

PAIN AND INFLAMMATORY DISEASE MANAGEMENT



INVENTIV HEALTH IS A LEADER IN PAIN AND INFLAMMATORY DISEASE RESEARCH

Pain is a complex, subjective experience with a significant emotional component associated with multiple conditions and underlying mechanisms that can differ from one patient to the next. The compassionate pain specialists at inVentiv Health have unmatched experience in the design and management of Phase I-IV clinical trials.

A DEPTH OF EXPERTISE

- **100+** pain management clinical studies involving over **30,000** patients since 2010
- Experience in **15** different pain and inflammation therapeutic product categories
- Physicians with fellowship training in pain management and research
- Long history of Phase I trial conduct for pain therapies and controlled substances
- Novel Phase 2 and 3 studies with adaptive designs specifically suited to any given clinical development program
- Strong working relationship with the FDA Analgesic Division
- Continuous successful NDA and MAA submissions within program timelines
- Broad Investigator and pain Key Opinion Leaders relationships worldwide

- Knowledge of multiple pain scales and disease-specific function and QoL measures
- Skilled in hospital critical care setting
- Significant expertise addressing placebo effect and therapeutic misconception
- Have assumed role of Quality Person in Charge (QPIC) for Schedule II substance writing pharmacy monitoring guidelines and instruction manuals
- Full suite of highly-sensitive, validated opioid assays including metabolites and glucuronides; low sample volumes using innovative Waters Xevo platform
- Bioanalysis of >100,000 samples for opioid and non-narcotic pain medicines in support of clinical trials

EXPEDITED PHASE I STUDIES

- Broad access to significant patient participants, including special populations, through strategic hospital partnerships and an extensive, centralized database
- Talent and capacity to develop customized pain models in normal, healthy volunteers and patients in a Phase I setting

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- **State-of-the-art facilities** in Quebec City, Princeton, and Miami
- Over 300 beds, both ICU-like and standard, for multiple complex studies of varying design
- Rigorous FDA and Pharma tested procedures to guide the import, handling and on-site storage of controlled substances, DEA registration and licensure in place
- Experienced on-site physicians and medical professionals, integrated clinical operations, expert project managers and skilled statisticians ensure a professionally executed study
- Bioanalysis support from two high-quality laboratories with a scientific team having worked in excess of 10 years together on highly-sensitive pain assays

PROOF OF CONCEPT

Our scientific team works closely with you to design proof-of-concept studies to reduce risk and avoid costly late-stage clinical development failures. In addition, because of our knowledge across a wide range of therapeutic indications and our collaborations with local hospitals, inVentiv can provide sponsors with enhanced access to study participants with special conditions and disease.

GLOBAL RATER TRAINING

- inVentiv's Rater Training Services team provides expert, comprehensive rater evaluation and training, centralized data review, and scales management services

PATIENT SUPPORTIVE INITIATIVES:

- > 22+ years experience
- > 10,000+ patient database
- > 2,000+ pain specialists database

OUR EXPERIENCE:

- > Abuse deterrent and liability
- > Cancer pain (chronic, breakthrough)
- > Headache and migraine
- > Low back pain (acute and chronic)
- > Neuropathic pain (diabetic, post-herpetic, fibromyalgia)
- > Osteoarthritis and rheumatoid arthritis
- > Post-operative/procedural pain
- > NSAIDS, opioids, corticosteroids, anti-anxiety, antidepressants, anticonvulsants...
- > Oral, topical, IV, subcutaneous injection and other drug administration routes

- Our team is operationally and analytically familiar with outcome measures in pain trials, both general and indication-specific
- Several of our team members are the founding representatives with continued involvement in IMMPACT (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials) over the past 15 years

CONTACT US TODAY

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ABOUT INVENTIV HEALTH

inVentiv Health is a top-tier professional services organization that accelerates the clinical and commercial success of biopharmaceutical companies worldwide. Our combined Clinical Research Organization (CRO) and Contract Commercial Organization (CCO) helps clients improve their performance to deliver much-needed therapies to market. With 13,000 employees providing services to clients in 70 countries, inVentiv Health designs best practices, processes and systems to enable clients to successfully navigate an increasingly complex environment. inVentiv Health, Inc. is privately owned by inVentiv Group Holdings, Inc., an organization sponsored by affiliates of Thomas H. Lee Partners, L.P., Liberty Lane Partners and members of the inVentiv Health management team.

For more information, visit www.inVentivHealth.com