



2020 Summer Newsletter

Mission Critical

Like many organizations, when COVID-19 hit and the shutdowns began, our staff's first concerns were personal. How do we keep ourselves safe? How do we protect our children, or our elderly parents? When will it be safe to leave home? Our fears then shifted to our work: with many pediatric clinical trials on hold, how could we fulfill our mission?

Once the initial shock subsided, it quickly became clear that our mission has never been more critical. In the race to find effective adult treatments and vaccines for COVID-19, I-ACT for Children has been at the forefront of ensuring that children's needs are addressed with the same level of urgency. While in many cases COVID-19 appears to affect children less seriously, reports of severe multi-system inflammatory syndrome in children (MIS-C) continue. Little is known about the consequences of transmission of COVID-19 during pregnancy and childbirth. And it remains to be seen what the long-term effects of COVID-19 may be, even in people with mild cases.

We are leading several efforts to ensure children are part of the COVID-19 discussion – and to pave the way for pediatric clinical trials of potential therapies and vaccines. In May, we launched our [COVID-19 Emergency Access Program](#), which allows any company developing COVID-19 treatments and vaccines to use our pediatric research network for their pediatric clinical trials.

We also hosted a virtual workshop on the development of pediatric COVID-19 treatments, which featured specialists who are treating infected children, FDA experts and researchers who are leading the testing of potential COVID-19 agents. Meanwhile, we have readied our site network for COVID-19 pediatric trials – organized according to specific expertise and relevant geography.

As we look to the fall – with so much still unknown with regard to the virus' resurgence – we are working closely with our sites and our members to determine how and when non-COVID-19 trials can resume. Our network sites have been incredibly creative in finding new ways to conduct the

daily operations of pediatric trials, using telemedicine, home health workers and other methods to reach patients without requiring a trip to the clinic. The good news is that COVID-19 is opening doors to innovation that could transform the conduct of clinical trials in ways that significantly increase both patient convenience and access to trial participation.



We are a very long way from the finish line, but it is inspirational to witness the speed and unprecedented collaboration that has arisen to fight this deadly pandemic. We won't rest until safe and effective treatments and vaccines for children are among the results of these efforts.

Laura Gordon
Chief Executive Officer

A handwritten signature in black ink, appearing to read 'G. Noel'.

Gary Noel, MD, Hits the Ground Running as I-ACT for Children's First Chief Medical Officer



We were thrilled to kick off 2020 by welcoming Gary Noel, MD, as I-ACT for Children's first full-time Chief Medical Officer. He hit the ground running in January, overseeing all of the organization's medical and scientific projects – and when the COVID-19 pandemic struck, directing initiatives such as our COVID-19 Emergency Access Program, our virtual workshop on pediatric therapeutic development and the publication of several reports in peer-reviewed journals.

Dr. Noel is a pediatrician, child advocate, specialist in Infectious Disease and Immunology and a seasoned expert in drug development. He joined I-ACT for Children after retiring from Johnson & Johnson, where he was a member of the Child Health Innovation Leadership Department in the Office of the Chief Medical Officer and chair of its Pediatric Expert Panel. He previously was Vice

President and Chief Medical Officer at Paratek Pharmaceuticals and Vice President of early clinical development in Infectious Diseases at AstraZeneca. Prior to his time in industry, Dr. Noel served on the full-time faculty at Cornell University Medical College; was the Chief of Pediatric Infectious Diseases and Immunology at The New York Hospital-Cornell Medical Center; and led the Pediatric Infectious Diseases Fellowship Program and an NIH-funded laboratory.

A lifelong champion of pediatric research and care, Dr. Noel also helped create the Foundation for Treatment of Children with AIDS (serving as its Executive Director and Board Chair) and played an important role in establishing Pediatric HIV-Comprehensive Medical Care Clinics at The New York Hospital and at the DAR-DAR Project in Dar es Salaam, Tanzania.

Please feel free to reach out to Dr. Noel at gary.noel@iactc.org. We are thrilled to have him on board!

I-ACT for Children Site Network Solidifies Global Operations, While Sites Innovate to Address COVID-19 Disruptions

The I-ACT for Children Site Network now has the full interoperability required to support sponsors conducting multi-country trials, thanks to agreements with the Maternal Infant Child and Youth Research Network (MICRYN-Canada) and a group of sites and national networks that currently create a pan-European network under IMI/conect4children. This builds on our site network's 68 contracted sites in the US, Australia, South America and Saudi Arabia.

