

Analgesia

At INC Research, we understand the clinical and regulatory requirements of pain-focused research. To establish the efficacy of a treatment for pain, the FDA and EMA encourage evaluation of a test drug or device in as many clinical models as possible. We have conducted a broad range of successful analgesic clinical trials, in both adult and pediatric populations, using a variety of pain models. Through our Trusted Process® methodology for delivering dependable trial outcomes, we have the resources, clinical expertise, and development know-how to help our customers with every facet of pain research.

Specialized expertise in analgesia

Our experienced team of pain specialists understands that there is no standardized approach to pain research. Early involvement with customers in the development of their regulatory and clinical strategy has proven highly effective to ensure studies are designed to meet their objectives and programs meet the current requirements of the FDA for analgesic products. We design clinical research programs incorporating the diversity of models required by today's international clinical and regulatory environment and execute protocols to ensure the successful outcome of each study. We also have extensive experience managing studies using Schedule II medications, in the U.S. and globally. At INC Research, we leverage our therapeutic expertise and our Trusted Process to ensure analgesic trials support the safety and efficacy of developmental analgesics.

Our pain-related clinical expertise encompasses a diverse range of indications including:

- Chronic and acute lower back pain
- Fibromyalgia
- Cancer pain and breakthrough pain
- Osteoarthritis and rheumatoid arthritis
- Chronic neuropathic pain including postherpetic neuralgia and diabetic neuropathy
- Acute postsurgical pain (dental, bunionectomy, gynecological, abdominal and orthopedic)
- Sprains and strains
- Migraine
- Pediatric pain
- Opioid-induced constipation

Our expertise spans analgesic development programs for oral (controlled-release, immediate-release and abuse deterrent) formulations, combination products, intranasal, topical, transdermal and buccal formulations.

Case study

INC Research managed a Phase III diabetic peripheral neuropathy (DPN) study at 95 sites in the United States and Canada. Enrollment was competitive as several DPN trials were running concurrently. Leveraging strong site relationships and research-based analysis, our team ensured Investigators with chronic pain research experience were selected. A multimedia advertising campaign was used to reach 81 sites across 45 markets.

For this study, we integrated new EDC technology into our Trusted Process to honor the Customer's request. In addition, 4 study medication expiry dates passed during the enrollment period, which required action. The first of three successful re-labeling efforts consisted of 71 site visits across the United States and Canada in less than 3 weeks by our CRA team who also successfully completed 13 site-to-site manual study drug transfers.

The study met enrollment targets and the database locked, on time. This DPN chronic pain study was the last dataset to be assembled for the Sponsor's NDA submission to the FDA and Health Canada. The positive results from this pivotal study may introduce a novel DPN medication for the Sponsor's analgesic franchise and importantly, a new treatment for patients suffering chronic pain associated with painful DPN.

For more information

about INC Research's capabilities in analgesia, please contact us at info@incresearch.com or at one of the telephone numbers below:

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