



Pediatric Research
INNOVATION FORUM



Advancing Pathways for the Development of Innovative Therapies for Children with IBD
Virtual Public Webinar Series

Real-World Data (RWD)/Real-World Evidence (RWE), Biomarkers & Endpoints

Wednesday, November 17, 2021: 9:00 – 13:00 ET/15:00 – 19:00 CET

Agenda

9:00 – 9:15 ET 15:00 – 15:15 CET	<p>Welcome—Gary Noel –<i>I-ACT for Children, Chief Medical Officer</i></p> <p>Meeting Logistics—Anushree Parikh –<i>I-ACT for Children, Clinical Project Manager</i></p> <p>Introductions—Collin Hovinga –<i>I-ACT for Children, SVP—Clinical & Scientific Development (Co-Chairs —Lissy de Ridder and Steven Steiner, and Facilitator—David Mc Neeley)</i></p>
9:16 – 10:05 ET 15:16 – 16:05 CET	<p>Introduction—"A Three-Question Summary of the Pre-Meeting Discussions" – Lissy de Ridder –<i>Associate Professor, Pediatric Gastroenterology (IBD-Treating Physician & Researcher)</i></p> <p>Working Group Summary of Key Evidence</p> <p>(1) FDA/EMA Guidelines for IBD/ Peds IBD and STRIDE II —Lissy de Ridder</p> <p>(2) Current Recommendations on RWE from EMA/FDA —Steve Steiner – <i>Professor of Pediatrics (IBD-Treating Physician & Researcher)</i></p> <p>(3) Status of Current Registries: Data Collected, Funding, Data Quality, etc. –Thomas D Walters –<i>Associate Professor (IBD-Treating Physician & Researcher)</i></p>
10:26 – 10:55 ET 16:26 – 16:55 CET	<p>Key Evidence's Panel and Q&A – (Moderated by <u>Lissy de Ridder</u> and <u>Steve Steiner</u>)</p> <p><u>Laurence Walkout</u> –<i>IBD-Treating Physician & Researcher</i>; <u>David Wohl</u> –<i>IBD-Clinical Scientist</i>; <u>David Boone</u> –<i>IBD-Scientist</i>; and <u>Peter Margolis</u> –<i>Physician & Researcher</i></p>

10:56 – 11:10 ET/ 16:56 – 17:10 CET Break

11:11 – 12:10 ET 17:11 – 18:10 CET	<p>Working Group Summary of Recommendations</p> <p>(4) RWE-Endpoints – Jeremy Adler–<i>Associate Professor (IBD-Treating Physician & Researcher)</i> and Stanley Cohen –<i>Adjunct Clinical Professor of Pediatrics (IBD-Treating Physician & Researcher)</i></p> <p>(5) Patient's Reported Outcomes (PROs) in IBD/Quality of Life (QOL) –Caeli Malloy –<i>Self-Management Interventions and QOL Researcher</i></p> <p>(6) Data Linkage: RWE with Basic/Translational Research –Eytan Wine –<i>Assistant Professor Pediatric Gastroenterology (Physician & Researcher)</i></p> <p>(7) Industry Perspective on the Benefits of RWE –Rick Strauss –<i>Pharmaceutical Industry Physician & Researcher</i> and Wendy Komocsar –<i>Pharmaceutical Industry Researcher</i></p> <p>(8) Executive Summary of Recommendations –Lissy De Ridder and Steve Steiner</p>
12:11 – 12:40 ET 18:11 – 18:40 CET	<p>Recommendations' Panel and Q&A – (Moderated by <u>Lissy De Ridder</u> and <u>Steve Steiner</u>)</p> <p><u>Laurence Walkout</u>, <u>David Wohl</u>, <u>David Boone</u>, <u>Peter Margolis</u></p>
12:41 – 12:50 ET 18:41 – 18:50 CET	<p>(9) Summary of the Feedback and Discussions –Review –Lissy De Ridder and Steve Steiner</p>
12:51 – 13:00 ET 18:51 – 19:00 CET	<p>Thank you—<i>Co-Chairs— Lissy De Ridder and Steve Steiner & Facilitator—David Mc Neeley</i></p> <p>Next Steps—Collin Hovinga –<i>I-ACT for Children, SVP—Clinical & Scientific Development</i></p> <p>Closing Remarks—Gary Noel –<i>I-ACT for Children, Chief Medical Officer</i></p>

**DRAFT FOR INFORMATION PURPOSES ONLY - FINAL AGENDA TO BE POSTED
CLOSER TO THE MEETING DATE**

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Working Group Members

<p>I-ACT for Children Facilitator David Mc Neeley, MD, MPHTM Senior Vice President, Clinical Development, Pediatrics</p>	
<p>Co-Chair Steven Steiner, MD Professor of Pediatrics Indiana University School of Medicine Director, Riley Pediatric Gastroenterology at IU North Medical Director, Pediatric Infusion Suite at IU North</p>	<p>Co-Chair Lissy de Ridder, MD, PhD Associate Professor, Pediatric Gastroenterologist at Erasmus MC, Netherlands</p>
<p>Members</p>	
<p>Jeremy Adler, MD, MSc Director, Pediatric Inflammatory Bowel Disease Program Director of Research for Pediatric Gastroenterology Clinical Associate Professor, Pediatric Gastroenterology and Health Services Research Susan B. Meister Child Health Evaluation and Research (CHEAR) Center</p>	<p>Michael Rosen, MD, MSCI Stanford University Endowed Professor for Pediatric IBD and Celiac Disease Director, Center for Pediatric IBD and Celiac Disease Division of Gastroenterology, Hepatology, and Nutrition Department of Pediatrics Stanford University School of Medicine</p>
<p>Michael Kappelman, MD, MPH Professor Dept. of Pediatrics, Division of Pediatric Gastroenterology School of Medicine University of North Carolina at Chapel Hill</p>	<p>Stanley Cohen, MD Pediatric gastroenterologist, Children’s Center for Digestive Health Care Children’s Healthcare of Atlanta Adjunct Clinical Professor of Pediatrics, Morehouse School of Medicine</p>
<p>Richard Strauss, MD Senior Director of Clinical Research, Janssen</p>	<p>Marco Schito, PhD Executive Director, Critical Path Institute US</p>
<p>Wendy Komocsar, MT(ASCP) SI Research Advisor – Medical Immunology Business Unit Eli Lilly and Company</p>	<p>Thomas D Walters, MBBS, MSc, FRACP Clinical Director, SickKids IBD Centre, Toronto Staff Gastroenterologist, Division GHN, SickKids, Toronto Associate Professor, University of Toronto, Toronto</p>
<p>Eytan Wine, MD, PhD, FCRPC Professor, Division of Pediatric Gastroenterology, Departments of Pediatrics & Physiology, University of Alberta</p>	



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