

Improving Regulatory Practices to Sustain Antibiotic Innovation

Webinar Agenda | Tuesday, December 12, 2023 | 1:00 – 2:15 pm ET

About the Webinar

The final installment of our three-part webinar series focuses on novel antibiotic development with emphasis on clinical trials and regulatory practices. Duke-Margolis invites policymakers and those invested in combating antibiotic resistant bacteria to consider developmental and regulatory approaches to sustain antibiotic innovation. Expert speakers will highlight:

- Regulatory expectations and their impact on clinical trials for novel antibiotics
- International regulatory harmonization and clinical trials beyond the United States
- Developmental partnerships toward novel antibiotics for unmet needs
- Post-market evidence development and the potential impact of real-world evidence (RWE)

Discussion will inform policy approaches to advance clinical trials, evidence development, and regulatory practices to sustain the market for critically needed novel antibiotics.

1:00 pm **Welcome and Opening Remarks**

Marianne Hamilton Lopez, Senior Research Director, Duke-Margolis Center for Health Policy

1:05 pm **Keynote Conversation**

Dr. Hamilton Lopez will moderate a keynote conversation with Dr. John Farley, Director of the Office of Infectious Diseases in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA).

- **John Farley**, U.S. Food and Drug Administration (FDA)

1:15 pm **Moderated Panel Discussion**

Moderator: Marianne Hamilton Lopez

Panelists will discuss policy approaches to advance clinical trials, evidence development, and regulatory practices for novel antibiotic innovation.

Webinar Panelists

- **Erin Duffy**, Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X)
- **Anthony McDonnell**, Center for Global Development
- **Sumathi Nambiar**, Johnson & Johnson
- **Tammy Pillay**, Global Antibiotic R&D Partnership (GARDP)

2:10 pm **Closing Remarks**

Marianne Hamilton Lopez

2:15 pm **Adjournment**

Funding Acknowledgement & Disclaimer

The AMR Action Fund provided funding for this Duke-Margolis webinar. However, the views and conclusions shared by webinar speakers are solely those of the speakers and do not reflect the official position nor endorsement of the AMR Action Fund or any organization associated with the speakers.