Germany started its eHealth initiative in 2010 and transformed it into an eHealth law in 2016. Its goal is to promote pilot projects to general use and create incentives to set up the necessary infrastructure for telemedicine. As the executive agency for the Federal Health Ministry, gematik has launched the online interoperability directory, called vesta (German language only), where eHealth players can register an interoperability standard. The application is free until Dec. 31, 2017. Furthermore, digitalization investments for hospitals will continue to receive support from the federal government.

Interest in, and demand for, innovative technologies is high in Germany. German healthcare players regularly travel to the United States; many doctors have studied in the U.S. or have participated in exchange programs via post docs; there is a natural affinity and many ongoing partnership and collaboration projects. Demand is high for eHealth incl. infrastructure, health apps, and security management; minimally invasive, home care/technical aids, orthopedic and implant, and diabetes management technologies as well as oncology diagnostics, molecular diagnostics, personalized medicine and patient management technology/systems.

**Best Prospects:**

- **E-health technology, products, services, in particular for chronic disease management; home care and preventive medicine. Monitoring of bodily functions via open source and standards directly into the electronic health record.**
- **Technology, products and services for next generation digital patient records; worldwide access; genetic profiles; workflow management; scientifically-supported second opinion management for physicians; computer-assisted diagnosis and therapy planning.**
- **Modelling and Simulation: for diagnostics and therapy planning, for example, of uncontrolled tumor growth (EU project CanPathPro funded with Eur 11 million 2016-2021).**

Digitization penetrates and affects all industries at high speeds and thus establishes challenges for companies and organizations. The digitization of the health economy also is gaining momentum. It is an important future issue for the Federal Government, which is noted in numerous initiatives and programs. With healthcare, digitization offers big opportunities for an aging population, where more people are afflicted by illnesses. Digitization helps recognize diseases earlier, and possibly reduce the duration of hospital stays and extend lives through telemedicine, apps, or nursing robots.

While other industries such as music, film or tourism already adapted the change, the degree to which digitization has changed health care in Germany is still relatively small. This is due in part to the complexity of the care structures, and also to the large number of participants and lack of standards for the exchange of data. For the medtech industry, digitization offers a range of opportunities and potential
for new technologies and optimized patient care. The following areas of digitization in healthcare have excellent potential for US suppliers to Germany.

**eHealth/ Telemedicine**

eHealth is a name for a variety of areas. It includes electronic healthcare, electronically supported disease and knowledge management, telemedicine services or remote care. The main point of the eHealth concept is to ensure the security of digital networks in the system. It offers the opportunity to improve the health care for the benefit of the patients.

For eHealth in Germany, the development of the telematics infrastructure is the central instrument for secure communication. On this basis, there is a chance to create efficient supply processes with all sectors involved by introducing applications. An instrument for this is the electronic health card (eGK).

With the “Gesetz für sichere digitale Kommunikation und Anwendung im Gesundheitswesen” (Law for Secure Digital Communication and Application in Health Care), adopted in 2015, the legislature wanted to ensure that information and communication technologies benefit from the patients, healthcare providers, and insurance companies.

**E-Commerce/ E-Procurement**

To date, information and communication technologies are evident in the hospital information system, primarily in medical and nursing data in hospital information systems (KIS). There are more and more organizations which recognize the importance of the IKT and procurement processes and would like to implement them for process optimization. Improvements can be made mainly through attainable standardized electronic processes.

Standards for electronic procurement processes between hospitals and medical device suppliers are available. There are certain standards for classifying the products, and they must be consistently applied. The members of the Forum eStandards, started by BVMed, consists of representatives from the industry, hospitals, and other organizations. They rely on the eClass Standard, which is used throughout Germany for classifying products and services. BVMed has ensured that “eCommerce Standards” can be linked to the HL7 standards of medical information when explaining a patient treatment plan.

**Age-related and Care-supported Technology**

Rollers with navigation systems and carpets with built in crash detection... thanks to modern technology, seniors can remain independent longer. Modern digital medicinal technology plays a vital role in the health problems of older people.

The older generation in the future will be accustomed to the use of informational technology. The technology of such aids has already become more evident. With advances in technology, the possibilities expand. Gerontology has become more apparent in areas such as rehabilitation and physical training. Gerontology requires ethical monitoring, as there exist certain hazards. Some hazards include the replacement of personal assistance in technical procedures or the processing of sensitive data that pose risk of misuse of information.
Industry 4.0

The “Internet of Things” or Machine-to-Machine Communication (M2M) has become increasingly more important for medical technology companies. Half of the companies involved in a 2015 BVMed survey saw potential for the manufacturing of medical technology for hospitals based on M2M communication. Web-based communication solutions such as the development of learning assistant systems have a high potential.

