Case Study

Successful Data Capture for a Phase IV Study with ePRO solutions

Starting Point

As part of a Phase IV study for a drug, commissioned by a German sponsor, the contract research organization (CRO) Pharmalog was spontaneously looking for a new eDiary solution for its clinical data capture in August of 2019. Previously, the sponsor had worked exclusively with paper-based patient diaries, which was no longer feasible due to the large time delays and high administrative workload. For this reason, a search for an electronic solution was to be conducted together with Pharmalog. After a successful audit of software company Climedo Health in August 2019, Pharmalog chose Climedo Health as the provider.

Project

The aim of the study was to use Climedo's **ePRO (electronic Patient-Reported Outcome)** solutions to survey **450 subjects in 22 centers** about their health status and medication use on a daily basis. In total, there were **88 active users** in the Climedo system on the part of the sponsor, the CRO and the study centers, whose roles and rights could be managed individually. This ensured, for example, that the sponsor could not view identifying subject data, such as email addresses. The recruitment phase was scheduled for **six and a half months**, but was successfully **completed after only four and a half months** in March of 2020.

Subjects received a **daily electronic patient diary** via text message and/or email over a **16-day period** and could conveniently complete the form at their discretion, which consisted of **five to eight questions**, from any device. This meant they did not have to travel to a center or fill out and mail paper questionnaires to share the information. In addition, **automated notifications and reminders** could be sent to subjects to ensure that all information was entered on time and that the study was still on track.

Results and Benefits

Although the Climedo solution required some additional initial time investments compared to paper, (CRAs and centers had to be trained in using the system), everyone agreed that it had a **highly positive impact on the data collection and data quality**.

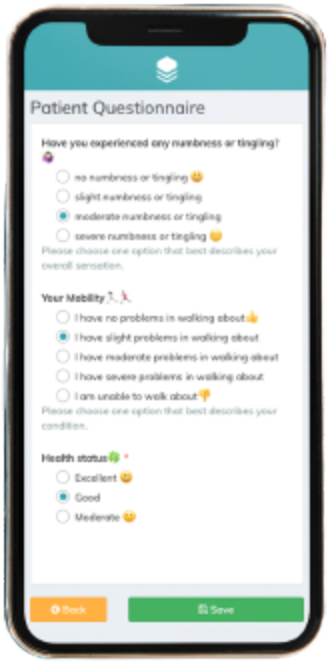

Fig 1: Example of a Climedo ePRO diary.

Benefits for Centers and Subjects

As for the participating subjects, 60% said they were "**very satisfied**" or "**satisfied**" with Climedo Health's ePRO solution. A survey of the study centers resulted in an **NPS** ("Net Promoter Score") **of 8.33**. The solution was perceived as "**reliable, high-quality and effort-saving**" and was described as **time-saving and practical** compared to paper – both for the subjects and the study centers.

"Climedo's Smart Views were particularly helpful for us, as they allowed us to get an overview of the most important information quickly and easily."

