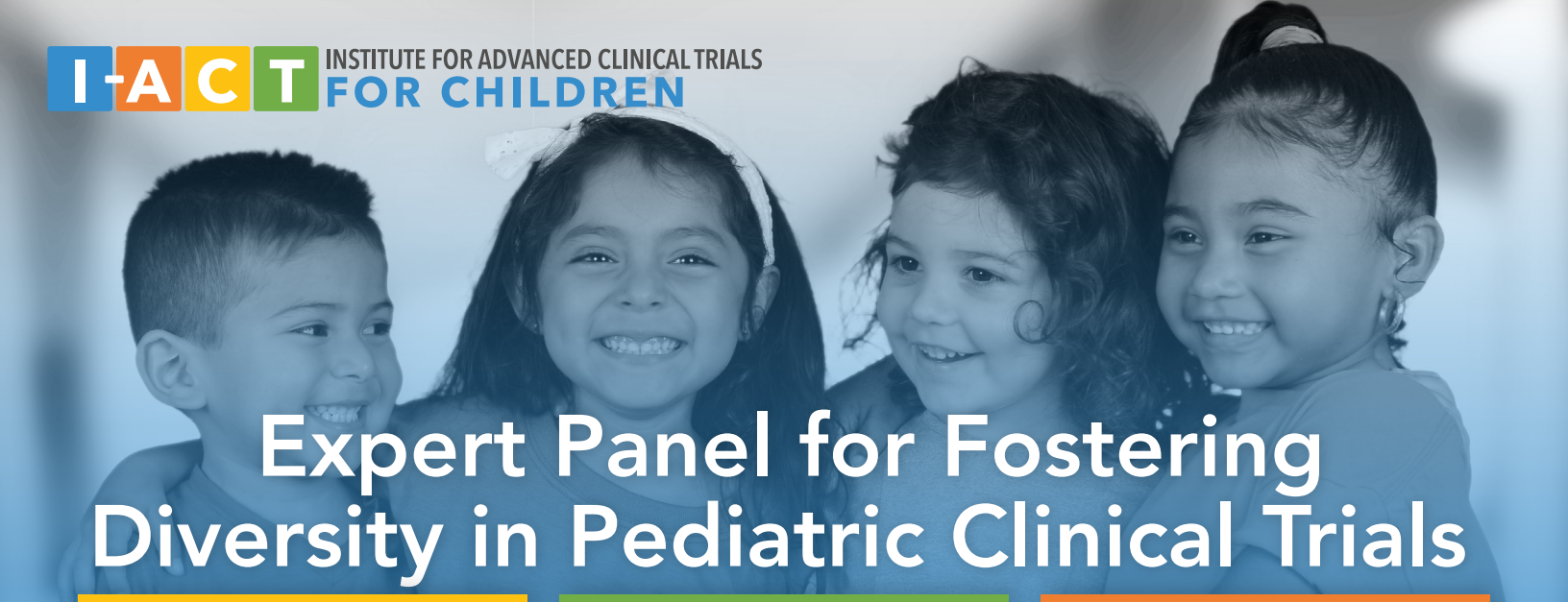
I-ACT INSTITUTE FOR ADVANCED CLINICAL TRIALS FOR CHILDREN



Expert Panel for Fostering Diversity in Pediatric Clinical Trials

Reviews clinical trial protocols and provide counsel to maximize feasibility and the inclusion of a diverse participant population.

Focuses on optimizing pediatric clinical trials to encourage inclusion and avoid the exclusion of diverse populations.

The Panel's optimized-trial would reflect better the patient population that will ultimately use the medicine or medicinal product and would produce more generalizable trial results.

I-ACT FOR CHILDREN'S MISSION IS TO ACCELERATE AND ENHANCE THE QUALITY OF PEDIATRIC CLINICAL TRIALS.

In 2020, the FDA's Center for Drug Evaluation and Research approved 53 novel medicines. Of the 32,000 study participants in the clinical trials that supported those approvals, **only 8% were black/African American and only 11% were Hispanic.**

THE PANEL MEMBERS ARE

Tamera Coyne-Beasley, *MD, MPH*

Derroll M. Dawkins, MD Endowed Chair in Adolescent Medicine and Professor of Pediatrics & Internal Medicine at the University of Alabama at Birmingham

Jaime Fergie, *MD*

Director of Pediatric Infectious Diseases at Driscoll Children's Hospital, Professor of Pediatrics at Texas A&M University College of Medicine and Medical Director of the Global Institute for Hispanic Health

Robert Nobles, *DrPH, MPH*

Vice President for Research Administration at Emory University

THE PANEL PROVIDES

- ***CONSENSUS RECOMMENDATIONS***
  Directed to improving diversity of participants enrolled in a pediatric clinical trial. These reviews include pre-work to evaluate the protocol and related study materials, followed by an online meeting to discuss and reach consensus on recommendations.

- ***EXPERT CONSULTATIONS***
  For targeted diversity questions of an open clinical trial, a project or a program. Input may be sought from one or more members of the panel at any stage in a trial's development or conduct.

For both types of consultations, the approximately time for completion from when the request is received to when the final recommendations are provided is two to three weeks, depending on the complexity of the question and the number of materials provided for review.

**To maximize panel's input, the preferred timing for consultation is during the early stages of protocol development, prior to country allocation and site selection, or when a study amendment is considered.

**Panel members are under contract with I-ACT for Children and thus can be convened rapidly and efficiently.

For information, send an email to Diversity.Panel@iactc.org