Worldwide
Clinical Trials

Pediatric Epilepsy Clinical Development at Worldwide

Worldwide Clinical Trials provides clinical development services to sponsors investigating treatments for epilepsies in children. Our scientific and medical teams have extensive medical, clinical development, and research experience in epilepsy and pediatric epilepsies. Our expertise includes rare pediatric syndromes such as Dravet and other pediatric developmental epileptic encephalopathies.

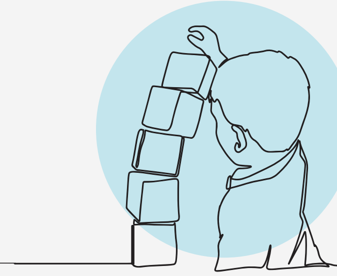
Your study is unique. Our teams leverage their depth of experience and lessons learned from rare, pediatric, and epilepsy studies to provide personalized solutions for you and your patients. A key part of our approach is partnering with patient-led research organizations and pediatric epilepsy consortiums to gain insights from patients, families, and key opinion leaders (KOLs). These relationships provide access to the patient population to recruit for your study and optimize your protocol for success, and they position us to be at the cutting edge of research developments. We also prioritize building strong relationships with sites to facilitate participation and have an in-house team of assessment specialists to ensure high-quality data collection.

Pediatric Epilepsy Experience

13 Studies

555⁺ Sites

2,100⁺ Patients



Recruiting & Retaining Pediatric Epilepsy Patients

For indications where the caregiver and study burden are high, we prioritize feasibility of participation for families. We work with you to ensure your trial has appropriate inclusion/exclusion criteria and collects only the necessary data to establish safety and efficacy. Additionally, our focus on building relationships with sites means we discuss your trial directly with the PI, walking them through the science behind your product and why your protocol is the right choice for their patients.

Our recruitment and retention efforts utilize:

- Relationships with KOLs and the Epilepsy Study Consortium for protocol reviews
- Prescreening efforts
- Patient education materials
- Advocacy organizations partnerships
- Participant concierge travel
- Partnership with Invitae, a medical genetics company
- Genetic testing and counseling resources
- Site coordinators
- Clinical Trial Liaisons

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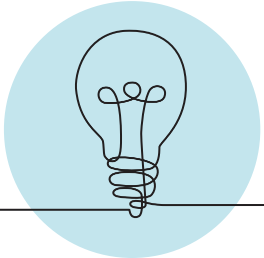

Rater & Scale Management Solutions

Our in-house Clinical Assessment Training and Surveillance team delivers integrated rater training, scale management, and assessment vendor relationship management to drive the reliability of epilepsy clinical assessments in your trial. They provide complete services needed to reduce the variability of outcomes data, including:

- Rater experience and assessment
- Scale and ePRO management
- Rater and conceptual training for PI and study team
- Placebo response mitigation
- Standardization of scale administration

Lessons Learned

- Select sites carefully as patients can be difficult to find, especially if participants are required to be antiseizure medication-naïve or on monotherapy
- Collaboration with advocacy organizations such as the Dravet Syndrome Foundation and associated parental/caregiver groups is essential for general study awareness
- Joint sponsor-Worldwide webinars foster excitement for the study in scientific and patient communities
- Pediatric consent and assent should include videos/graphics that are age-appropriate and foster understanding
- Engagement of parents and caregivers is vital
- Consent process needs to account for potential differences between the Institutional Review Board and the Independent Ethics Committee
- If targeting monogenic or syndromic forms of epilepsy, we recommend providing genetic counseling and testing resources
- Leverage concierge services for patients and families, including travel, visa services, lodging accommodations, and support for other children in the family
- Utilize home or telehealth visits when the schedule of assessments allows

Meet Your Team

The substantial individual experiences of each team member collectively bolster our corporate experience. Our pediatric epilepsy medical monitors have backgrounds in epilepsy and rare pediatric epilepsy clinical care and have collectively published extensive research in these indications. Together, they provide comprehensive and accessible medical monitoring throughout your trial.

Our Epilepsy Medical Monitors

North America
Florida | Pennsylvania | Kentucky | Texas

South America
Argentina

Europe
Germany | Czech Republic | Lithuania
Slovakia | Spain

Asia Pacific
Singapore | Taiwan

Our Featured Pediatric Epilepsy Medical Monitors

Idil Cavus, MD, PhD

Vice President, Therapeutic Area Medical Lead, Medical Affairs, Neuroscience

- Neuroscientist with 25+ years in the industry; provides medical oversight for epilepsy trials
- Clinical trial and medical expertise in epilepsy, including treatment-resistant and pediatric epilepsies like Dravet syndrome and infantile spasms

Herbert Achtereekte, MD

Senior Medical Director, Medical Affairs, Neuroscience

- Board-certified neurologist with experience in pediatric neurology
- 20+ years of experience in clinical trials, including Batten disease and pediatric epilepsy

Maria Elena Fontela, MD

Senior Medical Director, Medical Affairs, Neuroscience

- Board-certified neurologist and epileptologist with 20+ years of clinical epilepsy medical monitoring Clinical research experience in pediatric epilepsies and rare pediatric epilepsies, including Dravet syndrome, Lennox-Gastaut syndrome, and Rett syndrome

William Gerson, DO

Senior Medical Director, Medical Affairs, Neuroscience

- Neurologist with 18+ years of industry experience, including in epilepsy trials
- Fellowship in epilepsy and EEG intraoperative monitoring

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At Worldwide, we bring a depth of operational experience, a wealth of development experience, and a team ready to partner and support you throughout your program. To learn more about how our personalized services can support your pediatric epilepsy study, contact us.

Contact Us

05/13/25