Worldwide Clinical Trials

Case Study

Tailored Operational Strategy Supports Complex Post-Surgical Acute Pain Study Execution

Worldwide Clinical Trials partnered with a specialty pharmaceutical company on a Phase II study of an investigative analgesic for acute postoperative pain following bunionectomy. The project demanded fast start-up, rapid recruitment, and adaptability amid intense competition. Worldwide delivered clear outcomes through end-to-end support across project management, site operations, regulatory affairs, safety oversight, and clinical technologies.

Managing Variability and Bias in the Acute Pain Model

Variability and bias are the major challenges in this acute pain model, driven by placebo response, heterogeneity of the surgical procedure, use of rescue medication, pain intensity scoring, and unintended forms of bias. Worldwide mitigated these through rater training services to standardize assessment and selection of specialist sites experienced in the acute postoperative pain model.

The study ultimately screened 530 patients and randomized 239 subjects across U.S. sites, despite significant enrollment complexity and a higher-than-anticipated screen failure rate.

Study Metrics At a Glance

530
patients screened

239
patients randomized

4.35
enrollment rate

5
US sites

The Challenge

The study launched against a backdrop of intense competition for eligible postoperative pain patients, with multiple trials attempting to complete enrollment of the same surgical population from within a modest number of US-based clinical sites recognized for their ability to perform this surgery and associated study procedures and assessments within the framework of the standardized model. This competitive landscape, combined with aggressive enrollment expectations and shifting protocol requirements, created significant operational pressure from the outset.

Enrollment proved more challenging than projected. Initial timelines targeted completion within approximately 4 months, but the study ultimately required more than 11 months — largely due to a 55% screen failure rate, well above the anticipated 36%. While it is fairly easy to attract patients seeking surgery into this select group of qualified sites, strict eligibility criteria, timing constraints around surgery, and exclusionary medical histories characteristic of the bunionectomy acute pain model may all contribute to screen failures. Notable in this study, the rate of screen failure was 55%, significantly higher than the 36% anticipated, which hampered progress with participant accrual and contributed to a longer enrollment period than expected.

The Solution

Worldwide secured IRB approval for comprehensive recruitment strategies tailored to individual site preferences, adapted to counter the intense competition for eligible participants seeking elective bunionectomy surgery, and aligned to optimize individual site surgical volume capabilities and patient flow.

To address the higher-than-anticipated screen failure rate, Worldwide worked with the sponsor to adjust site compensation caps for screen failures, accurately reflecting the level of screening activity performed and ensuring sites remained engaged despite the added screening burden.

Worldwide maintained high-quality oversight across all functional areas throughout the study, achieving 95% of monitoring report metrics. This included active management of operational obstacles, such as laboratory kit supply continuity and EDC readiness, as they arose, along with continuous adaptation to protocol refinements and shifting site performance while preserving the flexibility required by the sponsor. To further support site engagement and performance, Worldwide leveraged its strategic Site Alliance Partnership Program, engaging leading neuroscience sites and site networks with established post-operative pain expertise. Through ongoing governance discussions, dedicated relationship management, and routine site capacity assessments, Worldwide maintained visibility into site capabilities, enrollment readiness, and operational performance across the study.

The Outcome

Despite significant enrollment complexity and operational hurdles, Worldwide successfully supported study completion and database lock within 11 days of the last patient follow-up visit.

The study screened 530 patients and randomized 239 participants across four primary US sites and one backup site. Worldwide's flexible operational model, proactive enrollment management, and rapid issue resolution enabled continuity throughout the study while maintaining data quality and sponsor confidence.

From this study and many others like it, Worldwide has a strong network of experienced pain clinics, which includes our Alliance Sites. Implementation of the Bunionectomy Acute Postoperative Pain model relies on the strength of our collaboration with site management organizations and specialist clinics experienced in offering this standardized test methodology.