The rollout of M2M application in the German healthcare system is delayed because of unresolved question of certification as a medical product, lack of reimbursement structures, and data transfer insecurities.

M-Health/ Apps

Mobile Health, or mHealth, is understood to mean the provision of healthcare by mobile communication devices. Mobile services such as apps for smartphones will fundamentally change the healthcare market. Half of all patients believe that M-Health will improve the health system. Also, the employees in healthcare, doctors, health insurance companies and the industry see enormous potential of mobile health services.

Health apps are certainly on the rise. In 2015, there were more than 400,000 fitness, wellness, and health apps offered on the German market. According to latest studies, the number of downloads of applications in fields such as medicine, health, and fitness amounted to 3 billion. The number of downloads doubled within two years.

Big Data Applications

There is high potential for data-based therapy recommendations. One example from BVMED member Molecular Health relates to personalized cancer management with modern diagnostics software which includes DNA sequencing of tumor tissue.

Diagnostic Software allows to compare molecular and clinical patient information with the help of scientific knowledge about the mechanisms and actions of drugs, and to make cancer treatment more transparent and individual. On the basis of a tissue sample, a clinical finding is prepared in which reliable and personalized treatment options are presented on the basis of a genetic tumor analysis and interpretation. In the case of an unusual very advanced disease, therapy decisions can be optimized. The program allows access to a global information network on clinical trials, including the approval and development status of investigational drugs and risk factors for drugs that are on the market.

Opportunities and Risk: Data Privacy

Medical technology companies see opportunities to optimize patient care through the integration of medical technology and IT. Doctors can then identify diseases earlier and provide better prognoses for health developments. The Big Data approach has much potential. The challenge is that the data is there, but is not yet available. This brings about the importance of data protection and anonymized patient data. According to experts, a uniform approach throughout Europe is needed. It must be clear which
data are open and when work with anonymous or pseudonymized data is required. The system needs to optimize opportunities and minimize risks. It is nearly impossible to exclude the misuse of data.

Compared to other European countries, Germans are particularly critical when it comes to handing over their data. Only 42% advocate the collection of health data to better identify or treat a disease. In Spain that number is 86% and in Italy 79%, according to a survey conducted by TNS Infratest on behalf of Vodafone Institute in January 2016. For specific applications, two thirds of the German population (65%) agree that their data are collected anonymously by healthcare institutions to improve treatment of diseases, signaling optimism for a general consent.

**Summary and Conclusion**

Digitization does not only change lives, but also attitudes toward health. The digitization boom is mainly driven by the healthcare market. Some fascinating examples include apps that measure and analyze vital parameters, making a hearing aid from a smartphone, or help in the detection of skin cancer. German health policy must aim at using these dynamics for the first healthcare market, the statutory health insurance. This would include a better connection of services and products and removal of gaps with the over 5 billion documents in the German healthcare system. This can only be achieved with open interface-based system operability.

Like each new technological advancement, digitization offers both opportunities and risks, and thus needs to be balanced. An excessive fear in Germany about the misuse of data can result in getting out of touch with digitization in other European markets, and in losing in gross value added. Germany will need a good balance between the technical possibilities /market chances and the privacy demands of people.

The German lead market of a “digital health economy” requires

1) A reliable legal framework for data security and regulation in Europe;
2) E-Health applications and telemonitoring solutions as a regular part of the healthcare and patient management;
3) Planning security and start-up funding for providers of telemedicine solutions;
4) Networking of IT systems beyond sectoral boundaries through global, uniform data formats and software interfaces.

Digitization is on the greatest growth opportunities in the medical environment. The regulatory framework must be adapted accordingly in order to benefit from the opportunities and provide benefits to the patient, according to all major industry associations and private players.

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conhIT 2018
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conhIT is Germany’s major annual ehealth event, bringing together over 500 exhibitors from 19 countries and close to 10,000 visitors in five exhibit halls on the Berlin fairgrounds. All major US digital health players including Microsoft, Cisco, GE, EPIC, Intersystems and innovative SME ehealth providers participate. Different zones available for exhibits such as mobile health zone, app zone; workshops throughout the show with speaker opportunities.

U.S. Commercial Service Contact Information
Name: Anette Salama
Position: Senior Commercial Specialist, Healthcare/Life Sciences
Email: Anette.Salama@trade.gov
Phone: +49 211 737 767 60