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A cooperation of

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Source: : Elenabsl/adobestock

THE STANDARD CARE CHALLENGE

With DiGA from zero to sixty

The first digital health applications (DiGA) have made it into standard care, thanks to the Digital Care Act, the next ones are in the starting blocks. One of the greatest challenges remains in demonstrating evidence of the positive healthcare effect.

Anxiety disorders, obesity, and sleep disorders - for all these diseases there is now an app available as a prescription for the first time. These apps are approved by the Federal Institute for Drugs and Medical Devices (BfArM) and reimbursed by the statutory health insurance companies. „This means that digital medical devices of lower-risk classes have an important entry point into standard care, which we highly welcome," says Anke Caßing, senior investment manager at High-Tech Gründerfonds (HTGF), which accompanies several digital health start-ups on their way to market.

BfArM draws a first positive balance

Some founders can hardly believe that the Digital Healthcare Act (DGV) and the reimbursement of digital health applications (DiGA) were successfully implemented in just 15 months. "With around 90 consultations since the beginning of May, and the first applications starting on the day the electronic application portal was published, we can say that the process has got off to a good start," says Wiebke Löbker, head of the BfArM innovation office. The fact that only a few apps were initially included in the DiGA directory at the beginning of October is also due to the tight deadlines. "The process is designed as a 'fast track' not only for us, but also for the manufacturer. If, after confirmation of the complete application, additional requests come from our side, the process does not stop until clarification, but the clock continues. For some companies this timeline was apparently too tight to remedy existing deficiencies," reports Löbker. Ten applications were therefore withdrawn but can be submitted again. This shows that despite extensive guidelines, interpretation and reading aids, there are still some challenges in the details. Nonetheless, there is great euphoria among founders. "We are doing pioneering work in digital medicine and can now use the opportunity to get into standard care. We therefore accept the uncertainty and dare to take the step," says Alexander Leber. The heart specialist at the Clinic for Cardiology at the Isar clinic in Munich founded iATROS in 2019, and the HTGF was on board as a seed investor from the start. Now, the team is about to submit a DiGA application to the BfArM.

Digital medicine in outpatient care

Leber has co-developed an app which helps patients with high blood pressure, for example, to be more closely networked with the doctor via continuous vital data monitoring. Artificial intelligence analyzes the data and, if necessary, provides information about a doctor's visit. "In this way, emergencies such as strokes or heart attacks can be identified and avoided more easily," says Leber with conviction. At iATROS, he wants to set up a virtual heart clinic in the long term, which on the one hand helps to channel digital patient data via a platform for doctors and patients, and on the other hand also provides a telemedicine offering. Part of this vision could now reach doctors' practices and patients via DiGA. "With DiGA in place, we can finally advance modern digital medicine in outpatient care – and that is urgently needed."

The evidence challenge

Nora Blum is already one step further. The founder of mental health company Selfapy – also part of the HTGF portfolio – was one of the first to apply at the BfArM after the DiGA process kicked off. "We expect approval for our app by the end of the year," she says. And although the company, which was founded in 2016, had already entered this phase well-prepared, a few hurdles still had to be overcome in the process – particularly regarding the therapeutic focus. Blum: "We were aware that our previous preventive psychological digital programs were not suitable for DiGA and that we still had a lot of work to do. Above all, the additional requirements for data protection, data security and interoperable interfaces were tough." On the other hand, Selfapy was already able to include data to prove the effectiveness of the web application in the approval process. A pilot study with the Hamburg Universtiy Clinic Eppendorf (UKE) has already been completed, and another study is currently underway with Berlin-based Charité. "These data will be available at the beginning of 2021 and will give us a tailwind in communicating with the doctors," Nora Blum is certain. She knows that app providers will only have good cards in future negotiations if they show quality and evidence. Discussions are currently ongoing

The DiGA directory – a way into reimbursement

When did the reimbursement for DiGA start?
On October 6th, 2020, the German Federal Institute for Drugs and Medical Devices (BfArM) included the first "Prescription Apps" in the new directory for digital health applications (DiGA).

How many DiGA are in the process?
More than 20 are in the application process (as of October). The assessment time at the BfArM is three months after receipt of the complete application in the fast-track process.

How does the process work?
The BfArM checks whether a DiGA fulfills the requirements defined in the Digital Health Applications Ordinance (DiGAV) for safety and functionality, data protection and information security as well as with regards to quality and, in particular, interoperability. In addition, they check that the proof to be provided by the manufacturer will demonstrate positive healthcare effects achieved with the DiGA . Preliminary access into the directory is possible, even if these results are not yet available. In this case, the manufacturer has to show other early promising data and show that the further requirements are met. Within a trial phase of up to one year, the necessary comparative study must be carried out. In exceptional cases, the option of a time extension is available.

