Actively helping to shape the digital transformation in the health care system.

Five recommendations
by the vfa for an innovation-friendly
enabling policy

vfa. Die forschenden Pharma-Unternehmen
Research-Based Pharmaceutical Companies

Five recommendations by the vfa for involving stakeholders in a digital action strategy:

1
Put patient benefit center stage when it comes to digital innovations and uniformly implement the electronic health record in a timely manner.

2
Actively use the opportunities provided by the intelligent linking of health and research data and by collaborations.

3
Integrate the digital assistance and database system without restricting physicians' therapeutic freedom and without controlling health care in a unilateral fashion.

4
Further strengthen and expand personalized medicine as a health care opportunity.

5
Develop a national eHealth strategy across stakeholders to optimize health care and apply innovations and to ensure balanced governance.

How deep is the change in the health care system caused by the digital transformation?

The digital transformation of the health care system is already a reality and an international race for innovation.

Digitization is not just technological progress but also a fundamental cultural, societal, and economic change that is already under way. This also means that collaboration and communication between stakeholders is becoming more decentralized, more interlinked, and more direct—and that new partnerships and health care networks are being created based on new digital technologies. As a result, digitization is realigning competition in the health care system. This is particularly true for all stakeholders involved in patient care, such as physicians, clinics, pharmacists, health insurance funds, and the research-based pharmaceutical companies.

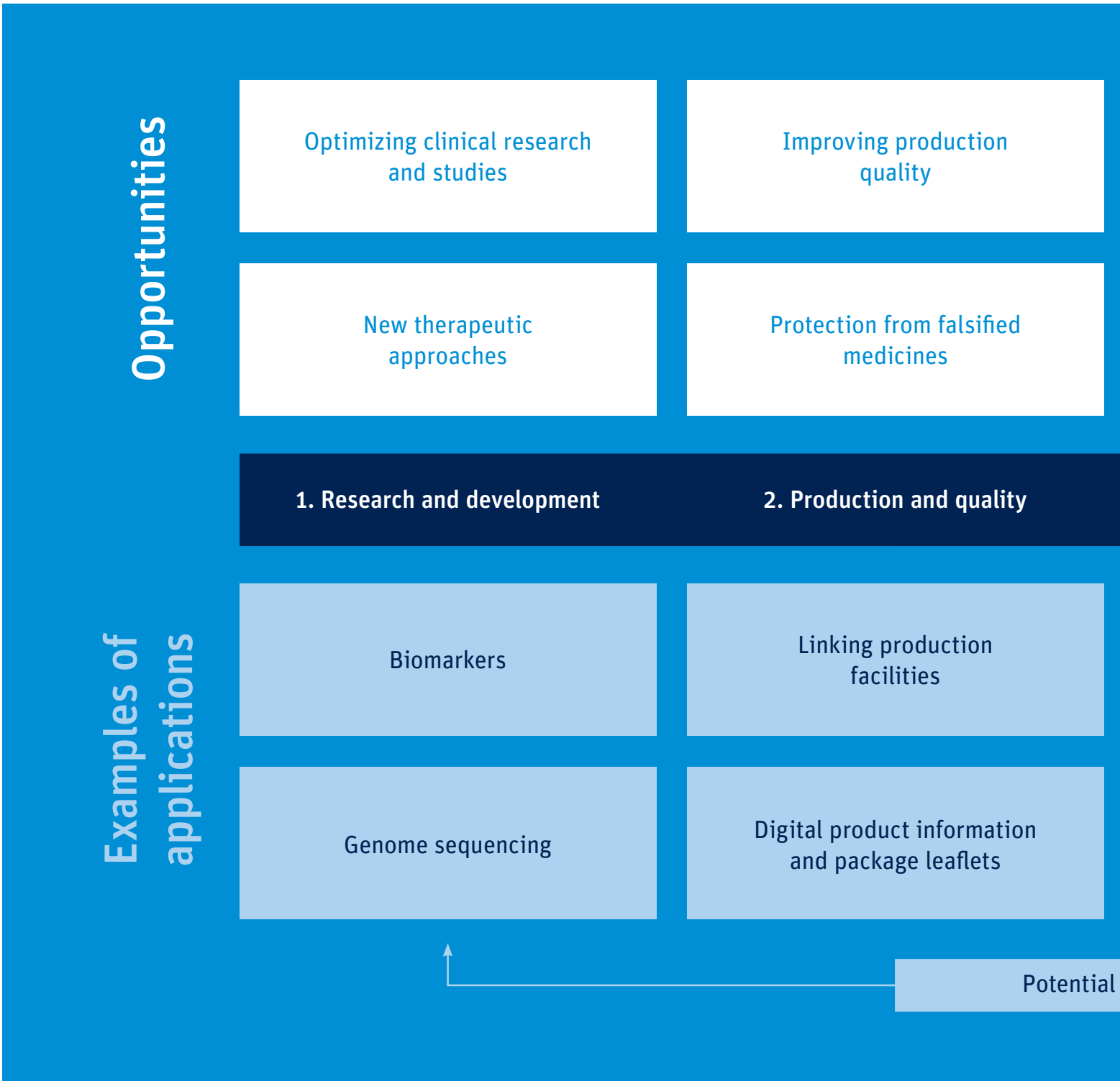
New stakeholders with new digital offerings are complementing traditional health and health care providers and their services. The boundaries between the different service areas are becoming more blurred. Patient care is beginning to change based on new digital technologies. For example, certified medical apps or telemedical consultations are supporting patient mobility and patient engagement. Overall, flexible, decentralized health care forms are increasingly moving into the focus. Digital analysis instruments and big data applications are making IT-based decision support systems possible. They can prepare information about complex, serious diseases from various medical databases for the physician and derive supplementary therapy information. They are providing new solutions for consultations, health care in rural areas, and for decentralized offerings of maximum treatment and care.

