

Advancing Bacterial Diagnostic Development

Duke-Margolis Center for Health Policy

Webinar Agenda | September 15, 2022 | 2:00 – 4:00 pm ET

2:00 pm **Welcome and Opening Remarks**

Mark McClellan, Director, Duke-Margolis Center for Health Policy

2:10 pm **Session 1: Developing Bacterial Diagnostics that Combat AMR — Regulatory Review and Clinical Utility**

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

Panelists will focus on how diagnostic developers generate evidence for regulatory review and explore the potential to harmonize measures of clinical utility that facilitate regulatory review, health care provider utilization, and payer coverage decisions.

Discussion Questions

1. What does the FDA require to clear a new bacterial diagnostic test that identifies drug-resistant infections or antibiotic susceptibilities?
2. What strategies might developers, regulators, and others pursue to improve the efficiency of bacterial diagnostic development?
 - a. Are there regulatory actions that might streamline diagnostic development and regulatory review?
 - b. Can public-private partnerships incentivize diagnostic development by reducing R&D costs or regulatory burden?
3. Is data generated for FDA clearance useful for clinicians treating drug-resistant infections?

Panel Discussion

- **Melodie Domurad**, Vice President, Medical Affairs, Day Zero Diagnostics
- **Vance Fowler**, Florence McAlister Distinguished Professor of Medicine, Duke University School of Medicine
- **Robin Patel**, Elizabeth P. and Robert E. Allen Professor of Individualized Medicine, Mayo Clinic
- **Fred Tenover**, Vice President, Scientific Affairs, Cepheid

3:15 pm **Session 2: Sustaining Bacterial Diagnostics that Combat AMR — Market Access, Incentives, and Diagnostic Stewardship**

Moderator: Mark McClellan, Director, Duke-Margolis Center for Health Policy

Panelists will focus on the market for bacterial diagnostics, including general bacterial diagnostics and those that identify drug-resistant infections and antibiotic susceptibilities. Panelists will discuss the key contributors to diagnostic market uncertainty and financial pressures on diagnostic development. Panelists will also discuss opportunities to facilitate and sustain market access through administrative and regulatory actions, incentives for diagnostic stewardship, and modified payment mechanisms.

Discussion Questions

1. What administrative and regulatory actions or incentives might streamline diagnostic market access and payer coverage decisions?
2. What innovative payment mechanisms might improve payment for diagnostics that combat drug-resistant infections?
3. How can policymakers support rapid diagnostic capacity and diagnostic stewardship to combat drug-resistant infections?
4. Are there circumstances that warrant the coordinated development and clinical use of a novel antibiotic and a complementary bacterial diagnostic?

Panel Discussion

- **Mara Aspinall**, Managing Director, Health Catalysts Group & Professor of Practice, College of Health Solutions, Arizona State University
- **Mark Miller**, Executive VP, Chief Medical Officer, bioMérieux
- **Fenan Solomon**, Director, Market Access & Payment Policy, BD
- **Betsy Wonderly-Trainor**, Alliance Director, CARB-X

3:55 pm **Closing Remarks**

Mark McClellan, Director, Duke-Margolis Center for Health Policy

4:00 pm **Adjournment**