



Oncology.

With a successful track record covering a wide spectrum of cancer-related therapeutic indications, Premier Research provides high quality full clinical research services from small dose finding and proof-of-concept studies to large, multi-national trials involving hundreds of patients in this complex area of research.

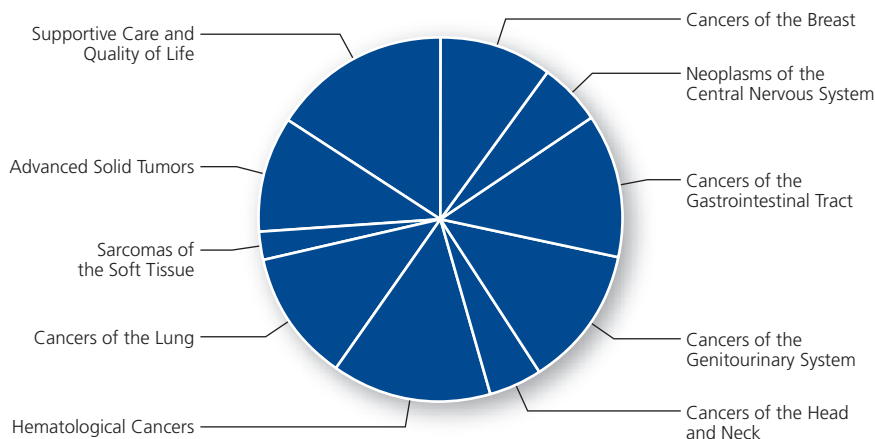
Proven Experience

- More than 120 oncology clinical trials and 15 consulting products conducted in oncology in the past five years
- More than 15,000 cancer patients treated in the past five years
- Dedicated specialty oncology clinic with on-site oncologist utilizing a central IRB
- Experience with nearly all oncology indications from solid tumors to rare pediatric cancers
- Experience in tumor response assessments (e.g. RECIST, WHO response criteria), validated QoL questionnaires, and NCI Common Toxicity Criteria for AEs

Expertise: The People

- More than 65% of project managers/directors and 69% of CRAs experienced in oncology clinical research
- Oncology team honored as 'Clinical Research Team of the Year' at the 2008 GCPj Awards
- Internal medical and operational experts in oncology drug development
- Long-term relationships with leading investigators and key opinion leaders in oncology research
- Global team with local knowledge and expertise allows us to recruit oncology trials
- In-house regulatory consultants provide guidance on development and regulatory strategy

Experience Within the Past 5 Years



Case Study: Managing a 3-Study Dose Finding Oncology Program

Premier Research was contracted by a Canadian biotechnology company to manage all aspects of a three-protocol Phase 1/2 program designed to determine the maximum tolerated dose (MTD) and evaluate the safety and efficacy of study drug in subjects with non-small cell lung, breast, and pancreatic cancers.

A project team, comprised of individuals with deep oncology experience, was assembled to manage this program. The team met and in some cases exceeded start-up timelines despite the fact that most of the participating sites were large academic institutions with key opinion leaders. Premier Research met this challenge by centralizing and proactively managing site start-up, ensuring rapid commencement of subjects recruitment.

One of the greatest challenges faced was coordinating KOLs' participation in critical bi-weekly teleconferences to review safety in ongoing subjects and potential subjects for upcoming enrollment slots. Based on experience with similar studies, the teleconferences were managed flawlessly by the team, and the Sponsor and sites appreciated the streamlined effort.

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Successful execution of oncology studies begins with a clear understanding of the tumor type to be evaluated, study design and analysis requirements, and the inherent challenges with conducting these complex studies. Premier Research has a broad base of oncology experience that has contributed to a successful track record in completing studies on time and within budget.

Clinical Trial Dynamics Unique to Oncology Product Development

Given the devastating effect of cancer and the urgent need to find more effective therapies, the regulatory requirement for approving oncology products continues to evolve.

As reported in the *Wall Street Journal* (July 10, 2006: FDA Signals It's Open to Drug Trials That Shift Midcourse), FDA is encouraging Sponsors, particularly in the field of oncology research, to consider adaptive design strategies by providing a more efficient regulatory review and evaluation process. The rate of patient attrition, differences among supportive care and adjuvant therapy, coupled with the variable kinetics ascribed to treatment response are frequently exacerbated in oncology studies. Premier Research considers these trial dynamics when designing oncology trials.

Adaptive Clinical Trial Designs and Interim Monitoring

Adaptive trial designs define pre-planned modification of some pre-specified elements (e.g. study sample size) of the study design, based on the data collected early in the study. This can be done without compromising the scientific and clinical integrity of the trial.

The objective of an adaptive design is to provide greater assurance of achieving the intended goal of the study if the therapy is effective, and simultaneously provide a mechanism for stopping the study if the response is not clinically meaningful. We have developed the expertise to provide sponsors with rational adaptive study design and analysis in oncology trials.

Premier Research continues to be a recognized leader in this field by constructing independent Data Monitoring Committees (DMC) that are an integral part of conducting clinical trials with adaptive design. These committees are instrumental in ensuring that patient safety and study integrity are maintained during interim monitoring.

Case Study: Providing Comprehensive Services for Prostate Cancer Implant

Premier Research assisted a biotechnology company in support of a new product for the treatment of prostate cancer involving an in vivo implant and a medical device for subcutaneous insertion.

Our expertise was called on to assist in many phases of the drug's development including consultative services, full service clinical development of the Phase 3 study, medical writing, harmonization of legacy data, submission of the NDA, safety reporting, and negotiations with the FDA. The NDA was filed after patients completed 12-months of observation; patients continued to be followed while the submission was under review and 30-day safety reports were completed. A crucial review point was maintaining the implant, and the likelihood of successful implantation using the device.

Premier Research was able to construct an analysis and present probability values that clarified the risk for explantation given the reported frequency. By combining our oncology expertise and excellence in clinical research, the Sponsor received full approval to market the drug and manufacture and distribute the device within 9 months of the initial submission.



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