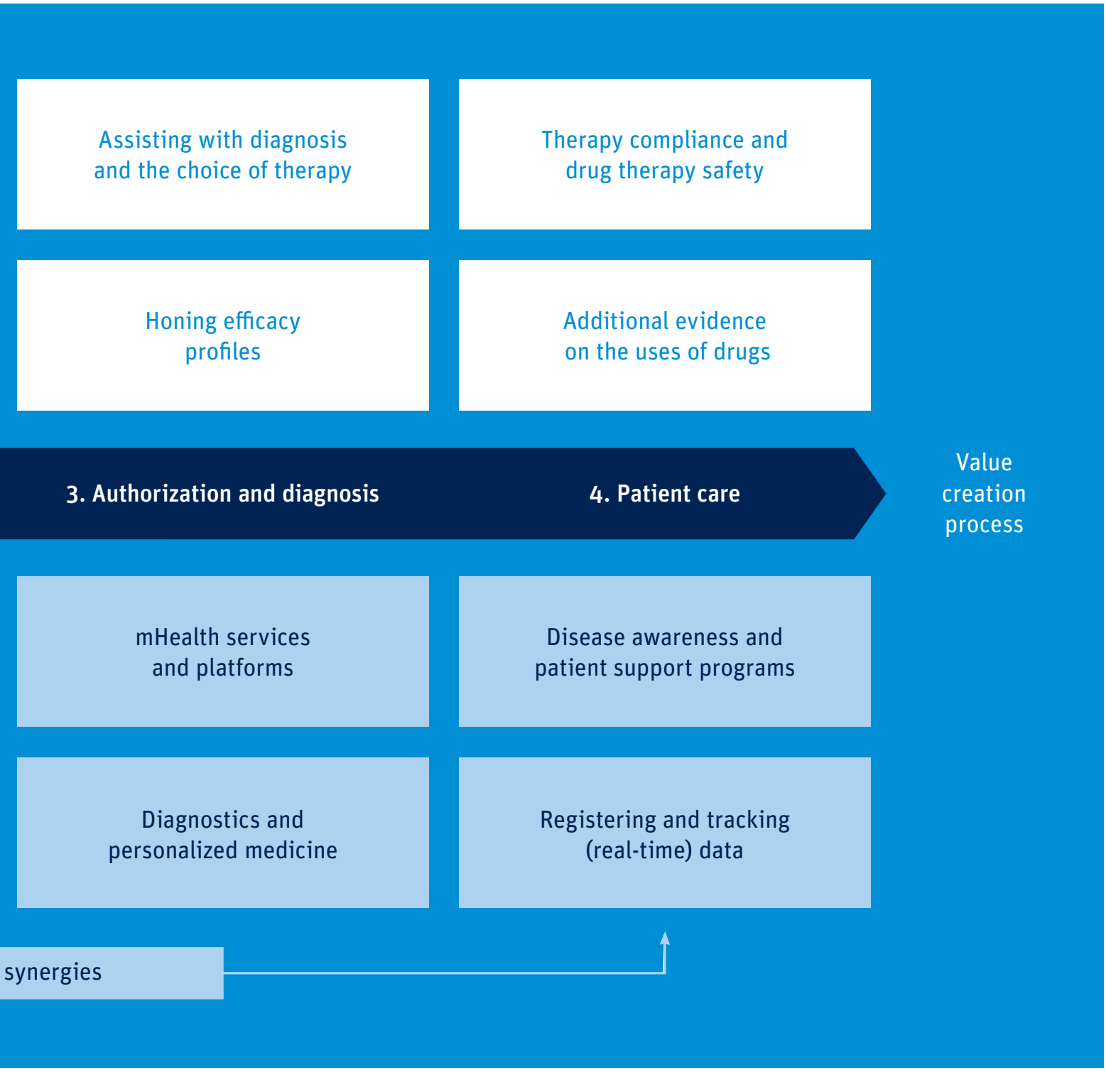
These developments can be seen globally in many health care systems and are frequently more advanced than in Germany (e.g. Denmark, Netherlands, or Switzerland). In the international race for innovation and in order to develop digital solutions, the German health care industry depends on a strong location with a reliable framework that is open to innovation in the health care system.

