

Development Considerations of Antimicrobial Drugs for the Treatment of Uncomplicated Urinary Tract Infections (uUTI)—June 3, 2022

Speakers and Panelists: Affiliations and Disclosures

Iain J. Abbott, MBBS, PhD

Infectious Diseases Specialist Physician & Clinical Microbiologist
Department of Infectious Diseases & Microbiology Unit, Alfred Hospital and Central Clinical School, Monash University
Melbourne, Victoria, Australia

Tomefa E. Asempa, PharmD

Associate Director, Clinical and Translational Infectious Diseases Research
Center for Anti-Infective Research and Development
Hartford Hospital
Hartford, CT

Timothy Bensman, PharmD, PhD

Clinical Pharmacology Reviewer
Division of Infectious Disease Pharmacology (DIDP), Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS), CDER, FDA
Silver Spring, MD

Radu Botgros, MD

Scientific Officer
Biological Health Threats and Vaccines Strategy
Clinical Studies and Manufacturing Task Force
European Medicines Agency (EMA)
Amsterdam, The Netherlands

Erica Brittain, PhD

Mathematical Statistician and Deputy Branch Chief
Biostatistics Research Branch
National Institute of Allergy and Infectious Diseases (NIAID), NIH
Bethesda, Maryland

Zhixia (Grace) Yan Danielsen, PhD

Deputy Division Director
DIDP, OCP
OTS, CDER, FDA
Silver Spring, MD

Dimitri Drekonja, MD, MS

Associate Professor of Medicine, University of Minnesota
Chief, Infectious Disease Section, Minneapolis VA Health Care System
Minneapolis, MN

Scott Evans, PhD, MS

Director, The Biostatistics Center
Professor and Founding Chair, Department of Biostatistics and Bioinformatics
Milken Institute School of Public Health
George Washington University
Washington, DC

Kerian Grande Roche, PhD

Reviewer, Clinical Microbiology
Division of Anti-infectives (DAI), Office of Infectious Diseases (OID)
Office of New Drugs (OND), CDER, FDA
Silver Spring, MD

Kalpana Gupta, MD, MPH

Professor of Medicine/Infectious Diseases, Boston University School of Medicine
Associate Chief of Staff and Chief of Infectious Diseases, VA Boston HealthCare System
Lecturer in Medicine, Harvard Medical School
Boston, MA

Tom Hadley

President and CCO
UTILITY therapeutics
Altrincham, Cheshire
United Kingdom WA14 2DT

Hiwot Hiruy, MD, PhD

Lead Physician
DAI, OID
OND, CDER, FDA
Silver Spring, MD

Thomas Hooton, MD

Professor, Clinical Medicine
Miller School of Medicine
University of Miami
Miami, FL

Dmitri Iarikov, MD, PhD

Deputy Division Director
DAI, OID
OND, CDER, FDA
Silver Spring, MD

Salim Janmohamed, BSc, MBBS

Senior Clinical Director,
Development Clinical Sciences, R&D, GlaxoSmithKline
980 Great West Road
Brentford
Middlesex TW8 9GS
United Kingdom

Nadia Kadry, PhD

Postdoctoral Fellow
DAI, OID
OND, CDER, FDA
Silver Spring, MD

Peter Kim, MD, MS

Division Director
DAI, OID
OND, CDER, FDA
Silver Spring, MD

Xianbin Li, PhD

Reviewer, Biostatistics
Division IV, Office of Biostatistics
OTS, CDER, FDA
Silver Spring, MD

Cristina Miglis, PharmD, MS, BCPS

Reviewer, Clinical Pharmacology
Division of Infectious Disease Pharmacology (DIDP), Office of Clinical Pharmacology (OCP)
OTS, CDER, FDA
Silver Spring, MD

Harry L.T. Mobley, PhD

Frederick G. Novy Distinguished University Professor
Department of Microbiology and Immunology
University of Michigan Medical School
Ann Arbor, MI

Mukil Natarajan, MD

Clinical Reviewer
DAI, OID
OND, CDER, FDA
Silver Spring, MD

Valerie Price

Patient Representative
Quebec City, Canada

Sailaja Puttagunta, MD

Chief Medical Officer
Iterum Therapeutics
Old Saybrook, CT

Jason A. Roberts PhD, B Pharm (Hons), B App Sc, FSHP, FISAC

Acting Director
University of Queensland Centre for Clinical Research, The University of Queensland,
Royal Brisbane and Women's Hospital, Butterfield St
Brisbane, Queensland

Keith A. Rodvold, Pharm.D., FCCP, FIDSA

UIC Distinguished Professor
Co-Director, Section of Infectious Diseases Pharmacotherapy
Colleges of Pharmacy and Medicine
University of Illinois Chicago (UIC)
Chicago, IL

