spaulding clinical
RESEARCH BEYOND RESULTS

CLINICAL PHARMACOLOGY CASE STUDY

Irritating Intravenous Dosing Fully Leverages Spaulding's Decentralized Clinical Research Unit Design

SITUATION:

Spaulding Clinical conducted a randomized, double-blind study that evaluated the safety, tolerability and pharmacokinetics of 7-day intravenous regimen of a novel next-generation antibiotic. An open-label evaluation followed, which included a 1-day sequential oral dose followed by an intravenous dose in healthy adult subjects.

As background, the biotechnology sponsor shared that previous formulations had a significant AE profile, so the sponsor required the elimination of inter-subject influence during dosing; they wanted all subjects dosed in separate rooms.

CHALLENGE:

The primary challenges presented by this study were:

- Each study subject needed a private room during dosing and thereafter to avoid inter-subject influence. This would enable the best chance to secure quality data.
- Having subjects in private rooms would require the CPU to have sufficient staff available to manage all patients, dosing, data management and blood draws.
- Sponsor also required experience with IV dosing for the intensive 7-Day intravenous dosing regimen.
- Due to the compound's past AE profile, the Sponsor required frequent study updates.
- Study design included rigid dosing timelines.

SOLUTION:

Spaulding Clinical's extensive clinical pharmacology expertise and unique site layout played significantly into successfully meeting the unusual needs of this study.

- Spaulding Clinical's facility design has many large subject rooms that accommodate 2 subjects. For this study, subjects were assigned 1 per room.
- Our decentralized approach to study operations includes all dosing, blood draws, and study procedures to be managed at the patient bedside.
- We scheduled additional staff during the busiest time-points allowing smooth study execution and data collection.
- We staggered dosing and blood draws to meet the rigid timelines for dosing. Three teams managed dosing, draws, IV infusion, and data management. One team dosed, another monitored subjects during the infusion, the last team completed the infusion.
- Spaulding's unique eSource solution enabled the assigned CRC to create, customize and send study information, including adverse event reports, to the Sponsor daily and in real time.

RESULTS:

Spaulding Clinical's unique physical footprint, our operational flexibility when confronted with complex study requirements, and our eSource solution resulted in a successful study. The Sponsor monitored the study remotely and gained important insights on the drug's adverse events using our daily reports. The daily data review enabled the Sponsor to request minor adjustments to procedures after each dose.

The Sponsor commented **"Thank you for the very helpful and extremely detailed notes included in our custom reports".**

Spaulding Clinical successfully completed the study with **99.6% of on-time dosing**. The study yielded results that enabled the Sponsor to move forward with confidence on next steps with this compound.