

**DEVELOPMENT OF NEW TUBERCULOSIS TREATMENT REGIMENS—  
SCIENTIFIC AND CLINICAL TRIAL DESIGN CONSIDERATIONS; PUBLIC  
WORKSHOP—July 19, 2017**

**Speakers and Panelists**

**Cathy Bansbach, PhD**

Portfolio and Platform Lead  
Global Health - TB  
Bill & Melinda Gates Foundation, Seattle, Washington

**Dakshina Chilukuri, Ph.D.**

Pharmacologist  
Office of Clinical Pharmacology, Office of Translational Sciences  
CDER, FDA, Silver Spring, MD

**Edward Cox, MD, MPH**

Director  
Office of Antimicrobial Products (OAP)  
CDER, FDA, Silver Spring, MD

**John Farley, MD, MPH**

Deputy Director  
Office of Antimicrobial Products (OAP)  
CDER, FDA, Silver Spring, MD

**Lawrence Geiter, PhD**

Vice President Global Clinical Development  
Otsuka, Rockville, Maryland

**Steve Gitterman, MD, PhD**

Deputy Director  
Division of Microbiology Devices (DMD)  
Office of In Vitro Diagnostics and Radiological  
Health (OIR)  
CDRH, FDA, Silver Spring, Maryland

**Debra Hanna, PhD**

Executive Director  
Critical Path to TB Drug Regimens (CPTR)  
Critical Path Institute, Tucson, Arizona

**Karen Higgins, Sc.D.**

Mathematical Statistician  
Division of Anti-Infective Products (DAIP), OAP  
CDER, FDA, Silver Spring, Maryland

**David Hughes, MD, MPH**

Senior Global Program Head – Infectious Diseases  
Novartis Pharma AG, Basel, Switzerland

**Dmitri Iarikov, MD**

Deputy Director  
DAIP, OAP  
FDA, Silver Spring, MD

**Erica Lessem, MPH**

Director, TB/HIV Project  
Treatment Action Group  
New York City, New York

**Christian Lienhardt, MD, PhD**

Team lead, Research for TB Elimination  
Global TB Programme (GTB)  
WHO, Geneva, Switzerland

**Philip LoBue, MD**

Director  
Division of Tuberculosis Elimination  
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention  
Centers for Disease Control and Prevention, Atlanta, GA

**Payam Nahid, MD, MPH**

Professor  
Division of Pulmonary and Critical Care Medicine  
UCSF School of Medicine, San Francisco, CA

**Sumathi Nambiar, MD, MPH**

Director  
DAIP, OAP  
FDA, Silver Spring, MD

**Eric Nuermberger, MD**

Associate Professor of Medicine  
Division of Infectious Diseases  
Johns Hopkins University School of Medicine, Baltimore, MD

**Sheral Patel, MD**

Medical Officer  
DAIP, OAP  
FDA, Silver Spring, MD

**Charles Peloquin, PharmD**

Professor, and Director, Infectious Disease Pharmacokinetics Lab  
College of Pharmacy, and  
Emerging Pathogens Institute  
University of Florida, Gainesville, FL

**Patrick Phillips, PhD**

Assistant Professor  
Department of Medicine  
Division of Pulmonary & Critical Care Medicine  
Department of Epidemiology and Biostatistics  
UCSF, San Francisco, CA

**Marco Schito, PhD**

Associate Scientific Director  
Critical Path to TB Drug Regimens (CPTR)  
Critical Path Institute, Tucson, Arizona

**Mel Spigelman, MD**

President and CEO  
Global Alliance for TB Drug Development, New York, NY

**Jeffrey Starke, MD**

Professor of Pediatrics, Baylor College of Medicine  
Director, Children's Tuberculosis Center  
Baylor College of Medicine, Houston, TX

**Joe Toerner, MD, MPH**

Deputy Director of Safety  
DAIP, OAP  
FDA, Silver Spring, MD

**Andrew Vernon, MD, MHS**

Chief  
Clinical Research Branch, Division of Tuberculosis Elimination  
Centers for Disease Control and Prevention, Atlanta, GA

**Charles Wells, MD, Sanofi**

Head of Development/Associate Vice President  
Infectious Diseases Therapeutic Unit  
Sanofi, Bridgewater, NJ

**Yuliya Yasinskaya, MD**

Medical Team Leader  
DAIP, OAP  
FDA, Silver Spring, MD

**Disclosures**

Dr. Spigelman is a full time employee of the Global Alliance for TB Drug Development.

Dr. Vernon works at CDC in a branch which supports clinical trials in tuberculosis. Several pharmaceutical companies have provided some support to these trials, in particular supplies of medications. One company, Sanofi, has also made donations to the CDC Foundation to support trials involving rifapentine.

Dr. LoBue has no personal disclosures. The division he directs has received support for tuberculosis clinical trials, in particular supplies of medications, from several pharmaceutical companies. One company, Sanofi, has also made donations to the CDC Foundation to support trials involving rifapentine.

Dr. Wells is a full time employee of Sanofi.

Dr. Hughes is a full time employee of Novartis Pharma AG.

Dr. Schito is a full time employee at the Critical Path Institute and is the scientific director of the Critical Path to TB Drug Regimens funded by the Bill & Melinda Gates Foundation.

Dr. Hanna is a full time employee at the Critical Path Institute and is the executive director of the Critical Path to TB Drug Regimens funded by the Bill & Melinda Gates Foundation.

Dr. Nuermberger has active research grants from the Global Alliance for TB Drug Development and Janssen Pharmaceuticals.