



Analgesia.

At the forefront of the pain management research industry for more than 25 years, Premier Research provides unparalleled expertise throughout the project team and the organization, helping to move your analgesia product through the drug development process—from proof-of-concept to market and beyond.

Proven Experience

- More than 170 clinical trials and 70 consulting projects conducted in analgesia in the past five years
- More than 44,000 pain patients treated in the past five years
- Experience with most classes of analgesics including formulations of 24 of the top 25 pain drugs currently marketed
- Dedicated analgesia research clinics owned and operated by Premier Research

Expertise: The People

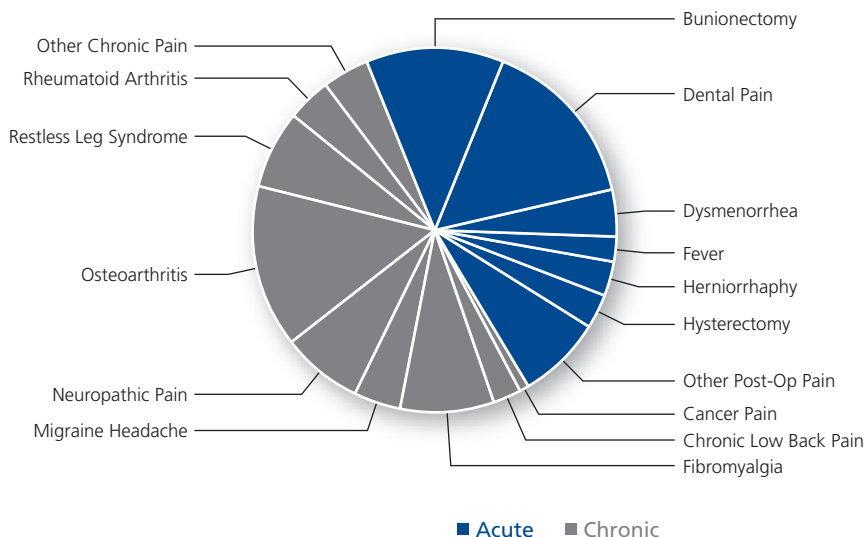
- More than 65% of project managers/directors and 61% of CRAs specifically trained and experienced in managing analgesia clinical trials
- More than 100 analgesia support professionals, including registered nurses, pharmacists, and certified clinical research coordinators
- Long-term relationships with leading scientists and experts in analgesia research
- Global team with local knowledge and expertise allows us to recruit analgesia trials
- In-house regulatory consultants provide guidance on development and regulatory strategy

Case Study: Accelerated Enrollment and Low Query Rates

Premier Research was contracted by a large pharmaceutical company to manage a three-study fibromyalgia program. We exceeded enrollment timelines in the first study despite a significant delay in drug supply availability. Due to high quality site monitoring and low query rates, the sponsor was able to meet aggressive database lock timelines.

The majority of the 100 sites required for the final study of this program were initiated within six weeks after the Investigator Meeting. The sponsor then requested an increased number of patient screening visits to accommodate the study design. We met this challenge by centralizing and proactively managing patient recruitment efforts with the sites.

Experience Within the Past 5 Years



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Premier Research helped pioneer the development of new research models and pain assessment methodologies that are now standard in drug development programs worldwide. We work with companies from early stages of clinical plan development through full clinical development programs and regulatory submissions for their compounds. We help companies to identify appropriate endpoints, study design, and the overall clinical plan for their products.

Analgesia Model Development

The Analgesia Model Development Team at Premier Research is devoted to the creation and validation of novel models for analgesic research. They help to meet the challenges of present day drug development by developing models with a high degree of scientific validity that are also able to address such practical considerations as rapid recruitment and reduction in the signal-to-noise ratio.

For example, the post-operative bunion model developed by the Premier Research team reduced patient recruitment times by 30–40% using a small number of sites while providing assay sensitivity equal to or better than existing post-operative surgical models.

Analgesia methodologies developed or refined include:

- Third molar extraction (wisdom teeth)
- Orthopedic/podiatric surgery (bunionectomy and hammertoe surgery, knee arthroscopy, ACL repair, knee/hip replacement)
- General/gynecologic surgery (hernia repair, cholecystectomy, hysterectomy)
- Pioneered sciatic block anesthesia techniques for bunionectomy
- Multi-day/multiple dose designs for acute pain
- Dysmenorrhea repeated dose model
- Postoperative nausea and vomiting model
- Two stopwatch method for onset measures

Unparalleled Regulatory Experience

Premier Research Regulatory Affairs has unrivaled experience with the FDA Division of Anesthesia, Analgesia, and Rheumatology Products (DAARP). Over 25 INDs have been submitted to DAARP covering a broad spectrum of analgesic mechanisms, methods of administration, and abuse resistant technologies. Virtually every type of IND amendment has been submitted, including Special Protocol Assessments, and every type of FDA meeting has been held to support these INDs. Three NDAs have emerged from this work, all of which were submitted in the eCTD format:

- An immediate release opioid formulation with abuse resistant properties intended for the treatment of moderate to severe acute pain
- An extended release opioid formulation with a comprehensive Risk Evaluation and Mitigation Strategy intended for the treatment of moderate to severe chronic pain in opioid-tolerant patients
- A new NSAID for the treatment of signs and symptoms of osteoarthritis

Case Study:

Access to Large Subject Population for Acute Pain Studies

After completing two successful large studies together, a major European pharmaceutical company partnered with Premier Research to conduct a 735 patient single- and multiple-dose phase factorial design post-operative dental pain study that employed eight treatment arms. The model required the extraction of 3–4 impacted third molars allowing for different doses of a novel non-opioid combination analgesic to be analyzed for a full 80 hours after the initial dose of study drug. The severity of the molar impaction and subsequent trauma of removing them created severe pain that the treatments could be evaluated in a multiple day, multiple dose study.

We enrolled the study in 10 months at three of our centers. Our experienced investigators and clinical staff ensured that the efficacy assessments (VAS pain assessments, VRS pain assessments, two-stopwatch methodology) and clinical procedures were performed consistently across all sites, increasing the signal-to-noise ratio.

The study results showed excellent model sensitivity, identification of the ideal dose combination of the individual active ingredients, and provided a number of key findings with regard to the minimal effective dose. Following the success of this study, the client awarded us additional business.



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