INSTITUTE FOR ADVANCED CLINICAL TRIALS FOR CHILDREN

NEWSLETTER

Welcome to Our December 2022

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Welcome

Cindy Jackson, DO, FAAP,
Chief Operating Officer

It has been a busy 6 months since our last newsletter in May. We moved just a few hundred yards from our prior address to a new space which will better suit our future needs. Our new corporate address is 9200 Corporate Blvd, Suite 350, Rockville, MD, 20850. All phone numbers remain the same.

Our Site Network staff has been on the road visiting several of our sites here in the United States. You will read more about those visits later in the newsletter.

To facilitate earlier interactions with our colleagues in biopharma who have innovative products aimed at pediatric populations, we have signed a letter of intent to work with Health Innovation Capital, a venture fund focused on pediatric development (Health Innovation Capital and I-ACT for Children announce joint collaboration). We believe we can provide unique insight into the process of funding and developing therapeutics and devices for people < 18 years of age.

We are extremely proud of our educational efforts focused on sites. The Site Network team has planned and held three educational webinars this year. All were extremely well-attended by our sites' staff as well as others outside our Site Network, including representatives from CROs, biopharmaceutical companies, and site staff working outside our network.

Enjoy this newsletter which should give you some insight into our current and upcoming activities. Again, as always, thank you for being a friend and partner of I-ACT for Children.

CMO CORNER

Gary Noel, MD, FAAP, FIDSA, FPIDS
Chief Medical Officer

I-ACT for Children will be hosting a webinar series entitled, **"Improving the Investigation of New Antibacterial Agents for Use in Children**," that is aimed at identifying the challenges being faced in completing work supporting the labeling and approval of new antibacterials, and making recommendations on how these challenges can be addressed. New antibacterials are urgently needed to treat children, especially infants, that develop infections caused by antimicrobial resistant pathogens. The experience over the last two decades is that it is taking more than six years for these life-saving drugs to receive regulatory approval for use in children after they have been approved for use in adults. The first of two webinars will be held on January 27th and the second will be held on February 2nd. Information on registering for the webinars will be available on the I-ACT for Children website in the coming weeks.

The International Neonatal Consortium held its annual meeting in Bethesda Maryland November 15th and 16th. The progress in developing, and the promise of access to a real-world database comprised of information from over a million neonates was presented throughout the two-day meeting. I-ACT for Children is a sub-awardee on the FDA grant supporting this work and congratulates those sites within the network that are contributing to this remarkable project.

FUNDRAISING FUN

Cindy Jackson, DO, FAAP,
Chief Operating Officer

I-ACT for Children will be rolling out several events in 2023 aimed at highlighting the importance of pediatric clinical research and development of therapeutics for children. The public has very limited knowledge of what it takes to get a drug approved for use in pediatric patients and surprisingly, many in the medical community do not know, either. The one positive by-product of the pandemic is that clinical trials became part of the national conversation. You read about them in the news, on social media and heard clinical trials being discussed on television and in a variety of other settings. What is even more important is that clinical trials were discussed in the context of approval of vaccines and drugs to treat COVID-19 in children. The conditional approval of the COVID-19 mRNA vaccines in 12–16-year-old adolescents, 6 months after adult conditional approval was obtained, became a talking point across a variety of platforms. We thought it was time to take advantage of this unique opportunity to engage the public and others to support and be educated about the clinical trial and drug development process.

In January 2023, we will begin publicizing and highlighting our **"Spin to Save Kids!"** campaign with the main event being held in Orlando, Florida, at Disney World, on March 3-5, 2023. What we need from you is to become involved by forming your own "Spin" teams by spinning and posting on social media. You can spin anything you want – yourself, a ball, on a cycle, frisbees, hula-hoops – you get the idea. The ways to participate are endless. Think about this as the Ice Bucket Challenge without having to get cold and wet 😊 and a fun and engaging way to support pediatric clinical research – spin, post, and donate if you wish. To get a sneak peek, check out the **Spin!** website at www.spinchallenge.org.

Educational Webinar Focused on Study Start-up Timelines

I-ACT for Children is passionate about shortening the time it takes to bring innovative therapies to children. This passion fueled our October 11, 2022, Educational Webinar on "Strategies for Improving Pediatric Clinical Trial Study Start-up Timelines." The webinar opened with Dr. Janice Sullivan from the University of Louisville and Norton Children's Research Institute, sharing the heartache of losing a patient because study start-up took too long. Fortunately, she added, this was followed by the joy of saving the sibling, who later participated in that same trial.

