



Clinical Research Centers.

Premier Research's dedicated sites provide consistent processes, proven patient recruitment techniques, and an experienced staff of doctors and nurses so your clinical trials run smoothly and efficiently. Our centers have helped to pioneer the development of new research models and pain assessment methodologies now standard in drug development programs worldwide.

Services

- Phase 1 including Oncology
- Phase 2–4 Multi-specialty
- Proof-of-Concept Studies
- Dose-Ranging Studies
- PK and PD Studies
- In-patient and Out-patient Capabilities
- Multi-day/Multi-dose Studies
- Novel Model Development

Benefits

- State-of-the-art, research-dedicated clinics with consistently superior patient recruitment allow for rapid study start-ups
- High assay sensitivity and low query rates mean more accurate trial data with reliable and repeatable results

Expertise: The People

- Investigators and full-time clinic staff highly trained and experienced in Phase 1/2 as well as pivotal Phase 3 trials
- Site managers, study coordinators, patient recruitment specialists, and support personnel trained in Premier Research SOPs
- ACLS certified nurses and clinical staff to ensure patient safety
- CCRC/CCRP certified nurses and clinical staff to ensure GCP compliance

Arizona

Specialties: Acute and Chronic Pain*, Cardiovascular, Dermatology, Gastrointestinal, Endocrine/Metabolic, Infectious Disease, Musculoskeletal, Neurology, Oncology, Ophthalmology, Psychiatry, Respiratory, Women's Health

Studies Completed: 350+

Texas

Specialties: Acute and Chronic Pain*, Cardiovascular, Dermatology, Gastrointestinal, Endocrine/Metabolic, Infectious Disease, Musculoskeletal, Neurology, Ophthalmology, Psychiatry, Respiratory, Women's Health

Studies Completed: 295+

Utah

Specialties: Acute and Chronic Pain*, Cardiovascular, Dermatology, Gastrointestinal, Endocrine/Metabolic, Infectious Disease, Musculoskeletal, Neurology, Ophthalmology, Psychiatry, Respiratory, Women's Health

Studies Completed: 50+

* **Acute Pain Models:** Bunion, Dental, Dysmenorrhea, Headache–Tension and Migraine, Acute Sprains and Strains, Delayed Onset Muscle Soreness, Hammertoe, and Orthopedic and Abdominal Surgery

Chronic Pain Models: Osteoarthritis, Chronic Low Back Pain, Fibromyalgia, Diabetic Peripheral Neuropathy, Postherpetic Neuralgia, and Restless Leg Syndrome

Additional Models: Anxiety, Fever, Nausea and Vomiting, and Sleep

Case Study:

A Pivotal Multiple-Dose Efficacy Study in Bunionectomy

Premier Research was contracted by a large pharmaceutical company to perform a multiple-dose, Phase 3 efficacy and safety study using the bunionectomy model to serve as a pivotal trial in their NDA submission for a novel opioid analgesic. The complex study design utilized a variable dosing schedule along with a combination of fixed and relative efficacy assessments, collected over 72 hours of dosing and in-patient stay. Other procedures included vital signs, ECGs, sedation assessments, pharmacogenomic sampling, multi-day pharmacokinetic sampling at select sites, and a nine-day open-label outpatient treatment period.

Using our network of sites, 600 randomized subjects were recruited and enrolled in under nine months. Our data management group then worked closely with the sponsor and the dedicated site teams to provide a timely lock to the large, complicated EDC database. The study results were very favorable, achieving sensitivity on all primary outcome measures, and the trial was among the cornerstones of the client's successful NDA submission and subsequent FDA approval.

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