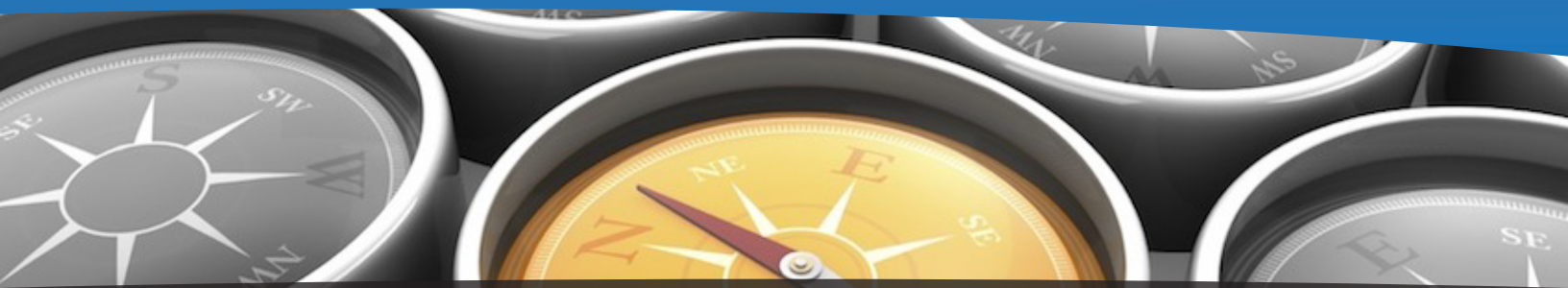
MULTICENTER, FULL SERVICE CRO CASE STUDY

CLINILABS



A Double-Blind, Parallel Group, Randomized, Placebo Controlled Sleep Laboratory Study

Study Information

Clinical Phase	Phase II
Indication	Primary Insomnia
Enrollment Period	Expected Enrollment Period: 10 months Actual Enrollment Period: 6 months
Study Design	A two-week single blind run-in period (placebo) followed by a 4 week double-blind, parallel group treatment with XXXX x mg., y mg., or placebo.
Study Populations	Male and female subjects, healthy, aged 18 - 80, suffering from primary insomnia across 9 sites. *Note: After the program was awarded to Clinilabs, the sponsor required an expansion of the target population from subjects aged 18-49, to include subjects aged 50-80 which are historically much more difficult to identify. Clinilabs carefully selected research sites with proven experience in enrolling both age groups. Not only was Clinilabs able to complete the study within the originally proposed timelines, but both stratified groups enrolled 4 months early.*
Number of Clinical Sites	Sponsor recommended: 12 Clinilabs recommended: 9 *Note: Clinilabs felt the sponsor's expectations and study objectives could be met with fewer clinical sites, resulting in a significant reduction in study expenses.*

Enrollment Metrics

	Screened	Randomized	Completed
Expected	600	150	120
Actual	289	137	127

Note: Due to the need to use multiple polysomnograms (PSGs) as inclusion/exclusion criteria, the subject screening costs for this trial were expected to be high. It was important for Clinilabs to maintain tight control of the screening activities and stress the importance of screening only the best-qualified subjects at each investigative site. This resulted in a significantly lower screen fail rate (52% vs 75%) and a higher completion rate (92% vs 80%) than experienced in previous trials by this Sponsor.

CRO Services

- Feasibility & Protocol Design
- Project Management
- Investigator Meeting Management
- Contract & Budget Administration
- Regulatory Agency Submission
- Clinical Site Monitoring
- Pharmacovigilence
- Data Management
- Biostatistics
- Clinical Supply Management
- Vendor Management (IVRS, Central Lab, Drug Importation)
- ECG & PSG Core Lab
- Medical Writing & CSR

Budget

As a result of Clinilabs' strong oversight of screening activities, the study completed 4 months ahead of schedule and came in 34% under budget.

Clinilabs, a contract research organization (CRO), was selected by an international drug discovery and development company to provide full-service CRO management of a phase II primary insomnia program. The sponsor selected Clinilabs for a variety of reasons, including expertise in the field of sleep medicine, established CRO infrastructure, and the ability to identify high-performing investigator sites in the field of sleep medicine.

Clinilabs worked closely with the sponsor to design a study that would meet approval with regulatory agencies. We then completed a feasibility survey to identify a small group of investigators in the US who had prior experience in insomnia trials. From its prior experience, the sponsor expected to utilize 12 research sites for this program. However, based on the experience of the sites Clinilabs identified, 9 sites were activated, which saved a substantial amount in study management expenses.

Following the study award, Clinilabs assembled an exceptional study team, including an experienced project manager, medical monitor, clinical monitors, data managers, biostatistician, and medical writer, and appropriate sub-vendors were identified (e.g., IVRS system, clinical laboratory, drug importation). Clinilabs also provided in-house core laboratory services for the processing of EKG and PSG data. There were no changes to the study team throughout the duration of the trial.

Overall, the study performance was remarkable. We screened subjects at a faster rate than anticipated, experienced a lower failure rate than projected, and completed the study for less cost than budgeted. The sponsor expected, based on its prior experience, an enrollment period of 10 months; we completed enrollment in 6. They also expected to screen 600 patients in order to randomize 150 and complete 120 subjects. As a result of effective screening and high retention rates at high-quality investigator sites, we actually screened 289 patients, randomized 137 patients, and completed 127 patients. The savings that resulted from screening and operational efficiencies resulted in a total project cost that was 34% less than projected - the savings were realized by the client.

> *"No doubt Clinilabs will be our first choice for our next CRO assignment."*
> *~ Clinical Study Manager*

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