



*We act because every child with a medical need deserves the best chance possible. That chance depends on a commitment to innovation, quality and urgency in advancing medical therapies specifically for children.*

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**I-ACT for Children** is an independent, neutral 501(c)3 non-profit organization that works to **accelerate and enhance the quality of pediatric clinical trials** so that children have access to medicines that have been proven safe and effective for them. We believe that children of all ages deserve innovative medical therapies that are developed with the same level of urgency and commitment afforded adults.

**I-ACT for Children has established the *COVID-19 Emergency Access Program* to allow all drug developers and other sponsors investigating COVID-19 therapeutics and vaccines to access its network for pediatric trials.**

I-ACT for Children collaborates with the public and private sectors to advance innovative products for child health. The institute is supported by membership fees, grants and philanthropy. In response to the COVID-19 pandemic, I-ACT for Children has established a ***COVID-19 Emergency Access Program*** that facilitates non-member access to its expertise and clinical trials network for studies of COVID-related investigational agents in pediatric patients.

Under this program, biopharmaceutical and other companies that are not members of the institute can work directly with its Chief Medical Officer and members of the **I-ACT for Children COVID-19 SWAT Team** to assist with planning and implementation of regulatory-grade clinical trials and related activities. I-ACT for Children is already working with its members and federal agencies to assist in these efforts. As new interventions to prevent and treat COVID-19 advance, it is critical to ensure that the needs of children are addressed through high-quality clinical trials.

I-ACT for Children's SWAT Team has deep expertise as well as public- and private-sector experience in the critical elements of pediatric drug and biologics development, including specialty expertise in infectious disease, assessment of products for respiratory viral diseases and pediatric, newborn and maternal pharmacology. As the pandemic is fast moving, I-ACT for Children is working with organizations to collect real-world and real-time data regarding the epidemiology of COVID-19 in children. As COVID-19 has multi-organ system manifestations, I-ACT for Children also has a panel of more than 50 experts in 19 subspecialties and functional areas under contract who consult with drug developers. The institute also provides expertise in areas such as innovative trial design & analysis techniques; pediatric-appropriate endpoints; trial feasibility; and PI engagement.

**The I-ACT for Children Site Network** is a globally collaborative research network that enables regulatory-grade scientific data to support the safe and effective use of new medicines and devices in children.

Key features of the site network include:

- 62 sites under contract in the US, Australia and Saudi Arabia
- MOUs with key European sites (Belgian hub) and MICYRN (Canada network)
- Collaborations with additional networks in Japan
- A “site champion” and operational point of contact at each site to support rapid site identification & ongoing site/PI engagement
- A central IRB in place that has reliance agreements with all sites

To prepare for COVID-19 therapeutic and vaccine pediatric trials, we are organizing a subset of our sites that:

- Are geographically located where COVID-19 cases are more concentrated
- 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

We also are collecting data in real time from our network to assess which sites are seeing cases of pediatric COVID-19, and can track these data over time to inform feasibility assessments.

These sites have interest in and capabilities to participate in COVID-19 studies and have been organized to enable efficient start-up and execution of trials that will meet requirements for regulatory registration of innovative products.

**I-ACT for Children** has worked with its current sponsors and collaborators to meaningfully advance product development in the interest of child health. While SARS-CoV-2 infection appears to cause serious disease disproportionately in adults compared with children, more and more symptomatic pediatric patients are being recognized – some who require hospitalization and advanced care in an ICU. I-ACT for Children is committed to working with sponsors to investigate the safety and efficacy of potential COVID-19 treatments in children as soon as appropriate based on risk/benefit.

The U.S. and international collaborative infrastructure for pediatric clinical trials has advanced considerably over the past decades. I-ACT for Children is a central component of this global resource and is working with the public and private sectors to advance therapeutics and devices for COVID-19 during this pandemic.

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