CLINILABS
DRUG DEVELOPMENT CORPORATION

# Clinilabs Puts Safety First in First-in-Human Trial, Designing Protocol to Mitigate Risk

## Business Challenge

Significant safety concerns, including cardiovascular and seizure risk were associated with the drug.

## Solution

Clinilabs negotiated a dosing schedule and designed a protocol to mitigate risk to subjects.

## Results

The Clinilabs team completed the project with no major protocol deviations, and the sponsor was pleased with the quality of our deliverables.

## OVERVIEW

This first-in-human trial highlights the ability of Clinilabs Drug Development Corporation to work collaboratively with sponsors to complete early phase studies. The integrated dose-escalation trial evaluated the safety, tolerability, and pharmacokinetics of a new investigational product in healthy volunteers. The protocol required morning dosing, the collection of PK and multiple other samples (blood and urine), and food and drug interaction cohorts. Intensive electrocardiographic (ECG) and electroencephalographic (EEG) recordings were obtained as safety measures. Thirty-nine subjects, divided into 4 treatment cohorts, were randomized into the trial in a 3-month period. The protocol directed Clinilabs to start the dosing with a full cohort of 9 subjects at the initial dose level.

> "In over 25 years of managing Phase I studies at big pharma companies, I cannot recall a better experience than we had with you. Thank you, Clinilabs!"
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> *–Senior Director, Clinical Pharmacology*

Recognizing the significant safety concerns associated with this drug, Clinilabs negotiated a dosing schedule that allowed us to pre-dose two subjects in each cohort in order to mitigate risk. The revised dosing schedule was designed so that it still met the sponsor's original timeline for the last-patient-out (LPO). Pre-clinical data suggested that there may be both cardiovascular and seizure risks associated with this drug. Therefore, Clinilabs worked closely with the sponsor to design a protocol that included intensive ECG and EEG monitoring at screening and after study drug exposure, with photic stimulation and hyperventilation employed as provocative stimuli. Clinilabs also proposed the inclusion of frequent assessments of orthostatic vital signs, which ultimately proved informative when we noted several episodes of fainting at higher doses of drug.

As with all studies, Clinilabs' staff completed protocol-specific training prior to study start-up, which enabled us to complete the project with no major protocol deviations. The sponsor was especially pleased with the quality of our templated source documents, contemporaneous electronic case report form (eCRF) entries, and internal quality control management, which resulted in a low number of queries.