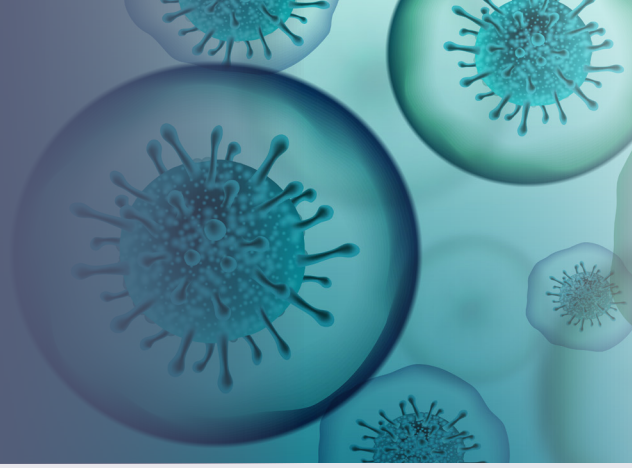
CLINILABS
DRUG DEVELOPMENT CORPORATION

Thrown a COVID Curveball, Clinilabs Swiftly Adapts Virtual DCT Approach for Sleep Study



Business Challenge

When the COVID-19 pandemic hit in the Spring of 2020, the Clinilabs team was in the midst of planning a large multicenter clinical trial that involved laboratory-based and home sleep testing of people with sleep-related breathing disorders. Uncertain of the impact of the pandemic, the study sponsor paused activity to assess the feasibility of completing the project and collecting good quality data. This led to a redesign of the study to minimize subjects' exposure to the virus while meeting pre-established study timelines.

Solution

The collective team from the sponsor and Clinilabs worked collaboratively to revise the protocol, converting the original clinic-based methodology to a decentralized clinical trial (DCT) approach. We leveraged telemedicine, electronic tools for informed consent and remote subject assessment, and wearable technology for home sleep testing to implement most aspects of the study. Our new design kept subjects at home and minimized time in the clinic, all without jeopardizing the rigor of the study or the integrity of the data.

OVERVIEW

Sleep apnea is a common and treatable sleep-related breathing disorder that impacts quality of life and is associated with significant health concerns. People with untreated sleep apnea are at greater risk for cardiac arrhythmia, hypertension, stroke, and cardiovascular death. Once diagnosed, treatment is available. However, the most common treatments are weight loss and continuous positive airway pressure (CPAP, which requires the patient to use a machine and headgear to deliver air to the upper airway) both of which often are difficult for patients to maintain.

The primary objective of our study was to evaluate a novel method of diagnosing and identifying a new drug treatment for sleep apnea. The original study design included an in-office screening visit, in-laboratory polysomnography (PSG), multiple in-office follow-up visits, and home sleep testing (HST). Traditional source documents were developed, including paper informed consent forms, rating scales, and other source documents designed to be completed during face-to-face sessions. HST devices were to be picked-up and dropped-off during office visits.

> "The DCT design implemented by Clinilabs highlights our patient-centric focus on data gathering and subject safety. And in this instance, it demonstrates our insight into DCTs as the way of the future in clinical trials."
>
> - Gary Zammit, PhD - President and Chief Executive Officer

Once the pandemic hit, the future of the trial was uncertain. We did not know if subjects would be interested in study participation, nor did we know the level of risk that might be associated with clinic visits. While meeting our commitments to the sponsor was important, subject safety was paramount. The project team was determined to find a path forward that would produce high quality data, meet project timelines, and maximize subject safety. The solution was a DCT approach. Consequently, the protocol was revised to conduct virtually all aspects of the study using telemedicine and technology such as video and mobile devices with the patients at home. This included pre-screening, screening, consenting, monitoring and guidance to the patients on how to use the in-bed sensor and HSAT devices to record, store and transmit data. Real-time video interactions provide a live exchange of information, including the opportunity for Q&A, between the trial personnel and the participants. The only part of the protocol not addressable by virtual means was the required in-person visit for the PSG, and here the Clinilabs team worked with each study site to implement a rigorous COVID-19 action plan to support patient safety. This DCT approach has since been used with other CNS trials, and is rapidly becoming a new standard in the design of clinical trials in psychiatry and neurology.