How artificial intelligence and innovative technology disrupt healthcare on both sides of the Atlantic
Digitalization. It’s here. It’s now. It’s you,” is the core message of AmCham Germany’s recently published film about digitalization. It therefore comes as no surprise that digitalization has also found its way into healthcare. No one would deny the fact that the current disruption and transformation in this sector is revolutionary and, across all industries, surely the one that affects our societies most: A 2018 PwC survey determined that 54% of people worldwide would be willing to engage with artificial intelligence (AI) in medicine.* Passionate digital health startups, e-health companies, scientists and politicians are promoting innovations in healthcare technology that contribute to increasing the quality, affordability and convenience of healthcare on both sides of the Atlantic. And when applying new technologies to healthcare products and services, both Germany and the US can learn a lot from each other. Both business locations hold huge potential. In many of their analyses of digitalization in healthcare, the European Public Health Alliance has stated that digital healthcare could result in a conversion toward a patient-centered system, advantages for the healthcare workforce and much more.

“Digitalization is the biggest opportunity to improve people’s health and increase efficiency in the healthcare system,” says Chantal Friebertshäuser, Managing Director at MSD Germany. MSD is a research-oriented pharmaceutical company and member of AmCham Germany that faces many challenges in keeping up with the speed of digital transformation. “One of our biggest tasks is the acceleration of our organization and our processes. We are aware that this demands a great deal of change on many levels,” Friebertshäuser says. Digital transformation in healthcare is therefore also closely linked to change management and adjustment of a company’s mindset. Another essential task for MSD is to work with AI and deep data: “Connectivity of data can help break silos for

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* Digitalization in healthcare overview by PwC: www.pwc.de/de/gesundheitswesen-und-pharma/digitalisierung-im-gesundheitswesen.html
In addition to the introduction of the App on Prescription, pharmacies are to be connected to the telematics infrastructure by September 2020 and hospitals by January 2021. Doctors in Germany’s statutory healthcare system must prove by June 2021 that they have the infrastructure required to access the electronic patient file (ePa). If these deadlines are not met, they risk a reduction in reimbursement. The associations of statutory health insurance physicians as well as inpatient and outpatient nursing facilities are also involved in the IT changeover. (Source: www.aerzteblatt.de/archiv/209024/Digitale-Anwendungen-Der-Weg-der-Apps-in-die-Versorgung)

Federal Minister for Health Jens Spahn explains the advantages of the Digital Care Act:

**APP ON PRESCRIPTION SOON PRESCRIBED BY A DOCTOR!**

For example, in **DIABETES** or **HIGH BLOOD PRESSURE**, health insurance companies reimburse the cost.

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**About the Digital Care Act**

The Digital Care Act (*Digitale Versorgung-Gesetz*) builds on the E-Health Act, which entered into force in 2016. It focuses on the development of the electronic health card and the electronic patient record as well as making sure the data stored in such files is protected against unauthorized use. The E-Health Act also includes the creation of a secure telematics infrastructure, the improvement of healthcare IT systems and the provision of telemedical services.

Under the new Digital Care Act, medical doctors will be able to prescribe new treatment methods to their patients, such as using an app. An app might, for example, remind chronically ill patients to take their medicine regularly or provide a diary function for users to note their daily well-being. In the future, German statutory health insurance companies have to reimburse the costs of health apps under certain conditions. Germany’s federal government agreed on the provisions of the Digital Care Act in July; the proposed law now has to be passed by the German parliament.

*Source: healtheuropa.eu*

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research and patient care,” Freibertshäuser explains. “Our data has been developed over several years, and we are actively investing in our legacy environments to ensure our foundation is set for the future.”

Not only well-known companies are keeping up with innovation in e-health, but also many startups have been founded in this area. Florian Bontrup, entrepreneur and CEO of Docyet, has been contributing to the transformation in healthcare with his Leipzig-based startup for more than two years now. Together with his cofounder and 15 employees, Bontrup created a digital health platform that helps patients access local and digital health services and make better healthcare decisions. Docyet provides a cohesive patient journey supported by an AI-based decision support system that improves healthcare for both the patient and for the insurance provider. “I had an initial idea of how Docyet could work when I became sick on vacation in China,” Bontrup says. “It was extremely difficult to find a doctor or any information about medical treatment.”

The situation in Germany is not that different when looking closer. When people become sick, they ask Google about their symptoms and then go to a doctor or even to the emergency room. “That’s why we need reliable online platforms that can inform patients and help them make an informed decision on the next steps they should take,” the startup-founder explains.

**The political framework for digital healthcare**

But working on his vision to help patients and contribute to a successful healthcare system is an everyday challenge for Bontrup. When founding a healthcare startup, entrepreneurs have to keep up with the many rules and regulations in Germany. “It’s a good characteristic of our country that we have so many regulations in the healthcare sector because it ensures that products and services are implemented safely,” Bontrup says. However, before Federal Minister for Health Jens Spahn (CDU) submitted the Digital Care Act (*DVG, Digitale Versorgung-Gesetz*) in July, it was very hard to establish digital innovations in healthcare. The DVG will enable doctors to prescribe use of apps and offer online consultations and public health insurance carriers will be able to use venture capital to invest into healthcare innovations. “We use digital products and services to improve healthcare for patients and to make doctors’ work easier,” Spahn said in a statement about the new law.

