CLINILABS
THE CRO FOR CNS

CASE STUDY

A Complex, Randomized, Double-Blind, Double-Dummy, Placebo-Controlled Comparative Study of the PK and PD Effects of Two Drug Formulations

STUDY INFORMATION

CLINICAL PHASE | Phase 1

ENROLLMENT PERIOD | Seven weeks from FPI to LPO

STUDY DESIGN | Screening visit followed by 3 treatment days separated by a 7-14 day washout period

STUDY OBJECTIVES | To assess the kinetic-dynamic relationship of two drugs with frequent pharmacokinetic (PK) sampling combined with pharmocodynamic (PD) measures including psychometric assessments, neuroendocrine assessments, and quantitative electroencephalographic (QEEG) recordings

OVERVIEW

This case study describes Clinilabs' execution of a complex, randomized, double-blind, double-dummy, placebo-controlled comparative study of the PK and PD effects of 2 drug formulations with frequent PK sampling, computerized psychometric assessments, neuroendocrine assessments, and QEEG recordings. The primary outcome measure of the study was post-dose EEG activity.

The sponsor contracted Clinilabs because of their confidence in our Phase 1 capabilities, having placed more than 15 studies with us in the past. The sponsor wanted a CRO that could work collaboratively with Key Opinion Leaders (KOLs) from academia to implement novel PD assessments in a complex study design.

The first-patient-in (FPI) occurred 10 weeks following the sponsor's first contact with Clinilabs, and within 17 days of receipt of the final protocol. Eighty-one healthy adults between the ages of 19 and 45 years were enrolled over a 5-week period, resulting in 70 completed subjects. All completers participated in a thorough screening visit followed by 3 treatment days separated by a 7 to 14 day washout period. On the evening prior to each treatment day, subjects reported to the Phase 1 unit for admission and pre-treatment procedures. They were dosed the following morning, after which they remained under constant observation. Twenty-two PK samples were obtained on each treatment day, and most samples were associated with multiple concurrent PD assessments, including QEEG assessments. The staffing ratio for this procedure-intensive study was 3 staff to 1 subject.

One of the main challenges of this study was the careful coordination and timing of PK and PD assessments, which had to be performed in accordance with a strict schedule that allowed no assessment windows. Clinilabs' team was able to adhere to this schedule without deviation in over 4.620 sample times.

> **"The execution of this study was impeccable. I heartily recommend Clinilabs to my neuroscience colleagues"**
>
> **– Vice President, Neuroscience R&D**

The successful execution of this study provided the sponsor with validated biomarkers that ere later sued in the identification of new investigational products for the treatment of a CNS disorder. Following the completion of the study, the Cllinilabs' team worked collaboratively with the sponsor and KOLs to complete the clinical study report and produce posters for presentation at scientific meetings. The sponsor was especially pleased with the study timeline, data quality, and overall responsiveness of the study team.