We had the privilege of hearing from sites across the country about their high-level strategies for improving their study start-up timelines. Laura Boywid, from Le Bonheur Children's Hospital, spoke about the importance of streamlining their study feasibility process. Kyle Hawkins and Kylie Baggett, from Johns Hopkins All Children's Hospital, described how they implemented a study start-up team during COVID to support their researchers. Dr. Steven Steiner shared how Riley Children's Hospital's GI division uses visual management boards to track timelines. And lastly, I-ACT's own Angie Price highlighted the benefit of working backward from the finish line when establishing timelines.

I-ACT is committed to sharing best practices. We look forward to offering ongoing educational opportunities in 2023. Stay tuned.

I-ACT for Children Educational Webinar 10/22

Site Engagement

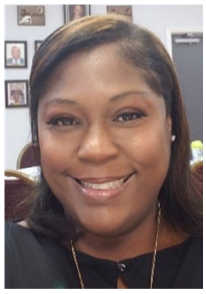
Much of what makes our site network unique and successful is the close relationships we have with Site Network personnel. Many of those relationships were strengthened this year during the amazing discussions that occurred between site staff and I-ACT for Children team members during the 28 on-site visits conducted. The primary purpose of our on-site visits is to listen and understand what the various site personnel are seeing, thinking, proud of, and grappling with in their roles related to pediatric clinical research. In addition to professional relationship-building, open discussion and site feedback, we also learn the status of pediatric research activities and discuss how I-ACT for Children services and educational opportunities may enhance and support site efforts.

The prevalent topics that came up this year included staffing resources (hiring, retention, and training), inadequate pediatric protocols (how to effect change prior to protocol finalization), juggling myriad technology systems used in trials (3-5 different systems/trial), desire for a way to collaborate with other sites (e.g., investigator-sponsored trials, technology systems to avoid having to re-invent the wheel, etc.), and trial budget issues (e.g., it would save so much time if the sponsor could provide ICD-9 codes for research activities). We hear your feedback and continue to work on answers to your questions and solutions to your problems.

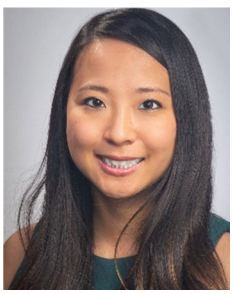
Educational Grant Awardees

I-ACT for Children understands the value of continuing education and the role it plays in enhancing pediatric clinical trials and advancing our mission. For the past several years we have set aside funds for Educational Grants to be awarded to individuals to further their education and benefit their institution's pediatric clinical trial capabilities. We recently announced the recipients of the 2023 grants for $2000 each, one designated for a pediatric research support staff member, and the other for an early-stage investigator. Keisha Bird, from Nemours Children's Hospital in Jacksonville, and Dr. Hellen Ko from the University of New Mexico Children's Hospital, are our winners.

Congratulations to Keisha and Hellen!



Keisha Bird
Nemours Children's Health System
Jacksonville, FL
Keisha is attending the 16th International Conference on Advanced Technologies & Treatments for Diabetes in 2023



Hellen Ko, MD
University of New Mexico Children's Hospital
Albuquerque, NM
Hellen is attending the Pediatric Academic Societies Meeting in 2023

I-ACT Operations

I-ACT for Children offers a variety of services to improve pediatric programs, with the goal of advancing new medicines and devices needed now and in the future for children everywhere. With access to our top-performing pediatric research sites, sponsors can utilize our Early Engagement Survey (EES). With an ever-changing site environment, EES is designed to quickly identify sites (within a few weeks) who have research experience and are ready to successfully conduct new pediatric studies matched to sponsor needs. I-ACT for Children is also uniquely positioned to serve as a point of contact/escalation during study start-up.

In addition to the site identification, I-ACT for Children can build a robust study engagement program designed to engage with key study leaders to provide feedback and tools to improve recruitment and retention. Engagement programs also help re-invigorate studies that may have lost the initial momentum and interest that comes with study start-up or identifies challenges that were not initially understood. To read a case study involving a National Leader program, visit https://www.iactc.org/wp-content/uploads/2022/01/Case-Study-Intensive-Site-Engagement.pdf.

Developing pediatric programs can be challenging, especially in designing protocols and programs that meet regulatory requirements while being likely to succeed in a pediatric population. I-ACT for Children offers many years of pediatric drug and device development expertise and can identify other experts to provide regulatory, therapeutic, disease-specific, or diversity expertise via consulting or through advisory panels. To learn more, visit Advisory Committee and External Advisory Panels | I-ACT for Children (iactc.org).

- I-ACT for Children: helping close the gap in drug approval for adults and children. Authors: Max J. Coppes, Cindy Jackson and Edward M. Connor. *Pediatric Research* 2002 October 21: 1-2
  I-ACT for Children: helping close the gap in drug approval for adults and children - PMC (nih.gov)