

Case Study

Clinical Study on a Dietary Supplement for Sleep Improvement

Summary

In 2020, Berlin-based contract research organization analyze & realize GmbH conducted a study for a sponsor from the pharmaceutical sector with around 300 subjects. The aim was to investigate the benefits and tolerability of a dietary supplement in healthy subjects with sleep problems. Climedo's electronic patient diary ("eDiary") was to be used for this purpose.

The Project

With the help of Climedo's eDiary solution, the monocentric study at analyze & realize GmbH was successfully launched in October 2020. Within the scope of the project, Climedo's electronic diary was sent to test subjects on a daily basis by email or SMS for three weeks. The diary contained up to 20 questions about subjects' intake of the study drug and its effects on their sleep problems. To make sure the subjects were up to speed on a technical level from the very beginning, they received a "mock eDiary" on the day of admission to the center to see the structure of the diaries and how they were supposed to be completed. After their first visit to the study site, all questionnaires could be answered from the comfort of their own home on their computer, tablet or smartphone, saving them unnecessary site visits.

Results

The results to date show that more than 99% of all subject questionnaires have been completed. Overall, Climedo is a great facilitator in data management: The answers are very easy for the CRA(s) to read. Another great advantage is being able to see the current data status as well as the progress in real time. With the help of Climedo's "Smart Views", specific data filters can be saved and accessed with just one click. This provides a quick overview of the development of particularly important core elements of the study. The client also praised the quality of the data. Even with test persons over 50 years of age, the study ran smoothly after a short training session with the digital questionnaire.

Customer Voices

"Even after a very short time, I was amazed by the good level of compliance in older subjects and the high-quality data. The diaries have all been filled out almost completely so far, which is very gratifying."

- **Felix Alt**, Head of Clinical Operations at analyze & realize GmbH

"I find the Climedo system very appealing and clear. After a short training session, everything is also very self-explanatory. We didn't even have to pull an export during the study because the data is presented so clearly."

- **Elisa Postrach**, Project Manager Clinical Research / Manager Scientific Affairs at analyze & realize GmbH

About Climedo

Climedo offers a digital platform for conducting clinical trials in an innovative way. The modular and user-friendly solution for Electronic Data Capture (EDC) enables pharmaceutical and medical device companies to efficiently validate their products and medical innovations in a decentralized and patient-centric way. By digitally connecting all parties involved, such as sponsors, doctors and patients, communication and data capture can be significantly simplified. The digital health company was founded in 2017 by Sascha Ritz, Dragan Mileski and Veronika Schweighart and is based in Munich. Learn more at www.climedo.com.

März 2021

© Climedo Health GmbH

www.climedo.de | hello@climedo.de

+49 89 3220 9394 0