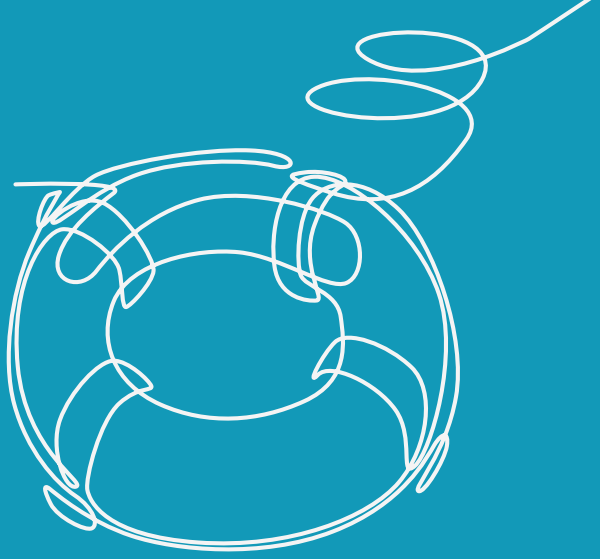
Worldwide Clinical Trials



Case Study

Rescuing Two Disease Monitoring Programs: An Efficient and Hands-On Approach

A biotech needed a nimble, responsive CRO to take over two Disease Monitoring Programs (DMPs) after their former CRO underwent acquisition and was no longer able to provide critical resources to their programs. Worldwide Clinical Trials leveraged their personalized approach and dedicated resources to execute an ambitious transition plan to rapidly get the studies back up and running efficiently.

The Challenges

1

CRO Underwent Acquisition Mid-Study

The sponsor had initially selected a CRO with global resources to conduct their pediatric DMPs for two commercialized rare disease drugs. During these studies, the CRO was acquired. The acquisition meant the CRO's internal priorities changed, preventing it from dedicating adequate resources to support the sponsor's studies.

2

Studies Faced Neglect, Resource Challenges

The studies were under-resourced and struggling, and a substantial number of site payments were delayed more than a year. Additionally, the CRO provided multiple points of contact despite the sites' repeated requests for a single point of contact. This approach created operational and administrative challenges for the sites, resulting in their disengagement.

3

Dissatisfied PIs Jeopardize Study Progress

These collective issues led to a backlog of study data, further delaying site payments and creating frustration among key Principal Investigators (PIs). Given that the studies were for commercialized products, if left unresolved, these issues could have severely impaired the sponsor's prospects for widespread adoption.

Initiating the Rescue

Assessing the ongoing challenges both studies faced, the sponsor proactively decided to search for a new CRO before the continuation of their studies could be threatened. During their CRO search, the sponsor prioritized evidence of:

- Successful delivery of rescue studies and pediatric rare disease experience
- The ability to create a comprehensive transition plan to revitalize the studies, support the sites, and clear administrative backlogs
- The resources to dedicate a hands-on team for the duration of the studies

During the bidding process, quality and speed were of the essence to rebuild trust among all stakeholders. Worldwide's strategic and operational rare disease teams showcased approaches for an efficient transition, demonstrated their ability to provide hands-on, accessible support to the sponsor and sites, and established a framework for study success. The sponsor chose Worldwide as the new CRO, and the transition process immediately began.

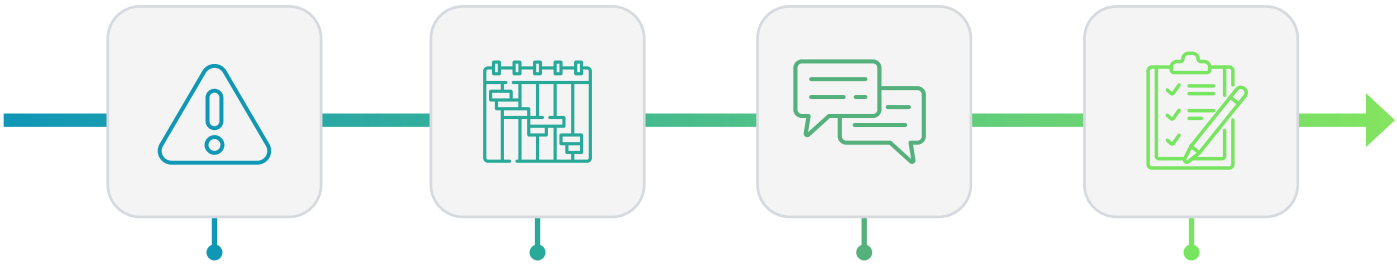
Worldwide had only 60 days to complete the transition process despite the typical 90-day recommendation. Only half of this time (30 days) had overlap with the outgoing CRO, meaning the traditional discovery phase had to be thoughtfully refined and risk managed accordingly.

