

**Critical Path Institute
Pediatric Trials Consortium
Advisory Report**

Executive Summary
December 2016





INTRODUCTION

The Pediatric Trials Consortium (PTC) is a global cross-stakeholder project of the Critical Path Institute (C-Path), a nonprofit, public-private partnership established in 2005 in response to the Critical Path Initiative. C-Path is dedicated to bringing scientists from the FDA, industry, and academia together to collaborate and improve the drug development and regulatory process for medical products. Since that time, C-Path has engaged more than 1,400 scientists and 61 companies in 12 consortia, including the International Neonatal Consortium and the Pediatric Trials Consortium.

The Pediatric Trials Consortium was established in October 2015 to advise C-Path in forming a new independent nonprofit, the Institute for Advanced Clinical Trials for Children (I-ACT). PTC's remit included the preparation of this Advisory Report, consisting of recommendations for I-ACT's strategy and operations. PTC includes more than 30 organizations and diverse US and international stakeholders from academia, the biopharmaceutical industry, government scientific/regulatory agencies, patient and parent advocacy groups, professional organizations, and other relevant sectors. On March 1, 2016, I-ACT was incorporated in Delaware as a 501(c)3 nonprofit organization. This report represents foundational advice to I-ACT's leadership as the organization matures.

ABOUT THIS REPORT

This report contains high-level recommendations for I-ACT's strategy and provides practical steps to frame operations. Collectively, these recommendations are intended to enable accelerated start-up and implementation of I-ACT's scope of work. It is anticipated that I-ACT'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 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.

CASE FOR CHANGE

In the last 20 years, progress has been made in generating scientific data that supports the safe and effective use of new drugs, biologics, and devices in children. Pediatric legislation in the US and EU has been the primary driver of this progress. However, 50%¹ of medicines used to treat children still do not have adequate scientific evidence to support safe and effective dosing, and for neonates, it is 90%. While there are no comparable data for pediatric devices, the low number of annual pediatric label approvals is a strong indicator that off-label use remains high.

Significant challenges exist in conducting pediatric trials of medicines and devices. Infrastructure for trials is built, dismantled, and reconstructed as trials open and close. Approximately 60% of US studies at the end of each of the last five years were still trying to enroll their first patient.² Approximately 40% of pediatric studies fail to establish either safety or efficacy, leading to an inability to label the product for use in children – primary contributors point to the design of the studies.³ With many pediatric sites recruiting less than five patients per study,⁴ it is difficult to retain well-trained staff and other infrastructure support under the current model. Given these challenges and the confluence of many other factors, pediatric research experts from all sectors – academia, regulatory, government research, foundations, and industry – recognized a need to change the approach to pediatric clinical research.

¹ Sachs, A. et al. Pediatric Information in Drug Product Labeling. *JAMA*, May 9, 2012—Vol 307, No. 18

² FDA website, accessed March 2016.

³ Momper, JD, et al. Failed Pediatric Drug Development Trials. *Clinical Pharmacology and Therapeutics*. Volume 98 Number 3. September 2015.

⁴ Simpkins, PL. Analysis of Evaluate Pharma database. Unpublished. 2016.

RECOMMENDATIONS

The recommended mission and vision statements are:

Mission: I-ACT, an independent nonprofit organization, will create and maintain a child-centered, cross-sector system focused on the development and completion of high-quality pediatric clinical research.

Vision: Parents and physicians will have access to robust scientific data for an increasing number of innovative drugs, biologics, and devices, helping to extend and enhance the lives of children around the world. These data will be generated according to the highest scientific and ethical standards; will inform the safe and effective use of therapies most valued by patients, caregivers, and their physicians; and will meet regulatory standards required for product labeling.

