FIRST-IN-HUMAN TRIAL CASE STUDY

CLINILABS

An Integrated Dose Escalation Study Evaluating the Safety, Tolerability, & Pharmacokinetics of a New Investigational Product in Healthy Volunteers

Study Information

Clinical Phase	Phase I
Time Schedule	Twelve weeks from FPI to LPO
Study Populations	Normal healthy volunteers
Study Objectives	To evaluate the safety, tolerability, and pharmacokinetics of an investigational product in healthy volunteers

This case study describes a first-in-human trial that highlights Clinilabs' ability to work collaboratively with sponsors to complete early phase studies. This 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. However, 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 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 syncope at higher doses of drug.

As with all studies, Clinilabs' staff completed protocol-specific training prior to study start-up. This 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 eCRF entries, and internal QC management, which resulted in a low number of queries.

> *"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!*
> *~ Senior Director, Clinical Pharmacology*

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