



## Clinical Trial Management.

Premier Research offers a highly experienced global team of clinical experts with the depth of knowledge necessary to effectively manage any situation that may arise throughout your clinical trial.

### Services

- Project Management
- Protocol Development
- Feasibility
- Site Identification and Selection
- Site Qualification
- Investigator Contract Negotiation
- Regulatory Document Management
- IRB Submission
- Investigator Meeting Preparation
- Site Initiation
- Clinical Monitoring
- Site Management
- Patient Recruitment Support
- Investigator Grant Management
- Trial Master File Management
- Vendor Management

### iTrack

Premier Research provides enhanced communication with a robust, central repository providing real-time project management and reporting through our proprietary, validated, customizable iTrack CTMS system.

### Benefits

- Project managers accountable for all project activities provide a single point of contact
- Quality and efficiency increased through therapeutically aligned project teams
- Extensive therapeutic-specific investigator network streamlines screening of sites
- Strong site relationships built through project teams highly experienced in site initiation activities
- Project-specific communication plans establish clear communication channels, accountability and accessibility throughout studies
- Review of project deliverable status by senior management ensures that all timelines are met and issues are resolved in a timely manner
- Commitment to undertaking only those projects which we can perform to the highest quality standards

### Expertise: The People

- Project managers have an average of 14 years of industry experience
- International network of site monitors with an average of nine years of industry experience
- Project management and medical staff familiar with KOLs and high enrolling sites
- Therapeutic expertise provided by in-house physicians and operations experts to assist in study design

### Case Study: Managing High Performance Global Project Teams

Premier Research recently managed two Phase 2/3 Chronic Myeloid Leukemia trials for which we were recognized as the "Clinical Research Team of the Year" at the 2008 GCP Awards.

These studies carried a unique set of challenges including targeting an uncommon subset patient population which greatly affected recruitment and the collection and evaluation of complicated genetic and molecular data.

To best support the studies, our experienced team covering nine time zones was led by a global director with bilateral project management in North America and Europe and team members in each country of the participating major cancer centers. Through proactive planning and continuous feedback, our team engaged the sites and provided innovative solutions completing all of the tasks and exceeding the client's expectations.

Our monitoring group worked with many of the centers to develop best-practices across the sites to integrate the use of their electronic systems with clinical trial documentation requirements. These interactions improved standards in busy centers making a significant impact on the future of clinical data and maintaining compliance with ICH/GCP guidelines.

### 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.