We believe that these recommendations can be best operationalized by implementing these three core activities:

Core Activities

1. **Strategy and Planning:** I-ACT should provide independent, expert advice and guidance to sponsors and others to help them produce pediatric plans, protocols, and generalizable solutions that address unmet therapeutic needs of children. Convening key stakeholders early and continuously to enable this work will be an important value driver.
2. **Capabilities, Tools, Education, and Best Practices:** I-ACT should lead, or participate as a member of, cross-sector teams that streamline and improve processes and systems to enhance the quality and timeliness of regulatory-quality data and reduce administrative burden.
3. **Infrastructure and Clinical Trial Execution (global network of sites):** I-ACT should manage a global network of pre-qualified, trial-ready sites. When appropriate, research infrastructure funding should be provided to these sites and such funding should be subject to performance targets. Collaborating with other pediatric networks will be important to achieve global coverage, especially with Europe's IMI2 and existing networks in Canada, Asia Pacific, and other countries/regions. Similarly, collaboration with existing disease-specific pediatric networks will help accelerate the development of scientific data needed to support new medicines and devices for children globally.

Tangible Deliverables

- Consult Reports that support scientifically strong and clinically relevant pediatric plans and protocols
- Feasibility Assessment Reports, which are prepared early (pre-protocol) and which are credible and reliable
- Educational program delivery, which improves awareness, deepens understanding, and builds capabilities
- New or revised cross-cutting and innovative product development tools, methodologies, etc.
- Effective and efficient planning and project management of pediatric studies with the highest ethical standards and data quality
- Streamlined processes and efficient systems that improve quality, efficiency, and timelines of clinical trials

Below is an overview of selected features of the proposed strategy. We recommend that I-ACT consider implementing these suggestions, in a staged approach determined by funding, staffing, and other factors, over the next five years:

Independent Advisory

Independent advisory work is a core part of Strategy and Planning activities. It should include both pediatric program-specific work (proprietary for sponsors) as well as the advancement of generalizable knowledge (i.e., not product-specific). Regardless of type, we recommend that, at its core, it reflects the input of patients, caregivers, regulators, academia, government researchers, industry stakeholders, and others, as appropriate. We believe that this cross-stakeholder engagement would produce comprehensive and useful input to enable development of innovative drugs, biologics, and devices for children. Key deliverables for program-specific work should include robust feasibility assessments and work to support sponsors' efforts to prepare pediatric plans and protocols. Generalizable solutions should focus on tools, methodologies, and approaches that

enable the development of medicines and devices in a particular disease/condition or can be applied across multiple diseases/conditions. The aim of generalizable work is to close important gaps, especially in study design (e.g., lack of validated endpoints), and to identify opportunities to use innovative scientific methods to generate robust data that would help inform the appropriate use of medicines and devices.

Cross-Cutting Tools & Best Practice Sharing

I-ACT should serve as a home for a knowledge base, provide education regarding best practices, and propose metrics for quality standards. This work will be generalizable and not specific to any product – designed to build/enhance global pediatric clinical research capabilities that may be used by all stakeholders. Examples include educational materials, information sharing/collaboration portals, common data definitions, common protocol templates, etc.

Training & Education

We recommend that I-ACT enable the delivery of a harmonized training and educational program that addresses the design and delivery of pediatric clinical studies. A multi-year training and education plan should be developed, working collaboratively with key stakeholders. Programs should be rolled out in a staged manner, moving from meeting core requirements relating to GCP and its implementation, and progressing to intermediate and advanced topics in pediatric clinical research.

Patient & Community Engagement

It will be critically important for I-ACT to ensure that meaningful systemic involvement of patients and caregivers occurs early in clinical development. This input will be instrumental in ensuring that patient and caregiver voices help shape the development of innovative therapies for children.

Clinical Study Groups

We recommend that I-ACT form Clinical Study Groups (CSGs) that provide advice and guidance regarding pediatric programs and generalizable scientific work. They should be standing advisory committees, comprised mostly of independent pediatric clinical research experts who provide advice/guidance across the pediatric clinical research continuum – from pre-protocol to trial close-out to long-term follow-up. Where appropriate, I-ACT should seek out the assistance of existing specialty networks to fulfil the CSG responsibilities.

