veeda clinical research®

Case Study

Veeda Oncology

Managing Complexities associated with BE (Bioequivalence) Study of an Oncology drug candidate

Type of Study

A multicentre, open-label, balanced, randomized, two-treatment, two-period, two-sequence, single dose, cross-over bioequivalence study of Doxorubicin Hydrochloride (Pegylated liposomal) concentrate solution for infusion 20 mg/10mL (2 mg/ml) in advanced ovarian cancer and/or metastatic breast cancer patients under fed condition

Situational Analysis

An Indian Pharmaceutical company was seeking marketing approval in the EMEA region for its Doxorubicin Hydrochloride (Pegylated liposomal) concentrate solution for infusion 20 mg/10mL (2 mg/mL).

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

- Study Design and Execution
- Volunteer Recruitment & Retention
- Quality Assurance
- Site Feasibility & Investigator selection across India
- Investigational Medicinal Product Management
- Biostatistics
- Medical Writing
- PK Blood Sample Management
- Clinical Study Report
- Ethics Committee Dossiers Submission
- Phlebotomist Management across all sites
- Project Management
- Clinical Sites Monitoring

Highlights of Results Delivered

Recruitment was completed within **05 months**

94 patients were enrolled

Safety Assessment parameters assessed throughout the study

- Clinical Laboratory Assessment (Haematology, Biochemistry, Serology, Urine analysis, etc.)
- Radiological Assessment (Chest X-ray)
- Cardiology Assessment (2D ECHO, ECG)
- Continuous Adverse Event Monitoring
- Clinical Examination & Vital Signs Measurements

Major Study Challenges and Action Plan

Challenges	Action Plan
Pre-study Qualification Visit was a challenge for the sponsor during the COVID era due to travel restrictions	Veeda's Clinical Research Monitor team helped sponsor conducting a telephonic Pre-study Qualification Visit
PEGylated liposomal Doxorubicin is a sensitive molecule in terms of its formulation, hence, PK sample management, collection, and processing was a big challenge	A dedicated, trained team of phlebotomists was formed, which ensured sterile conditions during the whole sample collection and management process
As per protocol, Granisetron and Dexamethasone was to be given as pre-medication to all volunteers during the study dosing	Veeda's clinical dosing team maintained the administration of the same brand of Granisetron and Dexamethasone in volunteers across all sites

Results

- 74 patients completed the study as per protocol
- Primary and Secondary endpoints were successfully achieved in statistical analysis

To know more about our
Oncology Drug-development capabilities, mail us at
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