The German health care system is working on digital transformation and requires more acceptance of innovation.

In order to successfully integrate this digital transformation into the structures of the German health care system, increasing acceptance of innovation will be required from all stakeholders. This is because, based on the outlined development, the role models and self-image of all participants in the health care system are also changing or at least being called into question. The key to success remains participants' acceptance and openness to collaborations, the accessibility of the health care system for innovations, and the targeted use of digital technologies. For successful use to be made of innovations, the public health care system and the industrial health care sector need to work together.

Opportunities and applications from research to patient care




Assisting with diagnosis and the choice of therapy
Therapy compliance and drug therapy safety
Honing efficacy profiles
Additional evidence on the uses of drugs
3. Authorization and diagnosis
4. Patient care
Value creation process
mHealth services and platforms
Disease awareness and patient support programs
Diagnostics and personalized medicine
Registering and tracking (real-time) data
synergies

What does digitization mean for the research-based pharmaceutical companies?

Digital technologies are already integrated into the key activity fields of the research-based pharmaceutical companies.

The research-based pharmaceutical companies are faced with the challenge of further developing their "core service"—the research and development of new and improved pharmaceuticals and therapy approaches—and aligning it with the new technological possibilities and the changing needs of patients in their everyday lives. In this respect, accurate, individual treatment packages of diagnosis, personalized medicine, and supplementary digital support offerings will determine the future of medical care.