Feasibility Assessments

We recommend that I-ACT fundamentally change the way feasibility assessments are done today. The assessments should be completed early and should include substantive input from patients, caregivers, investigators, site delivery staff, clinicians, and others. I-ACT should supplement this input with reliable, credible data sets drawn from epidemiological data, prescription volume and trends, real world data, clinical data, patient reported outcomes, etc.

Central Pharmacy Support

We recommend that I-ACT provide central pharmacy advisory support to help sponsors and sites with challenges and opportunities that are specific to the dispensing, storage, and disposal of medicines and devices. During feasibility and protocol development, these pharmacists should help sponsors clarify requirements to ensure that the unique challenges in preparing, administering, and storing medicine and devices are considered.

Standardized Contracts and Budget Templates

We recommend that I-ACT develop a core set of multi-year standard contracts in order to enable timely start-up of studies and reduce administrative burden. Given I-ACT's range of activities, we anticipate that there will be a need to memorialize the contractual relationships by and among several parties. To start, I-ACT should focus on the following three model templates:

1. Master Clinical Trials Agreement

2. Master Services Agreement – Sponsors
3. Master Services Agreement – Sites

These agreements should be harmonized to work well together as a package. Each should include standard terms and conditions to govern the overall relationship, and these terms and conditions should be applicable to each project/each activity.

Site Qualification Criteria & Selection

I-ACT should develop a site qualification tool, integrating input from relevant stakeholders. Sites should be selected based on the outcomes of this assessment tool and other factors that I-ACT deems important. We recommend that during this process, I-ACT consider sites of varying sizes and capabilities, recognizing that some will have a few core specialties and others may only have core competencies in one therapeutic area. Previous experience in (and strong commitment to) regulatory-grade clinical trials is important, and it is equally important to ensure that the institution demonstrates a commitment to professional development and recognition of investigators and site delivery staff for the work they do in developing new medicines and devices for children.

Site Infrastructure (including Site Champions)

We propose that I-ACT build a network of trial-ready sites that works together to complete global trials. I-ACT should consider providing funding and in-kind support, when needed, to help sites develop a core infrastructure of dedicated pediatric research staff. The network should share best practices, common tools, standardized processes, common training platforms, and other pooled services to reduce duplication of effort and improve efficiency. We recommend that most staff be able to handle multiple therapeutic areas and multiple study designs/phases and have privileges at affiliated research centers. It will also be important to identify a site champion who will help cultivate a strong relationship with site leadership, identify and manage potential roadblocks, and promote high-quality performance at the site(s).

E-Clinical Systems and Tools

We recommend that I-ACT deploy an e-clinical system across its network. It should be designed to promote sharing of information and streamline the planning and execution of clinical trials. I-ACT should adopt a modular solution since this will allow I-ACT to add functionality in phases. There is a wide range of options to explore and I-ACT should engage IT experts early on to complete the design.

Centralized IRB Model

We recommend that I-ACT collaborate with other organizations to design a centralized approach to US Institutional Review Board (IRB) ethics reviews, whereby I-ACT's US sites would rely on a central IRB for all studies or, if use of the central IRB is not practical or appropriate for one particular study, the sites may use a different single IRB for that multisite study. In both scenarios, one IRB is the IRB of record. This approach avoids the current practice where each study is reviewed independently by each US site.

Project Management

Experience in pediatric trial conduct has shown that quality of execution is highly dependent on strong, stable, and experienced project managers. We propose, therefore, that I-ACT hire Senior Clinical Trial Project Managers to support each sponsor's trial activities. They should have deep clinical study execution knowledge, understand the nuances and special requirements in pediatric studies, and be the single point of contact with research administration staff at sites, with sponsors, and with I-ACT operations and scientific colleagues.

NUMBER OF CLINICAL TRIALS

Over the next 8-10 years, we recommend that I-ACT, working in concert with other pediatric networks, plan to manage over **50%** of projected pediatric clinical programs that support the development of new drugs, biologics, and devices. Successful alignment across sites and networks will result in more meaningful public health solutions for children, improved stakeholder engagement, and more efficient clinical trial execution.

