Worldwide Clinical Trials FLEX

Case Study

Navigating Choppy Waters: Worldwide Flex Delivers Rapid Study Completion for Anti-Nausea Compound

A U.S.-based, development-stage pharmaceutical company needed a partner to manage a new study within an ambitious timeframe of nearly 4 months. Drawing on an existing partnership, the sponsor engaged Worldwide Flex — bringing multi-therapeutic global resourcing and functional service capabilities to the study — with Worldwide Flex resourcing data management and safety FTEs, and the sponsor managing site activity. The work finished ahead of schedule, and high-level results confirmed that the study endpoints were met.

119 Days

From IRB approval to database lock

500+ Subjects

Enrolled in a single month

Challenge

The study assessed the efficacy of an anti-vomiting and anti-nausea compound in humans. To test it, the sponsor enrolled more than 500 subjects in a single month during a series of boat rides, with participants assigned either a nasal gel or a placebo. The sponsor managed all site activities, while the FTEs that Worldwide Flex resourced completed the data management and safety databases. The goal was demanding. The expectation was to take the study from IRB approval to database lock in about 4 months.

Solution

Worldwide Flex was engaged to build an electronic data capture (EDC) system database and monitor subject safety. After listening to the sponsor's needs, Worldwide Flex appointed an experienced study team of a veteran project manager, data manager, coding specialist, safety manager, and programmer, each well-versed in TrialKit EDC.

The programmer had already built a similar database for the sponsor on a prior study, which sped up the build. Working with the sponsor, the programmer mapped the differences between the two studies and helped lead the Flex team to deliver the database in record time. The sponsor set up multiple teams at the site to enter and review data, and the Worldwide Flex data manager and coders confirmed it in close coordination with those teams so the database could be locked quickly.

TrialKit is one of several EDC platforms Worldwide Flex builds in, alongside Medidata Rave, Veeva, and others, so a fast, familiar build like this one is repeatable across tools rather than tied to a single platform.

Outcome

The partnership finished ahead of schedule, and high-level results confirmed that the study endpoints were met. The sponsor captured data on more than 500 enrollees, entered all of it into the EDC system, and completed monitoring quickly. Worldwide Flex reviewed the data and closed all queries, bringing the study from IRB approval to database lock in 119 days. The sponsor also valued its additional investment in a project manager who oversaw the Flex resources, ensured deliverables were of high quality and delivered on time, and reduced the load on the client team.

Much of this came from the history between the two organizations and from reusing the TrialKit EDC design from the earlier project. The sponsor's study design and system choice, combined with the Worldwide Flex data management team's experience, enabled fast, accurate data entry and review. The sponsor returned to Worldwide Flex because of how the team listened, remained flexible, and worked alongside the client to support an unusual protocol and a fast, clean data review.

Let's talk about how our personalized approach, therapeutic expertise, and global resources make us a strong partner for your drug development program.

Contact Us

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Worldwide is a leading full-service global CRO that offers innovative end-to-end customized solutions in partnership with biotechnology and pharmaceutical companies. Founded on an unwavering commitment to therapeutic excellence and personalized attention, we bring scientific expertise, a specialized and flexible oncology team, and a shared passion for advancing new medicines from discovery to reality.