

Pediatric Trials Consortium 2015 Year-End Message

Dear Colleagues,

A few months ago we announced that the Critical Path Institute established the Pediatric Trials Consortium (PTC) with the goal of supporting the formation of a new, independent non-profit organization that will 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 of the status of PTC and progress to date.

Mission

PTC is committed to enabling the creation of a sustainable solution that assures the timely and efficient evaluation of innovative drugs, biologics and devices for children by delivering the regulatory-quality data needed for product labelling.

Deliverables:

- Advisory Report
- Advice to support C-Path's work to form the non-profit

As we reflect on the significant progress made to date, we are honored and humbled by the high degree of interest, commitment and enthusiasm of the pediatric community in this initiative, and the quality and work ethic of those participating in moving us to the finish line. This includes the leadership and "home" that C-Path provides, our sponsors and collaborators who have provided funding and in-kind resources, and the community support and guidance along the way. We will update you regularly as PTC progresses along this journey to deliver on the promise to enable the formation of a sustainable infrastructure for regulatory-quality pediatric trials that deliver innovative products for children. Best regards, *Reference: **Special Article: 2014 Pediatric Clinical Trials Forum**. Clifford Bogue, Linda A. DiMeglio, Samuel Maldonado, Ronald J Portman, P. Brian Smith, Janice E. Sullivan, Charles Thompson, Heide Woo and Susan Flinn; on behalf of The Pediatric Clinical Trials Stakeholder Forum Planning Committee. *Pediatr Res* doi:10.1038/pr.2015.255; accepted article preview online December 9, 2015.

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Organization

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More than 30 senior international leaders from academia, industry, patient advocacy groups, government, non-profits, professional societies and law firms are actively engaged in the preparation of PTC's deliverables.

- Coordinating Committee has been formed
- 3 Subcommittees have been launched
- 5 Work Streams are now operating

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Advisory Report

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The structure for the report has been established and significant portions have been drafted. This document is the main vehicle for providing strategic and operations advice to the new non-profit organization. It will include a financial model and business sustainability plan.

- The initial draft will be completed in 1Q16

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Non-profit formation

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C-Path is in the process of obtaining input from PTC regarding plans for filing documents for incorporation of the new non-profit in early 1Q16.

- Outside legal counsel is engaged in drafting filing documents
- Filing for tax-exempt status will follow incorporation

Communication

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PTC leadership has worked to engage with professional organizations and other stakeholder groups with interest in this field. This has included regulatory, biopharmaceutical, academic and other stakeholders. Information and updates about PTC can be found on the [Critical Path](#) website.

Also, as you know, one critical milestone in the development of this work was the 2014 Pediatric Clinical Trials Stakeholders Forum sponsored by the American Academy of Pediatrics (AAP) with an unrestricted grant from Pharmaceutical Research and Manufacturers of America.

- AAP planning committee has summarized the meeting in a manuscript that has been accepted for publication in Pediatric Research and the article preview has been posted at [AAP Manuscript Pediatric Trials](#)*.

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