Virtual Public Webinar Series

Improving the Investigation of New Antibacterial Agents for Use in Children: Ensuring That Our Youngest Patients Also Benefit from Innovative Treatments of Infections Caused by Multi-Drug Resistant Bacteria

Webinar #1: THE CHALLENGES - Friday, 27 January 2023 (10:00-14:00 Eastern Time)

Topic	**Presenter(s)**
Introduction to Webinar Series (15 min)	Gary J. Noel, MD Chief Medical Officer, Institute for Advanced Clinical Trials for Children (I-ACT for Children)
The Global Impact of Antimicrobial Drug Resistance on Children's Health (20 min)	Julia Anna Bielicki, MD Senior Physician, Pediatrics & Pediatric Infectious Diseases University of Basel Children's Hospital Senior Lecturer in Paediatric Infectious Diseases, St George's, University of London (SGUL)
Focusing Efforts on Establishing the Safety and Efficacy of New Antibacterials in Treating Children with AMR Infections (20 min)	Phoebe Williams, FRACP DPhil Senior Lecturer, NHMRC Fellow School of Public Health, Faculty of Medicine, University of Sydney
Break (10 min)	
The Clinical Consequences of Not Having New Antibacterials Approved and Labeled for Use in Children (20 min)	Gary J. Noel, MD Chief Medical Officer, I-ACT for Children
The Challenges of Designing and Completing Clinical Trials Aimed at Supporting Regulatory Submissions for Innovative Antibacterial Use in Children (45 min)	Simon Portsmouth, MD VP, Head of Clinical Development Shionogi Inc. John Bradley, MD Distinguished Professor of Pediatrics University of California, San Diego Division of Pediatric Infectious Diseases Rady Children's Hospital
Q&A Panel Discussion* (60 min)	Moderated by Sumathi Nambiar, MD, MPH Senior Director, Child Health Innovation and Leadership Department, Johnson & Johnson

The webinar series has been supported by grants/sponsorships from the Pharmaceutical Research and Manufacturers of America (PhRMA), Shionogi, and Pfizer.

	Co-moderated by John Bradley, MD Distinguished Professor of Pediatrics University of California, San Diego Division of Pediatric Infectious Diseases Rady Children's Hospital <u>Panelist speakers include Presenters above plus</u>: Randi Gower, MHA Senior Director, Infectious Diseases Clinical Research PPD (part of Thermo Fisher Scientific) Kamal Hamed, MD, MPH Chief Medical Officer, Spero Therapeutics Mark Needles, MD Senior Clinical Reviewer, Division of Anti-infectives Office of Infectious Diseases, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration (FDA) Peter Kim, MD, MS Director, Division of Anti-Infectives Office of Infectious Diseases, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration (FDA) Mark Turner, MBChB, PhD Professor of Neonatology and Research Delivery University of Liverpool, Liverpool, UK Brandy Hicks, Parent

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Summary (5 min)	Gary J. Noel, MD Chief Medical Officer, I-ACT for Children

*Additional information to follow

Webinar #2: ADDRESSING THE CHALLENGES - Thursday, 2 February 2023 (10:00-14:30 Eastern Time)

Topic		**Presenter(s)**
Introduction (10 min)		Gary J. Noel, MD Chief Medical Officer, I-ACT for Children
Shortening the Gap between Adult and Pediatric Regulatory Approvals and Labeling	Establishing the Dose Regimen of Innovative Antibacterials in Children (30 min)	Christopher M. Rubino, PharmD Executive VP, Institute for Clinical Pharmacodynamics
	Extrapolation (20 min)	Lynne P. Yao, MD Director, Division of Pediatric and Maternal Health, Center for Drug Evaluation and Research, Food and Drug Administration (FDA)
	Involving Adolescents in Adult Phase 3 Trials and NDA/MAA Submissions (15 min)	Richard D. England, MD, PhD Clinical Development and Operations Pfizer, Inc
	Sequential Labeling and Approval (10 min)	Sumathi Nambiar, MD, MPH Senior Director, Child Health Innovation and Leadership Department, Johnson & Johnson
Building a Pediatric Anti-Infective Drug Development and Study Community (15 min)		C. Buddy Creech, MD, MPH Edie Carell Johnson Chair in Pediatrics Professor, Pediatric Infectious Diseases Vanderbilt University School of Medicine
Break (10 min)		