Digital technologies and applications can already be found at all stages of the pharmaceutical value chain: from research and development to production, market access, and health care. Examples:

Research and development
Optimization of clinical research and studies through big data applications

The decoding of the genome (genome sequencing) and the use of diagnostic tests (biomarker identification) through big data applications facilitate advances in research, e.g. by potentially improving clinical trials and leading to new therapeutic approaches. In this respect, large data quantities, which are processed and evaluated with the help of big data technologies, play a key role. Successful genome sequencing has already significantly strengthened the importance of genomics in medicine. The next step now goes toward proteomics in order to better understand the individual protein constellation and the associated metabolic processes, e.g. during cancer treatment.

Production and quality assurance
Optimization of pharmaceutical safety through digital linking

During the production of pharmaceuticals, digital monitoring and the intelligent linking of production units safeguard and optimize the quality of results. Another step in improving the safety of pharmaceuticals in health care is the development of digital product and package leaflets. Examples in this respect are the pilot projects "Package Leaflet 4.0" and "securPharm" under the leadership of the vfa. Throughout the entire supply chain and during application, they pursue the goal of further increasing the safety of prescription drugs through targeted electronic package leaflets and summaries of product characteristics and protecting patients from falsified medicines in the legal supply chain by making individual packages completely traceable.

Market access and diagnosis
Optimization of health care quality based on personalized medicine

The combination of modern diagnostics and innovative pharmaceuticals facilitates personalized medicine that further hones the efficacy profiles of pharmaceuticals and provides patients with the best possible therapy tailor to their illness. A special research effort is required in order to identify and validate the appropriate biomarkers for personalized medicine. Biobanks link patient data from clinical trials with genetic data (sequencing data). The goal is the development of new biomarkers to help patients obtain a suitable therapy more quickly.

In view of this increasing complexity in every medical setting, supplementary digital offerings can provide additional information, e.g. for the treating physician. This requires quality-assured, efficient digital platforms for medical data. For example, these can help with finding a suitable clinical trial for patients with serious diseases and no available therapy options. In addition, these new instruments will support physicians in the usage and control of personalized therapy approaches through the fast and reliable reconciliation of patient profiles with their genetic data and the existing medications and therapy options.

Health care
Improvement of therapy compliance and evidence based on data usage and digital offerings

The collection (tracking and registering) and evaluation of (real-time) data from everyday health care can create additional evidence regarding the benefit of pharmaceuticals. Digital offerings actively support patients in increasing their therapy compliance and further improving the safety and quality of pharmaceutical therapy through medical monitoring of the treatment data, some of it in real time. Complementary digital offerings provide patients with personal education programs for their disease and with therapy information that is relevant for everyday life (disease awareness and patient support programs) or for prevention.

Examples include personalized disease management programs and targeted lifestyle coaching sessions that combine the use of apps, Web portals, and personal education programs. The vfa member companies are involved in projects, e.g. with health insurance funds as well as information and communication technology companies, so that physicians and expert medical staff can make patient treatment more individualized and more independent of locations, allowing them to integrate it better into patients' everyday lives. For example, electronic patient journals and electronic case files support physicians' services for complex challenges and existing resource problems. These telemedicine projects create added value for patients and for the quality of health care, particularly for chronic or rare diseases that require a high level of documentation and make it necessary for professionals in different health care fields to liaise with one another quickly.

Another example is the intelligent linking of pharmaceuticals and medical devices used in the care of chronic patients. These smart devices can digitally measure and record medical data and safely share it in real time with the medical personnel in charge. This allows more individual adjustments to the patients' needs and everyday lives as well as an improvement in medication control and data sharing across sectors.

What are the key recommendations of the vfa to the stakeholders involved?

1
Put patient benefit center stage when it comes to digital innovations and uniformly implement the electronic health record in a timely manner.

The key touchstone for digitization in the health care system must be patient benefit. Patient autonomy, benefit, and adherence can be increased through digital offerings and services. This helps improve health care quality and patient safety.

