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Navigating Complexities of Inhalation Clinical Studies:

A Comparative Bioavailability Study of Tiotropium Bromide Inhalation Solution for COPD Management

Type of Study

An open label, randomized, parallel-group, single period, single-dose, single centre comparative bioavailability study of three test formulations, of Tiotropium bromide inhalation solution in healthy, adult, male, human subjects under fasting condition.

Molecule Overview

Tiotropium Bromide is indicated for the long-term, once-daily, maintenance treatment of Bronchospasm associated with Chronic Obstructive Pulmonary Disease (COPD), including Chronic Bronchitis and Emphysema. It is also indicated to reduce exacerbations in COPD patients.

Veeda supported the client in following services for the successful execution of the study

01 Study Design & Execution

02 Volunteer Recruitment & Retention

03 Investigational Product Management (IMP) & Administration

04 Local Regulatory Applications & Ethics Committee Dossiers Submissions

05 PK Blood Sample Management

Highlights of Results Delivered

- A total of **116** volunteers were screened for the study
- **72** Vollunteers enrolled

Safety Assessment parameters assessed throughout the study as below

- Subjects throughout the study were monitored, and safety and preventive measures were ensured to minimize the risk of AEs
- Subjects were trained on inspiratory flow rate, duration of inhalation, and handling of inhalers independently and correctly

Major Study Challenges & Actions

Challenges	Action Plan
Dosing Challenges due to the usage of two different complex formulations- Nebulizers and Inhalers for drug delivery	Monitoring of the nebulizer and inhaler devices was upheld to mitigate potential dosing challenges. Due to the usage of two types of complex formulations, there was a need to train the volunteers to handle the formulations effectively for optimal dose delivery
It was necessary to maintain ideal storage conditions for the IMP due to the complex nature of the molecule	The stability chambers were monitored and maintained to ensure proper storage of the IMP in addition to verifying the dispensing activities of the Investigational Medicinal Product (IMP)

Conclusion

Within the designated timeline, the study was successfully concluded, meeting the requirements for submission to the US Food and Drug Administration (USFDA)

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