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Real World Data Supporting Conclusions of Safety and Efficacy (20 min)	Collin Hovinga, PharmD VP, Rare and Orphan Diseases Critical Path Institute
Developing a Pediatric Antimicrobial Clinical Trial Network (20 min)	Antonio Arrieta, MD Division Chief, Infectious Diseases Children's Hospital of Orange County (CHOC) Clinical Professor, UCI Department of Pediatrics
Prioritising Antibiotic Treatments for Neonates – Role of International Research Networks (20 min)	Seamus O'Brien, PhD Director of Research & Development Global Antibiotic Research & Development Partnership (GARDP)
Q&A Panel Discussion* (60 min)	Moderated by Gary J. Noel, MD Chief Medical Officer, I-ACT for Children Co-moderated by Christopher M. Rubino, PharmD Executive VP, Institute for Clinical Pharmacodynamics <u>Panelist speakers include Presenters above plus:</u> Ritu Banerjee, MD, PhD Professor and Interim Division Director, Pediatric Infectious Diseases Director Pediatric Antimicrobial Stewardship Program Vanderbilt University Medical Center Chair of the Pediatrics Working Group of the Antibacterial Resistance Leadership Group (ARLG) Radu Botgros, MD Senior Scientific Officer Specialist in Infectious Diseases EMA Lead on AMR (human medicines) Health Threats and Vaccines Strategy

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	Mark Needles, MD Senior Clinical Reviewer, Division of Anti-infectives Office of Infectious Diseases, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration (FDA) Peter Kim, MD, MS Director, Division of Anti-Infectives Office of Infectious Diseases, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration (FDA) Jeff Loutit, MBChB Chief Medical Officer Qpex Biopharma Michael Neely, MD, MSc, FCP Chief, Division of Infectious Diseases, Children's Hospital of Los Angeles Director, Laboratory of Applied Pharmacokinetics and Bioinformatics, The Saban Research Institute Professor of Pediatrics and Clinical Scholar, Keck School of Medicine of USC
Webinar Series Summary and Next Steps (20 min)	Gary J. Noel, MD Chief Medical Officer, I-ACT for Children

*Additional information to follow

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Panelist	Question
Webinar #1: Challenges	
Randi Gower, MHA Senior Director, Infectious Diseases Clinical Research, PPD	What are the challenges you've experienced in working with sponsors in organizing pediatric antibacterial clinical trials that you believe have had the greatest impact on trial conduct efficiency?
Kamal Hamed, MD, MPH Chief Medical Officer, Spero Therapeutics	From the perspective of a sponsor, what are the 2-3 major challenges you face in completing antibacterial clinical trials in infants and children?
Mark Needles, MD Senior Clinical Reviewer, Division of Anti-infectives, FDA	What are the most difficult challenges regulators face in assessing the safety and efficacy of new antibacterials in infants and children?
Peter Kim, MD, MS Director, Division of Anti-Infectives, FDA	How has streamlining adult programs aimed at addressing urgent unmet medical needs related to AMR affected the development of pediatric programs, particularly when the antibacterial being assessed belongs to a new class of drugs?
Mark Turner, MBChB, PhD Professor of Neonatology and Research Delivery, University of Liverpool, UK	What are the unique and most challenging issues encountered in conducting antibacterial clinical trials involving newborns?
Brandy Hicks (Parent)	Can you please describe your concerns as a parent of a child with an antibiotic-resistant bacterial infection, and how those concerns influence your willingness to have your child participate in and have access to investigational trial(s)?
Webinar #2: Addressing the Challenges/Recommendations	
Ritu Banerjee, MD, PhD Chair of the Pediatrics Working Group of the Antibacterial Resistance Leadership Group (ARLG)	What role does ARLG play in the development of and improving the appropriate use of new antibacterial therapies for infants and children with MDR infections?
Radu Botgros, MD Senior Scientific Officer, Specialist in Infectious Diseases, EMA	What are your recommendations for optimizing the alignment of pediatric antibacterial drug development plans to meet EMA and US regulators' requirements?
Mark Needles, MD Senior Clinical Reviewer, Division of Anti-infectives, FDA	What would be the pros/cons of opting for sequentially studying new antibacterials from older to younger children rather than for conducting trials that simultaneously assess children from birth through adolescence?
Peter Kim, MD, MS Director, Division of Anti-Infectives, FDA	What are the circumstances in which RWE might play a role in serving to complement or even supplant pediatric clinical trial data in pediatric development plans for new antibacterials?
Jeff Loutit, MBChB Chief Medical Officer, Qpex Biopharma	What changes could be made in the processes leading to PSP/PIP development, in organizing, or in conducting pediatric clinical trials that would have the greatest impact on the efficient completion of work required for the approval and labeling of new antibacterials?
Michael Neely, MD, MSc, FCP Chief, Division of Infectious Diseases, Children's Hospital of Los Angeles	How could we best leverage existing and/or emerging technologies to speed up completing the work needed in establishing a new antibacterial as being safe and effective in treating children?