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CASE-STUDY:

Overcoming Challenges in a Bioequivalence Assessment Study of Octreotide Acetate Injection

Study Details

The study aimed to compare the bioavailability and characterize the pharmacokinetic profile of Octreotide Acetate Microspheres for intramuscular Injection (30 mg), with the reference product.

An open-label, balanced, randomized, two-treatment, single-period, parallel, single-dose bioequivalence study was carried out by Lambda in normal healthy adult male subjects under fasting conditions. The study was sponsored by a prominent pharmaceutical company in China and intended for submission to the US FDA, adhering to the necessary standards.

Challenges Overcame

Challenges	Solutions
Long-duration study having multiple ambulatory visits for post dose PK sampling lasting spanning nearly 6 months.	The extensive experience in conducting studies of extended duration played a pivotal role in substantially reducing incidents of subject non-reporting. This was achieved through diligent adherence to timely follow-ups and effective communication strategies with the study participants, resulting in heightened compliance levels.
High sample size	A qualified, trained, and highly experienced study team was employed to handle all logistics with precision, ensuring consistent on-time execution of study-related activities. This approach guaranteed strict adherence to timelines and efficient management of tasks, particularly in relation to the timely collection of samples.

Challenges Overcame

Challenges	Solutions
Subject recruitment	Utilized a substantial volunteer database and a dedicated team of experienced subject recruiters to efficiently address subject recruitment challenges.
Additional safety tests in screening i.e. USG abdomen, TFT, S. Amylase, S. Lipase, S. ALP.	Utilized an in-house Central Lab with capabilities for real-time processing of safety samples, enabling quick generation and release of safety reports, thus ensuring swift screening of eligible subjects with minimal Turn Around Time.
Number of expected AEs and SAEs	24/7 Medical Oversight: Implemented round-the-clock availability of Study Physicians during housing and ambulatory visits to handle any unexpected Adverse Events or Serious AEs, closely monitored by the Principal Investigator.

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Achievements:

- Enrolled approximately 250 healthy male volunteers based on stringent selection criteria, aligning with the study protocol, involving multiple ambulatory sample visits.
- Demonstrated expertise in managing stratified (Based on subjects' body weight) randomization during subject enrolment.
- Effectively addressed clinical conduction challenges by implementing meticulous micro-level manpower management strategies to handle multiple study groups simultaneously.