CLINILABS

Sleep Disorders

A Leader in Insomnia, Sleep Apnea and Other Sleep Disorders

Phase I Units with Accredited Sleep Laboratory

Our phase 1 units in New York and New Jersey offer 20 bedrooms that are specially designed to support clinical trials in the field of sleep medicine. Each bedroom provides single occupancy for subjects in a temperature, sound, and light-controlled environment suitable for sleep studies. Each bed is fully-outfitted for polysomnographic (PSG) recording using state-of-the-art equipment. Our team of investigators, support staff, and certified PSG technologists enables us to provide experienced study teams capable of executing the most complex study protocols. Psychometric assessments using objective measures of sleepiness (e.g., computerized cognitive assessment, psychomotor vigilance tasks, quantitative EEG) and self-report measures are completed by skilled clinicians. Driving simulator studies to assess residual sleepiness are provided using realistic, multiscreen systems. We have extensive experience in Phase 1 studies, proof-of-concept experimental models of insomnia (e.g., first-night-effect, phase advance), and phase 2 and 3 PSG and outpatient studies. We also have established teams to conduct human abuse liability (HAL), Asian bridging and thorough QT studies. Our database includes thousands of people with insomnia, sleep apnea, restless legs syndrome, circadian rhythm disorders (e.g., jet lag), and excessive sleepiness.

PSG Core Laboratory

Clinilabs' core data center is a recognized leader in centralized polysomnographic (PSG), actigraphy, and video recordings, providing support for global, multicenter sleep trials. We deploy the latest instrumentation, and pair this with time-tested standard operating procedures for use at investigator sites and at our high performance data center in New Jersey. Data collected at the investigator site are transmitted electronically to our secure data center so that tracings can be scored by our team of board certified readers. A helpdesk is available 24/7 to support investigator sites around the world. We have successfully completed trials in 42 countries, and have supported over 500 investigator sites.

Advisory, Regulatory, and Medical Writing Services

Clinilabs' team provides expert advisory and medical writing services rendered by people who are key opinion leaders and published authors in the field of sleep medicine. We pair this with an intimate understanding of the regulatory aspects of clinical development programs to offer an unparalleled level of service.

Global CRO Services

Clinilabs maintains in-house capabilities to support domestic multicenter Phase I and Phase II sleep trials. When asked to provide full-service CRO capabilities for large, global, multicenter studies that exceed our capacity, we are able to work with trusted partners to deliver an integrated, therapeutically-focused project team. This team is unparalleled in its understanding of the challenges associated with the development of new drugs for sleep disorders. Our therapeutically-focused team is supported by integrated services that manage site selection, regulatory, study startup, patient recruitment, data management, statistics, and medical writing.

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