An effective electronic health record is essential for the practical implementation of the patient's informational right to self-determination and increasing efficiency at the interfaces in the system. This is evident from examples of other European health care systems. The regular and uniform introduction planned in Germany through the "eHealth Act" in 2019 is an important and central step toward strengthening patient centricity in the health care system. It is welcomed by the vfa member companies.

2
Actively use the opportunities provided by the intelligent linking of health and research data and by collaborations.

The smart processing of research and health data offers enormous opportunities for improving patient care and increasing efficiency in the health care system to make it more sustainable.

The health and research data collected in the health care system must also be accessible to users and providers such as the research-based pharmaceutical companies to allow them to use this information in a meaningful manner, thereby facilitating efficiency increases in health care. As a result, the health care system should comprehensively recognize and take into account the captured health data. Quality assurance must be ensured in the process. The necessary assessment criteria for quality standards must be jointly developed and defined by politicians and regulatory agencies, medical service providers and medical societies, patient organizations, cost payers and providers from the pharmaceutical industry, i.e. with balanced governance.

In light of this situation, the EU General Data Protection Regulation (EU-GDPR) of May 24, 2016, is a milestone in European data privacy law and plays a key role in the political framework-setting process for the digital transformation of various industries and for handling data as a raw material. With the EU-GDPR, regulations were also passed that provide the member states with maneuvering room to pass specific regulations. Such regulatory options are specifically provided for the processing of research and health data. The use of this maneuvering room in the EU-GDPR by the German legislature will significantly help in shaping the continuing digital transformation in the German health care system and its sustained efficiency.

The implementation of the EU-GDPR and the specific development of the regulations on the processing of research and health data in Germany must not create a special national situation compared to other EU member states. This would isolate medical research from the remaining EU states and obstruct the digital evolution of the German health care system in its initial stages.

3

Integrate the digital assistance and database system without restricting physicians' therapeutic freedom and without controlling health care in a unilateral fashion.

New methods of intelligent data analysis and the further development of big data technologies toward smart data applications with the inclusion of artificial intelligence are important components for the digital transformation of the health care system. Prominent examples of artificial intelligence include the supercomputers "Watson" by IBM or "HANA" by SAP, which in oncology, for example, show initial applications for cancer research and for the diagnosis and treatment of cancer patients.

The therapy decision by the treating physician can be supported through digital assistance systems or intelligent digital databases. However, the use of IT and artificial intelligence in the health care system must not lead to rationalization in health care and restrictions on the physicians' therapeutic freedom for non-medical reasons, because this would be a violation of the principle of equity in health care. Furthermore, patient participation must be ensured when integrating such assistance systems, so that there can be a patient-friendly evolution of health care.

4

Further strengthen and expand personalized medicine as a health care opportunity.

Almost 40% of the advanced research projects for new pharmaceuticals by the vfa member companies are already accompanied by a search for suitable biomarkers for therapy personalization. In Germany, 51 pharmaceuticals have been approved so far for personalized medicine. A constantly updated list can be found at www.vfa.de/personalisiert. The combination with supplementary services, such as supporting tools for physicians to determine and manage an appropriate therapy, increases health care quality and improves the quality of life of individual patients.

These developments and opportunities go hand in hand with new requirements regarding the use of diagnostics and personalized therapies. This raises the question of what approach should be taken to data ownership and data usage for research in order to discover new biomarkers and verify their significance, for example. Developing Germany as a hub for personalized medicine will heavily on how existing hurdles and limitations in the research of personalized medicine and cost reimbursement for biomarker diagnostics by the health insurance funds are handled.

5

Develop a national eHealth strategy across stakeholders to optimize health care and apply innovations and to ensure balanced governance.

