

PTC Meets Its Deliverables

April 11, 2017



Dear Colleagues,

In the fall of 2015 C-Path established the [Pediatric Trials Consortium](#) (PTC), with the goal of supporting the formation of a new, independent nonprofit organization that would develop a network of clinical trial sites with the specific capability to conduct registration-quality clinical trials for new medical products for children. The purpose of this communication is to provide you with an update on the status of PTC and its progress to date.

We are thrilled to report that we have achieved the two specific objectives of PTC. The first was the completion of an Advisory Report, which has served as the main vehicle for providing strategic and operations advice to the new nonprofit organization. The second was to provide advice and support to C-Path during the formation of the new nonprofit: the [Institute for Advanced Clinical Trials for Children](#) (*I-ACT for Children*).

The [Advisory Report](#) is the culmination of almost a year of work with input from more than 30 senior international leaders from academia, industry, patient advocacy groups, government, nonprofits, professional societies, and law firms. This report contains high-level recommendations for *I-ACT for Children*'s strategy and provides practical steps to frame operations. Collectively, these recommendations are intended to enable accelerated start-up and implementation of *I-ACT for Children*'s scope of work. It is anticipated that *I-ACT for Children*'s board and senior leadership team will decide which elements are most helpful and how and when those elements should be implemented.

Paul Hastings LLP, an international law firm familiar with various sectors involved in the report, and special outside counsel for PTC, reviewed the report and provided comments and guidance regarding potential legal and/or compliance implications of its recommendations and other matters covered by this report. Their work doesn't constitute a formal legal opinion or an endorsement of the report's recommendations.

The Institute for Advanced Clinical Trials for Children was [formally announced](#) April 10, 2017.



I-ACT for Children serves as a neutral forum for public-private collaboration in addressing common challenges in pediatric trials to help demystify the studies. It will also assist in optimizing study designs, protocols, best practices, training, and engagement of patients and parents.

I-ACT for Children is headquartered in Rockville, MD. For more information, visit www.iactc.org.

Best Regards,

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