spaulding clinical
RESEARCH BEYOND RESULTS

CLINICAL PHARMACOLOGY CASE STUDY

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

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 assure success:

- Develop a customized recruitment strategy; gain approval from the Sponsor's project manager; include:
  - Assign a dedicated subject recruitment team
  - Use email, telephone, online/news advertisements, and social media to recruit
  - Hold multiple dedicated screening days to increase the probability of finding appropriate subjects with correct pharmacogenetic markers
  - Manage pharmacogenetic testing to facilitate rapid result turnaround and subject entry into study
- Develop and verify EDC build to assure that all events are present, timed properly and accurate as per protocol
- Provide detailed training of clinical staff; delegate all tasks
- Inform all subjects at time of ICF signing regarding study demands and requirements for participation
- Provide study schedule; make confirmation calls to each subject for each visit
- Maintain rigorous communication plan with Sponsor. Hold 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 completed subject recruitment and enrollment within 17 days.

Spaulding's staff correctly managed all dosing and PK draw events, (of which there were 1000), as per the protocol.

Spaulding'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 time lines, which enabled timely planning of future projects.