The European agreement provides our members with access to more than 300 pediatric trial sites in 20 countries. Once the successor organization to conect4children in Europe is in place, our collaboration in those countries will shift to that organization and its single point of contact (SPOC) for all sponsors active in Europe.

We also are expanding our network this year to include private-practice sites. These sites complement our network with a mix of single- and multi-pediatric subspecialty practices that have experience in conducting pediatric trials. They also can be a robust source of healthy patients for vaccine trials.

Meanwhile, the disruption caused by the COVID-19 pandemic has fueled innovation across our network sites, as site staff work to maintain clinical trial operations and provide necessary care to their patients. The pandemic affected studies throughout our network, forcing changes in areas such as data collection and drug delivery due to regional stay-at-home orders and restricted

patient access to sites. Virtual study screenings, use of home health care and home drug delivery are now being used at multiple sites. I-ACT for Children processes also have adapted to meet pandemic-era needs, including conducting virtual site visits to qualify new sites in our network.

Visit our [site-network page](#) for a map of our sites. For more details about the network, contact Lisa Benson, SVP, Clinical Research Site Network, at lisa.benson@iactc.org.

COVID-19 Emergency Access Program Launched to Speed Pediatric COVID-19 Clinical Trials

To accelerate the development of pediatric COVID-19 treatments and vaccines, I-ACT for Children has launched the COVID-19 Emergency Access Program, which allows all companies developing COVID-19 pediatric treatments and vaccines to access our trial-planning experts and pediatric trial network. Under this program, even biopharmaceutical companies that are not members of the institute can work directly with our medical and scientific staff to plan and execute their regulatory-grade clinical trials.

I-ACT has organized a subset of our sites that:

- ◆ Have deep expertise in infectious disease
- ◆ Are linked to scientists who have made important contributions to our understanding of respiratory viral diseases
- ◆ Have ready access to healthy patients for the conduct of vaccine trials

To help inform feasibility assessments, we continue to connect with our sites as the geographic regions most significantly affected by the pandemic shift over time. Our sites have been organized to enable efficient start-up and execution of trials that will meet requirements for regulatory registration of innovative products.

For more information about the program, contact Chief Medical Officer Dr. Gary Noel at gary.noel@iactc.org.

I-ACT for Children's Collin Hovinga, PharmD, Named to FDA Advisory Panel



Collin Hovinga, PharmD, has been named to a four-year term as a member of the U.S. Food and Drug Administration’s Drug Safety and Risk Management Advisory Committee. Dr. Hovinga, SVP of Clinical and Scientific Development at I-ACT for Children, joined the organization in 2018 and plays a lead role on many of our proprietary and pre-competitive initiatives. Based in Austin, Texas, he also is a Clinical Associate Professor of Pharmacy at the University of Texas at Austin College of Pharmacy.

In his FDA Advisory Committee role, Dr. Hovinga will review and evaluate information on risk management, risk communication and quantitative evaluation of spontaneous reports for drugs for human use that fall within FDA responsibility. The committee advises the FDA Commissioner on the scientific and medical evaluation of all information gathered by the US Department of Health and Human Services and the Department of Justice with regard to the safety, efficacy and abuse potential of drugs or other substances.

Please join us in congratulating Dr. Hovinga on this important honor!

COVID-19 Virtual Workshop a Success



On May 28, I-ACT for Children held a virtual workshop – “Developing Pediatric Treatments for COVID-19” – with regulators, biopharma developers and experts on the front lines of treating children with COVID-19. Speakers shared the latest on the clinical presentation of COVID-19 in children, the state of COVID-19 therapeutic research and innovative approaches to collecting the data required to advance safe and effective COVID-19 therapies for children.

More than 300 people participated in the workshop, which was co-moderated by I-ACT for Children Founder and Board Chair Edward Connor, MD, MBE, and Susan McCune, MD, Director of the Office of Pediatric Therapeutics at the US Food and Drug Administration.

A summary report and recommendations from the workshop have been submitted for publication consideration to a peer-reviewed journal. The workshop presentations and a recording of the meeting can be found [here](#)

