The focus of this public workshop is Pediatric Irritable Bowel Syndrome and Pediatric Functional Constipation. The co-sponsored workshop will facilitate the ongoing dialogue among relevant parties on issues related to Pediatric Irritable Bowel Syndrome and Pediatric Functional Constipation.

AGENDA

8:00 a.m. Welcome and Introduction: PFC and IBS-C in children
Tara Altepeter, MD

8:15 a.m. Extrapolation of Efficacy in Pediatric Drug Development
Hari Sachs, MD

8:30 a.m. Rome Criteria for PFC and IBS-C
Carlo Di Lorenzo, MD

8:55 a.m. Clinical Outcome Assessments
Elektra Papadopoulos, MD, MPH

9:15 a.m. Break

PEDIATRIC FUNCTIONAL CONSTIPATION

9:30 a.m. Diagnosis, Natural History, Available Therapies
Sam Nurko, MD

9:50 a.m. Behavioral Issues Pertaining to PFC
Miranda A.L. van Tillburg, PhD

10:10 a.m. Endpoint and trial design considerations
Marc Benniga, MD

10:35 a.m. Parent Perspective
Ceciel Rooker

10:45 a.m. PFC OPEN DISCUSSION SESSION
Moderators: Marc Benniga and Carlo Di Lorenzo.
Panelists: Nikhil Thapar, Sam Nurko, Ceciel Rooker, Ajay Kaul, and Miranda A.L. van Tillburg
AGENDA (cont.)

12:30 p.m. LUNCH BREAK

1:30 p.m. Diagnosis, Natural History, Available Therapies
Jose Garza, MD

1:50 p.m. Endpoint Considerations For Pediatric IBS-C
Miguel Saps, MD

2:15 p.m. Reliable Change Index
John Lavigne, PhD

2:25 p.m. IBS-C DISCUSSION SESSION
Moderators: Kalyan Ray Parashette and Nikhil Thapar
Panelists: Anthony Lembo, Jose Garza, Manu Sood,
Bruno Chumpitazi, John Lavigne, Robert Shulman,
Laurie Keefer, Miguel Saps, William Chey, and Ceciel Rooker

4:45 pm CLOSING REMARKS
Carlo Di Lorenzo, MD
GREAT V Speakers and Panelists

Tara Altepeter, MD, Clinical Team Leader
Division of Gastroenterology and Inborn Errors Products
Center for Drug Evaluation and Research
Food and Drug Administration

Professor Marc Benninga, MD, PhD
Pediatric Gastroenterologist
Emma Children’s Hospital
Amsterdam
The Netherlands

William D. Chey, MD, FACG, AGAF, FACP, RFF
Timothy T. Nostrant Collegiate Professor of GI & Nutrition Sciences
Director – GI Physiology Laboratory
Director – Digestive Disorders Nutrition & Lifestyle Program
Medical Director – Michigan Bowel Control Program

Bruno P. Chumpitazi MD, MPH
Director, Neurogastroenterology and Motility Program
Texas Children’s Hospital
Associate Professor of Pediatrics
Baylor College of Medicine

Carlo Di Lorenzo, MD
Chief, Division of Pediatric Gastroenterology, Hepatology and Nutrition
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Jose M. Garza MD, MS
GI Care for Kids
Medical Director, Neurogastroenterology and Motility
Children’s Healthcare of Atlanta

Ajay Kaul, MD
Professor of Clinical Pediatrics
Director, Neuro-Gastroenterology Center
Cincinnati Children’s Hospital Medical Center

Laurie Keefer, PhD
GI Psychologist
Associate Professor of Medicine
Icahn School of Medicine at Mount Sinai
New York, NY
John V. Lavigne, Ph.D., ABPP
Chief Psychologist
Lurie Children's Hospital
Professor of Psychiatry and Pediatrics
Feinberg School of Medicine, Northwestern University

Anthony Lembo, MD
Associate Professor of Medicine
Harvard Medical School

Sam Nurko, MD, MPH
Director, Center for Motility and Functional Gastrointestinal Disorders; Director, Functional Abdominal Pain Program at Boston Children’s Hospital
Professor of Pediatrics, Harvard Medical School

Elektra Papadopoulos, MD, MPH
Director, Clinical Outcome Assessments Staff,
Office of New Drugs, Center for Drug Evaluation and Research
Food and Drug Administration

Kalyan Ray Parashette, MD, MPH, FAAP, FACG
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Ceciel T. Rooker
President
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Hari Cheryl Sachs, MD
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Miguel Saps, MD
The George E. Batchelor Chair in Pediatrics
Chief of the Division of Pediatric Gastroenterology, Hepatology and Nutrition

Robert J. Shulman, MD
Professor of Pediatrics
Baylor College of Medicine

Manu Sood, MD
Professor and Chief
Division of Pediatric Gastroenterology, Hepatology and Nutrition
Medical Director of Pediatric Gastroenterology
Children’s Hospital of Wisconsin
Miranda A.L. van Tilburg, PhD
Associate Professor of Clinical Research, Campbell University
Adjunct Professor of Medicine, University of North Carolina
Affiliate Associate Professor of Social Work, University of Washington

Dr. Nikhil Thapar BM MRCP FRCPCH PhD
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