CROSS-STAKEHOLDER BOARD OF DIRECTORS

Given our emphasis on independence, we suggest that Board composition be balanced to reflect a range of disciplines and affiliations – academia, foundations, networks, biopharmaceutical industry representatives, and government. In addition, it should have diverse representation – global experience, gender, culture, and ethnicity.

SENIOR LEADERSHIP TEAM

A few of the critical leadership skills and job requirements relevant for the entire senior leadership team are:

- **Visionary Leadership:** Demonstrate passion, commitment, and courage; be champions for children and inspire employees and stakeholders to make a difference
- **Trusted Organization:** Build and preserve I-ACT's reputation as a trusted, neutral, credible organization
- **Engagement:** Promote early, comprehensive, and integrative engagement with global stakeholders to build better studies from the start; engage experts and the public around a shared vision for children's health
- **Global Perspective:** Bring new perspectives and experiences to help shape I-ACT's decision making; combine openness and awareness of different cultures and requirements to enable better health outcomes for children
- **Results Orientation:** Develop and execute a comprehensive global strategy; translate into concrete steps that produce results aligned with I-ACT's role as an independent, patient-centered organization
- **Stewardship & Fiduciary Responsibilities:** Ensure compliance with legal, regulatory, and financial requirements; ensure that assets are used wisely; model behaviors that demonstrate the importance of everyone's stewardship

VALUE PROPOSITION

Value will be measured differently by each stakeholder. However, the drivers listed below capture some of the most important drivers for all. We encourage I-ACT to ensure that its outcomes produce most (if not all) of the value noted below:

Direct value will be demonstrated by...

Evidence to support safe and effective use of therapies
Age-appropriate formulations
Greater global alignment of studies
Innovative study designs
Operational quality, speed, and efficiency
Accepted biomarkers
Validated outcome measures

Additional benefits will be...

Enhanced public health solutions for children
Improved stakeholder collaboration and engagement
Improved pediatric investigator retention
Streamlined clinical trial processes and systems
Best practice sharing across stakeholder groups
Consolidated pediatric-specific training/education
Regulatory compliance

PERFORMANCE MEASUREMENT

A core set of metrics, designed to measure value creation for patients, their families, sponsors, regulators, investigators, and other key stakeholders, should guide outcomes-oriented planning and execution. The metrics should directly support the value proposition (examples above). In addition, they should be designed to promote joint ownership of results, and should

form the basis for performance expectations shared by I-ACT, sponsors, and sites. At a minimum, we recommend that I-ACT measure (1) patient and other stakeholder views of the quality of its engagement with them; (2) quality of its strategy and planning work; (3) clinical trial operations quality, timeliness, and efficiency, especially in clinical trial start-up and trial conduct; and (4) ultimate outcomes, primarily enhancement of child health.

DIFFERENTIATION

Describing I-ACT's mission, vision, values, and three core activities inevitably leads to questions about *how I-ACT's model is different from existing models*. The table below helps articulate the answers to those questions. It reflects PTC's high-level assessment of I-ACT's differentiating attributes versus common comparators.

Distinguishing Attributes	I-ACT	Specialty Pediatric Networks*	Commercial CROs
Focus on new medicines and devices; evidenced-based use	Yes	Mixed	Mixed
Services include independent advisory <u>and</u> trial conduct services	Yes	Mixed	No
Cross-sector collaborative approach: regulatory, industry, academia, gov't researchers	Yes	Mixed	No
Independent advice and guidance provided to sponsors and others	Yes	Mixed	No
Funds site infrastructure – performance based	Yes	Mixed	No
Performance metrics used to assure accountability for quality, timeliness, efficiency	Yes	Mixed	No
Inclusive, comprehensive patient and parent engagement	Yes	Mixed	No
Regulatory standards are required	Yes	Mixed	Yes
Innovative clinical research – extrapolation, master protocols, Bayesian techniques	Yes	Mixed	No
Career development focus across pediatric research stakeholder groups	Yes	Mixed	No
Global reach	Yes	Mixed	Yes
Multiple therapeutic areas	Yes	No	Yes

