"Even if some stakeholders remain sceptical—the DiGA Fast-Track is bringing momentum to the digitalisation of the healthcare system."

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A turning point for the German healthcare system

The presentation of the draft bill of the Digital Healthcare Act (the DVG), drafted by the BMG in May 2019, outlined for the first time, a path for digital health applications, "DiGA", to achieve structured access to the statutory health insurance system and thus to be financed by health insurers as part of standard care. The global attention that the law received reflects the novelty and innovation of the DVG: no other integrated healthcare market in the world had yet articulated clear requirements, a structured qualification process, and, simultaneously, clear reimbursement rules for digital health applications. With the implementation of the DiGA Fast-Track process in statutory health insurance law, the final hurdle was removed for qualified DiGA to be made available to the more than 73 million statutorily insured German citizens.

Previous story/History/Prehistory

Prior to the Digital Healthcare Act (DVG), providers of digital health tools could only obtain payment for their products through niche programs, such as 'selective contracts' ('Selektivverträge')—that is, contracts with individual health insurers, e.g., in the area of preventative care solutions. With 'selective contracts,' health insurers are freer to set budgets, however, uncertainty around the future of digital tools remained high. DiGA

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could not be meaningfully assigned to an existing category, such as medical aids, drugs, or therapeutic methods of non-physician providers (e.g., physiotherapy, speech therapy, [see chapter 5 *Pathways for digital solutions to enter the statutory [regulated] healthcare market*], for a good summary, see: Thelen 2018).

As a result, there was no consistent approach to digital applications in Germany, as has also bene the case in most of the world's healthcare systems. Only the Scandinavian countries, Israel, Singapore, the UK, and parts of the USA already use digital applications for patients care in a structured way. In these countries, however, digital applications are mostly used only in small subsets of the healthcare system, thus impacting only relatively small populations and subject to very different authorisation processes and reimbursement models.

Why is the German healthcare system concerned with DiGA at all? Why are they medically relevant? To date, ambulatory physicians have essentially acted only in the short time in which they can see and examine their patients. On average, a patient visit lasts 7.6 minutes in Germany (Nier 2017). Only the information that is provided, explained, and understood by patients in those 7.6 minutes can resonate with patients, and thus impact an individual's health. Whether medications are taken, prescriptions for physiotherapy are utilized, aids such as orthopaedic insoles are actually used—physicians can only learn about all of this by skilfully asking questions during subsequent visits—and only if they have the time, recall, and patience to do so.

A new reality thanks to digital health applications

With DiGA, however, medicine can now be integrated into patients' everyday lives in a low-threshold way. Whether in the form of a digital diary, relaxation exercises, sensor technology for home monitoring, or nutrition coaching, first generation DiGA can be smartphone- or browser-based, and support ambulatory care *outside* of the average 7.6 minutes of doctor-patient interaction. They can collect longitudinal data from patients' daily lives and induce and track behavioural changes. With DiGA, the everyday implications of patients' conditions can also be established and improved upon to a greater extent than before. In terms of health technology assessments of DiGA, the focus is placed not only on purely medical benefits, but also on a holistic view of the patient's broader health situation.

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The fact that the German healthcare system, which has so long and so successfully resisted almost any form of digital technology, is now creating a structured opportunity for such tools to be introduced is a turning point. This step does not yet mean that all sceptics are convinced, nor that broad swaths of clinicians, the Association of Statutory Health Insurance Physicians, health insurers, and hospitals are suddenly ardent supporters of DiGA in particular or digitalisation in general. Nevertheless, DiGA can now prove themselves in the reality of care. Everyday practical experience can be gained and the advantages and disadvantages as well as opportunities and risks of digital health applications can be better understood.

The digital health application environment

It is worth taking a somewhat more detailed look at the players to be able to better understand their history and current behaviour. This assessment is subjective, but based on many intensive conversations and interactions with different players over the last 14 months:

Health insurers

Health insurers guard and manage insurance premiums on behalf of their members in order to provide the best possible care for each statutorily insured individual. As early as 2014, the first health insurers began to pilot digital offerings for their beneficiaries. Kassel-based Stottertherapy is one of the pioneers of digital therapy through its collaboration with the Techniker Krankenkasse (Germany's largest statutory health insurer). The software solution—although not a medical device—enables speech therapy from the home PC (Institute of Kassel Stutteringtherapy 2018). In 2015, the Techniker Krankenkasse enabled its beneficiaries to use a digital medical device, the tinnitus therapy app Tinnitracks. In 2016, Barmer health insurance followed suit with apps from Mimi Hearing Technologies for hearing prevention and testing (Barmer 2018). These are just individual examples. Since then, many health insurerers have offered digital medical devices to their beneficiaries through selective contracts or prevention budgets. Contracts with manufacturers were often exclusive and time-limited. Nevertheless, since 2015, no other player has been as bold in trying out digital medical devices and gaining experience as Germany's statutory health insurers.

