DAY ONE:

8:00 – 8:30 - Registration and Continental Breakfast (provided)

8:30 – 9:00 - Introduction to Pediatric Clinical Research
Susan Devine, CCRP, Research Consultant
Ms Devine will provide an introduction and overview to the Pediatric Research Conference. During this time there will be discussion to assist the faculty in getting to know our attendees and their learning objectives.

9:00 – 10:00 - Opening Plenary Session – Device Research
Vasum Peiris, MD, Chief Medical Officer, Pediatrics and Special Populations, Center for Diagnostic and Radiological Health, FDA

10:00 – 10:15 - Break and opportunity for discussion

10:15 – 11:15 - Development of Pediatric Research Studies
Mark Krailo, PhD, Professor, Department of Preventive Medicine, University of Southern California, Keck School of Medicine
Dr. Krailo will discuss methods for identifying outcome measures in pediatric research studies. Dr. Krailo will also explain the importance of recognizing quality of life issues and of dealing with the challenges of long term participant follow up.

11:15 – 12:15 - Pediatric Rare Diseases Clinical Research
Grace Wentzel, BA, CCRP, Director, Clinical Research Services, Nationwide Children’s Hospital
Ms. Wentzel will discuss the challenges and rewards seen in pediatric rare disease research.

12:15 – 1:00 - Lunch (Provided)

1:00 – 1:45 - Regulatory and Ethical Considerations in Pediatric Research
Amanda Galster, MPH, CCRP, Director, Clinical Research Program, University of Minnesota Department of Pediatrics
Ms Galster will review the regulatory considerations and ethical principles in the context of pediatric research. She will review regulatory requirements, the consent process and discuss therapeutic misconception.

1:45 – 2:45 - Round Table Discussions
Susan Devine, CCRP, Research Consultant
Lisa Benson, BS, CCRP, CRCP, Vice President, Clinical Research Operations, Quality and Education, Institute for Advanced Clinical Trials for Children
Through a series of directed questions, participants will engage in discussion related to pediatric research in their specific research areas.

2:45 – 3:00 - Break and Opportunity for Discussion

3:00 – 4:00 - Pediatric Medical Device Development: Clinical Trials Challenges and Opportunities
Kolaleh Eskandanian, PhD, MBA, PMP®, Vice President and Chief Innovation Officer, Children’s National Health System
There are a number of challenges associated with conducting clinical trials in the pediatric population, and especially in the younger subgroups. As such, off-label use of drugs and devices in children—while may be the only option to save lives—has become a public health problem. The use of real-world evidence (RWE) could potentially provide a much-needed solution to the scarcity of available medical devices for children. Paradoxically, the extensive off-label use of medical devices in children has contributed to the compilation of real-world data (RWD) that could be leveraged to increase the number of medical devices with labeling for pediatric patients.

4:00 – 4:30 - Pediatric Clinical Research – Recruitment of Sites - The Sponsor Perspective
Kathi Durdon, BA, MA, CCRP, Director, Operations and Innovation Partnerships, CNY Biotech Accelerator, SUNY Upstate Medical University
Ms. Durdon will discuss the sponsor perspective in choosing sites to participate in device related clinical research.

4:30 – 5:00 - Device Poster Presentation
Collin Hovinga, PhD, Senior Scientific Advisor, Institute for Advanced Clinical Trials for Children
8:00 – 8:30 - Continental Breakfast (provided)

8:30 – 9:15 - Project Planning and Management
Susan Devine, CCRP, Research Consultant
Ms Devine will discuss project planning and management of pediatric research trials based on a project management approach. Helpful templates geared to enhance efficiency will be shared.

9:15 – 10:45 - Budgeting and Contracting for Pediatric Trials
Lisa Benson, BS, CCRP, CRCP, Vice President, Clinical Research Operations, Quality and Education, Institute for Advanced Clinical Trials for Children
Ms. Benson will discuss special considerations for developing pediatric research study budgets including a review of “hidden costs”. Ms. Benson will present best practices for contract negotiation and payment collection.

10:45 – 11:00 - Break and Opportunity for Discussion

11:00 – 12:30 - Consenting in the Pediatric Population
Sharon Smith, MD, Research Director, Pediatric Emergency Medicine, Connecticut Children’s Medical Center
Dr. Smith, along with a student from her research assistant program will provide hands on training and practice in consenting in the pediatric population.

12:30 – 1:15 - Lunch (Provided)

1:15 – 3:15 - Challenges in Pediatric Research
Janelle Allen, MS, BS, CCRP, Director, Clinical Research Operations, Quality & Education, Institute for Advanced Clinical Trials for Children
Ms. Allen will discuss the challenges faced in recruitment, enrollment and retention of participants in pediatric trials. Specific strategies and approaches to bolster recruitment and retention will be discussed. This presentation will also include managing the transition from childhood to young adulthood by study participants.

3:15 – 3:30 - Break and Opportunity for Discussion

3:30 – 4:30 - Monitoring, Auditing and Compliance
Lisa Benson, BS, CCRP, CRCP, Vice President, Clinical Research Operations, Quality and Education, Institute for Advanced Clinical Trials for Children
This session will consider monitoring and auditing issues specific to pediatric research. Ms Benson will review techniques for audit preparation and the importance of self-monitoring. The concept of minimizing risk through good clinical practice will be explored as well. A discussion on financial compliance will follow.

4:30 – 5:00 - Close Group Discussion/ Q & A Day 2 Sessions