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**Novartis Joins the Institute for Advanced Clinical Trials for Children
as Newest Sustaining Member**

Membership will Drive Programs to Enhance Speed, Success of Pediatric Clinical Trials

Rockville, MD, October 12, 2018 – The Institute for Advanced Clinical Trials for Children (I-ACT) today welcomes another sustaining member with the addition of Novartis Pharmaceuticals Corporation. I-ACT is a non-profit organization focused on improving the quality, speed and efficiency of global pediatric studies to address the gap in evidence on the best use of therapeutics in children.

“Today, 50 percent of medicines used in children and 90 percent used in newborns are not labeled for pediatric use. We look forward to working with Novartis to help correct that disparity,” said Laura Gordon, CEO of I-ACT.

“At Novartis, bringing new medicines to the market to benefit children is a top priority,” said Ron Portman, Executive Director of Pediatric Development, Science and Innovation at Novartis. “Becoming a member of I-ACT will allow us to accelerate and maximize that commitment, while working with other stakeholders to advance the field of pediatric research across the board.”

Pediatric clinical trials face a variety of unique hurdles. More than 60 percent of pediatric clinical trials stall and 40 percent fail. As a result, it takes an average of nine years for an adult therapy to secure pediatric labeling. Barriers to efficient, successful pediatric trials include issues with trial designs that haven’t been properly adapted for children, difficulty identifying enough qualified patients and until recently, lack of a dedicated clinical trial infrastructure that can be quickly activated when a therapy or device is ready for testing.

I-ACT was created to identify and find solutions for these and other critical barriers. It has built a network of pre-qualified pediatric trial sites that will share common training tools and best practices and are coordinated under the I-ACT umbrella. Site feasibility can be assessed through real world data analysis to determine which sites have enough patients with a given disease or

condition to enroll in a trial. In 2019, a quality improvement system will be embedded in the network to measure and track each site's ability to speed start-up and enrollment time, retain patients in a trial and reduce time to completion.

I-ACT also works with its members to introduce innovative study designs that produce advances such as reducing sample size and adapting study endpoints to better reflect the pediatric population.

About the Institute for Advanced Clinical Trials for Children

I-ACT for Children is a 501(c)3 that serves as a neutral and independent organization on behalf of children everywhere, bringing a dedicated voice to the advancement of new medicines and devices needed now and in the future. Its work is to engage public and private stakeholders through research and education to ensure that healthcare for children is continually improved by enhancing the awareness of and support for pediatric clinical trials.

To learn more about I-ACT, visit www.iactc.org

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