
2018 Annual International Neonatal Scientific Workshop

Bethesda North Marriott Hotel & Conference Center, Maryland

Agenda – Day 1, April 11, 2018

8:00 am – 12:00 pm	INC Hemodynamic Adaptation Workgroup Meeting <i>Heike Rabe and Janis Dionne, co-chairs</i>
8:00 am – 12:00 pm	INC BPD Workgroup Meeting <i>Robin Steinhorn and Wolfgang Göpel, co-chairs</i>
12:00 pm – 1:00 pm	Lunch
1:00 pm – 5:00 pm	INC Communications Workgroup Meeting <i>Christina Bucci-Rechtweg and Jennifer Degl, co-chairs</i>
1:00 pm – 5:00 pm	INC Clinical Pharmacology Workgroup Meeting <i>Karel Allegaert, Robert Ward and Jeffrey Barrett, co-chairs</i>
6:00 pm – 9:00 pm	DINNER at Pinstripes (near Marriott) for all Workshop Participants

Agenda – Day 2, April 12, 2018

Meeting Objectives:

- Share regulatory perspectives on developing safe and effective therapies for neonates.
- Develop a framework for applying real world evidence: how to standardize data elements and clinical methods, what types of data should be collected, how should quality assurance be addressed.

- Discuss approaches for both simplifying and standardizing the evaluation and reporting of adverse events in neonatal trials.
- Review the extent and nature of influences of parenteral nutrition on very low birth weight infants and identify ways to take nutrition into account during clinical trials.
- Review the progress and plans of INC workgroups.

8:00 – 8:30 am	<p><u>Welcome</u></p> <p><i>Susan McCune</i> (Director, Office of Pediatric Therapeutics, FDA)</p> <p><u>Applying Innovative Approaches to Developing Neonatal Therapeutics</u></p> <p><i>Gerald Dal Pan</i> (Director, Office of Surveillance and Epidemiology, CDER/FDA)</p>
8:30 – 10:15 am	<p><u>Real World Evidence to Inform Regulatory Decision-Making on Neonatal Medicinal Products</u></p> <p><i>Neena Modi</i> (Imperial College, London) and <i>Prakesh Shah</i> (U-Toronto), co-chairs</p> <ul style="list-style-type: none"> • <i>Dominique Haumont</i> (St-Pierre University Hospital, Brussels) • <i>Michael Padula</i> (Data Workgroup Co-Chair; Children’s Hospital of Pennsylvania) • <i>Rebecca Kush</i> (Founder, CDISC) • <i>Nicole Thiele</i> (EFCNI) • <i>Kristjan Kahler</i> (Novartis) • <i>Jeffrey Barrett</i> (Sanofi) • <i>Lily Mulugeta</i> (CDER/FDA) • <i>Jacqueline Corrigan-Curay</i> (CDER/FDA) • EMA/PDCO/Health Canada/PMDA
10:15 – 10:45 am	<p>Coffee Break</p>

10:45 – 12:30 pm	<p><u>Standardizing Safety Approaches for Neonatal Clinical Trials</u></p> <p><i>Jon Davis</i> (Tufts U and INC Co-Director) and <i>Gerri Baer</i> (OC/FDA), co-chairs</p> <ul style="list-style-type: none"> • <i>Danny Benjamin</i> (Duke University) <i>by Webex</i> • <i>Matt Laughon</i> (UNC) • <i>Karel Allegaert</i> (University of Leuven) • <i>Isamu Hokuto</i> (St. Marianna University, Japan) • <i>Hidefumi Nakamura</i> (NCCHD, Tokyo) • <i>Mary Short</i> (Lilly) • <i>Laura Fabbri</i> (Chiesi) <i>by Webex</i> • <i>Alexandra Mangili</i> (Shire) • <i>Jennifer Degl</i> (Premie Parent Alliance) • <i>Carole Kenner</i> (COINN) • <i>Michael Blum</i> (CDER/FDA) • <i>Joseph Toerner</i> (CDER/FDA) • <i>Agnes Klein</i> (Health Canada) • <i>Barry Magnum</i> (Paidion Research, Inc.)
12:30 – 1:30 pm	<p>Lunch</p>
1:30 – 3:00 pm	<p><u>Regulatory implications of nutritional influences on outcomes of preterm birth</u></p> <p><i>Mark Turner</i> (U. Liverpool and INC Co-Director) and <i>Mary Hise Brown</i> (Baxter), co-chairs</p> <ul style="list-style-type: none"> • <i>Brenda Poindexter</i> (Cincinnati Children’s Hospital) • <i>Thibault Senterre</i> (University of Liege) • <i>Satoshi Kusuda</i> (Tokyo Women’s Medical University) • <i>Thomas Miller</i> (Bayer) • <i>Andrea Lotze</i> (CFSAN/FDA) • <i>Suna Seo</i> (CDER/FDA) • <i>Cynthia Pellegrini</i> (March of Dimes)
3:00 – 3:30 pm	<p>Coffee Break</p>
3:30 – 4:45 pm	<p><u>INC Workgroup Updates</u></p> <p><i>Ronald Portman</i> (Novartis, INC Co-Director), chair</p> <ul style="list-style-type: none"> • Hemodynamic Adaptation (<i>Heike Rabe, Janis Dionne</i>) • Data (<i>Thomas Diacovo, Michael Padula</i>) • Bronchopulmonary Dysplasia (<i>Robin Steinhorn, Wolfgang Göpel</i>) • Clinical Pharmacology (<i>Karel Allegaert, Robert Ward, Jeffrey Barrett</i>) • Communications (<i>Christina Bucci-Rechtweg, Jennifer Degl</i>)

4:45 pm	Closing Remarks <i>Mark Turner</i> (INC Co-Director)
5:00 pm	Workshop Adjourns