Dan Rubin, PhD

Statistical Team Leader
Division of Biometrics IV, Office of Biostatistics
OTS, CDER, FDA
Silver Spring, MD

Nicole Scangarella-Oman, MS

Scientific Director
Clinical Microbiology
Infectious Diseases Research Unit (IDRU)
GlaxoSmithKline Collegeville, PA

Jalal Sheikh, PhD

Clinical Microbiology Reviewer
DAI, OID
OND, CDER, FDA
Silver Spring, MD

Ann Stapleton, MD, FACP, FIDSA

Professor Emeritus of Medicine, University of Washington
Program Director, Infectious Disease Fellowship and Attending Physician
Eisenhower Health
Rancho Mirage, CA

Barbara Trautner, MD, PhD

Professor, Infectious Diseases, Department of Medicine, Baylor College of Medicine
Deputy Associate Chief of Staff for Clinical Research, Michael E. DeBakey VA Medical Center
Director, Network of Dedicated Enrollment Sites (NODES), Michael E. DeBakey VA Medical Center
Houston TX

Janice Tufte

Patient Representative
Seattle, WA

Voluntary Disclosures

Iain J. Abbott: Advisory Board consultancy for Merck Sharp & Dohme (Australia) (June 2021).

Tomafa Asempa: received research grants from the FDA (CDER/OID), Spero Therapeutics, and Venatorx.

Scott Evans: receives grant support from the National Institutes of Health (NIH) and Aceragen. He receives royalties from Taylor and Francis and funding for editorial activities from DeGruyter. He has been a Board member for the American Statistical Association, the Society for Clinical Trials, and Frontier Science Foundation. He has received travel support or honorariums from the NIH; FDA; Council for International Organizations of Medical Sciences (CIOMS), the American Statistical Association; Osaka University; National Cerebral and Cardiovascular Center of Japan; Society for Clinical Trials; the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTION); the Deming Conference on Applied Statistics; the International Chinese Statistical Association; and the Clinical Trials Transformation Initiative (CTTI). He has been a consultant to the Breast International Group (BIG), Janssen, Takeda, Pfizer, Roche, Novartis, Genentech, AstraZeneca, Teva, Vir, Tracon, Candel, Microbiotix, Endologix, Chemocentryx, Becton Dickenson, Atricure, International Drug Development Institute, Akouos, Apellis, DayOneBio, Alexion, Roivant, Neovasc, Nobel Pharma, Horizon, Rakuten, Duke University, University of Pennsylvania, Nuvelution, Abbvie, Clover, FHI Clinical, Lung Biotech, and SAB Biopharm.

Kalpna Gupta: receives research support on the topic of UTI from VA Health Services Research and Development. She has served as a consultant for Qiagen, Utility Therapeutics, Nabriva Therapeutics, GlaxoSmithKline, Rebiotix, Spero Therapeutics, First Light Diagnostics, Shionogi, Iterum Therapeutics, Paratek Pharmaceuticals. She receives royalties from UpToDate. She receives honoraria and consulting fees from Pri-Med Institute for development and delivery of Continuing Medical Education material. She receives honoraria (deferred) from Harrison's Textbook of Internal Medicine. She is the Chair of the current Infectious Diseases Guideline for Treatment of UTI and a member of the IDSA UTI Guideline update committee.

Salim Janmohamed: Full time employee of GlaxoSmithKline

Harry Mobley: has served as consultant for GlaxoSmithKline

Sailaja Puttagunta: is an employee and shareholder of Iterum Therapeutics

Jason Roberts: Consultancies/Advisory Boards – Wolters Kluwer (2022); Gilead (2021); Summit (2021); Pfizer (2020); Sandoz (2020); MSD (2019)

Speaking Fees – MSD (2022); Pfizer (2021), Cipla (2021)

Industry Grants – British Society of Antimicrobial Chemotherapy (2021) QPEX (2021); Biomerieux (2019)

Keith Rodvold: received consulting fees from Janssen Pharmaceutica N.V. as a member of a data safety monitoring board. He has received consulting fees from Bria Bioscience, Clinartis LLC (for research studies with Sinovent, Spero Therapeutics, and Venatorx Pharmaceuticals), Shionogi Inc., Spero Therapeutics, Qpex/The Medicines Company, and Utility Therapeutics.

Nicole Scangarella-Oman: full time employee and shareholder of GlaxoSmithKline.

Barbara Trautner: is a full-time employee of Michael E. DeBakey VA Medical Center and has received research funding for a clinical trial from Genentech. Dr. Trautner also served as a one-time consultant for Genentech.