



Strategic Product Development.

Our Strategic Product Development (SPD) group focuses on minimizing the time to key milestones while maximizing the value of products under development. Working closely with your team, SPD integrates 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
- Clinical Study Protocols and Investigator Brochures Development
- Strategic Statistical Consulting
- Site Selection and Enrollment Enhancement Solutions
- Data Monitoring (DMC and DSMB)
- Key Opinion Leaders Networks
- Publication Planning and Review of CSRs and Scientific Manuscripts

Benefits

- Focused team approach draws on Premier Research strengths in order to provide clients with comprehensive development solutions
- Flexible integration of our experts within the client team extends sponsor's internal capabilities
- Deep strategic and tactical knowledge of the current clinical development environment and challenges allows sponsors to implement better clinical plans
- Overall scope and geographical presence allows sponsor to gain knowledge of what it takes to develop products on a global basis

Expertise: The People

- Comprised of medical and scientific senior executives
- 100% of team has post-graduate degrees
- Expertise closely matches our focus in analgesia/anti-inflammatory, neuroscience, oncology, hematology, infectious disease, and pediatrics

Case Study: Comprehensive Clinical Plan Development

Premier Research was contracted to assist a client in creating a comprehensive clinical development plan for a novel product to treat Panic Disorder. The sponsor sought to characterize the medical need and the potential market for the product, determine the most efficient path to market (including the evaluation of potential indications), evaluate risks in development, and determine the clinical trials needed.

Among the critical activities for the SPD group was an extensive literature review for potential indications, a face-to-face meeting with a panel of clinical experts in the therapeutic area, evaluation of study feasibility, and comprehensive costing of proposed studies. The information from the plan was subsequently used by the client to make decisions regarding product investment.

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