletter/bvmed-newsletter-43-19/bvmed-newsletter-43-19.pdf/innovationsklima-2019

Photo credits:

Page 19: Herzschlag-Icon_106382612.jpeg: martialred/stock.adobe.com, dna-strang-medtech-10860196.jpg: vege/Fotolia, Molekuelstruktur-des-Proteasoms_169135237.jpeg: raimund14/stock.adobe.com, Mann-misst-Blutzuckerspiegel_302447896.jpeg: nito/stock.adobe.com, Kreis-aus-Haenden_130999164.jpeg: bevisphoto/stock.adobe.com, Smartphone-als-Messgeraet_198870620.jpeg copyright: scharfsinn86/stock.adobe.com, pp. 7/8/12/29/40/44: VDE e.V., Fig. 1.1 Sebastian Zaunseder, Fachhochschule Dortmund, Fig. 2.1, Fig. 3.1 Gerald Urban, Institut für Mikrosystemtechnik – IMTEK, Fig. 2.1, Fig. 2.3, Fig. 3.1 Thomas Stieglitz, Institut für Mikrosystemtechnik - IMTEK / BrainLinks-BrainTools, Fig. 2.3., Fig. 4.1 Kurt Becker, APOLLON Hochschule der Gesundheitswirtschaft, Bremen, Fig. 1.2, 1.3, 1.4, 3.2: VDE e.V..

Square de Meeûs 35 - 1050 Brussels - BELGIUM
eurel@eurel.org – www.eurel.org