

INNOVATIVE SOLUTION SHORTENS TIMELINES BY TWO MONTHS: THOROUGH QT CASE STUDY

Our sponsor engaged us to conduct a comprehensive thorough QT study involving a large number of volunteers with lengthy confinement and washout periods. Championing innovation, we recommended conducting the study at two clinical research units (CRUs) to shorten study timelines.

Understanding the Challenge

- ▶ Meeting aggressive timelines for the go/no-go decision
- ▶ Maintaining consistent data and operations between two CRUs

Revealing Opportunities to Deliver Results

To minimize variability between the two CRUs, we selected a single project manager to oversee the study at both clinics and act as the primary point-of-contact for the sponsor and the main liaison between sites. We also developed a plan to increase enrollment and timeline efficiencies by dosing volunteers at the different clinics using overlapping schedules. As a result, the clinical portion of the study was completed two months early.

Our team called upon the same ECG vendor to conduct training at both CRUs. This thorough approach to clinical operations minimized discrepancies in data collection. Furthermore, regular data review enabled the rapid addressing of issues and queries. Two monitors – one for each site – reviewed and released data on an ongoing basis to help ensure real-time data transfer, preventing backlogs at the end of trial. Accordingly, database lock was completed ahead of schedule and our client made their go/no-go decision more than two months sooner than planned.

Seamless coordination of staff procedures, processes and planning all contributed to dependable data that set our client up for reliable decision making. Our teamwork also demonstrated that a thorough QT study conducted at two sites can provide results in an effective and efficient manner.

Innovative thinking often reveals opportunities and new pathways. Let us help you champion innovation and get the results you need by bringing together proven ideas and novel concepts that make solutions real.

Learn more about our drug development solutions at www.covance.com

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