Pilot Study for the Approval of a DiGA for Therapy Support in the Treatment of Depression

Starting Point

At the end of 2021, Elona Health was searching for an EDC or ePRO provider to conduct a pilot study for the approval of its digital health application (DiGA). The concept of the DiGA "elona therapy" is to accompany patients during the therapeutic treatment of medical conditions such as depression or anxiety and panic. The goal is to enable therapists to individualize the available content of the application based on the progress of the therapy. In this way, the DiGA can be integrated into the existing therapy and patients can be accompanied and supported by their therapists outside the practice through digital elements.

Fig. 1: The elona therapy DiGA

To achieve approval of their DiGA, Elona Health planned to conduct a pilot randomized controlled trial. For the successful implementation of the clinical trial, a digital solution was needed that met Elona Health's requirements. Among other things, it needed to be possible to pre-schedule the sending of ePRO questionnaires, capture data automatically, and send regular reminders. After comparing different providers, the project finally started with Climedo. A decisive criterion was that Climedo's platform met the most important requirements thanks to its flexibility in the ePRO and EDC application. A total of 80 patients participated in the study, which was conducted over a period of 12 weeks.

Project Description

For the pilot study, Elona Health used Climedo's EDC and ePRO solutions.

At the beginning, Elona Health's team received a short onboarding for the software. As part of the training, Climedo's CS (Customer Success) team, trained the company's managers and executives. Thanks to Climedo's intuitive self-setup, only a small amount of time was required to configure the study. Through regular check-ins, Climedo's CS team supported this phase. If necessary and on demand, further training was provided. This was followed by a final review from Climedo to uncover hidden potential for improvement. Finally, Elona Health activated the pilot study independently.

After successful completion of the pilot study, "elona therapy" received approval as a DiGA.

Fig. 2: ePRO questionnaires from elona therapy

Benefits and Results

In general, Elona Health particularly appreciated the ease of use, self-service and intuitiveness of Climedo's software. Although the company had not used an EDC or ePRO system before, Elona Health definitely sees the benefits of electronic data collection.

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The time and cost savings from using automated ePRO questionnaires were also great for the company compared to sending out paper-based questionnaires by hand. Elona Health found the reminder function for completing the ePROs and the ability to schedule them in advance to be particularly practical in this regard. Another positive aspect was that the questionnaires could be structured individually and self-determined. Elona Health liked the fact that the team was able to work independently and was not dependent on much support. At the same time, a contact person was always available in case of queries.

The Climdo software enables constant insight into the current data situation and the progress of the participants - quickly and at a glance. Elona Health particularly appreciated the clearly designed Climedo dashboards, which provide a structured overview of all participants' diagnoses and offer data insights in real time.

The randomization of the participants into the intervention group and the control group was also done via Climedo's EDC system. Since the participants' data were already stored in the EDC system after consenting to participate in the study, Elona Health was

able to perform the important step of randomization easily and quickly.

Overall, the implementation of the study was a complete success, as everything from the set-up of the study to its conclusion went as desired and the goal of DiGA approval was achieved. The results showed that patients had significantly improved effects in terms of relevant symptoms through the additional use of the "elona therapy" app compared to conventional therapy (i.e. without the additional use of the DiGA). As a result, the DiGA is now available to the 3.5 million people with statutory health insurance in Germany who seek psychotherapeutic help each year. Once a prescription has been issued, the costs of the DiGA can now be covered by a statutory health insurance fund.

Conclusion and Perspective

Following the successful completion of the pilot study and the successful collaboration with Climedo's software, joint projects between Elona Health and Climedo are planned for the future, including a follow-up study. This will further deepen the knowledge gained from the pilot study. At the same time, it will be examined to what extent "elona therapy" can also provide support for other clinical pictures and symptoms in addition to therapy.

Customer Testimonials

"The cooperation with Climedo was very professional and goal-oriented from the very beginning. The Climedo team supported us with an intuitive and flexible software solution that fully met our needs in terms of conducting our pilot study and legal requirements. We really appreciated the ease of use and self-service of the Climedo platform and the straightforward support from the Customer Success team helped us to successfully implement the study. The results speak for themselves: Not least thanks to the efficient data collection, we were able to achieve our DiGA approval. We look forward to further projects with Climedo!"

- Magnus Schückes, Founder and Managing Director, Elona Health

About Climedo

Climedo offers a digital health platform for hybrid clinical trials and observational studies. Its easy-to-use, modular and secure solutions for data management include electronic data capture (EDC), ePRO, eCOA, and Telemedicine. This enables pharma and medtech companies to validate their medical innovations more efficiently in the post-market phase and to capture data in decentralized, real-world settings. As a result, they accelerate studies, save costs, and improve data flow and quality, while fostering innovative trial designs. By connecting all stakeholders (industry partners, study sites, physicians and patients) in one cloud-based system, Climedo is revolutionizing clinical research and making trials more accessible and patient centric. Learn more at www.climedo.com.

About Elona Health

Elona Health develops innovative digital solutions for tomorrow's psychotherapy that support patients and psychotherapists alike. Elona Health's digital health applications accompany patients before, during and after therapy and support the transfer of psychotherapy into everyday life – parallel to their existing psychotherapy with their therapist. In this way, what has been learned is consolidated and sustainable processes of change are initiated. Elona Health attaches great importance to the perspective of the psychotherapist. The aim is to enable practitioners to have more time for their patients and to offer the best possible therapy – with the support of digital tools and smart processes that make everyday work easier. Last but not least, Elona Health is researching and developing solutions for on-site psychotherapeutic care together with psychotherapists in initial partner practices. With therapy-focused processes in a pleasant atmosphere for patients and therapists.