Case Study

veeda clinical research

USFDA submission in Fresh / Relapsed Multiple Myeloma patients

Vigilant approach to significantly reduce the Screen Fail Ratio

Situational Analysis

An Indian multinational pharmaceutical company was planning the marketing approval in the US for Fresh/Relapsed Multiple Myeloma patients. Veeda was bestowed with 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, Biostatistics, Medical Writing & Lab Logistics.

Highlights of Results Delivered

Completed the study in only **7 months**

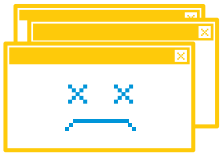
Randomized **44 patients in 7 months**

Significant reduction in the Screen Failure Ratio

Study Details

Randomized, Two-treatment, two-period, Single dose, Crossover, Bioequivalence study of Bortezomib S.C. Injection 3.5 mg/mL: USFDA Submission

Challenges

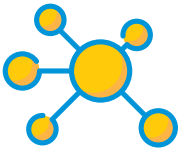


High Screen Failure

At the outset of the study many patients ended up having screen failure, which was initially observed to be around as high as 50%. It came across as a major challenge during the patient screening

Patient Recruitment

Veeda faced patient recruitment challenges, as one more competitive study with higher per patient grant was parallelly ongoing in India during this study conduction period



Molecule Sensitivity

PK sample collection and processing became a challenge considering the sensitivity of molecule

Equipment Challenges

Few sites reported the breakdown of deep freezers at the last moment

Additional Challenges

Delayed deliveries by logistics vendors & the transportation of patients to sites due to travel restrictions imposed by Covid-19 across the country

Action Plan

1. Entire team of PM, CTL, CRAs and CTA were working nonstop on emergency response strategies to ensure delivery of quality results within stipulated time

2. A detailed trend analysis was carried out by the team in order to identify recurrent reasons for screening failure. At the end of trend analysis, few lab parameters were identified leading to high ratio of screen failure. The same was conveyed to all the investigators and they were requested to have more vigilant review of patients' clinical conditions and lab parameters prior to screening any patient into the study

3. Veeda initiated additional sites to complete the patient recruitment along with rigorous follow-ups with site managers, study coordinators & SMOs to overcome the challenges imposed by one of the competitive study's alongside patient recruitment

4. Veeda provided trained Phlebotomist and Bio analyst to all the sites. Further, considering photosensitive nature of molecule, yellow monochromatic lights were also provided to sites to handle the ultra-sensitive nature of molecule

5. Due to various logistics restrictions, shipping samples to central lab was challenging. Considering the same NABL accredited local labs were approached for conducting screening and end of study assessments

6. PK sampling material, IMPs, Compassionate medications were identified well in advance and additional material was sent to sites proactively to manage any emergency situations

7. As few sites were at locations highly affected by COVID-19 , thereby affecting patients recruitment. Hence new sites were identified in regions less/not affected by COVID and were brought on board quickly to ensure timely recruitment.

8. As transportation facility was not available for phlebotomists and Bioanalysts to travel to sites, phlebotomists from respective sites were identified and trained to conduct PK sampling activities. They were also guided by Veeda monitors and phlebotomists to ensure appropriate PK sampling

Results

- Early identification of lab parameters followed by timely trend analysis helped the team reduce the screen failure ratio significantly
- Patient retention and compliance to study requirements was achieved by social hospitalization of patients during entire course of study conduction period
- Total 44 patients were randomized in 7 months from 19 sites in India by Veeda Clinical Research
- In spite of competitive studies and various restrictions imposed by Government during COVID pandemic, patient recruitment could be achieved as per timelines agreed with the sponsor