synteract®
BRINGING CLINICAL TRIALS TO LIFE

Kidney Disease

Synteract Exceeds Enrollment Expectations in Complex Parallel Studies

Highlights

- Synteract helped to coordinate enrollment of two complex, simultaneous studies.
- It exceeded goals, with 349 patients enrolled across 31 sites ahead of schedule.
- It helped the sponsor come in under budget and save on efficiencies.

Introduction

A late-stage biopharmaceutical company addressing kidney disease and complications of hemodialysis needed to coordinate rapid enrollment of two complex studies going on simultaneously. Synteract shared monitoring services and was responsible for helping to enroll 300 patients across 30 sites domestically for the first study, and 500 patients across 40 sites for the second.

Challenges

- The large trials posed logistical challenges with several sites and multiple vendors for data management, IxRS, serum labs and ultrasound.
- Even with prescreening, patients could not be enrolled until surgery to ensure all criteria was met.
- Studies needed to be coordinated so that enrollment of the first study did not impact the second, and vice versa.
- With services for clinical operations shared between Synteract, the sponsor, and multiple vendors, transparency and strong lines of communication were necessary.
- Sponsor team member transitions occurred between, and within, studies.
- Logistics and timing could be challenging, including coordinating outpatient surgeries in the early morning before one site's pharmacy opened.
- With data management and the electronic trial master file (eTMF) managed by the sponsor, Synteract needed to also ensure managers were constantly in the loop with upcoming visits with Institutional Review Boards (IRBs).

Our Solutions

- **Synteract provided support and training to sites to encourage successful enrollment.**
- The Synteract study director instituted processes to make sure he and the team had a clear snapshot at any given time to ensure no gaps in data. Custom tracker and gap reports were produced weekly in the maintenance phase and daily as deliverables approached.
- Synteract regularly assessed and tracked information that might be missing using metrics reports and extra level of oversight related to third parties responsible for entry. Coordination was critical, as multiple vendors were used for data management, IxRS, serum labs, and ultrasound. Additionally, the ultrasound provider had four CRFs per ultrasound that its employees were in charge of entering.
- Synteract identified necessary steps and potential issues in the clinical database build, study reports, and IWRS with CRAs to appropriately coordinate timing–when the patient could be scanned, treated, prepped for surgery–to tighten enrollment timelines. This was essential, given feedback from the FDA and a number of other factors that must be met in advance of enrollment and surgery.

Program Success

- **Synteract exceeded goals, with 349 patients enrolled across 31 sites in 16 months (two months ahead of schedule).** It closed out final patient visits a week ahead of schedule. It was then able to work with the other CRO to lock the database a month later.

- This fast turnaround was possible due to good data management, with Synteract averaging 94% verification complete throughout the study, necessitating only 6% review.
- This enabled the stats team to get data sooner, sites to get activated on the second study faster, and the team to come in under budget. **Originally planned at $1.8 million, the project was reduced to $1.7 million, saving about $130,000 through efficiencies.**
- Some of these savings could be shifted to the second project, which, despite being off to a slower start, later moved ahead of schedule.

About Synteract

Synteract is an innovative, full-service CRO supporting biopharma companies across all phases of drug development to help bring new medicines to market. Synteract has conducted 4,000 studies on six continents and in more than 60 countries, working with more than 26,000 investigative sites and 750,000 patients. It has contributed to more than 240 product approvals. Synteract offers a notable depth of expertise in oncology, general medicine, dermatology, and neuroscience indications, as well as rare and orphan, pediatric, and immunotherapy studies.

For more information on how we can support your clinical trial, please visit www.synteract.com/Services/Clinical-Operations or ContactUs@synteract.com.

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