

Pediatric Academic Societies Meeting State of the Art Plenary

May 1, 2016

3:30 PM – 5:30 PM

Baltimore Convention Center

Baltimore, Maryland

Session Details:

Global Efforts to Accelerate Neonatal Drug Development

Session Number: 2665

PAS State of the Art Plenary

Baltimore Convention Center ~ 337/338

Neonatologists and scientists interested in the pharmacology, pathophysiology, genetics, and treatment options for commonly encountered neonatal conditions.

Chairs: Christine A. Gleason, University of Washington, Seattle, WA and Jonathan Michael Davis, The Floating Hospital for Children at Tufts Medical Center, Boston, MA

The enormous challenges of developing therapies for conditions commonly encountered in neonatal care brought together a diverse international cast to form the International Neonatal Consortium (INC). More than an academic research collaboration, the consortium involves regulators, the academic community, industry scientists, nurses, families, and advocacy organizations. The major focus is neonatal lung injury, neonatal brain injury, perinatal and neonatal infections, neonatal gastrointestinal injury, retinopathy of prematurity (ROP), and neonatal abstinence syndrome (NAS), as well as prevention of preterm labor. This symposium will highlight how consortium members share data, expertise, and resources to reach consensus on standardized methods, standards of care, biomarkers, clinical endpoints, master protocols, guidance on clinical pharmacology for neonates, decision criteria for extrapolating results to neonates, and more.

Panelists:

Sharing Data, Expertise, and Resources to Conduct Rigorous Clinical Trials That Can Improve Outcome for Neonates

Mark Turner

School of Reproductive & Developmental Medicine, Liverpool, UK

A Unique Time in the History of Neonatology: Global Efforts To Improve the Outcome for Neonates

Jonathan Michael Davis

Vice-Chair of Pediatrics for Academic Affairs, Chief of Newborn Medicine, The Floating Hospital for

Children at Tufts Medical Center, Professor of Pediatrics, Tufts University School of Medicine, Boston, MA

Moving Beyond the Regulatory Check-Box To Develop New Medicines for Neonates

Ronald J Portman

Pharmaceutical Research Institute, Princeton, NJ

Global Efforts To Accelerate Neonatal Drug Development: The FDA Perspective

Dianne Murphy
Food and Drug Administration, Alexandria, VA

European Efforts To Accelerate Neonatal Drug Development: Who Else Can We Include?
Ralph Bax

From Legislation To Collaboration: Launch of the International Neonatal Consortium
Lynn Hudson
Critical Path Institute, Tucson, AZ