



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



"When I was working in the NICU, I was taking care of an infant with a serious bacterial infection. We used the dose of clindamycin that PTN had published, and the infection improved dramatically. We were able to save the life of this infant because of the work of PTN."

Matthew Laughon, MD, MPH Neonatologist at The University of North Carolina at Chapel Hill (UNC) PTN Investigator

> When it comes to dosing medications, children cannot be treated as small adults. Their growth, metabolism, and developmental factors can lead to adverse reactions, even if the medication is deemed safe for adults.

From a child suffering from an ear infection to a newborn in the neonatal intensive care unit (NICU), when a child takes a prescription medication, there is a 90% probability that the Pediatric Trials Network (PTN) has investigated some aspect of the medication's dosing, safety, or efficacy. PTN's research provides clear guidelines so that healthcare providers can safely prescribe medications to children.

PTN is a nationwide collaborative network of more than 300 research sites that conducts the extensive research required to provide the necessary information to update the Food and Drug Administration (FDA) drug labels for safer and more effective use in pediatric populations, including: newborns, children, adolescents, and breastfeeding mothers.

PTN's primary goal is to generate the data necessary to produce evidence-based clinical practice guidelines. Studies are conducted primarily with medications that have a generic option (off-patent drugs*) that are lacking data on safety, efficacy, and dosing in pediatric populations.

Since 2010, PTN has undertaken extensive research to provide data to the FDA. The work conducted has resulted in the updating of 23** medication labels with pediatric dosing information, with an additional 7 medications submitted to the FDA for review.

PTN's work began with the authorization of the Best Pharmaceuticals for Children Act (BPCA) in 2002 and is up for reguthorization 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.



To learn more and subscribe to our newsletter, scan the QR Code or visit pediatrictrials.org

*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