*Specialty pediatric networks focus on a therapeutic area, geography, or a subpopulation (e.g., neonates)

Based on this high-level comparison, we recommend that I-ACT's response to questions about its differentiation be:

I-ACT is a child-centric, nonprofit organization that will operate the first multi-therapeutic, globally collaborative system that enables the delivery of regulatory-grade scientific data. These data support the safe and effective use of new medicines and devices in children.

ROADMAP

Given the complexity and breadth of the recommendations in this report, I-ACT should spend the first 24 months on hiring the leadership team/staff and building its operations core (e.g., office space, IT systems, etc.). It should also begin delivering Independent Advisory services and Feasibility Assessments during that time. To accomplish this, Clinical Study Groups, Patient & Community Engagement, and Standardized Contracts & Budget Templates should be in place. Inaugural sites should be selected and under master contract within 18 months, and clinical trial activities should follow. All other activities should be operational by year 5 or 6.

KEY SUCCESS FACTORS

The following should be used to guide prioritization of actions (not ranked in order of importance):

- **Strong Governance and Leadership:** Build a cohesive, supportive board; identify talented and committed leaders
- **Trusted Patient Engagement:** Establish trusted relationships early
- **Health Authority Engagement:** Establish appropriate engagement pathways with regulators
- **Ability to Raise Unrestricted Seed Grants:** Secure seed funding early
- **Results Orientation:** Focus on the mission, vision, and values – use as a guide to deliver tangible outcomes for patients
- **Compliance, Stewardship, and Fiduciary Responsibilities:** Demonstrate integrity and responsible management of resources

LEGAL AND COMPLIANCE CONSIDERATIONS

The strategy and operations recommendations above have important potential legal implications. Should the major elements of this advisory report be implemented, the following areas are among those that should be examined closely for their specific legal implications: (1) contractual relationships among I-ACT, sponsors, and sites; (2) senior leader compensation; (3) intellectual property; (4) conflicts of interest; (5) confidentiality; (6) anti-trust related to protection of proprietary data/information; and (6) management of contractors, volunteers, and consultants.

UNRESTRICTED SEED FUNDING

In the second half of 2016, I-ACT should begin to secure seed funding to support I-ACT's official launch in early 2017. Seed grants can be received in installments over the 2017 to 2019 period. The seed grants should be used to hire the senior leadership team, build infrastructure at the inaugural group of sites, pay for the formation and operations of external advisory groups, open an office and establish administrative infrastructure, install systems and equipment, and pay for legal fees. I-ACT should aim to achieve self-sustainability five years after launch and, thereafter, rely on fees it generates from program grants, strategy and planning, clinical trial management, and, to a lesser extent, annual membership dues.

SUMMARY

I-ACT has the potential to be a critically important patient-centered organization that enables the development of new drugs, biologics, and devices for children globally. As an independent organization led and staffed by pediatric experts, it can be the catalyst for the dismantling of the most significant barrier to conducting pediatric studies – lack of a sustainable, integrated, clinical trials infrastructure dedicated to child health. By taking on this challenge, I-ACT will improve access to important scientific data for an increasing number of innovative drugs, biologics, and devices, thereby improving and extending the lives of children globally. This can be achieved by emphasizing quality by design; engaging and educating stakeholders early and continually; streamlining systems and processes; developing and sharing best practices; managing a global network of well-trained, committed, and properly resourced sites; and helping to build a stronger talent pool of researchers, nurses, and other research staff. While there are many strategic and operational elements to consider, PTC believes that the ones put forth in this report are the most important components of a highly effective system. PTC is enthusiastic about the establishment of this new nonprofit and hopes that I-ACT finds the ideas and frameworks in this report to be useful. PTC team members look forward to supporting the organization in its transition to launch and beyond.

