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CASE-STUDY:

Overcoming Challenges in a Multicenter Oncology Clinical Trial

Study on Bioequivalence Assessment of Doxorubicin Hydrochloride Liposome Injection

Study Details

The study aimed to characterize the pharmacokinetic profile and to assess the bioequivalence of Liposomal doxorubicin (TEST) in comparison to RLD (Caelyx® - liposomal doxorubicin), in patients with **advanced ovarian cancer or metastatic breast cancer**, providing valuable insights into potential advancements in oncology treatments.

Study Design

A Multicenter, Open Label, Balanced, Randomized, Two-Treatment, Two-Period, Two-Sequence, Single Dose, Crossover Bioequivalence Study between two formulations of Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL (2 mg/mL) in Patients with Advanced Ovarian Cancer or Metastatic Breast Cancer.

The study is intended for ANVISA submission, ensuring compliance with the necessary standards.

Challenges Overcame

Challenges	Solutions
Identification of Patients with Advanced Ovarian Cancer or Metastatic Breast Cancer & patient retention for PK study.	• Identification of investigator sites with a substantial patient pool, excellent clinical trial experience, and the requisite infrastructure for the PK study.
Storage of Doxorubicin Hydrochloride Liposome Injection 20 mg/10 mL: • Store between 2°- 8°C (36°-46°F) in a refrigerator. Do not freeze. • Freezing or temperature excursion may lead to a change in Liposome formulation & could result in toxic effects.	• A comprehensive cold chain management to ensure the integrity of the investigational products. • A strict protocol to prohibit the use of IMP in case of any temperature excursion.
IMP Preparation and Administration within Stipulated Timeframe.	• Close oversight of IMP preparation and robust calculations. • Utilization of infusion pumps for accurate and timely IMP administration. • Conducting in-depth training for the site team on IMP calculations and administration, including on-site demonstrations to ensure proper handling.
Handling of PK samples considering the sensitivity of the molecule, as mishandling can lead to leaching of liposomes.	• A dedicated, trained, and experienced team of Phlebotomists was deployed to the site to perform all PK sample-related activities, from collection to storage. • Continuous oversight of PK sample storage to ensure the preservation and integrity of the sensitive molecules.

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Achievements:

- **74 patients** were successfully randomized within a remarkable **period of 3 months**, demonstrating effective patient enrollment strategies.
- **Efficient trial execution with a timeline of just 6.5 months**, starting from the first site initiation visit (SIV) until the last patient's last visit.

Oncology Excellence: A Proven Track Record

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Leverage Lambda & Novum's extensive experience & proven track record to accelerate your Oncology clinical trials.

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