More information: **https://diga.bfarm.de**

between representatives of the manufacturers' associations and the GVK on the details of the DiGA implementation. Evidence plays an important role for health insurers, emphasizes GKV representative Johanna Gregor-Haack: "The success of the DiGAs will depend crucially on the quality of the products – there will only be acceptance if the insured experience a real improvement in their care. We therefore see it as our task to pay attention to high quality and beneficial DiGA in the course of the price negotiations." For the first year after approval by the BfArM, the GKV proposes a maximum price level. The law gives this price cap as an option. "In our opinion, the completely free price setting by the manufacturers in the first twelve months should be limited by maximum prices for product groups of comparable DiGA. This is particularly because DiGAs that are subject to approval have not yet been able to sufficiently demonstrate a positive healthcare effect," says Gregor-Haack. However, manufacturers consider upper price limits and product groups to be difficult, emphasizes Natalie Gladkov, digital medicine expert at BVMed. "We currently see no need for a price cap. Setting maximum amounts to simplify pricing makes sense in an established market. Maximum amounts used too early, in turn, significantly reduce the manufacturer's interest and thus become a "stumbling block" for future innovations. Due to the great variety of DiGAs, it is currently very difficult to form reasonable product groups," she explains. The association wants to stand up for appropriate remuneration in the negotiations. Gladkov: "In view of the current reluctance of many doctors, we do not expect any cost explosion in the first year of prescribing.

THE DIGITAL MEDICINE BUSINESS MODEL

DiGA as entry into the market

Only those who are able to convince doctors and patients equally of the digital application benefits will establish themselves in the market. Entrepreneurs and investors discuss how business models will develop in the future.

Markus Riemenschneider is considered to be one of the old hands in the digital health business. His company Personal MedSystems GmbH launched 7,000 Cardiosecur devices for mobile ECG analysis in 2011, and the DiGA application is currently being prepared. "For us, quality comes before speed. We are still in the process of making our study design watertight for the test phase," says Riemenschneider. Because what sounds so simple is not trivial: "We don't just have to show that our digital offering works, but that we provide a medical proof of benefit." Riemenschneider can quickly convince doctors that Cardiosecur makes sense. By using his mobile application, cardiac patients are able to record a personal reference ECG. If necessary, further online recordings then start if there are complaints. "It has long been clear to cardiologists that diffuse heart problems cannot be captured using traditional EKG methods in the doctor's office. With our mobile ECG, patients can take measurements themselves and as soon as faults occur, this is visible in the data and a visit to the doctor is recommended," he reports. Despite the clear benefit, doctors have hesitated so far - with the reimbursement option via DiGA, that is now set to change. But Riemenschneider is still working on the question of how many patients actually suffer from such diffuse complaints. So far this has hardly been documented. "Many cardiologists state that half of their patients have something, but they don't know exactly what," says Riemenschneider. Without meaningful figures, however, he cannot determine a realiable parameter for the study size – a central factor for all start-ups that are currently applying for DiGA approval and have to prove healthcare effects during the one-year trial phase.

Convince doctors with evidence

Good study planning is also central with regards to the market entry. "The evidence of the product emerges from the results, and will largely determine the price at the end," emphasizes Markus Dahlem, CEO of Newsenselab. In August, his company submitted the DiGA application for a migraine app. He expects approval by the end of the year. According to him a study with 300 patients under the leadership of the Charité is in the starting blocks. "In the preparation process, we again deliberately focused on migraines and left out the tension headache," reports Dahlem. His goal is clear: to score with evidence and convince medical professionals. His good contacts with doctors and key opinion leaders will help, but he is realistic: „I do not assume that more than 30% of the doctors are open to digital applications."

Jörg Land from Sonormed knows how important doctors are when it comes to selling digital medical products. "We have been working for years with ENT doctors who prescribe our tinnitus app as a care solution. It is advisable to act as a problem solver for the doctors and to shift as little effort and processes as possible into the practice," he emphasizes. Dahlem and Land see great long-term potential in cooperation with the pharmaceutical and medical technology industries, whose sales expertise would clearly be an advantage.

Other income in addition to DiGA important

iATROS founder Alexander Leber also considers several pillars of income in his own business model to be important: „We are not only looking at the DiGA, but also at selective contracts with private health insurance companies and the so-called German Hospital Future Act, with which the intersectoral care should be improved." For him, a telemedicine infrastructure is essential in this context. "In a few years, patients will run into us with lots of data, and we have to be able to deal with it in a structured manner," predicts Leber. Investor Thom Rasche, partner at Earlybird, also believes in completely new supply constellations in the digital context. "In future, we will have to think more in terms of indications and supply chains instead of individual product groups." For him, DiGA is a first step in this direction, but it does not justify a gold rush mood. "Every digital application is ultimately controlled by the doctors. To evaluate if the company is really well positioned we have to look at its sales strategy."

Source: Elenabsl/adobestock

Higher class digital medical devices

In addition, he points to the fact that the DiGA currently only include lower-risk products with little patent protection. According to him, the wave of low cost digital generics is inevitable and business models only based on DiGA are therefore a challenge. New investment candidates are therefore primarily evaluated in terms of their ability to penetrate further markets, Rasche says. Markus Dahlem is also convinced that the future of digital medicine lies in higher-class products. "We have exciting ideas in the wings. It is therefore all the more important today to create the infrastructure for digital products that can do more." Natalie Gladkov from BVMed sees it similarly:: "If we want to exploit the healthcare potential of digital therapies, we have to open the DiGA to medical products of higher-risk classes."

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High-Tech Gründerfonds

The High-Tech Gründerfonds, an initiative of the Federal Ministry for Economic Affairs and Energy, the KfW, Fraunhofer Society and 33 companies, supports young technology companies with seed financing to advance research projects at least until a prototype status or until market entry.

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The German Medical Technology Association (BVMed) is an industry association that represents over 230 industrial and commercial companies in the medical technology sector. Among its members are 20 of the largest medical device manufacturers worldwide in the field of consumer goods.

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