APPENDICES

1. Acknowledgements
2. About Our Team
3. Foundational Elements



ACKNOWLEDGEMENTS

PTC benefited greatly from the assistance and expertise of many individuals and groups who contributed ideas, shaped various sections of this report, and provided a wealth of experience to enable us to build a cohesive strategy and operations plan.

Early on, important information and insights came from separate meetings that were organized by various organizations and created a much-needed platform for discussion. These sessions were hosted by the American Academy of Pediatrics (AAP), the Pharmaceutical Research and Manufacturers of America (PhRMA), Biotechnology Innovation Organization (BIO), Pediatric Academic Societies (PAS), Drug Information Association (DIA), US Food and Drug Administration (FDA), European Medicines Agency (EMA), and Innovative Medicines Initiative in Europe (IMI). We are thankful to all of these organizations for their support.

We are deeply grateful to pediatric clinical research experts who shared valuable suggestions from their experience with pediatric clinical trials networks. Of particular note is Clinical Research Network: Children (CRN: Children) in the UK, a multi-specialty children's research network, now in its 7th year. Their team shared best practices, which resulted in an accelerated pathway for learning and integration of ideas pertaining to patient engagement, Clinical Study Groups, pharmacy support, education/training, and site infrastructure. We also gathered important insights from Maternal Infant Child and Youth Research Network (MICRN) in Canada, and the Pediatric Trials Network (PTN) in the US. In addition, we benefitted from valuable lessons gleaned from the National Institute of Health's (NIH) long history in overseeing a number of pediatric research networks.

This advisory report also benefited greatly from the lawyers at Paul Hastings, LLP, who enthusiastically took on the review of this document to ensure that we clarified intent in some areas, incorporated legal, privacy, and compliance safeguards in others, and strengthened overarching governance principles and practices. In addition, the attorneys at Rusing, Lopez, and Lizardi, PLLC, worked diligently to complete C-Path's work to incorporate I-ACT and file the related tax confirmation. We greatly appreciated the guidance and prudent advice provided by both law firms.

We thank the entire team at C-Path, where we found a home, formalized a team, created clear objectives, and delivered on our promise to catalyze the development of a new paradigm that we believe will improve and extend the lives of children globally.

Also, we extend warm thanks to all of our team members, but especially the patient advocates who provided countless real-world examples that shaped our thinking and expanded our options. We were most fortunate to have their insight and be inspired by their commitment to child health. They kept us grounded and helped us integrate unique views from a child's and caregiver's perspective.

Special thanks to our work-stream and subcommittee leaders for their thoughtful facilitation and skillful distillation of the many ideas and suggestions put forth. Their dedication, commitment, and flexibility enabled on-time completion of PTC's deliverables.

Last, none of this would have been possible without the dedication and commitment from PhRMA and the biopharmaceutical companies. They provided numerous platforms for sharing our mission with senior leaders across the world, donated in-kind project management and communications support, and generously provided unrestricted grants to fund this work.

