

Pediatric Expertise

In Phase II – IV Clinical Studies

DEDICATED PEDIATRIC EXPERTISE

PharmaNet's pediatric team has successfully conducted more than seventy five pediatric studies in infants, children and adolescents. Our professional staff has the hands-on experience to develop intelligent solutions for your pediatric clinical development programs in the Americas, Europe, and Asia-Pacific region.

GENERAL AND PEDIATRIC-SPECIFIC SERVICES

PharmaNet offers a comprehensive range of general services for defining the development plan for your drug, achieving agreement with regulators and managing your clinical studies.

Our depth of experience allows us to help you address the challenges of your pediatric drug development program. We can provide advice whether juvenile toxicity animal studies are needed to support clinical studies in children, and if so, design and conduct such studies according to recent EU and FDA guidelines. We also provide insights into regulatory and legal mandates, including the US Pediatric Research Equity Act, the Best Pharmaceuticals for Children Act (the FDA's Amendment Act or FDAAA), and the EU Regulation on Medicinal Products for Paediatric Use.

As you begin your program, PharmaNet can identify the appropriate pediatric investigators from our extensive database and through our ongoing relationships in academia and pediatric pharmacology research units. Once investigators are selected, we can provide and deploy strategies to boost enrollment that are consistent with all applicable ethical and age-based standards. We have expertise in the generation of materials to ensure a successful informed consent and assent process and offer site specific recruitment planning workshops. We also provide extensive training to sponsor personnel on the diverse aspects of clinical research in children and the aims of the various regulations to which sponsors are obligated.

During an active clinical trial, studies are monitored by experienced clinical research associates, preferentially with previous pediatric study experience, and medical monitors experienced in the conduct of studies in children, with an emphasis on patient eligibility and the monitoring of efficacy and safety in pediatric populations.

Let PharmaNet's experience and in-house experts **Work for You.**

OTHER SERVICES INCLUDE:

- Compilation of Paediatric Investigational Plans according to the European Paediatric Regulation and (EC) No 1901/2006
- Support for the obtaining of scientific advice from the regulators In the USA and EU
- Interdisciplinary strategic development planning; preclinical and clinical
- Protocol development
- Clinical development plan compilation
- Gap analysis for in-licensed drug candidates
- Quality control/assurance
- Biostatistical support for study design and analysis
- Case report form development
- Data entry/management/database construction and analysis including EDC
- Study monitoring and site management
- Pharmacovigilance and risk management plans
- Regulatory affairs (IMPD/MAA/NDA submissions)
- Medical writing for protocols, material for patient and parent information, clinical study reports and regulatory submissions

Experience

Our experience includes completed and ongoing studies for:

- Acne
- ADHD
- Allergic Rhinitis
- Anemia
- Anorexia Nervosa
- Asthma
- Cystic Fibrosis
- Diabetes Type I
- Diabetes Type II
- Emesis (oncology related)
- Epilepsy
- Fabry Disease
- Hepatitis B vaccine
- Hunter Syndrome
- Hyperbilirubinaemia (neonatal)
- Hypertension
- Nutrition (neonatal)
- Oral Moniliasis
- Osteopenia
- Pain Management
- (drug/device for delivery of local anesthesia)
- Rheumatoid Arthritis
- (juvenile)Schizophrenia
- Vaccine Studies