The DiGA-Fast-Track changes things for health insurers. With Fast-Track approval, DiGA manufacturers now have direct access to reimbursement in the entire German statutory health insurance market. However,

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individual health insurers can continue to offer additional services for DiGA via selective contracts, such as coaching to accompany a mental health DiGA, or approaches to integrate a DiGA into a more complex care concept so that further parts of the patient journey are mapped. Overall, this opens up more opportunities for health insurers to improve the care of their beneficiaries through (digital) innovations. This also includes innovations in the DVG, which provide health insurers with previously unavailable opportunities:

1. health insurers can now also actively participate in the development of digital innovations, e.g., in the form of digital medical devices or telemedical care concepts, in accordance with § 68b German Code of Social Law (SGB V)]. By participating in the development of offerings for their beneficiaries, health insurers take an even more active role in managing the health of their beneficiaries.
2. thanks to the DVG, health insurers can, for the first time, also directly recommend DiGA to their beneficiaries and approve their use in accordance with section 33a (1) sentence 2 number 2—insofar as the health insurer has a corresponding medical diagnosis of the individual patient. For example, a health insurer could recommend a specific DiGA or an entire portfolio of appropriate DiGA to all of its already-diagnosed beneficiaries with back pain. Interested members then do not have to go to doctors or psychotherapists separately in order to be prescribed a DiGA as treatment, but receive the prescription -code directly from their health insurer, e.g., via the health insurer's app.

Health insurers will continue to use digital medical devices to position themselves in the marketplace as particularly innovative and relevant compared to the competition. Through the DVG, they have additional opportunities to interact more with their members and recommend and approve diagnosis-appropriate DiGA.

Physicians

During the COVID-19 pandemic, the vast majority of physicians had other priorities than dealing intensively with DiGA, given that the DiGA Fast-Track was launched in October of 2020. Phsicians are also more likely to have the recently-introduced electronic patient record on their radar and, if applicable, e-prescription. Thus far, DiGA are seen by many as a "gimmick". Physicians are strongly guided by the assessments and guidelines

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of their medical scientific societies when it comes to the use of new diagnostic or therapeutic options (see chapter 6.1 *Involvement of care expertise—ask a doctor or …*). In recent decades, the use of digital technologies in everyday practice has been problematic overall. The day-to-day of outpatient healthcare providers is characterized by frequent IT problems and failures, be it malfunctioning TI-connectors or problems with the ambulatory information system (PVS). Digital technologies have rarely been able to meet the expectations of physicians in the past decades; in most cases, new solutions were not interoperable with the existing infrastructure (and vice versa), required high manual maintenance efforts, and were also frequently not aligned with physicians' existing processes and routines.

There exists a technology-savvy and very open-minded minority of physicians who, even before Fast-Track, piloted digital medical devices in outpatient care. This group is likely to be heavily courted as early adopters for DiGA in the coming months. The vast majority of physicians, however, will follow as best practices emerge, as key opinion leaders report successful deployments of DiGA at medical conferences, and as more evidence becomes available. For a detailed analysis of this important target group, see chapter 6.1 *Involvement of care expertise—ask a doctor or …*

Psychotherapists

In addition to physicians, psychotherapists are key players in the DiGA environment, as they can also prescribe DiGA for their patients. Manufactuers of mental health solutions will focus on this group of healthcare providers accordingly. Over the course of the pandemic, psychotherapists have shown that they are quite open to digitalised medicine, especially in the form of video consultations (hih 2020a). Nevertheless, a basic skepticism prevails among the majority.

In addition to physicians, psychotherapists are a relevant target group for DiGA and they are generally open to digital offerings. Here, too, the aim is to convince early adopters of the proven benefits of DiGA for patients.

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Hospitals

According to the DVG, Physicians in hospitals can only prescribe DiGA for discharge management. The vast majority of German hospitals are modestly positioned in terms of IT capabilities, and documentation is often still predominantly paper-based. With the exception of flagship institutions such as some university hospitals and a few privately owned clinics, the majority of German hospitals are still in the early stages of digitalisation-both within the hospital itself and in terms of communication with other parties.

There will be some DiGA that can be prescribed at the time of hospital discharge. These DiGA will focus on the inpatient market, primarily targeting university hospitals and other flagship institutions. The large remainder of hospitals will remain busy with other substantial challenges and are likely to devote themselves to DiGA only over the course of the years ahead. For details, see chapter 6.3 *Hospitals—digital health tools*.

Patients

The high acceptance of the "Corona-Warn-App" (the German app for contract tracing during the COVID-19 pandemic that was launched in the summer of 2020) with > 12 million downloads in the first week (representing a more successful launch than Pokémon Go [statista 2016]) and > 26 million by the spring of 2021, indicates that the public discourse and reality are currently divergent. While media concerns about data protection and security are being pitched against rapid adoption of DiGA and older people are often written off for their lack of user skills for DiGA, we belive that a majority of statutorily insured individuals are broadly open-minded towards DiGA. This thesis is confirmed by data from surveys (see, for example, bitkom 2020). For many patients, two things seem to be particularly important: digital offerings must convey their benefits clearly and in an appealing form, and the protection of health data must be explicitly guaranteed.

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However, the attitude of their doctors and psychotherapists is also likely to be decisive for patients. If healthcare providers explicitly recommend and prescribe a DiGA, patient groups beyond early adopters will also start to use DiGA.

Important digitalisation projects beyond the Fast-Track

In addition to the DiGA-Fast-Track, there is a key digitalisation project, which is the basis for many other projects and initiatives, and which—if successfully implemented—could create the basis for a flourishing digital health ecosystem in Germany: the telematics infrastructure (TI) with its various applications will provide enormous impetus for digitalisation throughout the healthcare system. Important components include the electronic patient record (ePA), the emergency data record (NFD), the electronic medication plan (eMP), the e-prescription, and the electronic certificate of incapacity for work (eAU) (see chapter 10 *The electronic patient record and the telematics infrastructure—a look beyond the DiGA horizon*). Manufacturers of digital health tools should keep a close eye on these developments.

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