

# Decentralized Product Test on an Ergonomic Mattress



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## Starting Point

In 2021, Berlin-based contract research institute (CRO) analyze & realize GmbH launched a product test for a mattress manufacturer. For this, participants also wore activity trackers at night to analyze their movement during sleep.

This product test would require a digital solution that could record surveys and product tests within one system. The solution also needed to offer a way to invite people to participate in the product test via a newsletter or by scanning a QR code and to pre-select suitable test subjects.



Furthermore, participants were supposed to receive electronic questionnaires from the product test automatically and it should be possible for analyze & realize GmbH to check participant entries in real time using a reporting function and interim evaluation.

All of this was to take place in a decentralized setting. The data protection regulations were also particularly important, as the participants' consent was required for the

collection of personal data. Since analyze & realize GmbH had already had positive experiences with Climedo, they suggested the platform to the sponsor as a solution.

## Project

The six-month product test was completely decentralized, meaning that participants did not have to travel to a center to fill out a questionnaire or diary, but could do so from the comfort of their own homes.

For the product test, the eDiary solution was used together with Climedo's study module. Setting up the survey including User Acceptance Test (UAT) and release took four weeks. This was followed by onboarding and project planning as well as review and setup in Climedo. The test phase and release took place during regular meetings between analyze & realize GmbH and Climedo's Customer Success Management (CSM) team. All meetings took place remotely, which enabled dynamic collaboration from different locations. As part of a "train the trainer" process, Climedo's CSM team trained the project manager at analyze & realize GmbH, who in turn familiarized the other users from his team with the system.

Based on their information, a pre-selection of potentially suitable product test participants could already be made in the participation survey. Interested parties were able to make an appointment by telephone with analyze & realize GmbH's call center directly from within the survey. During the telephone call, the call center employee confirmed the final eligibility of subjects and then enrolled selected participants in Climedo's study module, which had been adapted for the product test.

A total of 60 healthy participants from Germany were included in the decentralized product test. Their mattresses were shipped directly to them from the product manufacturer. The automatically delivered electronic diary contained 15-20 parameters, which varied according to the information provided with the help of dependencies in the questionnaire.

Participants received the web link to the respective electronic diary on a daily basis (in the morning) via email or SMS, and for a period of up to 3 weeks. If the questionnaires were not completed on time, an automatic reminder from the Climedo system would follow. Validations and fixed scheduling of the web links ensured that only realistic information was provided at comparable times of day.

Within the eDiary, questions would address areas such as sleep behavior, e.g. "How would you rate your sleep quality last night?" (on a scale of 0-10) or "Did you wake up last night? How often?"

The activity trackers were sent directly to the participants as well. They wore them at night in order to measure movement, temperature and light intensity, and to draw conclusions about sleep behavior.

## Results and Benefits

Climedo offered several benefits compared to paper or Excel spreadsheets. Creating the initial survey for product test participation via a QR code was quick and easy. In addition,

an immediate pre-selection of suitable participants for further contact was possible by means of a smart query within the survey. This enabled analyze & realize GmbH to stay within the specified time schedule of six months.

Climedo's software environment also enabled the inclusion of suitable survey participants and an overview of the status of the survey and the product test at a glance.

Another advantage was the scheduled, automated and flexible send-out of eDiaries to participants before and after the product delivery. analyze & realize GmbH was able to easily monitor the number of survey and product test participants and their data entries in real time.

In addition, analyze & realize GmbH benefited from a real-life data collection. An overview of the completion status displayed all data entries by the participants, as well as their compliance with the eDiaries. In case of any incomplete entries, it was possible to schedule automatic reminders. In addition, repeated missing entries were immediately visible, allowing for study subjects to be contacted directly.

Furthermore, it was possible to export data in a flexible, role-specific way for interim analysis at any time. Climedo was also able to record the reimbursement status for those participants who had completed the product test.

The Climedo users at analyze & realize GmbH particularly appreciated the ease of use and quick familiarization with the Climedo system. The client also emphasized the excellent support and exchange with the Climedo team during the onboarding and implementation phase.

analyze & realize GmbH enjoyed the pleasant cooperation with Climedo on this project as part of their long-term partnership. They also found it particularly valuable that all data at Climedo is hosted exclusively on German servers and is subject to German data protection laws.

## Conclusion and Perspectives

Due to the positive outcome of the joint project, the team at analyze & realize GmbH is likely to collaborate with Climedo again for future studies and tests. Decentralized clinical studies in particular are becoming increasingly popular and offer numerous advantages for patient recruitment and retention.

## Customer Testimonials

"Climedo offers user-friendly solutions with many features that simplify data collection and provide a real-time overview. "

- Hannes Riemenschneider, Project Manager, analyze & realize GmbH

## About Climedo

Climedo'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, they 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, pharmaceutical companies, CROs, hospitals and patients), Climedo allows for increased performance, better cost-efficiencies – and ultimately – accelerated medical innovation.

February 2022

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