PRA Health Sciences

FACT SHEET

Center for Pediatric Clinical Development

At the Center for Pediatric Clinical Development (CPCP), we are committed to bringing safe and effective treatment options to children. Our unparalleled pediatric expertise and global resources provide exceptional strategic and operational study delivery, designed to save our clients time and resources and keep our patients and their families at the center of all we do.

Navigating The Unique Complexities of Global Pediatric Studies

The NIH reports that 70% of medicines given to children have only been studied in adults; therefore, most drugs used to treat diseases in children are used off-label – without an adequate understanding of the appropriate dose, safety, or efficacy. Off-label prescribing has become the treatment of choice because of the lack of clinical trials in the pediatric population.

Compounding this issue are the unique challenges of conducting studies in the pediatric population. Physiological and psychological diversity of pediatric age groups can affect study designs and increase timelines and costs.

PRA's Solutions

The CPCD is the focal point and repository for PRA Health Sciences' global pediatrics knowledge. Powered by analytics, effective partnerships, and broad experience, our highly skilled experts help bring innovation to pediatric clinical development, pediatric trial design, and implementation.

Unique Challenges For Pediatric Studies

Finding The Patients
- Identifying the right site
- Optimal protocol design
- Family considerations

Consent and Assent
- Parents reluctant to enroll their child
- Complex assent process

Logistics
- Limits of blood volume draws
- PROs rarely validated in pediatrics
- Normal values are age sensitive

Safety
- Trials with safety-only parameters are difficult to enroll
- Breaks for DMCs to review safety data result in prolonged timelines

Regional/Country Specifics
- Travel is time consuming and expensive
- Country-specific regulatory requirements

Protect children THROUGH research, not FROM research

Regulatory Solutions

Pediatric legislative initiatives have been enacted to encourage the development of safe and effective medicines for children. These items of legislation are encouraging, but they have not resolved all the challenges inherent in pediatric drug development. The CPCD is at the forefront of interpreting new laws and regulations affecting clinical development in this special population.

Customer Benefits

- Early strategic consultation to assess feasibility that continues through the program's duration and saves time and resources
- Extrapolation as well as modeling and simulation studies to support efficient pediatric development
- Help navigating the unique complexities and challenges of pediatric trials
- An understanding of the diverse country-specific regulatory and legal complexities in the pediatric environment
- Experts dedicated to improving patient engagement and retention

Commitment to Patients

There's no better investment in the future than today's children.

The CPCD is committed to bringing treatment options to children through our conscious and effective focus on the development of pediatric clinical breakthroughs. We work to keep the patient and their family at the center of all we do, and we never lose sight of our goal: a better tomorrow for our children.

Expertise

The foundation of the CPCD is formed by the Pediatric Collaboration Team, an advisory and consultative group within PRA with extensive experience in the facets of pediatric clinical trials. By coordinating our technical and strategic expertise in a single cross-functional global resource, PRA can seamlessly integrate services and focus on each aspect of the client's pediatric product development needs.

Cross Functional Team

Therapeutic Expertise
Clinical Development
Clinical Operations
Study Start-Up
Global Regulatory Strategy & Affairs
Medical Informatics
Center for Vaccine Research
Feasibility
Site Engagement
Proposals
Patient Experience

Clinical Research Associate
892+ Staff
Average 3 years of pediatric experience

Project Manager/Director
292+ Staff
Average 3 years of pediatric experience

Clinical Team Manager
428+ Staff
Average 3 years of pediatric experience

70 Medical Directors with pediatric experience
27 pediatricians, 16 board certified

Experience

We have a broad background in managing pediatric clinical studies in all ages groups – neonates, infants, toddlers, children, adolescents, young adults–and multiple therapeutic areas. Our success is demonstrated in our contribution to 20 pivotal and/or supportive trials that secured FDA and/or international regulatory approvals for pediatric patients (original and supplemental approvals as a new subject population).

Clinical Studies: 145+
Non-clinical projects: 42+
Patients: 21,700+
Sites: 7,000+

Next Steps

For additional information, please contact CenterPediatricClinDev@prahs.com