Dear Future Stakeholder,

The Best Pharmaceuticals for Children Act (BPCA) was passed in 2002, and reauthorized in 2007, 2012 and in 2017, to encourage both the government (the National Institutes of Health-NIH and the US Food and Drug Administration-FDA) and industry to conduct research in support of safe and effective medications for children. Many drugs used in children today are used off-label, without adequate understanding of the pharmacokinetics/pharmacodynamics of the drugs in children, with limited safety data on the drugs in children, and with the lack of dosing information in children, which can all ultimately impact the effectiveness of the medication. The goal of the NIH BPCA Program is to improve knowledge gaps in pediatric therapeutics through clinical trials.

The primary objectives of the BPCA program are to:

- Identify therapeutic gaps in pediatric diseases, disorders, or conditions that still need to be studied in children due to lack of dosing, safety or efficacy data and publish a priority list of needs in pediatric therapeutics every three years;
- Sponsor clinical trials for the identified therapeutics;
- Submit data from the clinical studies to the FDA for consideration of label modification;
- Make the study data available to investigators and the public.

YOUR ROLE

We invite you to become a stakeholder with the NIH BPCA Program. We provide quarterly updates to our stakeholders and invite you to participate in our stakeholder meetings. **To be added to the BPCA Stakeholders Distribution List, please input your name and contact details at the following link: https://www.surveymonkey.com/r/bpca2020**

BACKGROUND INFORMATION

The Pediatric Trials Network (PTN) conducts the clinical trials that improve pediatric drug labeling and ultimately child health. The network, a BPCA-funded clinical program, is poised to address many of these gaps and is structured to study age-appropriate drug dosing, efficacy, safety, formulations, and device validation in pediatric medicine. To date, the PTN has enrolled more than 8,000 children in over 200 pediatric sites in five countries, has covered more than 20 therapeutic areas, and includes a wide array of therapeutic approaches – ranging from drugs used in the intensive care unit to those commonly used in the general pediatric population. For more information on the PTN, please click the following link: https://pediatrictrials.org/.

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) supports the BPCA Program. If you are interested in learning more about the research of the NICHD or the Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB) where in the BPCA Program is housed, please click the following links:
https://www.nichd.nih.gov/
https://www.nichd.nih.gov/research/supported/bpca/about

You can also contact BPCA program staff at bpca@infinityconferences.com if you have any additional questions.

We look forward to hearing from you and having you as part of the team.

Best Regards,

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