



Public Workshop— Facilitating Anti-infective Drug Development for Neonates and Young Infants

Thursday September 15th, 2016		
Time	Topic	Presenter
7:30 AM-8:30 AM	Registration	
	Session 1: Current State and Challenges Associated With Neonatal Anti-infective Drug Development	
8:30 AM-8:35 AM	Introductory Remarks	Sumathi Nambiar, CDER, FDA
8:35 AM-8:55 AM	The Landscape of Neonatal Anti-Infective Drug Development	John Farley, CDER, FDA
8:55 AM-9:15 AM	FDA Perspective on Establishing Efficacy for Common Indications in the Neonatal Population	Tom Smith, CDER, FDA
9:15 AM-9:35 AM	CNS Dissemination in Neonatal Infections	Danny Benjamin, Duke
9:35 AM-9:55 AM	Pharmacokinetic and Pharmacodynamic Considerations in Neonates	Lily Mulugeta, FDA
9:55 AM-10:15 AM	Adequate and Well Controlled Trials in Neonates: Lessons Learned from Neonatal Candidiasis Program	Laura Kovanda, Astellas
10:15 AM-10:35 AM	Break 1	
10:35 AM-10:55 AM	The Role of Clinical Trial Networks in Neonatal Studies	Brian Smith, Duke
10:55 AM-11:40 AM	Clarifying Questions From Audience/Panelists	
11:40 AM-12:40 PM	Lunch	
	Session 2: Resources and Path Forward in Neonatal Infections/Studies	
12:40 PM-1:10 PM	Use of In Vivo and In Vitro Models to Guide Dose Selection for Neonatal Infections	William Hope, University of Liverpool
1:10 PM-1:30 PM	Using Pharmacometrics to Facilitate the Design and Analysis of Anti-Infective Drug Studies in Neonates	Chris Rubino, Institute for Clinical Pharmacodynamics
1:30 PM-2:00 PM	Obtaining Clinical Safety and Efficacy Data in Neonatal Infections	Gary Noel, Johnson and Johnson
2:00 PM-2:20 PM	Neonatal Master Protocols in Neonatal Infections: Pharmacokinetic, Safety and Outcome Assessment	Mark Turner, University of Liverpool
2:20 PM-2:35 PM	Public Comments	
2:35 PM-2:50 PM	Break 2	
2:50 PM-3:50 PM	Panel Discussion (Covering All Topics)	
3:50 PM-4:00 PM	Concluding Remarks	



Panel Session Moderators: John Farley, John Bradley

Panel Members: FDA: Sumathi Nambiar, John Farley, Tom Smith, Yuliya Yasinskaya, Susan McCune, Lily Mulugeta, John Alexander

William Hope (University of Liverpool), Gary Noel (J&J Pharmaceutical Research and Development), Danny Benjamin (Duke University), Brian Smith (Duke University), John Bradley (University of California San Diego), Mark Turner (University of Liverpool), Laura Kovanda (Astellas), Anne Zajicek (NICHD/NIH), Chris Rubino (Institute for Clinical Pharmacodynamics)

Speaker slides and other workshop material can be found at:

<http://www.fda.gov/Drugs/NewsEvents/ucm507958.htm>

Public Wi-Fi Access:

1. Click on Sheraton
2. Next, click on LobbyAccess
3. Password: Meeting291