



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 80 acute pain clinical trials conducted in the past five years
- More than 85 chronic pain clinical trials conducted in the past five years
- More than 48,000 analgesia 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

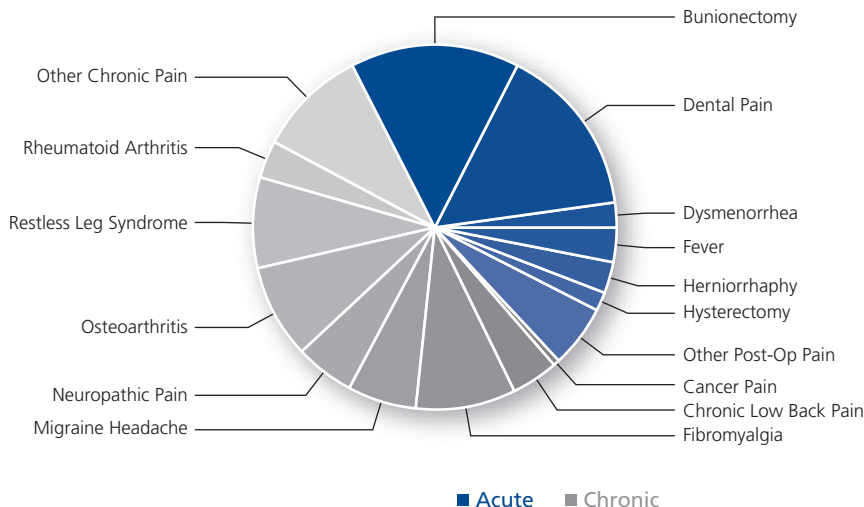
- More than 45 project managers/directors and 90 CRAs specifically trained and experienced in managing analgesia clinical trials
- More than 100 analgesia support professionals, including registered nurses, pharmacists, and certified clinical research coordinators
- Long-term relationships with leading scientists and experts in analgesia research

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.

Clinical Trial 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.

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

Case Study: Overcoming Challenging Timelines

A long-term client approached Premier Research with a challenging request in August. Before launching their blockbuster analgesic in Europe that October, their marketing department requested a formal head-to-head study against a leading analgesic available in Europe. They requested a double-blind, randomized, placebo-controlled third molar extraction study.

Premier Research responded quickly to the challenge, finalizing the protocol and obtaining IRB approval within weeks. By expediting processes and working efficiently, the team was able to enroll the first patient on September 3. All 304 patients were enrolled and dosed by September 30. Data management and statistical analysis were finished in the ensuing weeks enabling the sponsor to obtain top line efficacy and safety results in time for their scheduled launch.



Premier Research

North America: 215.282.5500

Europe: +44 (0) 118 936 4000

info@premier-research.com

www.premier-research.com

Visit our website for our global locations.