Worldwide Clinical Trials

Case Study

Getting Back on Track: Optimizing Site and Patient Engagement in an Oncology Transition Study

While in Phase 2 of their oncology program, a small biotech realized their study was struggling with slow recruitment, poor site engagement, and data entry delays under their current CRO. Recognizing the risk to their study's success, the sponsor decided to bring in a new CRO to move the study forward. Worldwide Clinical Trials was selected to revive the struggling program and bring operations back up and running as quickly as possible.

In less than 90 days, Worldwide completed a seamless transition, conducted thorough feasibility, and got the study back on track.

Pre-Transition Challenges

Prior to the transition, the large CRO struggled with various challenges, including:

Patient Recruitment and Retention

80% of sites had been activated, but the study was far behind enrollment.

Site Management

Sites were not being closely managed, and start-up was slow.

Data Management

Data was not entered promptly, even for the primary endpoint.

Worldwide's Solutions

To transition this study, Worldwide created a customized and flexible approach using three key strategies:

Increasing the Focus on Patients

Competing with an approved therapy that provided stable outcomes to the target population had challenged recruitment. We dove into the patient pathway, working with stakeholders to understand key inclusion criteria, severity scales, visit schedules, and how to best reach patients and families that would be interested. We then crafted a recruitment approach tailored to locating that population.

Partnering Closely with Sites

Worldwide took an intentional approach to re-engage sites and physicians. We worked with each site to identify their individual needs and provided solutions to address their unique challenges. We also conducted regular site education and extra outreach when needed. Through our efforts, we re-engaged 15 sites that had not been actively recruiting.

Conducting Detailed Data Reviews

Our team manually reviewed data compliance daily in preparation for the study's team interim analysis, which helped justify initiating a Phase 3 efficacy program and supported the product for commercialization.

Transition Outcomes

Worldwide completed the transition in less than 90 days, and the study progressed into operations ahead of schedule, resulting in operational outcomes that surpassed the expectations of the sponsor.

Patient Recruitment and Retention

Worldwide fully enrolled the study on time, exceeding the recruitment target and more than doubling the prior recruitment rate.

Site Management

Worldwide increased the number of active sites from 19 to 24, while significantly improving site engagement and recruitment for the study.

Database Lock

The study achieved database lock (DBL) on schedule, with interim analysis of key data points completed within three weeks. Worldwide was able to recruit for the study, manage all vendors, and bring in the data needed for the end-of-Phase 2 meeting with the FDA.

	Active Sites	Screenings Per Month	Recruitment	Data Management
Pre-Transition	19	8.3	37 patients enrolled in 7 months	Delayed, compromising data integrity and endpoint management
Post-Transition	24	19.5	56 patients enrolled in 4 months	On-time DBL with interim analysis completed in 3 weeks

Because of the successes in this program, the sponsor has since awarded two additional pivotal Phase 3 studies for this product to Worldwide, and Worldwide continues to utilize the lessons learned from this study to deliver seamless transitions to our sponsors.

Explore what a transition could look like for your program by contacting 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.

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