An open dialog between all stakeholders involved in patient care and joint political and technical platforms with balanced governance are the basic prerequisites for optimizing health care. Digitization requires a cultural transformation in the health care system overall and a new openness in the collaboration between the parties involved. This must coincide with an innovation-friendly enabling policy that supports the digital transformation in the health care system with courage and farsightedness and takes into account the following items:

Strengthening the digital health care industry by creating the necessary foundation and a suitable, reliable framework for Germany (e.g. broadband expansion, evolution of the telematics infrastructure with interactive or participation options; adaptation of the legal framework in terms of the EU-GDPR and questions of data ownership and data usage).

Establishing a dialog on the digital transformation between the health care system, the information and communication (ICT) industry, and the research-based pharmaceutical companies on issues relating to the implementation of digital applications, linking, and the translation of medical research and care (e.g. on unresolved matters relating to cloud computing, integration and usage of real-time data, telemonitoring, etc.).

Political bundling of interdisciplinary activities and projects on the digital evolution of the health care system. These are frequently still fixated on the respective care areas or economic sectors. Only with neutral and balanced governance—which is moderated by politicians and considers health professionals and medical societies, users, patients, cost payers and providers in the health care system equally—can practicable and patient-centered digital solutions for existing health care problems be developed and offered. This way, the existing political commitment to digital transformation in the health care system could be strengthened in a targeted manner. The next step is the scaling of innovative eHealth applications from pilot project planning to the broad integration into regular care.

What can the research-based pharmaceutical companies do to help make the digital transformation a success and improve of patient care?

As shown, digital technologies are already an integral part of the activity fields of the research-based pharmaceutical companies. Existing processes and offerings are being further improved by digital technologies, and new offerings and services to supplement and improve individual health care quality in a targeted manner will be added. This is increasingly resulting in new therapy and health care concepts by the research-based pharmaceutical companies, who are focusing on existing hurdles in health care and working with their network partners to develop and implement corresponding solutions.

As a partner to both traditional and new stakeholders, the research-based pharmaceutical companies can further optimize patient care and are prepared to make a joint contribution to harnessing and successfully shaping the digital transformation in the German health care system. To this end, the potential, opportunities, and unresolved issues regarding on the further development of the digital transformation that affect all participants in the health care system must be jointly tackled.

The vfa and its member companies are on hand as a discussion partner and as a stakeholder to leverage the core expertise of the research-based pharmaceutical companies in order to forge ahead with new innovative ideas for the improvement of existing processes, structures, and safety in the health care system.

Digital transformation in the health care system: a broad issue which is highly complex and dynamic …

Flood of data

33 %

… of all data collected in the future is expected to be attributable to the health care system, according to BITKOM (2 terabytes per person a year).

Autonomous data

75 %

… of all patients are prepared to make their medical data accessible, according to global studies.

Unstructured data

80 %

… of all data generated worldwide is unstructured and a huge 95 % cannot be analyzed automatically (BITKOM).

Personalized medicine

Almost 40 %

… of the vfa member companies' advanced drug projects are accompanied by a search for suitable biomarkers for personalization.

… combined with high hopes and expectations

Investment shortfall

1,5 – 2,0 %

… of turnover is all health care providers in Germany set aside for their IT budget (by comparison, 3.3% is the cross-industry average), according to figures from BITKOM.

Market potential

€ 200 billion

… is Roland Berger's estimate for the global eHealth market's turnover in 2020, including turnover generated by the pharmaceutical industry

