AGENDA

8:00-8:10am  Welcome and Introductory Remarks
Lynne Yao, MD, Acting Director, Division of Pediatric and Maternal Health, Center for Drug Evaluation and Research, FDA

8:10-9:30am  Session I: Normal neurocognition and how it is measured in children of varying ages
Session Chair: Peter Como, MD, Center for Devices and Radiologic Health, FDA

Presentations (20 minutes each)
Normal neonatal and infant neurocognitive development and measurements in this age group
Marilee Allen, MD, Professor of Pediatrics, The Johns Hopkins School of Medicine

Normal toddler, school age and adolescent neurocognitive development and measurements in these age groups
Gahan Pandina, PhD, Senior Director, Janssen Research and Development

NIH Toolbox for the assessment of neurological and behavioral function
Richard Gershon, PhD, Vice-Chair for Research, Department of Medical Social Sciences, Feinberg School of Medicine, Northwestern University

The PING Study: Pediatric Imaging, Neurocognition, and Genetics
Natacha Akshoomoff, PhD, Associate Professor, Department of Psychiatry and Center for Human Development, University of California, San Diego

9:30-10:00am  Discussion
- Discuss specific clinical areas for which current measurements of neurocognitive function have been most useful.
- Discuss the limitations present in the current standards of measurement of neurocognitive and behavioral function in children.
• Discuss gaps, if any, in the current standards of age-specific measurement of neurocognitive and behavioral function in children.

10:00-10:10 Break

10:10-11:30am Session II: Neurocognitive signals from animal and human studies: Examples of the effect of medical interventions on long-term neurocognition
Session Chair: Philip Sheridan, MD, Senior Medical Reviewer, Division of Neurology Products, Center for Drug Evaluation and Research, FDA

Presentations (20 minutes each)

Long-term neurocognitive effects of therapy in survivors of acute lymphocytic leukemia: Novel approaches
Deborah Waber, Ph.D., Professor, Department of Psychiatry, Harvard medical School

Strategies for studying cognitive and behavioral effects of antiepileptic drugs
Philip Sheridan, MD, Senior Medical Reviewer, Division of Neurology Products, Center for Drug Evaluation and Research, FDA

Neonatology follow up: Long-term effects of NICU treatment
Marilee Allen, MD, Professor of Pediatrics, The Johns Hopkins School of Medicine

CNS safety evaluation in drug development: Signals from animal studies that suggest the need for further investigations. Case study: Anesthetic-induced neurodegeneration in the developing brain
R. Daniel Mellon, PhD, Pharmacology Toxicology Supervisor, Division of Anesthesia, Analgesia, and Addiction Products, Center for Drug Evaluation and Research, FDA

11:30-12:00pm Discussion
Discuss how signals from animal and human studies would prompt neurocognitive safety studies in children.

12:00-1:00pm Lunch

1:00-2:00pm Session III: Tools and strategies in the evaluation of neurocognitive and behavioral outcomes in products used to treat children
Chairs: Heather Adams, PhD, Associate Professor, Department of Neurology, University of Rochester School of Medicine and Dentistry
Elsa Shapiro, PhD, LP, Professor of Pediatrics and Neurology, University of Minnesota, University of Minnesota School of Medicine

**Presentations (20 minutes each)**
Regulatory considerations related to evaluation of long-term safety in pediatric patients
Ann McMahon, MD, MS, Office of Pediatric Therapeutics, FDA

Environmental exposures and neurodevelopment outcomes
Marilyn Bull, MD, FAAP, Pediatrics, Developmental Pediatrics
Riley Hospital for Children at Indiana University Health

**What are the major challenges in the evaluation of long-term neurocognitive and behavioral outcome?**
Elsa Shapiro, PhD, LP, Professor of Pediatrics and Neurology, University of Minnesota, University of Minnesota School of Medicine

**Discussion**
- Discuss the adequacy of currently available tools to assess neurocognitive and behavioral outcomes
- Discuss potential endpoints that may be used in assessing short-term and long-term neurocognitive and behavioral outcomes

2:00-2:15pm Break
2:15-4:30pm Discussion
- Discuss study design consideration to optimally assess short-term and long-term neurocognitive and behavioral outcomes.
  - Appropriate length of studies
  - Critical age windows of growth and development
  - Additional study design issues: Blinding, Controls, and Timing of Testing

4:30-5:00pm Conclusions, Summary of Morning and Afternoon sessions and Next Steps
Ann McMahon, MD, MS, Office of Pediatric Therapeutics, FDA

5:00pm Adjourn