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EMA Submission

Quetiapine Fumarate Prolonged Release Tablets EQ 400 MG

Situational Analysis

An Indian multinational pharmaceutical company was planning the marketing approval in the EU for Schizophrenic patients. Veeda was given the responsibility of providing full services to the client for this study which included identification & selection of Investigator, Ethics committee submission, budget negotiation, contract investigator, Project Management, Patient Recruitment and Retention, Investigational Medicinal Product management, Data Management, Biostatics, Medical Writing & Lab Logistics

Study Details

Randomized, open-label, two-treatment, two-period, cross-over, multiple dose, steady state, multi-centre comparative bioequivalence study of Quetiapine Fumarate prolonged-release tablets EQ 400 mg base: EMA Submission

Highlights of Results Delivered

64 patients were enrolled from 4 sites in 1.5 months

Product was successfully approved by EMA

Patient recruitment was achieved well before study milestones

Challenges

- PK sample collection and processing became a challenge for phlebotomist considering enrolment in batch of patients
- Safety of patient during housing considering psychiatric patient
- Difficulty of handling the patient during housing
- Difficulty in maintaining diet and posture restriction

Action Plan

- Veeda provided trained Phlebotomists to all the sites for PK sample collection and processing
- Veeda had a Custodian appointed 24 X 7 as back up for safety of patients
- Veeda ensured allocation of specialized nurses for handling of psychiatric patients
- Proper counselling was done by well experienced nurses & duty doctors to ensure diet and posture restriction

Successful Execution

- Study involved Veeda providing regulatory preparation and submission services to DCGI which was achieved within stipulated time
- Patient recruitment was achieved well before study milestones and high patient retention with low drop out was maintained
- Database Lock was achieved before study milestone resulting in quality clinical study report being provided to sponsor as per committed timelines
- Veeda also provided technical support to sponsor post dossier submission
- Total 64 patients were enrolled from 4 sites in just 1.5 months
- Team of PM, CTL, CRAs and CTA were working nonstop to ensure delivery of quality results within stipulated time

Outcome

- Patient retention and compliance to study requirements was achieved by hospitalization of patients during entire course of study conduction period
- Hospitalization of patients resulted in less drop outs and 60 patients out of 64 enrolled had completed the entire study
- Product was successfully approved by EMA based on the results of this study

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