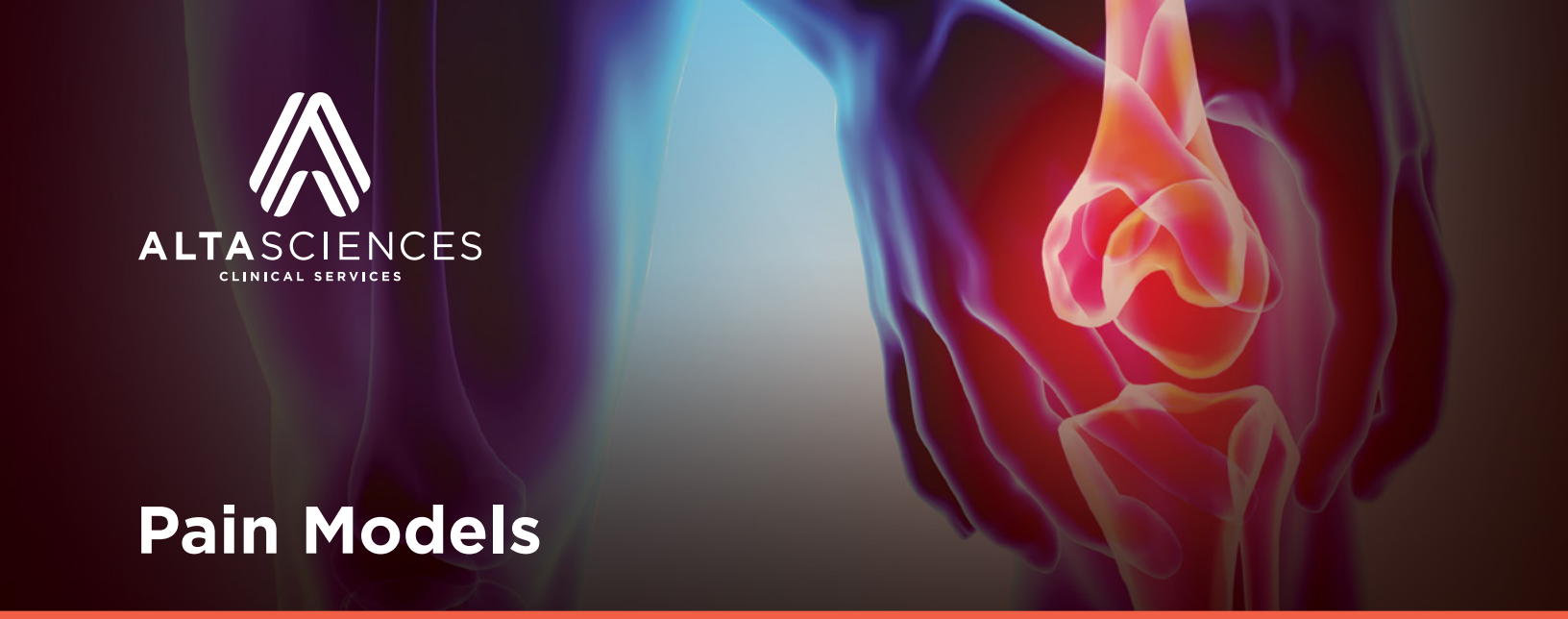

ALTASCIENCES
CLINICAL SERVICES

Pain Models

Altasciences has designed and conducted clinical pharmacology studies on pain medication for over 20 years. Our experience includes the completion of pharmacokinetic (PK) studies to demonstrate equivalence between two formulations, as well as studies on extended release and transdermal formulations. In the past 10 years, we have added the assessment of parameters for PK and pharmacodynamics (PD) on stand-alone studies and as part of a FIH protocol. The PD measures we have examined include abuse liability, cognition, biological biomarkers, as well as a number of different pain assessments in healthy and select patient populations.

The pain models we have tested examine various aspects of pain depending on the target of the compound, such as neuropathy or inflammation. The models focus on peripheral or central sensitization looking at allodynia or hyperalgesia. Our scientists are accustomed to designing studies and providing feedback on synopses or protocols provided. We have a number of key opinion leaders with whom we consult, as needed.

Experience

- Broad range of clinical pharmacology studies on analgesic drugs, narcotic and non-narcotic, including:
  - First-in-Human (FIH) – single and multiple ascending dose
  - Proof-of-Concept as part of FIH with a number of pain models
  - Phase II dose-ranging studies exploring safety and efficacy
- Different pain models used to assess pain due to neuropathy or inflammation, and tolerance at varying pain intensities following a multi-dose treatment as per the FDA guidance
- Pain models in healthy participants or patient populations
- A wide range of pain scores using objective measures, questionnaires or visual analogue scales

Patient Access

- **800+** patients with chronic pain disorders
- Lead recruitment and enrollment site for patients with osteoarthritis of the knee
- Collaboration with highly experienced knee surgeon for study setup and endpoint evaluation
- Easy access to healthy subjects through combined database of over 345,000 participants
- Ongoing outreach efforts to maintain and increase patient database

Clinical Expertise

- Full project management for multi-site trials, including training sites on recruitment and/or pain models
- Pain Models
  - Heat pain threshold and heat pain tolerance assessment
  - TENS, cold pain, mechanical stimulation model
  - and cutaneous freeze injury
  - Barostat model for visceral pain assessments
- Administration of medication via multiple routes, including parenteral injections

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Case Studies

Study on Analgesia on Visceral Pain, Rectal Sensory Threshold Using the Barostat Method

A Proof-of-Concept Study Assessing NEO6860 in Osteoarthritis Pain

Support Services

Bioanalysis

- Bioanalytical capabilities are supported by over 100 highly-trained specialists, working with the latest equipment in state-of-the-art, purpose-built laboratories
- High throughput bioassays for drug quantitation (operating 24/7), capacity of 60,000 samples per month
- Method feasibility, transfer, development and validations in multiple matrices
- LC-MS/MS and ligand binding assay capabilities

Medical Writing

- Team with over 20 years of experience
- Study design in line with current regulations
- Clinical trial protocol development, review and evaluation
- Integrated ICH E3-compliant clinical study report (CSR)

Project Management

- Project Manager (Project Leader) oversees the complete program conduct and deliverables
- Extensive expertise in managing single or multiple site clinical trials, across a wide range of therapeutic areas
- Close collaboration with key internal and external stakeholders ensures seamless and timely communication for successful project completion

Toxicokinetics and Pharmacokinetic Analysis

- Comprehensive preclinical TK and clinical PK and PD data analysis and interpretation
- Robust non-compartmental analysis using WinNonlin® v8 (Phoenix)
- Rapid turnaround for interim PK evaluation between dose escalation cohorts
- Stand-alone report and/or CSR integration

Data Management

- Team with over 20 years of experience
- Electronic Data Capture
- CDISC standards fully integrated in workflow
- Medical coding using latest versions of medical dictionaries (MedDRA, WHO-DDE)
- Database lock available typically within 2 to 4 weeks of last subject's final visit

Biostatistics

- All Programming done using SAS®
- Randomization list
- Statistical Analysis Plan, including mock TFLs
- Statistical results and appendices (TFLs) for CSR
- Reconciliation of external data e.g. safety lab
- Creation of CDISC-compliant FDA submission-ready package

Updated July 2019.

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