Case Study

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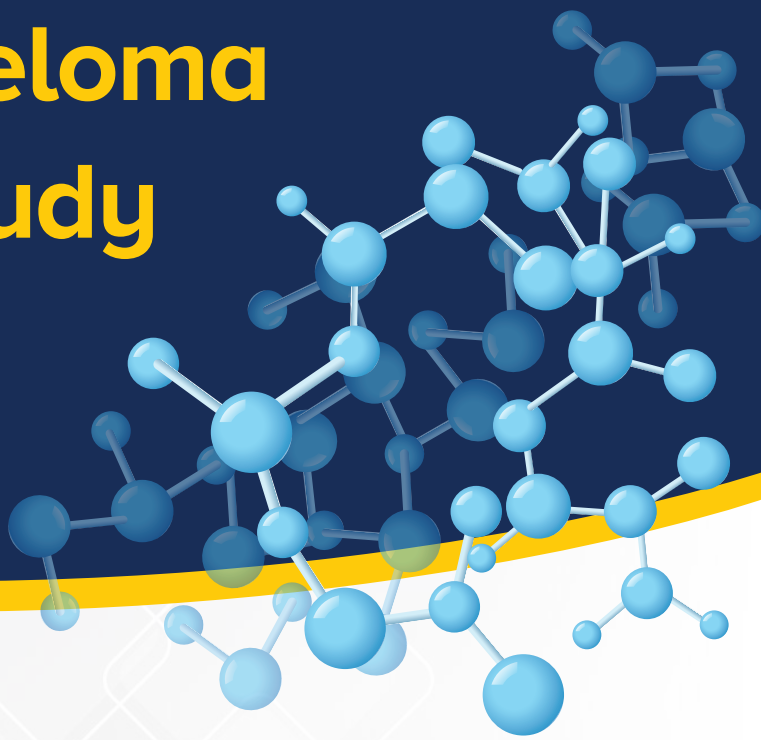
Bioanalytical Aspects of Multiple Myeloma Patient Trial Study



Situational Analysis

A Multinational pharmaceutical company that specializes in development, manufacturing, and distribution of niche generic products was planning to conduct Multicenter, Bioequivalence study in previously untreated Multiple Myeloma and/or Relapsed Multiple Myeloma patients within a stipulated timeframe. Veeda was given the responsibility of providing full services to the client

Study Details

A Multicentre, Open label, Balanced, Randomized, Two-treatment, Two-period, Single dose, Crossover, Bioequivalence study of Bortezomib for Injection 3.5 mg/vial in previously untreated Multiple Myeloma and/or Relapsed Multiple Myeloma patients

Highlights of Results Delivered

Method Development and Validation with Concomitant Medicated drugs

Trained Bio analytical Staff sent On-site for critical Sample handling and Buffering Precautions

44 subjects were randomized in 10 months from 19 Sites

Analysis performed Within 5 days of LPLV Preliminary Results shared within **10 Days** with the Sponsor

The Un-Expected Setback

The COD sites were finalized and it was realized that drug showed plasma instability in presence of the planned concomitant medication drug, which could have stood as setback for the overall study execution. BA team stood up to the challenge and started investigating the cause and feasible conditions which would help in smooth execution of the study and establish ample stability duration for sample handling & analysis.

Challenges

The study was challenging in certain aspects of handling patient samples under the controlled buffering conditions, drug showing instability in the presence of the concomitant medication drugs, shipment planning and analytical analysis in timely manner under challenging circumstances imposed by COVID-19 globally.

Clinical Challenges

- Training of man power at sites for specific handling of patient sample
- Considering light sensitive molecule, site specific arrangement were required
- Due to covid-19 patient recruitment was struck

Sample Management and Analytical Challenges

- Overall tracking of sample shipment to sample receipt at the BA site
- Monitoring the sample conditions and planning the analysis within the stability duration

Action Plan

- Clinical team was well informed about the sample handling challenges and observed stability issues
- Sites were provided additional guidance for patient recruitment
- Analytical team stepped forward to provide hand to hand support for handling the samples onsite
- Analytical team also handled sample shipment process to maintain sample integrity
- Effective training techniques were used for personnel trainings
- One instrument was specially allocated and kept ready each time samples were shipped for analysis to prevent stability issues
- Phase wise planning was done for the analysis of study samples

Outcome

- The Bio analytical team was extremely prompt in terms of coming up with quick solutions to the faced stability issues
- Analysis performed Within 5 days of last patient last visit (LPLV)
- Preliminary results shared with sponsor within 10 Days, and thereby facilitating the sponsor to smoothly plan further
- % of ISR Acceptance of greater than 95% was observed