- Study Center

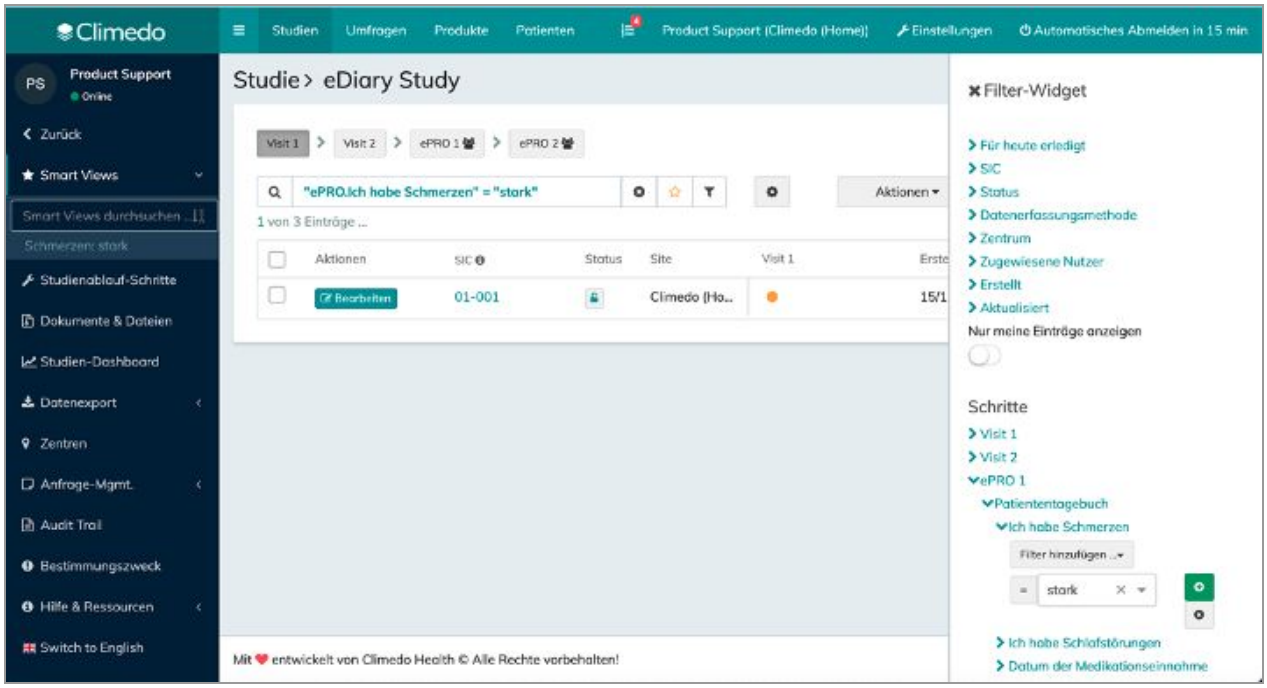

Fig. 2: Example of a Smart View in Climedo.

Benefits for Monitors

Monitors also saw many advantages to Climedo Health's ePRO solution. It was described as "**useful, reliable** and effort-saving." The **Remote Data Review** saved monitors about **10-20% in time**. The monitors also benefited from **improved data quality** compared to paper.

"We were looking for a new system with an eDiary feature. Thanks to Climedo's fast and flexible support, we could start our study in a short amount of time. We plan to use the system for additional studies in the future."

- Dr. Jens Milde, Managing Director, Pharmalog Institute for Clinical Research

Improved Patient Compliance and Safety

In terms of **data management** during the study, it was a great advantage to have all **data immediately available in a digital form**. Entries could be made in a timely manner and were thus also closer to the actual medication intake time of the subjects. Thanks to the **pre-set reminders via SMS**, subjects could be reminded to make their entries promptly and before the deadline at the end of the day. It also became possible to **identify potential dropouts** well in advance and thus to know immediately whether a patient might need to be replaced. Thanks to the **decentralized (remote) monitoring**, medication adherence could be checked in real time, and thus patient safety could be better assessed.

Improved Data Quality

This ultimately led to significantly improved data quality. Climedo also offered significant advantages in terms of **data cleansing**: Unlike paper questionnaires, **no arbitrary comments** from subjects were possible, which made data cleansing much easier and **fundamentally improved patient compliance**.

"Thanks to Climedo, we have achieved a significantly higher response rate as well as an improved completion rate for our eDiaries. The solution was also well received by patients. An interim evaluation of the study was possible in no time – this would have been unthinkable with paper. The ePRO solution and the associated rapid data insights have therefore saved us a lot of time."

- Thomas Huber, Head of Data Management, Pharmalog Institute for Clinical Research

Additional Benefits

Last but not least, the monitors particularly appreciated the **customer support**, the **data export** (via Excel), the **viewing of patient entries** in real time, even between on-site visits, and the traffic light system if, for example, information was missing or the schedule could not be met. The study sponsor, in turn, found the **Smart Views** (saved, pre-filtered views) particularly helpful in quickly getting an **overview of the information** most relevant to the study progress. In addition to the mentioned data quality and patient compliance, it was also possible to better **implement GDPR requirements**, as the electronic questionnaire did not allow subjects to provide unsolicited information, such as identifying data. The ePRO solution was well accepted **by all age groups**.

