spaulding clinical
RESEARCH BEYOND RESULTS

CLINICAL PHARMACOLOGY CASE STUDY

150 Subject TQT Trial & 16 Subject "Cooperstown Cocktail 5+1" DDI Trial Exceeds Sponsor's Goal for NDA Filing Target Date

SITUATION:

A biopharmaceutical company awarded a parallel-designed TQT trial and a DDI trial. Their aim was to meet an aggressive timeline to file their NDA within 6 months from the first subject screened. They needed fast startup, quick enrollment, and well-run trials to yield high-quality data to meet their target time line.

CHALLENGE:

Manage the multiple demands as defined by the Sponsor :

- Complete trials in time to target NDA filing 6 months from first subject screened
- Meet an 11-week timeline for clinical conduct to database lock for the TQT trial and 8 weeks for the DDI trial
- Provide rapid start-up and recruitment of 166 subjects for 2 trials and provide ~1:1 Male: Female ratio for study participant enrollment
- Manage Dual-arm IV infusion of Investigational product for 3 hours (TQT)
- Manage 2-dose reference times, IV infusion and 6 probe drugs dosed (DDI)
- Mitigate risk of potential histamine-like infusion reactions and injection-site phlebitis
- Protocol delayed due to seasonal storm at Sponsor's location

SOLUTIONS:

Supporting these studies in our 200-bed unit and using our fully-integrated, paperless, EDC-system, robust recruitment database, Spaulding Clinical's ECG Core Lab, and full-service Biometrics capability, Spaulding Clinical:

- Screened 2:1 ratio to meet enrollment expectations and enrolled 100% gender mix 5 weeks ahead of schedule
- Leveraged previous IV medication trial expertise; had a skilled and highly-trained nursing team conduct IV dosing
- Overlapped the TQT and DDI trials to complete the trials faster
- Dosed 150 subjects in the TQT trial in 6 groups over a 16-day span, dosing 2 groups/week
- Performed DDI trial check-in within 1 week of screening
- Attained a 99% Subject completion rate for TQT trial and 100% for DDI trial
- Achieved complete on-time query resolution by intensive, ongoing coordination with Internal Data Management
- Maintained frequent review meetings to achieve timeline expectations
- Provided Sponsor with real-time access to all study safety labs, vital signs, and ECG analysis throughout the study
- Maintained emergency preparedness for histamine-like infusion reactions; Certified ACLS staff present

RESULTS:

Spaulding Clinical is dedicated to deliver upon its commitments. Challenged with extraordinary time lines, our team worked to accomplish the goal. Our expertise and full-service offering, coordinated with our paperless eSource solution, provided a winning combination of services. The enrollment for this study was originally scheduled to occur over 2 months. Spaulding Clinical completed enrollment in only 3 weeks. Overlapping trials was the most efficient way to meet the time lines. The resulting high-quality study data provided a strong basis for the Sponsor's NDA filing and resulted in a satisfied and repeat customer.

"I can't say enough great things about your team and the set-up at Spaulding including 2 of the best coordinators I have ever worked with. We are so impressed with the enrollment, timeline management, and data capture. You guys have won my business for sure!" Client Clinical Project Director