Martha

Martha Brumfield, PhD
President and CEO
Critical Path Institute

Ed

Ed Connor, MD, MBE, FAAP
Executive Director and
Scientific Lead

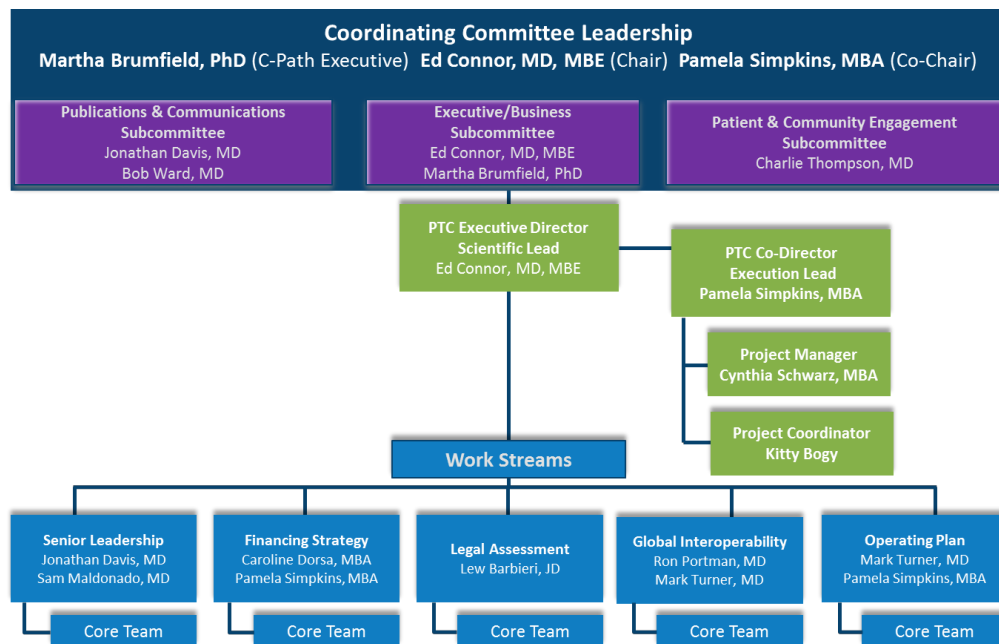
Pam

Pam Simpkins, MBA
Co-Director and
Execution Lead



ABOUT OUR TEAM

The PTC team is a diverse group of passionate, committed individuals who collaborated to prepare the recommendations in this advisory report. The team began its work in October 2015 and completed the content of this report in August 2016. Our members come from more than 30 organizations across the US, EU, Canada, Japan, and Argentina, and reflect representation from academia, patient and parent advocacy groups, the biopharmaceutical industry, government scientific/regulatory agencies, foundations, and professional organizations.



- American Academy of Pediatrics
- Arkansas Children's Hospital
- Children's Hospital Argentina
- Children's National Health System
- Clinical Research Alliance, LLC
- Connecticut Children's Medical Center
- Critical Path Institute
- Drug Information Association (DIA)
- Duke University
- Eli Lilly
- University of Utah
- Food & Drug Administration (FDA)
- Independent Patient Advocates
- Innovative Medicines Initiative (IMI)*
- International Children's Advisory Network (iCAN)
- Istituto G. Gaslini
- Janssen R&D
- National Center for Child Health and Development (Japan)
- National Institute for Child Health and Human Development (NICHD)*
- Nationwide Children's Hospital
- Novartis
- Paul Hastings LLP
- Pfizer
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- Rady Children's Hospital- San Diego
- Rusing, Lopez & Lizardi, PLLC
- Sczudlo Advisors LLC
- Tufts University
- Uniform Services University of Health Sciences
- University of British Columbia
- University of Liverpool
- University of Michigan - Mott Children's Hospital

* Observers



FOUNDATIONAL ELEMENTS

Strategic Focus: This table summarizes what we recommend the scope to be – the focus is on **new medicines and devices for children**:

Focus	Description
<i>In Scope</i>	
Age Groups	Newborn to Adolescent (age 18 or age 21, depending on jurisdiction)
Phases	Phase 1 to Phase 4 (post-marketing studies)
Interventions	New drugs, biologics, and devices (Class III devices)
Cross-Cutting Solutions	Research tools, methods, measures, guidance, etc. (biomarkers, outcome measures, etc.)
Product Status	New (i.e., on-patent)
Standards	Standards and practices prescribed by regulatory authorities – e.g., Good Clinical Practices
Primary Data Use	Support new or updated pediatric labeling
Therapeutic Areas	All (cardiovascular, oncology, immunology, infectious diseases, respiratory, neurology, etc.)
Sponsors	All (industry, foundations, government, network, etc.)
Other	Disease-state registries, pre-clinical advice to support upcoming clinical research programs
<i>Out of Scope</i>	
Interventions	Vaccines
Product Status	Off-patent (already in scope for other networks)

End of Advisory Report