Potential savings

A 6,5 – 10,8 %

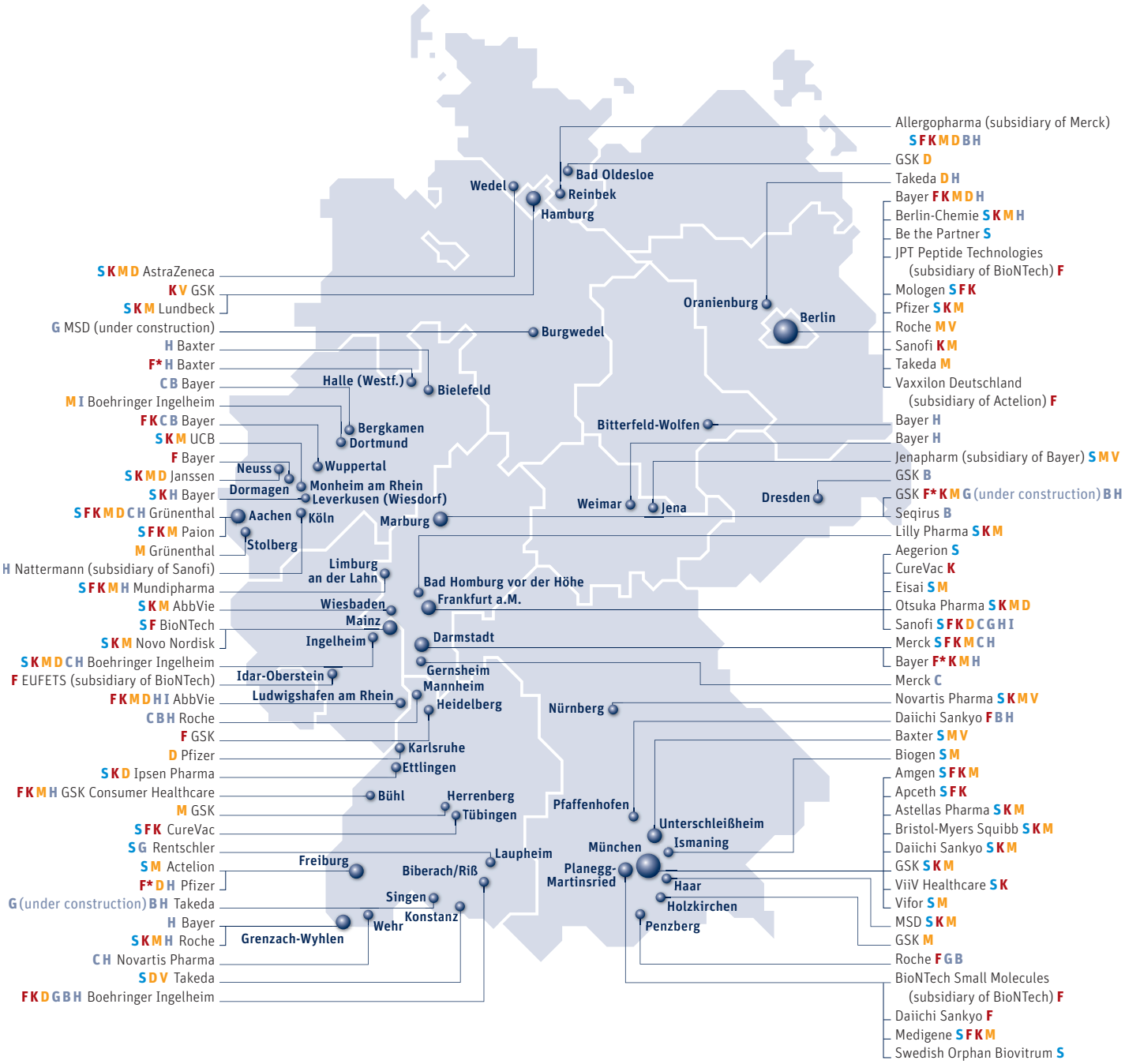
… reduction in health expenditure should be possible with digital health applications, a McKinsey study found.

Value creation

$ 600 – 800 billion

… of value should be generated by digital health as soon as 2018, according to McKinsey.

Sites of the vfa member companies and their subsidiaries in Germany



S Site address
F Research/preclinical development
F* Preclinical development
K Clinical development

M mMarketing and sales
D Distribution/logistics
V Administration

C Production of chemical drug substances
G Production of recombinant drug substances
B Production of non-recombinant biological drug substances
H Manufacturing of medicinal products
I Production of inhalers or injection devices

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