

**Second Annual Neonatal Scientific Workshop at the FDA  
March 7-8, 2016  
FDA White Oak Campus**

**Satellite INC Workgroup Meetings at the Sheraton Silver Spring Hotel  
March 8-9, 2016**

**SESSIONS OVERVIEW**

March 7, 9:00 am - 5:00 pm	Full day at the FDA
March 7, 6:00 pm – 8:30 pm	Working Dinner at Sheraton Silver Spring for INC Members
March 8, 9:00 am - 5:00 pm	Full day at the FDA
March 8, 6:00 pm - 8:30 pm	Working Dinners for Individual INC Workgroups
March 9, 8:00am - 4:00 pm	INC Workgroups (Seizures, Bronchopulmonary Dysplasia, Data) at Sheraton Silver Spring Hotel

## AGENDA FOR DAY 1 – March 7, 2016

- 9:00 am Welcome – Jon Davis, INC Co-Director (Tufts Medical Centre)
- 9:10 am Regulatory Science for Neonates –Rob Califf (US Food and Drug Administration)
- 9:30 am – 12:30 pm Retinopathy of Prematurity (ROP): Overview of the Needs and Regulatory Science Strategies for Improving Neonatal Outcomes  
Mark Turner, INC Co-Director (University of Liverpool), Chair
- 9:30 am Challenges in Conducting Clinical Trials to Treat ROP and Strategies for Overcoming those Challenges  
Olaf Dammann (Tufts Medical Centre)
- 10:00 am Melissa Liew (Novartis)  
Adina Tocoian (Shire)
- 10:20 am COFFEE BREAK
- 10:50 am Expert Panel (continued)  
Alistair Fielder (City University London)  
Neil Marlow (University College London)  
Ann Hellstrom (University of Gothenburg)  
Wiley Chambers (US Food and Drug Administration)  
Reiko Shimizu (Pharmaceuticals and Medical Devices Agency - Japan)  
Ralph Bax (European Medical Agency)
- 12:15 pm Voting on Priority Projects for ROP
- 12:30 pm LUNCH
- 1:30 pm – 5:00 pm Bacterial Infections, including Necrotizing Enterocolitis (NEC): Overview of the Needs and Regulatory Science Strategies for Improving Neonatal Outcomes  
Danny Benjamin (Duke University), Chair
- 1:30 pm Challenges in Conducting Clinical Trials to Treat Infections/NEC and Strategies for Overcoming those Challenges  
Danny Benjamin (Duke University)  
Karel Allegaert (University of Leuven)
- 2:30 pm COFFEE BREAK
- 3:00 pm Expert Panel on Infections and NEC in Neonates  
Raafat Bishai (AstraZeneca)  
Gary Noel (Janssen Research & Development)  
Michael Caplan (University of Chicago)

Kelly Wade (Children's Hospital Philadelphia)  
Mark Turner (University of Liverpool)  
Sumathi Nambiar (US Food and Drug Administration)  
Daniel Keene (Health Canada)

- 4:45 pm Voting on Priority Projects for Infections and NEC
- 5:00 pm SHUTTLE TO Sheraton Silver Spring Hotel
- 6:30 pm WORKING DINNER for INC Members at the Sheraton Silver Spring Hotel
- Leveraging INC Multi-Stakeholder Collaboration to Address Neonatal Needs  
Christina Bucci-Rechtweg (Novartis), Chair
- Giving Voice to the Parents' Perspective – Cristal Grogan (Premie Parent Alliance)
  - Giving Voice to the Neonatal Nurses' Perspective – Wakako Eklund (National Association of Neonatal Nurses) and Carole Kenner (Council of International Neonatal Nurses)
  - Giving Voice to the Industry Perspective – Jeff Barrett (Sanofi) and Ron Portman (Novartis)
  - Giving Voice to the Non-clinical Researcher – Connie Chen (HESI)
  - Giving Voice to Policy Advances – Christina Bucci-Rechtweg (Novartis), Jon Davis (Tufts Medical Centre)
  - Finale of the Neonatal Chorus – Jon Davis (Tufts Medical Centre)

#### **AGENDA FOR DAY 2 – March 8, 2016**

- 9:00 am Welcome to Day 2 and Brief Highlights of Day 1 – Susan McCune (US Food and Drug Administration)
- 9:10 am Regulatory Science for Neonates – Janet Woodcock (US Food and Drug Administration)
- 9:30 am – 12:30 pm Hemodynamic Adaptation: Overview of the Needs and Regulatory Science Strategies for Improving Neonatal Outcomes  
Mark Turner (University of Liverpool), Chair
- 9:30 am An Overview of Hemodynamic Issues that Pose Regulatory Challenges  
Keith Barrington (University of Montréal)  
Heike Rabe (Brighton and Sussex Medical School)
- 10:15 am COFFEE BREAK

10:45 am Expert Panel to Identify Strategies to Overcome Regulatory Challenges  
Gene Dempsey (University College Cork, Ireland)  
Jeffrey Jacobs (John Hopkins Hospital)  
Janis Dionne (British Columbia Children’s Hospital, Vancouver)  
Neil Marlow (University College London)  
Tonse Raju (National Institute of Child Health and Human Development)  
Shari Targum (US Food and Drug Administration)  
Ralph Bax (European Medical Agency)

12:15 pm Voting on Priority Projects for Hemodynamic Adaptation

12:30 pm LUNCH

1:30 pm – 4:30 pm Progress of the International Neonatal Consortium:  
INC Workgroup Updates  
Ron Portman, INC Co-Director (Novartis), Chair

1:30 pm Clinical Pharmacology Workgroup – Bob Ward (University of Utah)  
Karel Allegaert (University of Leuven)  
Jeff Barrett (Sanofi)

2:00 pm Seizures Workgroup – Janet Soul (Harvard University)  
Ronit Pressler (Great Ormond Street Hospital)

2:30 pm COFFEE BREAK

3:00 pm Bronchopulmonary Dysplasia (BPD) Workgroup –  
Robin Steinhorn (Children’s National Hospital)  
Wolfgang Goepel (University of Lübeck/ VOC)

3:45 pm Data Workgroup – Tom Diacovo (Columbia University)  
Kate Costeloe (Queen Mary University of London)

4:30 pm Concluding Remarks – Jon Davis, INC Co-director (Tufts Medical Center)

5:00 pm SHUTTLE TO HOTEL

6:30 pm – 8:30 pm WORKING DINNER for each of the following workgroups:

- Seizures
- Bronchopulmonary Dysplasia
- Data

**AGENDA FOR DAY 3 – March 9, 2016**  
**Sheraton Silver Spring**

8:00 am – 4:00 pm Individual Workgroups

- Seizures Workgroup to finalize Master Protocol for Seizures
- BPD Workgroup to finalize definition of BPD
- Data Workgroup