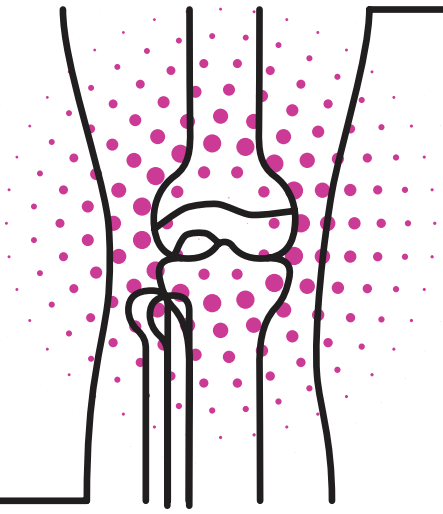
Case Study

Strategic CRO Transition for Enhanced Outcomes in Osteoarthritis Knee Pain

Worldwide Clinical Trials

A biotech company initially partnered with a CRO that failed to meet their expectations and faced slow site activation and lagging recruitment for their osteoarthritic (OA) knee pain study. Recognizing the need for a swift change, they turned to Worldwide Clinical Trials, who successfully transitioned the study and put operations back on track.



After considering Worldwide Clinical Trials for their osteoarthritic knee pain study, a biotech company contracted with another CRO that promised a recruitment rate approximately double what Worldwide presented as feasible. The sponsor chose the other CRO despite Worldwide's expertise in pain studies and successful recruitment and participant retention track record. After the study began, the sponsor realized the recruitment rate was significantly slower than the initial promise and understood the need to pivot promptly to keep their study afloat. The biotech company contacted Worldwide to take over and deliver their study successfully.

Challenges that Precipitated the Transition to Worldwide

01

Staffing Issues Hampered Site Identification & Activation

The sponsor was keenly aware they were not receiving the promised attention needed for site activation. The study faced CRA staffing issues, which led to significant and unnecessary delays in site identification and activation, delaying participant recruitment.

02

Recruitment Did Not Progress as Projected

The outgoing CRO made unrealistic recruitment projections and failed to deliver as expected once the study began. The sponsor also discovered that some of the subjects who had been recruited were less protocol. Despite a high screening volume, the sponsor noticed an abnormally high Kellgren and Lawrence (K-L) screen fail rate, which resulted in half the potential participants being considered ineligible.

03

Outgoing CRO Was Not Dedicated or Agile Enough

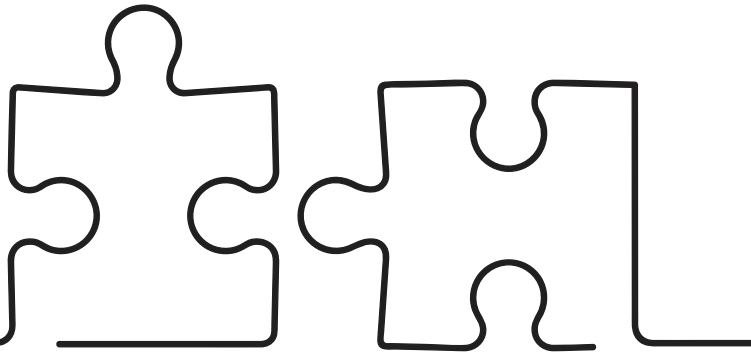
The biotech company knew that without a flexible, responsive, and dedicated team, they would continue to experience delays and accrue unnecessary costs that could significantly impair their trial. They needed a team capable of navigating and proposing solutions to fix the low participant recruitment and better prepared to run the trial specific to the sponsor's needs.

The Sponsor Took Charge & Brought in a New CRO

It can be challenging to switch CROs after a study has started. However, the sponsor determined that bringing in a new CRO was optimal. Based on low participant recruitment, they knew they needed an expedited timeline to correct course and avoid ongoing trial delays and additional sunk costs.

Recalling the proposal Worldwide had provided during the bid defense process, the sponsor approached Worldwide to rescue the failing study. The sponsor recognized that while our recruitment projections were slower than the transitioning CRO, they were data-driven, realistic, and achievable, a collective result of our expertise in conducting pain studies.

With Worldwide spearheading the initiative, we targeted a 90-day transfer of responsibilities from the outgoing CRO.



Transition & Solutions

01

We Set Realistic & Achievable Expectations

When reapproached, Worldwide stood by the achievable, data-driven strategy presented in the initial proposal. In drawing on our expertise in clinical trials for pain indications, we were confident in our participant recruitment and retention estimates and the importance of site education and management.

We Clearly Defined the Recruitment Strategy

We implemented a new site feasibility exercise, adding sites with historical K-L data while simultaneously pausing and closing incumbent non-performing sites to direct resources where they were most effective. Moreover, we established access to imaging for the K-L screening, requiring sites to have either X-ray or MRI capabilities as a requisite for study participation. Our site educators ensured every site staff member was fully trained from screening through trial conduction, assuring uniformity across all the active sites.

02

For OA studies, it is common to use only one central rater for K-L screening to ensure consistency. However, in some contexts, this can contribute to screening out individuals who would otherwise qualify. To reduce the previously high SF rate, we enhanced prescreening efforts. In formal screening, we included a “tie-breaking” central reader for K-L screening for potential screen fails and found eligible participants who would have previously been screened out. These processes collectively saved resources through higher quality screening up front, reducing the natural SF rate to the rates normally expected in an OA knee pain study.

03

We Performed with Operational Excellence

When the transition began, Worldwide seamlessly assumed responsibility of the 45 active sites and immediately started recruiting new sites. We provided additional on-site education and training and dedicated weekly time for sites to have an open phone call with the Worldwide team to raise any questions, concerns, or updates. Our dedicated pain experts quickly addressed all site needs, course-correcting before the study could lose ground.

Results

Worldwide set realistic expectations from the start and rapidly transitioned the study. Despite the 90-day timeline agreed upon, we transitioned the study in full within 27 days, minimizing study delays and accelerating recruitment.

Worldwide transitioned the study in 27 days, 63 days ahead of schedule.

Within the first three months, our strategic recruitment efforts double the enrollment rate seen from the transitioning CRO. We also achieved a notable 29.3% reduction in the K-L SF rate, going from 55.1% to 25.8%. Worldwide accomplished these outcomes by leading with our pain research expertise and our emphasis on:

- Close site management and education, beginning with participant screening
- Active and ongoing engagement with the sponsor and sites
- Clear instructions to all site staff
- Weekly drop-in calls for site staff to ask questions, report concerns, or celebrate successes

Our addition of a non-traditional “tie-breaking” central reader for knee imaging converted a significant number of individuals who would have been ineligible screen failures to eligible participants.

Our pain research experience, customer-first mindset, and flexible, personalized approach collectively fostered a seamless and successful transition. The complete handover took 70% less time than planned, improved participant SF by nearly 30%, and employed a strategy that significantly increased site functionality.

Why Worldwide?

Worldwide is a global contract research organization (CRO) with a global team of experts who bring decades of combined experience in managing pain research, ensuring your study has knowledgeable professionals at your side. We offer comprehensive in-house services for clinical assessments facilitated by our specialized clinical assessment team, allowing for in-depth training on placebo response mitigation and eliminating the need for third-party vendors. We prioritize individualized attention and dedicated resources.

Learn more about our Clinical Assessments Team →

Worldwide Clinical Trials

By partnering with us, you can expect a commitment to excellence and a tailored approach to achieve outstanding results.

Contact Us