The University of Maryland Center for Excellence in Regulatory Science and Innovation and the U.S. Food and Drug Administration Present:

Pediatric Master Protocols

Friday, September 23, 2016

FDA White Oak Campus
Silver Spring, MD

Conference Agenda

Time	Activity
	Introduction/Regulatory and Scientific Concerns Related to Pediatric Master Protocols **Moderator:** Gilbert J. Burckart, PharmD, Associate Director for Pediatrics, Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research (CDER), Food and Drug Administration
8:30-8:35 a.m.	**Welcome** **Gilbert J. Burckart, PharmD** Associate Director for Pediatrics Office of Clinical Pharmacology, CDER Office of Translational Sciences, CDER Food and Drug Administration
8:35-8:50 a.m.	**Increasing Trial Efficiency through the Use of Master Protocols (Video Presentation)** **Robert Califf, MD** Commissioner Food and Drug Administration **Link to lecture:** http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials
8:50-9:20 a.m.	**Pediatric Drug Development: Successes and Problems** **Lynne Yao, MD** Director, Division of Pediatric and Maternal Health Office of New Drugs, CDER Food and Drug Administration
9:20-9:50 a.m.	**Industry Perspective on Master Protocols and Platforms** **Hubert Caron, MD, PhD** Professor and Senior Medical Director, Global Development Team Leader, Pediatric Oncology Genentech/Roche
9:50-10:15 a.m.	**International Considerations for Pediatric Master Protocols** **Jean Temeck, MD** Office of Pediatric Therapeutics Commissioner's Office Food and Drug Administration
10:15-10:30 a.m.	**Trial Design Considerations in Developing Pediatric Master Protocols**

Dionna Green, MD
Pediatric Clinical Pharmacology, Guidance and Policy Team
Office of Clinical Pharmacology, Office of Translational Sciences
CDER
Food and Drug Administration

10:30-10:45 a.m. — BREAK

10:45-11:05 a.m. — DESIGNING A DISEASE-SPECIFIC MASTER PROTOCOL
Lisa LaVange, PhD
Director, Office of Biostatistics
Office of Translational Sciences, CDER
Food and Drug Administration

11:05-11:25 a.m. — PRECURSORS TO PEDIATRIC MASTER PROTOCOLS
Kevin Watt, MD, PhD
(Substituting for Danny Benjamin, MD, PhD, MPH)
Assistant Professor of Pediatrics
Duke University School of Medicine

11:25-11:45 a.m. — LESSONS LEARNED IN BUILDING NATIONAL AND INTERNATIONAL CONSORTIA
Steven Hirschfeld, MD, PhD
Associate Director for Clinical Research
National Institute for Child Health and Human Development
National Institutes of Health

11:45-12:30 p.m. — MODERATED PANEL DISCUSSION

Panelists: Maura O'Leary, MD (FDA); Edress Darsey, PharmD (Pfizer); and Drs. Yao (FDA), Caron (Genentech/Roche), Temeck (FDA), Green (FDA), LaVange (FDA), Watt (Duke), and Hirschfeld (NIH)

12:30-1:30 p.m. — LUNCH

APPLICATIONS OF PEDIATRIC MASTER PROTOCOLS IN SPECIFIC PEDIATRIC THERAPEUTIC AREAS

Moderator: Jill Morgan, PharmD, Associate Professor and Chair, Department of Pharmacy Practice and Science, University of Maryland School of Pharmacy

1:30-1:55 p.m. — WHAT IS THE POTENTIAL FOR PEDIATRIC MASTER PROTOCOLS WHEN PEDIATRIC EXTRAPOLATION IS NOT POSSIBLE (E.G., ONCOLOGY)?
Gregory Reaman, MD
Associate Director for Oncology Sciences
Division of Oncology Products
Office of New Drugs, CDER
Food and Drug Administration

1:55-2:20 p.m.	**What Is the Potential for Pediatric Master Protocols When Partial Extrapolation Is Applied (e.g., Analgesics and Anesthetics)?** **Kevin Watt, MD, PhD** Assistant Professor of Pediatrics Duke University Medical Center Duke Clinical Research Institute
2:20-2:45 p.m.	**What Is the Potential for Pediatric Master Protocols in Infectious Disease?** **P. Brian Smith, MD, MHS, MPH** Chief, Division of Quantitative Sciences, Pediatrics Duke University
2:45-3:10 p.m.	**The Role of In Vitro Diagnostic Tests in Pediatric Master Protocol Development** **Anand Pathak, MD, PhD, MPH** Medical Officer Center for Devices and Radiologic Health Food and Drug Administration
3:10-4:00 p.m.	**Moderated Panel Discussion** **Panelists:** Gary Noel, MD (Chair, Pediatric Advisory Committee, J&J); Maura O'Leary, MD (CBER, FDA); Drs. Reaman (FDA), Watt (Duke), Smith (Duke), and Pathak (FDA)
4:00-4:30 p.m.	**Pediatric Master Protocols – Overall Assessment and Pathway Forward** **Brian Smith, MD, MHS, MPH** (Substituting for Danny Benjamin, MD, PhD) Neonatologist Department of Pediatrics Duke Health

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