Rho completed enrollment 6 weeks early for a phase 3 pain study with 800 patients and 37 sites. Some keys to our success:

- Maintaining a close relationship and continuous communication with both the Sponsor and the sites.
- Creating Sponsor and IRB approved advertising templates that could be used at each site without gaining additional approvals.
- When an advertising campaign worked for one site, sharing it with the rest of the sites and increased funding.
- Analyzing the results of sites’ advertising projections to ensure the venue worked well for the specific regional area.
- Continuing to run advertising campaigns throughout the enrollment period.
- Hosting webinars with the sites to share tips and tricks.
- Closing underperforming sites and increasing the enrollment cap for high performing sites.

Rho has experience with a broad range of pain indications, including the following areas:

**ACUTE**
- Post-operative pain
  - Bunionectomy
  - Knee Arthroplasty
  - Hernia Repair
  - Hysterectomy
  - Lumbar fusion
- Ophthalmic procedures
- Musculoskeletal pain
- Acute Otitis Media
- Dental pain
- Migraine Headaches
- Gastrointestinal pain

**CHRONIC**
- Neuropathic pain
- Musculoskeletal pain
  - Osteoarthritis
  - Low Back Pain
  - Fibromyalgia
  - Rotator Cuff/Shoulder Joints
  - TMJ
- Cancer pain

**ASSOCIATED CONDITIONS:**
- Opioid Induced Constipation
- Respiratory depression
- Opioid Abuse and misuse

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**Analgesia Trial Experience**

**150+ STUDIES | 2,400 SITES | NEARLY 40K PATIENTS**

Rho has supported five recent NDAs reviewed by DAAAP and supported five sponsors at FDA advisory committee meetings in the last five years.

“At Rho, you work with people to build your solution, not a rigid set of policies and timelines.”

“I have so enjoyed working with Rho. I’ve been in this business for 13 years, and I have to say that Rho has been the BEST CRO I have ever worked with.”

rhoworld.com
Overcoming the challenges of analgesia trials

Clinical trials in pain indications present unique challenges. Subjects drop out of pain trials for reasons including insufficient pain relief, treatment side effects, burden of multiple study visits and assessments, and use of rescue medication. Recent studies in chronic and short-term pain suggest drop-out rates ranging from 5-40%. Missing data resulting from subject drop-outs make it difficult to interpret the results of pain trials and the impact to drug development programs can be great.

Rho has extensive experience addressing these challenges and would like to be a part of your successful program. Here are a few ways we can help you:

### TRIAL DESIGN
Successful outcomes start with a strong trial design. Rho's experts have designed analgesia-related trials that minimize drop outs, increase study execution efficiency, and lead to robust data analyses. Our experts can help you:

- Strategize to identify the appropriate end points for trials.
- Placebo effect mitigation
- Provide input on when to measure and how to summarize the data. Simplifying assessments and visit frequency will reduce the number of drop-outs.
- Explore alternative trial designs. Flexible dosing, active control run-in, and add-on designs may provide benefits for your trial.
- Suggest considerations for Inclusion/Exclusion criteria based on the input we have from our site relationships

### TRIAL STRATEGY
Rho's project teams are well versed in the successful execution of analgesia-related clinical trials. We emphasize strategies that facilitate recruitment and maximize retention. Our teams can help you:

- Identify and select high-enrolling and quality-driven clinical sites with proven track records.
- Create and implement strategies to increase retention rates by limiting subject burden.
- Implement robust Investigator and clinical site staff training to ensure understanding of the importance of subject retention and complete data.
- Monitor data collection and identify problems with retention and other missing data early, so that issues can be addressed and corrected.

### ANALYSIS
Rho's experts have years of experience providing analyses to the FDA and the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP). We understand the current landscape and expectations related to analgesia data and analyses.

- Rho's experts will help you navigate suggested guidelines on missing data as outlined in the recently FDA-endorsed guidance on missing data from the National Academy of Sciences (NAS).
- Rho is familiar with the most up-to-date analysis methods for missing data in analgesia-related trials, including:
  - Sensitivity analysis
  - Multiple imputation
  - Pattern mixture model
- Rho can help you select an analysis design that is right for your trial and meets the expectations set by the new NAS guidance document.