veeda clinical research®

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**

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**