



Veeda's Successful Execution of Pharmacokinetic Bioequivalence Study of Inhalation powder

Type of Study

Two-way crossover PK study of Inhalation powder in healthy volunteers

Regulatory Parameters:

USFDA Submission: Fluticasone Propionate 500 mcg and Salmeterol 50 mcg Inhalation Powder using Inhaler

Situational Analysis

A multinational pharmaceutical company was planning the marketing approval in India for Fluticasone Propionate 500 mcg and Salmeterol 50 mcg Inhalation Powder for Inhalation. Veeda was responsible for providing services as per the need of the client.

Veeda Supported the client in the following services:

- Identification & Selection of Investigator
- Ethics Committee Submission
- Project Management
- Subject Recruitment and Retention
- Investigational Medicinal Product Management
- Data Management & Biostatics
- Medical Writing & Lab Logistics

Highlights of Results Delivered

Completed the clinical part in less than 01 month

Required subjects were randomized

Achievement of all study objective

Zero SAEs



Safety / tolerability parameters assessed throughout the study included

Clinical Examination

Clinical Laboratory Assessments

Adverse Events monitoring

Vital Signs measurement



Major Study Challenges & Actions

Challenges	Action Plan
Study-specific testing in screening was required, like Chest CT scans and other tests to ensure pulmonary function tests are within an acceptable range, which was more time-consuming and required more skilled staff.	Veeda's trained staff was given the responsibility to conduct screening tests including study-specific testing & measurement to make the process efficient and ensure minimum turnaround time
Dosing device (Inhaler) training to each individual volunteer	Veeda's team of trained project coordinators provided inhalation dosage training to each and every volunteer to achieve maximum dosing/dosage compliance
Due to COVID-19 Pandemic, extra precaution was required starting from screening and during housing	Veeda ensured the allocation of a specialized team to handle any adverse situations and ensure that all precautionary measures were taken during the study
Repeated inhalation device training was required to be given to all volunteers to achieve maximum dosing compliance	Proper counseling was conducted by experienced staff to ensure proper dosing/dosage compliance



Our Roadmap for Successful Execution

- Veeda has provided regulatory preparation and submission services to regulatory agency which was achieved within stipulated time
- Volunteer recruitment was achieved well as per plan and high volunteer retention with low drop out was maintained
- Veeda also provided technical support to sponsor post dossier submission
- Required volunteers were enrolled
- Team of PM, Investigator, PC, Pharmacist, QC were working nonstop to ensure delivery of quality results within stipulated time


Veeda's Approach that helped in Smooth Execution of the Study:

- A trained clinical research physician/Investigator was available from pre-dose till completion of housing of subject in each period/cohort
- Veeda's Clinical facility is well equipped with ICU for management of medical emergencies. All lifesaving equipment's like defibrillator, suction apparatus, laryngoscope and emergency medicines are available in our clinical facilities
- Experienced Study Physicians were appointed round the clock in clinical facility for subjects' monitoring
- Veeda has contacts with multi-specialty hospitals for emergency management of subject during the study
- At the time of end of study, iron supplements were provided to subject sufficient for one month

Result

Vigilant approach to complete the study under COVID-19 situation by establishment of controlled environment to the subjects and study staff was successful.

- Volunteer retention and compliance to study requirements was achieved
- All enrolled volunteers had completed the entire study
- Product was successfully passed based on the bioanalytical results of this study

 India: +91 79677 73000
Europe: +30 210 699 7247

 info@veedalifesciences.com

 <https://veedalifesciences.com/>

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