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Case-study

OVERCOMING CHALLENGES IN PALIPERIDONE PK STUDY IN SCHIZOPHRENIA PATIENTS, DURING COVID-19 PANDEMIC

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OVERVIEW

During the COVID-19 pandemic, a study was conducted to assess the pharmacokinetics of Paliperidone, an antipsychotic medication used to treat schizophrenia in adults. The patient-based study involved administering six intramuscular injections of Paliperidone 1m depot.

The study was conducted for USFDA submission and was challenging due to the pandemic. However, the study was completed successfully, and the sponsor received Marketing Authorization for the product from the FDA. The study was carried out at nine different sites, with two sites inspected by the FDA.

COMPLEXITIES & CHALLENGES

- The study faced several challenges due to the **COVID-19 pandemic**.
- Patient visits were to be completed within **a specific window period**, and the **patients needed to be housed for 28 days**.
- Moreover, the study required the **stabilization of patients before enrollment**, which added to the complexity of the study.
- The pandemic made it difficult for patients to commute from their homes to the site during the first phase of COVID.
- **Site monitoring visits, IMP and other study supplies**, and **PK sample management** were also challenging during this time.
- Another challenge was **to restrict withdrawn numbers.**

EXECUTION

- To overcome the challenges, a **COVID-19 manual** was prepared, which outlined the measures to be taken during the study.
- The sponsor used **IMP transport vehicles** to supply the drug to the sites.
- **Ambulance management** was arranged for patient site visits, and **Principal Investigator (PI) virtual calls** were conducted to minimize face-to-face interactions.
- **Remote monitoring and CRA motivation for visits** were also implemented.

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ACHIEVEMENTS

- Despite the challenges, the study was completed successfully, and the sponsor received **marketing authorization for the product from the FDA**.
- **The regulatory inspection was conducted successfully at two sites**.
- **Excellent Recruitment period**
- **A total of 240 patients were targeted, and all were randomized, with 226 completing the trial**.

Patient Recruitment Status

Target	Screened	Screening Failed	Randomized	Ongoing	Withdrawn	Completed
240	267	27	240	00	14	226

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