PEDIATRIC TRIALS NETWORK

Making Drugs Safer & More Effective for Use in the Youngest Patients

Behind every medicine, medical device, and therapy, research studies have taken place to learn more about dosing, safety and efficacy. **However, the majority of medications that are commonly prescribed for pediatric use have not been specifically tested for use in pediatric populations.**

Research supported by the Pediatric Trials Network (PTN) helps fill this gap by ensuring that pediatric dosage is based on robust scientific evidence found in the pediatric population rather than from data provided by adults. **From a child suffering from an ear infection to a newborn in the NICU, when a child takes a prescription medication, there is a 90% probability that PTN has investigated some aspect of the medication's dosing, safety, or efficacy.**

PTN is a nationwide collaborative network of more than 300 research sites that conducts extensive research on off-patent* medication which is used to update the Food and Drug Administration (FDA) drug labels, (printed information about dosing that is included with medication). PTN's research sites are spread across more than **40 states** and have enrolled over **12,500 participants** to help improve drug safety and efficacy in children. The findings from PTN's research contribute to safer, more effective healthcare practices for children in both hospital and outpatient settings.

The research of PTN has been supported by federal funding through the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). The BPCA was enacted in 2002, while the PREA became law in 2003, both with the primary aim of enhancing the safety and efficacy of pharmaceuticals and medical devices for pediatric use. **Without reauthorization and expansion of funding through Congress, the Pediatric Trials Network and its partners cannot continue to engage in this critical research, which protects the health of our most vulnerable citizens: children and mothers.**

To date, PTN's groundbreaking research into pediatric health has resulted in **23* FDA label changes,** with an additional 7 medications submitted to the FDA for review. For families and healthcare providers, these updates mean greater peace of mind when prescribing and administering medicines to newborns, children, adolescents, and breastfeeding mothers. **Each label change represents a step forward in protecting the health of our youngest and most vulnerable populations.**

*Off-patent drugs are medications whose patent protection has expired. This means that the original manufacturer no longer holds the exclusive rights to produce and sell the drug. As a result, other companies can manufacture generic versions of the drug.

**As of October 2024

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To dive deeper into PTN's work, visit our website to explore the latest research reports, case studies, and updates on FDA-approved drug labeling changes. Share PTN's research and advocacy efforts with your colleagues and networks, and help raise awareness of the need for safe and effective drug treatments for newborns, children, adolescents, and breastfeeding mothers. **Your voice can play a key role in influencing broader support for pediatric drug research and development.**

PTN's work began with the authorization of the Best Pharmaceuticals for Children Act (BPCA) in 2002 and is up for reauthorization and increased funding in 2027. Increased funding would allow PTN to expand its capacity and conduct larger-scale trials, which is crucial for accurately determining drug safety and efficacy in children and mothers.

Stay connected with PTN by subscribing to our newsletter. By signing up, you'll receive regular updates on the latest pediatric trials, groundbreaking research findings, and advancements in drug safety.

PTN conducts research that fills a crucial gap in pediatric healthcare. With your support, they can continue providing peace of mind to parents and families across the country and inform prescribing physicians with the latest research, data, and publications.

Label changes resulting from PTN research under the BPCA Program (as of October 2024):

- Acyclovir
- Caffeine
- Ampicillin
- Clindamycin (2)
- Diazepam
- Doxycycline
- Fluconazole
- Furosemide
- Levetiracetam
- Lisinopril
- Lithium
- LorazepamMercy babyTAPE
- 2D and 3D Mercy TAPE
- Meropenem
- Oxcarbazepine
- Oxycodone
- Propylthiouracil
- Pralidoxime
- Rifampin
- Sodium Nitroprusside
- Trimethoprim-Sulfamethoxazole (TMP-SMX)

Therapeutic study areas:

- Anesthesiology/ Pain medicine
- Cardiology
- Critical care medicine
- Dermatology
- Disaster preparedness
- Emergency medicine
- Endocrinology
- Gastroenterology
- Genetics/rare diseases
- Global Health
- Hematology
- Infectious diseases
- Maternal Health
- Neonatology
- Nephrology
- Neurology
- Psychiatry
- Pulmonology
- Reproductive Medicine
- Rheumatology
- Urology

"What sets PTN apart is their focus on medicines that might otherwise fail to receive the attention of researchers and their commitment to ensuring that the information garnered finds its way into the product label. It's not just about conducting research and sending the results into the ether, but about working hard with regulatory colleagues to guarantee meaningful dissemination and application of the findings."

Susan Abdel-Rahman , PharmD I Chief Scientific Officer for Health Data Synthesis Steering committee member for the Pediatric Trials Network

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