Case Study

Pre-Clinical Study for a Digital Health Application

Starting Point

Following the introduction of the DVG (Digitale-Versorgung-Gesetz / digital healthcare act) in Germany in December 2019, patients insured by the public health system can claim the prescription of digital health applications (Digitale Gesundheitsanwendungen or DiGAs). As an 'App on prescription', these applications can support the identification and treatment of conditions and help patients to lead a self-determined, healthier life. As medical devices of risk classes I or IIa, DiGAs must undergo a testing procedure at the German Federal Institute for Drugs and Medical Devices (BfArM).

After successful testing, they are listed in the DiGA directory and can be prescribed by physicians and psychotherapists, and reimbursed by health insurance. The procedure is regulated by the supplementary Digital Health Applications Ordinance (DiGAV) and is depicted in Figure 1. The evaluation period by the BfArM takes up to three months. The required product properties and the positive care effects that can be realized with the DiGA are assessed. If the proof of positive care effects has not yet been provided, manufacturers have 12 months to collect corresponding data.

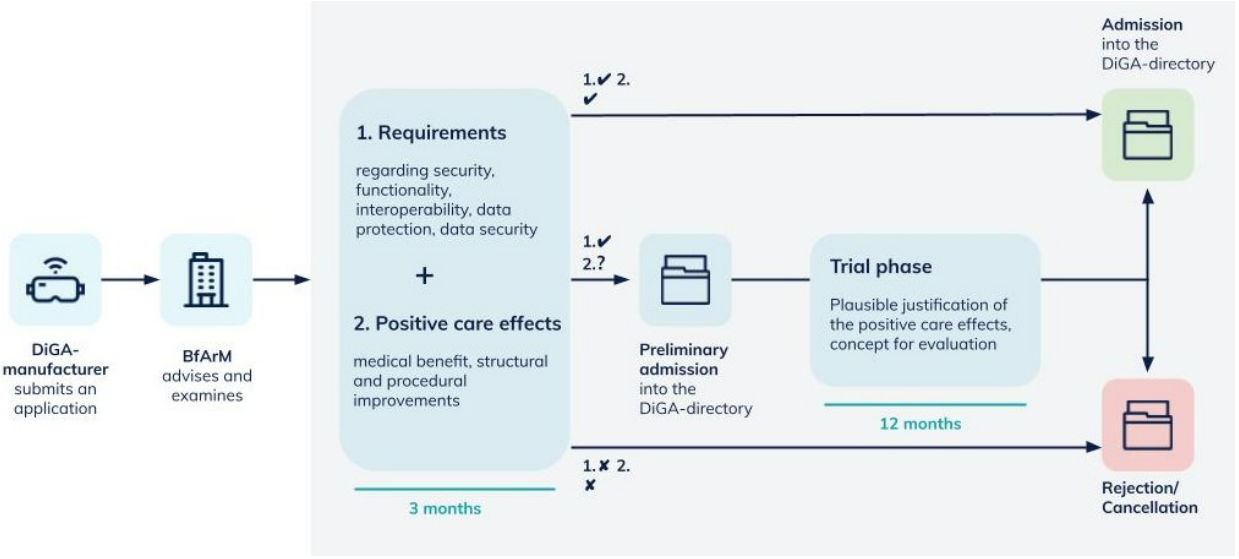

Fig. 1 Illustration of the evaluation procedure at BfArM (Source: BfArM)

ReHub GmbH is a manufacturer specialized in the development of digital rehabilitation technology for patients with hemiplegia, such as stroke patients. The team develops the therapeutic software *Rehago*, which is used in combination with Virtual Reality (VR) glasses. The regular therapy consists of physiotherapy and occupational therapy as well as analog mirror therapy. Training with Rehago training will be implemented in addition to the regular training methods.

With the help of Rehago, patients may learn faster and more independently to move their paralyzed arm again through virtual exercises based on mirror therapy. This therapy is location independent and uses the advantages of VR for immersive training. Additionally, Rehago motivates patients through a playful approach, which transforms repetitive and strenuous routines into interesting tasks and games. The software is therefore designed to accelerate the patient's progress, as training can be continued independently outside of therapy sessions.

Fig. 2 Application example of the VR glasses from Rehago (Source: Rehago)

Project

Following the application for preliminary admission for DiGA testing, positive care effects need to be proven in a study. According to DVG and DiGAV, these positive care effects are either a medical benefit or patient-relevant structural and procedural improvements in care. According to the BfArM evaluation procedure, Rehago must provide at least one positive care effect to get accepted permanently into the DiGA directory.

The primary objective of this study is to prove that therapy with Rehago leads to significantly improved health status in terms of higher functional independence. As secondary objectives, it aims to show that Rehago contributes to improved therapy adherence through more frequent training and increased quality of life with hemiplegia.

The evaluation of the therapeutic software is based on a prospective, comparative, randomized superiority study. Between July 2021 and April 2022, this study will measure the effects on health status, therapy adherence, and quality of life during a four-month training period with Rehago. The comparison group will be treated with standard therapeutic care as well as additional analog mirror therapy. The plan is to include 320 study participants at a minimum of three clinics.

Rehago chose the Climedo software for its data capture activities. The data collected by therapists and patients is recorded via surveys directly in Climedo. Therapists can simply log into their account and send the questionnaires to the patients via a link. Access to Climedo is based on a restrictive rights and roles allocation system – this ensures that only therapists who have created a patient account can view the patient's information. Patients only have access to their current survey. The ReHub GmbH is only provided with the pseudonymized data for the analysis, so that an identification is no longer possible.