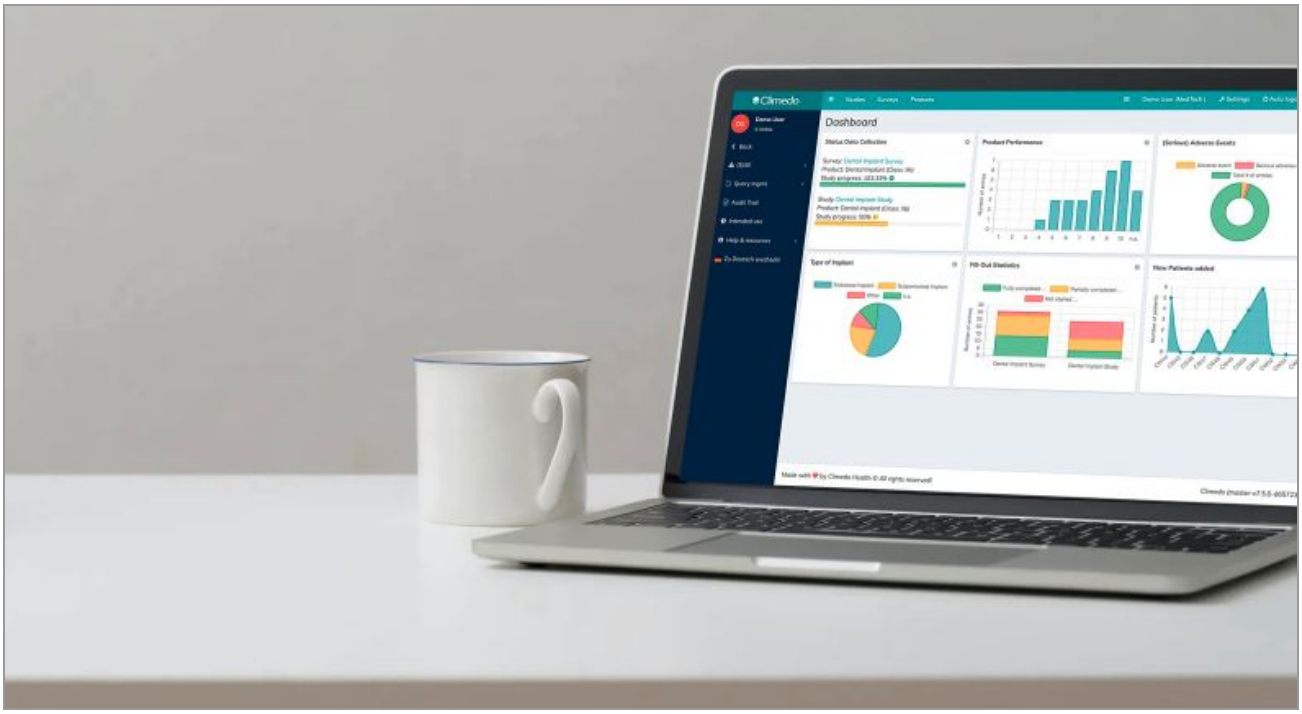

Fig. 3: Example of a Climedo dashboard.

Conclusion and Outlook

Given the **high level of satisfaction**, the study sponsor could also envision **future projects** with Climedo Health. Pharmalog, the monitors and the study centers enjoy the **great communication**, the **solution-oriented exchanges** and the **easily accessible Climedo support**. Shortly after, Pharmalog already started its next study project with Climedo. A major advantage of having a preferred partner for digital solutions is the fact that the system becomes more and more familiar to Pharmalog's staff. Thus, the implementation of new studies becomes faster with each project and the **data evaluation becomes easier**, which can translate into even **greater time savings** in the medium term.

"Thanks to Climedo's digital patient diaries (eDiaries), we achieved a high response rate. With the automated reminders, the study plan was complied with very well. We could always see the data entered by the patient immediately in the system and thus always had a quick overview of the current study status. We could imagine using Climedo's eDiary again in the future and would definitely recommend the solution to others!"

- Study Sponsor

About Climedo Health

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, 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.

About Pharmalog

PHARMALOG is one of the leading full-service CROs (Contract Research Organizations) in Europe, based in Ismaning near Munich, Germany. With over 37 years of experience, we are experts in the field of clinical research. Compliance with national laws, European guidelines and the international standard (ICH-GCP) is important and a matter of course for us.

Our company employs highly qualified and motivated staff who conduct clinical studies of phases I to IV for the pharmaceutical and biotechnology industry as well as clinical studies for manufacturers of medical devices. Our range of services also includes support for post-marketing studies and pharmacoeconomic studies.

February 2021

www.climedo.com | info@climedo.de
+49 89 3220 9394 0