SPAULDING CLINICAL
First in Phase I

Pharmacogenomic Study Rescued With On-Time Database Lock and 100% Subject Retention

Clinical Pharmacology Case Study

Situation:

A top 50 pharmaceutical company needed to establish bioequivalence between two formulations of a drug used to treat multiple sclerosis. The study was ongoing but burdened with enrollment and retention problems due to various complex requirements, including finding subjects that fit a specific genotype. The retention problem was problematic as the subjects that did not complete the study represented a significant loss of study data.

Challenge:

Find an early-phase site that could help with subject enrollment and retention. Additional challenges to be addressed by Spaulding Clinical included:

- Identify healthy volunteers who are homozygous for the CYP2C9*1 (wild type) allele. This requirement caused a higher than usual screen fail rate.
- Manage a complex study design: three-period, three-treatment, six-sequence, single dose, crossover design at each of two dose levels.
- Attempt to reduce subject withdrawal rate of 31% (representing loss of data) experienced by 2 previous Phase I sites.
- Complete the study on time to adhere to original database lock dates.

Solution:

Spaulding Clinical took the following steps to ensure success:

- Gained approval from the Sponsor's project manager by developing a customized recruitment strategy including:
  - Assigning a dedicated subject recruitment team
  - Using email, telephone, online/news advertisements, and social media to recruit
  - Holding multiple dedicated screening days to increase the probability of finding appropriate subjects with correct pharmacogenetic markers
  - Managing pharmacogenetic testing to facilitate rapid result turnaround and subject entry into study
- Developing and verifying EDC build to assure that all events are present, timed properly, and accurate as per protocol

- Providing detailed training of clinical staff and delegating all tasks
- Informing all subjects at time of ICF signing regarding study demands and requirements for participation
- Providing study schedule and making confirmation calls to each subject for each visit
- Maintaining rigorous communication plan with Sponsor. Holding weekly calls reviewing study status, enrollment, challenges, risk mitigation

Results:

Spaulding Clinical successfully delivered the study to the Sponsor, meeting all needs in the time required.

- Even with the complexity of the study design and restrictive genotype requirements, Spaulding Clinical completed subject recruitment and enrollment within 17 days.
- Spaulding Clinical's staff correctly managed all dosing and PK draw events, (of which there were 1,000), as per the protocol.
- Spaulding Clinical's data collection/management was prompt and accurate. The time from the last subject visit to database lock was well within the Sponsor's requirements and happened in only 8 days.
- The Sponsor did not experience the loss of any study data related to subject withdrawal as 100% of subjects enrolled by Spaulding Clinical completed the study.

The Sponsor was extremely pleased with Spaulding Clinical's overall plan and performance, and was able to meet their study timelines, which enabled timely planning of future projects.

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**.

SPAULDING CLINICAL
First in Phase I