A Message from the Lead Principal Investigator

In the last issue of the PTN Post, we noted that one of our studies resulted in a label change for the widely used drug, lisinopril. The change could affect hundreds of children who are prescribed lisinopril after kidney transplants each year. Label changes, like lisinopril, mark important milestones and underscore the continuing significance of the work we do. With that in mind, I'd like to review the progress we have made to date in other therapeutic areas as well.

Thanks to the hard work and dedication of PTN investigators and sites, the list of accomplishments is long. However, there is much more work to be done to determine the safest and most effective use of medications and devices in the pediatric population. This issue of the PTN Post celebrates the progress we've made and the work that lies ahead.

As of September 15, 2016...

The following Food and Drug Administration (FDA) labels have been updated under Best Pharmaceutical Children’s Act (BPCA) programs:

- **Propylthiouracil** for hyperthyroidism: label changed for safety and dosing
- **Pralidoxime** relabeled for use in organophosphate poisoning
- **Sodium nitroprusside** for hypertension: label changed for efficacy, safety, and dosing
- **Meropenem** for complicated abdominal infections: label changed for safety and dosing, efficacy extrapolated
- **2D and 3D Mercy TAPE devices** to assess weight without electricity in children 2 months through 16 years of age
- **Lisinopril** for hypertension: label changed for treatment of hypertension in pediatric renal transplant patients
- **Lorzepam** for seizures: label changed for efficacy, safety, and dosing

**BPCA legacy (prior to PTN) and PTN-led studies submitted the following clinical study reports (CSRs) to the FDA**

**Final CSR Submitted**

- **Ampicillin** for treatment of complicated infections in pre-term neonates to determine safety and dosing (PTN) — this CSR is on the FDA docket for label change
- **Clindamycin** for treatment of complicated infections

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**Check out our refreshed website: pediatrictrials.org**

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Sulfamethoxazole and trimethoprim for treatment of soft tissue infection to determine efficacy, safety, and dosing (PTN in partnership with NIAID)

Caffeine citrate for treatment of apnea of prematurity to determine efficacy, safety, and dosing (PTN in partnership with NHLBI)

Ondansetron for treatment of nausea and vomiting after chemotherapy or surgery in normal weight and obese children and adolescents

Pantoprazole for treatment of gastroesophageal reflux disease (GERD), in obese children and adolescents

Doxycycline for treatment of common severe infections including tick born illnesses in children and adolescents

Since September of 2015, PTN faculty members have published eleven manuscripts in professional journals:


For a full listing of PTN publications, click here.