The Solutions

Dedicated Transition Team

Worldwide dedicated an experienced team to handle the rapid transition. Worldwide's experts employed a change-management approach, identifying critical risks and minimizing negative effects.

One key to success was the Worldwide transition team's use of a clearly defined process and streamlined stages for the transition and handover. This process included:



Extensive risk mitigation strategies

Clear timelines and review points

Structuring open and continued communication between Worldwide, the sponsor, and the outgoing CRO

Plans for the roll-off and handover to the permanent study teams after transition

Worldwide's approach also included functional area working groups that met weekly during the transition. These meetings enabled the sponsor and their studies to quickly benefit from the knowledge of Worldwide's subject matter experts. They performed a comprehensive gap analysis by functional area, in addition to risk assessment, mitigation, and critical issue remedy.

Focus on Site Support

Worldwide promptly established a resource-dedicated, global team to quickly address operational obstacles and devise new solutions as needed. Many sites had not received payment in more than a year, making resolution a top priority. Worldwide set up a new site payment process to ensure accurate payments over the course of the study by performing reconciliations at each payment cycle.

Many sites had become disengaged due to frustration from the outgoing CRO's acquisition. Worldwide study team members were assigned strategically and promptly. As the Worldwide Clinical Research Associates (CRAs) began engaging with sites, several new issues were identified, including a backlog of open queries and regulatory forms requiring immediate attention. It was equally important to conduct regular reviews and complete virtual site monitoring visits to troubleshoot issues and provide support. Both Worldwide Clinical Trial Managers and the Worldwide Global Project Lead (GPL) were in frequent contact with Worldwide CRAs, providing guidance, helping prioritize key activities, and ensuring the sponsor was aware of issues, risks, and mitigations.

Strong Relationship with Sponsor

With a shared goal of keeping the studies running smoothly during the transition, Worldwide and the sponsor prioritized opportunities to forge a strong relationship. This strong relationship was built upon a clear change management framework that focused attention on critical risks and fostered openness during difficult conversations. Worldwide's GPL participated in near-daily meetings to ensure steady progress. Sponsor-shared insights about the studies' patient and site experience enhanced Worldwide's understanding of priorities and strengthened the partnership.

Additionally, Worldwide and the sponsor collaborated to create a governance charter that set performance metrics for each study. Key team members and senior executives from both Worldwide and the sponsor gathered in-person for an informal meeting to delve into lessons learned to date and set monitoring and performance goals for the years ahead.

"Working with Worldwide has felt like a true partnership. The special relationship and camaraderie built in such a short time is unheard of! It feels like they're an extension of us. I've lost count of the number of times I've needed someone and called them — and they are always there."

Vice President, Disease Monitoring Programs

Biotech Sponsor

The Results

Despite rapid timelines and challenges from the outgoing CRO, Worldwide transitioned both studies successfully. The first study met the preset goal of complete transition by Day 60. The other, larger study required an additional ten days due to MSA signing delays but soon followed its sister study into full operations 20 days ahead of the standard transition timeframe. Both continue to operate efficiently.

Additionally, sites received the support they deserved. Following establishment of the site payment process, invoices were promptly sent to sites. Automatic quarterly payments were set up to ensure sites would have no further payment delays.

As requested, and per Worldwide's standard approach, each site has one designated point of contact. Worldwide CRAs, with the support of two Worldwide Clinical Trial Managers, are continuing to strengthen relationships with the sites and explore avenues to build confidence in the partnership.

Throughout this rapid transition, the sponsor and Worldwide formed a strong partnership built upon trust and a seamless working relationship. The sponsor has since awarded additional full-service studies to Worldwide, and Worldwide has leveraged best practices from this opportunity to refine their transition management process for future rescue studies.

Why Worldwide?

Worldwide is a leading CRO across therapeutic areas, with the personalized resources needed to rescue studies and provide hands-on support and guidance during each phase of your program. With dedicated transition teams, seamless handoffs to project teams, and a resourcing approach that ensures your study receives the care it deserves, Worldwide rescues studies for long-term success.

Let's talk about your trial

Worldwide Clinical Trials

Worldwide Clinical Trials (Worldwide) is a leading full-service global contract research organization (CRO) that works in partnership with biotechnology and pharmaceutical companies to create customized solutions that advance new medications – from discovery to reality.

For more information on Worldwide, visit www.worldwide.com or connect with us on LinkedIn.

Last Update: 01182024