



Pediatrics.

Premier Research has the experience and expertise to successfully conduct studies in neonates, infants, children, and adolescents. We manage pediatric clinical trials from plan development and study design to successful study completion and submission of pediatric data to regulatory agencies, in compliance with FDA Written Requests for marketing exclusivity as included within the Best Pharmaceuticals for Children's Act (BPCA), Pediatric Research Equity Act (PREA) commitments, and Pediatric Regulations under the EMEA.

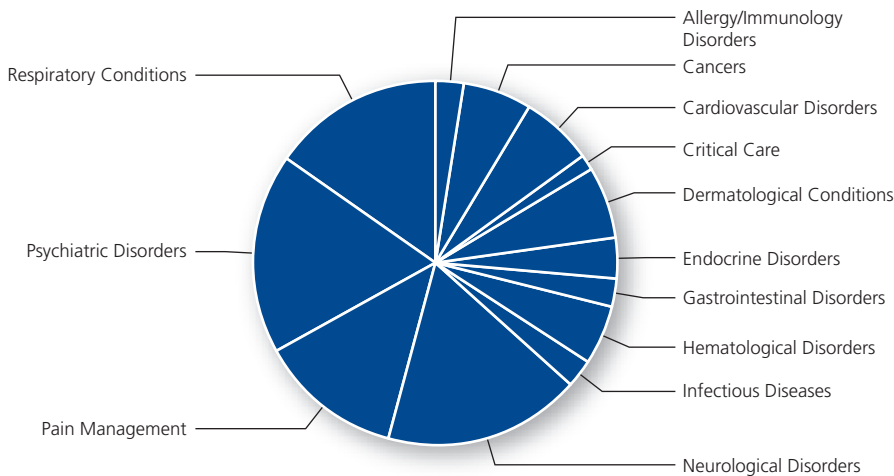
Proven Experience

- More than 65 pediatric trials and 10 consulting projects conducted in a pediatric population in the past five years
- More than 15,000 children treated in the past five years
- Includes outpatient, inpatient, NICUs, PICUs, ORs, ERs, and Analog Classrooms
- Six years as the Coordinating Center for the BPCA under the purview of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) within the NIH

Expertise: The People

- More than 44% of project managers/directors and 37% of CRAs experienced in pediatric clinical research
- Relationships with more than 50 of the foremost pediatric hospitals
- Global team with local knowledge and expertise allows us to recruit pediatric trials
- In-house regulatory consultants provide guidance on development and regulatory strategy including support for submissions related to PREA, BPCA, and the European Regulations

Experience Within the Past 5 Years



Case Study: Managing a Pediatric Trial in an Orphan Indication

Due to our extensive pediatric experience, a biopharmaceutical company focused on the discovery and development of novel products to address unmet medical needs contracted with Premier Research to manage a 30-site, 212-patient double-blind placebo controlled trial in pediatric patients with Eosinophilic Esophagitis (EE), an often undiagnosed illness. We provided full service management of the study including clinical trial management, data management utilizing Oracle Clinical RDC, IVRS, medical monitoring, pharmacovigilance, and quality assurance services.

Study challenges included obtaining IRB approval from local IRBs, training naïve investigators and staff members on Good Clinical Practice (GCP) and study specific procedures, difficult patient enrollment due to limited population, invasive protocol procedures including esophageal biopsies and monthly IV infusions, and protocol amendments based on lessons learned in this indication.

Our experienced pediatric team conducted a thorough investigator meeting, assisted sites with their IRB submissions, performed intensive site initiation visits, and provided continual training and support while the sponsor reached out to the EE community for enrollment assistance. By working very closely with both the sponsor and the sites through all phases of the study, we were able to successfully mitigate the study challenges and exceed the sponsor's expectations in this difficult indication.

Pediatrics.

Premier Research understands that pediatric research involves unique challenges, but that research can and must be conducted in this vulnerable population in order to support appropriate clinical care and product labeling. Premier Research recognizes the nuances associated with pediatric trials, for both the patient and the family, and has the experience and expertise to meet those challenges.

Vulnerable Population

Through various initiatives including the work we have conducted as the Coordinating Center for NICHD as part of the BPCA, dosing and safety information for pediatric medications has improved in recent years. However, the need for increased pediatric research continues and as seen in legislation passed in the United States and Europe in 2007, has been acknowledged by regulatory agencies.

Special protection must be given to children participating in clinical research. Because their involvement is essential to making improvements in children's healthcare, enrolling a child in a trial is ethically acceptable and necessary. Premier Research has the experience with pediatric trial design and execution to ensure that while children benefit from medical progress, they are not exposed to unnecessary risks by participating in clinical trials.

Premier Research understands pediatric research and has insight of working with both sponsors and regulatory agencies in developing novel approaches to successfully manage pediatric clinical trials.

Pediatric Recruitment

Patient recruitment and retention is one of the biggest challenges in pediatric research. Premier Research has the expertise to evaluate the requirements of the clinical trial and develop recruitment plans in partnership with the sponsor and investigative sites in order to meet project timelines. We work with site staff to achieve recruitment goals. Collaborative efforts with the sponsor and site staff include evaluation of study design and impact upon the parents and patient, education of the parents and patients in order to ensure that they understand their obligation to study procedures, and consideration for the needs of the families, such as scheduling visits after school hours.

Premier Research ensures that investigators are fully trained and understand their responsibilities in the parental permission/informed consent and assent process. In order to ensure a successful trial for all involved, it is essential that the investigators provide understandable study information and clearly explain expectations to both the patient and the parents during the parental permission/informed consent and assent process and for the duration of the study.

Case Study: Overcoming Enrollment Challenges in a Pediatric Study

Pediatric trials typically require obtaining permission/informed consent from the parents and assent from the patient.

Premier Research was challenged with managing a study in which a trial arm enrolled patients admitted to the emergency department in status epilepticus. This clinical setting and the acute needs of the patient presented a challenge for the standard informed consent/assent process. In an effort to overcome this challenge, parental permission/informed consent and assent were obtained in advance from parents and patients at risk for status epilepticus during routine check-ups and, patients were given special bracelets that emergency staff was trained to recognize and that the children would want to wear.



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