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*Source: healtheuropa.eu*
However, passing the DVG is only one of the few steps political leaders have taken to support digitalization in healthcare. “Of course, we’d like to see improvements happen a lot quicker,” Bontrup says. “We can’t afford to fall behind as we currently see in the automotive sector. We have the largest automotive companies in Germany, but the first self-driving car was established in the US.” This development clearly shows that innovation happens where it is allowed to be tested or used, and it should serve as a wake-up call for regulators and political leaders across the political spectrum. “If we can’t test our products here, innovation will happen elsewhere,” Bontrup states.

The e-health motor: Artificial intelligence

The power of AI is the key to success when digitalizing healthcare. Startups with innovative ideas such as Docyet will surely also disrupt the US healthcare market. Establishing new products and services in healthcare can be a sensitive topic when founding a new company. Nevertheless, the US is among the easiest countries to do so, states Pat A. Basu, President and CEO of the Cancer Treatment Centers of America. Basu served as a White House fellow and senior adviser while helping to execute portions of former President Barak Obama’s economic and health agenda. “There is tremendous access to capital and expertise, which makes founding a company financially feasible. And the bar to get started from a legal, regulatory and tax perspective is lower than in many nations,” Basu says. That is one of the reasons why e-health is developing so rapidly in the US. But technology is only one factor in this context: ‘At this point, the technology may no longer be the limiting factor; rather, the behavioral changes around adoption,

A challenge for the healthcare industry: The Medical Device Regulation

The Medical Device Regulation (MDR) came into force in May 2017 and, after a three-year transitional period, will apply from May 26, 2020. The MDR aims to ensure more patient safety, better protection of public health and the creation of a modernized and more solid EU legal framework.

Some changes that will apply in 2020 are, for example, the Unique Device Identification (UDI), a product number that can only be assigned once for each medical device. Moreover, clinical evaluations and trials will be tightened up: With the introduction of the MDR, clinical data must continue to be collected, documented and evaluated — even after market introduction — and also provided for products that have already been on the market for a long time. Furthermore, there is a higher classification for some medical devices.

The MDR poses a number of challenges for manufacturers: The new EU regulatory framework will significantly complicate the process of placing medical devices on the market and lead to considerable additional regulatory and cost-intensive efforts. Yet the biggest problem is that the regulatory system is not ready to function. There is, as just one example, a lack of necessary certification bodies. If this problem isn’t solved, thousands of medical devices will become noncompliant and will not be authorized for use by surgeons, doctors, hospitals and patients as of May 26, 2020.
the resistance from those who stand to lose and certain regulations are more the likely factors to slow adoption than the technology itself,” Basu explains. He believes that data and analytics programs will help lead to cures and far earlier detection of cancer in the next three to five years.

**AI can lead to better and quicker outcomes and lower costs**

Digitalization in healthcare has become a prime concern for companies, as Ariane Schenk, Pharma and E-Health Consultant at the digital organization Bitkom, says: “Digitalization is no longer a secondary aspect of health, but a necessary priority in a comprehensive health economy.” AI can lead to better and quicker outcomes and lower costs when it comes to pharmaceutical research and the early detection of diseases and their diagnosis and treatment, Schenk explains. Bitkom works on many projects and initiatives in e-health, including, for example, providing platforms and an ecosystem for close communication between health and pharmaceutical companies and software and analytics companies to realize the maximum potential of AI for the healthcare sector. This progress creates many advantages for the patient: “There are already many health-related apps that help people stay healthy, become active or monitor their own heart rate or weight. Patients in rural areas and people with reduced mobility can video chat with their doctors and order medicine online,” Schenk outlines. She also agrees with many startups and companies when they assert that Germany needs a reliable, easy-to-access regulatory framework, further stating: “We need more acceptance and awareness for AI-related technologies. This applies not only to patients, but also to doctors and users.”

**AmCham Germany’s policy activities in healthcare**

Not only enthusiastic startups work on healthcare innovations but also established companies and members of AmCham Germany, such as Medtronic. As a global leader in medical technology, Medtronic was founded in 1949 and has always kept up with new technological developments in healthcare. “We currently work with AI in our diabetes unit in particular,” says Dorothee Stamm, Government Affairs Manager at Medtronic and Co-Chair of AmCham Germany’s Healthcare & Life Sciences Committee. Even a well-established, successful company like Medtronic faces challenges in the digitalization of healthcare: “The current reimbursement system in Germany is not designed for digital medical devices,” Stamm states. “In some cases, it can take up to 10 years before new products or therapies receive coverage by the health insurance system and thus become available to all insured individuals. This long process stands in stark contradiction to the speed of digital developments.” To work on these issues and develop a suitable political framework, the Healthcare & Life
Communication with a doctor via chat: Patients are open to digital options like this.

Policymakers must ensure that unnecessary barriers to market access be removed

Companies like Medtronic and startups like Docyet both agree with Stamm when she suggests, “Policymakers must ensure that unnecessary barriers to market access and to reimbursement be removed and that processes become generally faster and more transparent.” It’s not only possible that startups could invent their ideas in other countries than Germany, but also bigger companies could withdraw from the German market. That would not only weaken the economy, but also result in patients no longer having access to innovative healthcare products. Digitalization in healthcare can only be successful within a reliable, open-minded political framework that enables entrepreneurs, companies and scientists to work together across the Atlantic.