

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

Clinical Pharmacology Case Study



Situation:

A biopharmaceutical company awarded a parallel-designed Thorough QT (TQT) trial and a Drug-Drug Interaction (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 timeline.



Challenge:

Manage the multiple demands as defined by the Sponsor:

- Complete trials on 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 startup 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

"I can't say enough great things about your team and the setup 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 have won my business for sure!" — Client Clinical Project Director



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 delivering on its commitments. Challenged with extraordinary timelines, 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 timelines. The resulting high-quality study data provided a strong basis for the Sponsor's NDA filing and resulted in a satisfied and repeat customer.

**Taking You to the Next Milestone
by Delivering Quality Data, Fast.**

CONTACT SPAULDING CLINICAL

ABOUT SPAULDING CLINICAL RESEARCH

Founded in 2007, Spaulding Clinical is a full-service, state-of-the-art paperless Phase I clinical pharmacology unit. Our facility, originally a hospital, features fully integrated bedside electronic data capture and sets the standard for patient care. We specialize in IND-enabling clinical pharmacology studies, cardiovascular safety, and clinical proof of concept. We provide expertise on study design, offering in-house medical writing, clinical data management, biostatistics, project management, clinical laboratory, and PK/PD analysis. For high-quality data to inform your decisions, Think Spaulding First. To learn more, visit spauldingclinical.com.