Results and Benefits

A major advantage of EDC (Electronic Data Capture) systems such as Climedo is the possibility of **real-time monitoring**. The challenge of paper- or Excel-based studies is that it's not possible to identify ad hoc, which results are already available and which are still required. This is especially important for DiGA manufacturers in the trial phase, as they have to prove the positive care effects of their product within 12 months.

Another advantage is **data capture and analysis** with a digital tool. Compared to paper-based solutions, digital systems offer different possibilities to make the process of data capture and analysis more efficient and effective. For example, predefined fields and direct validation in the system can prevent incorrect formats and implausible values. In addition, the surveys can be sent to the patient at any point and end up in the system in real time. Previously, Rehago has had negative experiences with paper-based studies, as the questionnaires were not available to all study participants at all times, resulting in delays. Furthermore, transmission errors can now be avoided, which leads to a higher level of data quality. As an example, some participants had previously commented "tired" when asked about their quality of life on a scale of 1 to 100, which was difficult to translate into a numeric value.

Last but not least, digital data capture usually **saves time and cost**. Thanks to the intuitive and flexible system of Climedo, the preparation of the data capture, such as the survey creation, can be done much faster. For example, the Rehago team was able to

build the questionnaire completely independently in Climedo before the project was officially launched. Since DiGA manufacturers are usually smaller companies, cost savings through digital data collection represent a significant advantage.

"With Climedo Health as our partner, we are confidently looking forward to data capture and analysis of a multicenter study with over 112 subjects with a small team!"

- Johannes Höfener, Chief Technology Officer, ReHub GmbH

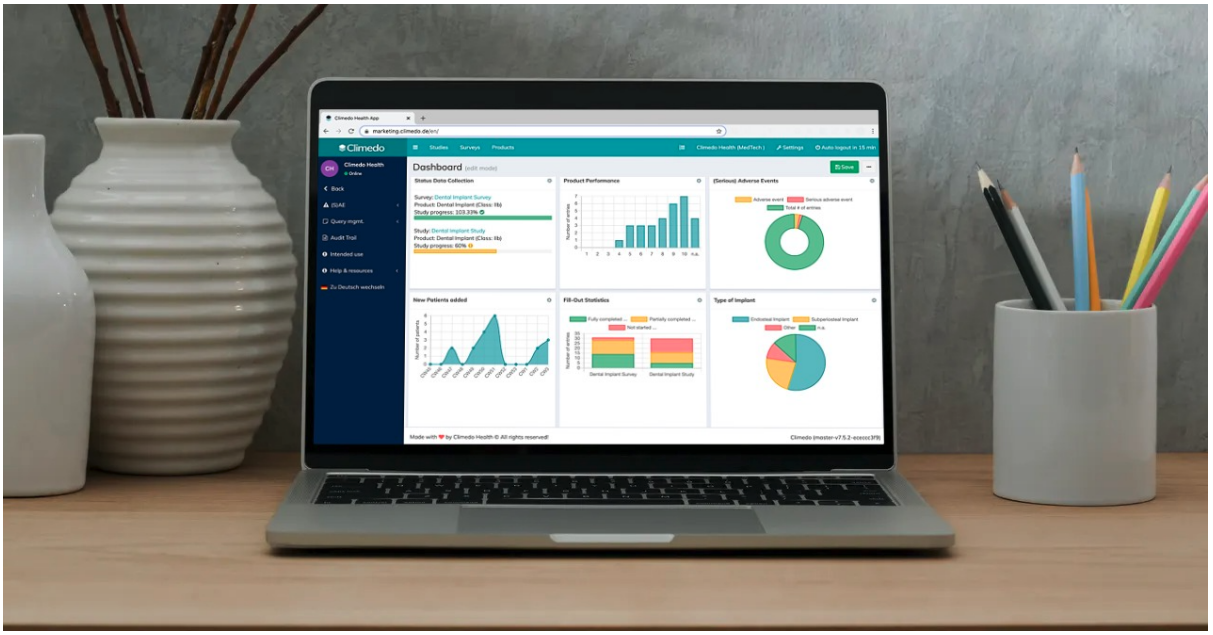

Fig. 3 Climedo's intuitive user interface

Conclusion and perspectives

Given that the Ethics Committee had no objections to the planned study, registration with the BfArM was made possible. The study is scheduled to start in July 2021. By April 2022, the positive care effects are to be proven, so that Rehago can be included in the DiGA directory.

In light of the EU Medical Device Regulation (EU MDR 2017/745), DiGA manufacturers must also take Post-Market Surveillance (PMS) measures. This proactive and systematic collection of data throughout the lifecycle of their devices ensures post-market performance and safety after market introduction. Web-based solutions such as Climedo provide an efficient, secure, and affordable way to collect clinical data for PMS activities in addition to regulatory studies. For example, patients can provide feedback on a DiGA anytime, anywhere via links sent as an SMS or email.

About Rehago

Rehago is a software-based medical device designed to help hemiplegic patients return to a self-determined life more quickly and is based on the proven principle of mirror therapy. Instead of training in front of a physical mirror, patients train in a virtual environment. The immersion in a different world and the playful approach increases motivation, leading to more regular and frequent training. Both can be crucial for a positive therapeutic progress. Rehago offers different and individually adaptable exercises. Thanks to its mobility, training can be done at any time of the day as well as from any location – at the patient's desired pace.

About Climedo Health

Climedo Health's mission is to bring the best treatment to every patient by empowering healthcare professionals with intelligent software solutions. Together with Europe's leading hospitals, we have developed a cloud-based platform for cutting-edge clinical validation and post-market surveillance of medical devices and pharmaceutical products.

By digitally connecting all stakeholders (Medical Device manufacturers, Pharma companies, CROs, hospitals and patients), Climedo allows for increased performance, better cost-efficiencies - and ultimately - accelerated medical innovation.

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