



## Medical Affairs and Strategic Consulting.

Our team focuses on minimizing the time to key milestones while maximizing the value of products under development. Working closely with your team, we integrate the therapeutic and functional expertise necessary for success in today's complex clinical development environment.

### Services

- Clinical Development Program Consulting
- Medical and Scientific Support for Regulatory Submission Planning and Preparation
- Protocol, Informed Consent, and CRF Design and Review
- Investigator Brochure Development
- Laboratory Data Review
- Medical Data Review
- Medical Coding
- 24-hour Medical Monitoring
- Data Monitoring Committee Coordination (DMC and DSMB)
- Independent Review of Clinical Endpoint Committees Coordination
- Regulatory Agency Support
- Support for Pediatric Regulation Compliance
- Physician-to-Physician Interface
- Site Selection and Enrollment Enhancement Solutions
- Key Opinion Leaders Networks
- Publication Planning and Review of CSRs and Scientific Manuscripts

### Benefits

- Focused team approach provide clients with comprehensive development solutions
- Flexible integration of Premier Research experts extends sponsor's internal team capabilities
- Strategic knowledge of the clinical challenges in the current research environment helps sponsors to implement better clinical plans
- Overall scope and balanced global geographic presence allows sponsor to more easily develop products worldwide

### Expertise: The People

- Board certified/registered in-house physicians in key therapeutic areas
- Medical monitors with medical practice experience understand and relate to the challenges faced at investigative sites
- Clinical expertise closely matches our focus in analgesia/anti-inflammatory, neuroscience, oncology, hematology, cardiovascular, and pediatrics
- Team fluent in the local languages, medical practices, and culture allows for effective communications with site staff
- Commitment to continuing education regarding evolving regulatory requirements

### Case Study: Preferred Medical Monitoring Vendor

Based on our consistent and thorough support, an emerging biotechnology company designated Premier Research as their preferred provider for all medical services. Premier Research has provided medical monitoring and cohort review management to the client.

Premier Research has worked on numerous studies in a range of cancer indications for the novel small molecule drug demonstrating the expertise to understand different tumor types. Premier Research has proven that we are receptive to small clients.

### Premier Research

North America: 215.282.5500  
Europe: +44 (0) 118 936 4000  
info@premier-research.com

[www.premier-research.com](http://www.premier-research.com)

Visit our website for our global locations.