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Eli Lilly and Company Joins the Institute for Advanced Clinical Trials for Children as Newest Sustaining Member

Shared Goal is to Enhance Speed, Quality, Success of Pediatric Clinical Trials

Rockville, MD, March 18, 2019 – The Institute for Advanced Clinical Trials for Children today welcomes Eli Lilly and Company as its newest Sustaining Member. 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. Lilly's membership in I-ACT demonstrates its commitment to helping to correct that disparity," said Laura Gordon, CEO of I-ACT for Children. "We look forward to working together to help ensure that innovative medical therapies are developed for children with the same level of urgency and commitment afforded adults."

"Children in medical need deserve the best care our health care system can provide, and Lilly is committed to this cause," said Albert J. Allen, M.D., Ph.D., senior medical fellow, pediatric capabilities, Eli Lilly and Company. "Lilly looks forward to partnering with I-ACT and other stakeholders to accelerate the delivery of game-changing medical innovation for children."

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 for Children was created to identify and find solutions for these and other critical barriers. It has built a network of pediatric trial sites that will share common training tools and best practices and are coordinated under the I-ACT for Children umbrella. Study and site feasibility

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can be assessed through real world data analysis to determine factors such as which sites have enough patients with a given disease or condition to enroll in a trial. A quality improvement system will be launched this year within the site 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 for Children 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 I-ACT 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, support for and success of pediatric clinical trials.

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

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