Pediatric Clinical Research Conference
Conducting Clinical Trials in the Pediatric Population

Day 1 (Thursday February 25, 2016)

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

8:30-9:00  Introduction to Pediatric Clinical Research Conference
Susan Devine, CCRP, Research Manager, Royal Victoria Regional Health Center
Ms. Devine will provide an introduction and overview to the Pediatric Research Conference. Highlights of historical and current events and issues in pediatric research will be shared.

9:00-10:00  Regulatory Considerations in Pediatric Research
Michael Link, MD, Professor of Pediatrics, Stanford University School of Medicine
Dr. Link will discuss regulatory considerations specific to pediatric research. This presentation will review the consent process and other regulatory requirements to consider when working with a vulnerable population.

10:00 – 10:15  Break

10:15 – 11:45  Role of the Data Monitoring Committee in Pediatric Clinical Trials
Michael Link, MD, Professor of Pediatrics, Stanford University School of Medicine
Dr. Link will explain the role and function of the data safety monitoring board (DSMB) in pediatric trials and how it supports safety of a vulnerable population.

11:45 – 12:30  Lunch (provided)

12:30 – 1:45  Project Planning and Management
Susan Devine, CCRP, Research Manager, Royal Victoria Regional Health Center
Ms. Devine will discuss project planning and management for pediatric research trials. Using pediatric case studies Ms. Devine will lead discussion on critical pathways for developing project plans and operationalizing clinical research.

1:45 – 2:15  Developing Metrics in Pediatric Clinical Trials
Susan Devine, CCRP, Research Manager, Royal Victoria Regional Health Center
Ms. Devine will discuss metrics for pediatric clinical research trials. In addition Ms. Devine will discuss a mechanism to determine workload based on protocol complexity. (PedsOPAL)

2:15 – 3:15  Development of Pediatric Research Studies – Part 1
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.

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

3:30-4:30  Monitoring, Auditing and Compliance
Lisa Benson, BS, CCRP, CRCP, Director of Research Administration & Sponsored Programs, Connecticut Children’s Medical Center
Susan Devine, CCRP, Research Manager, Royal Victoria Regional Health Center
This session will consider monitoring and auditing issues specific to pediatric research. The speakers will review techniques for audit preparation and the importance of self-monitoring. The concept of minimizing risk through good clinical practice will be explored followed by a discussion on financial compliance.

4:30 – 5:00  Group Discussion
Q & A Day 1
Day 2 (Friday February 26, 2016)

8:00-8:30  Continental Breakfast (provided)

8:30 – 9:30  **Development of Pediatric Research Studies – Part 2**  
*Mark Krailo, PhD, Professor, Department of Preventive Medicine, University of Southern California, Keck School of Medicine*  
Dr. Krailo will discuss the importance of recognizing quality of life issues and of dealing with the challenges of long term participant follow up.

9:30 – 10:30  **How has the US Law and Regulations changed Pediatric Drug Development**  
*Pamela Simpkins, MBA, PMP, Strategic Leader, Operations & Decision Support*  
Child Health Innovation Department (CHILD), Janssen Research & Development  
This session will introduce the unique challenges of conducting clinical trials in a pediatric setting. Ms. Simpkins will discuss current trends in clinical research and identify how these trends are influencing pediatric trials.

10:30-10:45  Break and Opportunity for Discussion

10:45 – 12:00  **Budgeting and Contracting for Pediatric Trials**  
*Lisa Benson, BS, CCRP, CRCP, Director of Research Administration & Sponsored Programs, Connecticut Children’s Medical Center*  
Ms. Benson will discuss special considerations of developing budgets for pediatric research studies. Ms. Benson will present best practices for contract negotiation and payment collections.

12:00-12:45  Lunch (provided)

12:45-2:30  **Challenges in Pediatric Research**  
*Janelle Allen, MS, CCRP, Project Manager, Cincinnati Children’s Hospital Medical Center*  
Ms. Allen will discuss the challenges faced in recruitment, enrollment, and retention of participants in pediatric trials. Specific strategies and approaches for recruitment and retention will be discussed. This presentation will also include managing the transition from childhood to young adulthood by study participants, and facilitating optimal research tactics across the lifespan.

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

3:00 – 4:00  **Kids Talking to Clinical Researchers – From the Mouths of Babes**  
*Pamela Simpkins, MBA, PMP, Strategic Leader, Operations & Decision Support*  
Child Health Innovation Department (CHILD), Janssen Research & Development  
Ms. Simpkins will provide an overview of international efforts to coordinate the formation of young patient advisory groups designed to give children a voice in medicine, research and innovation.

4:00-4:30  **Closing Remarks, Group Discussion and Questions**  
*Lisa Benson, BS, CCRP, CRCP, Director of Research Administration & Sponsored Programs, Connecticut Children’s Medical Center.*  
**Q & A Day 2**  
Ms. Benson will facilitate discussion regarding participants learning objectives as discussed during Day 1. Participants will have the opportunity to ask questions of all Presenters and provide feedback for future direction of the Pediatric Clinical Research Conference.