Meeting objective: A number of factors diminish the success of rapid diagnostics for bacterial diseases, including technical challenges with developing devices that are rapid, sensitive, and specific; high costs of clinical trials; complexities of hospital adoption; and uncertain coverage and reimbursement. This meeting will explore some of the challenges associated with bringing a rapid diagnostic device for bacterial disease to market, and will identify steps that can be taken to improve the viability of these products.

8:30am Registration

9:00am Welcome and overview

Mark McClellan, Robert J. Margolis, MD, Center for Health Policy, Duke University
Gregory Daniel, Robert J. Margolis, MD, Center for Health Policy, Duke University

9:15am FDA opening remarks

Ed Cox, Office of Antimicrobial Products, Center for Drug Evaluation and Research, U.S. Food and Drug Administration (FDA)

9:20am Session I: Defining the needs of users of diagnostic results

Presenters:
- Ephraim Tsalik, Duke University and Durham VA Medical Center
- Angela Caliendo, Alpert Medical School of Brown University and Rhode Island Hospital
- Nicholas Anderson, Polarity TE (formerly Intermountain Healthcare)

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

10:30am Break

10:45am Session II: Overcoming the challenges associated with the clinical development of a rapid diagnostic for bacterial diseases

Opening presentation:
- Vance Fowler, Duke University Medical Center

Moderator: Gregory Daniel, Duke-Margolis Center for Health Policy

Panelists:
- Vance Fowler, Duke University Medical Center
- Jorge Villacian, Janssen
- Sheila Farnham, bioMerieux
- Chris Bernhard, Curetis, Inc
- Tobi Karchmer, BD

12:00pm Lunch (Off-site)
1:00pm  
**Session III: Balancing risk and uncertainty in the development and use of diagnostics**

**Opening presentation:**
- Steve Gitterman, Division of Microbiology, Center for Devices and Radiological Health, FDA
- Fred Tenover, Cepheid

**Moderator:** Gregory Daniel, Duke-Margolis Center for Health Policy

**Panelists:**
- Steve Gitterman, FDA
- Fred Tenover, Cepheid
- Ed Cox, FDA
- Evan Jones, OpGen and jVen Capital, LLC

2:00pm  
**Session IV: Addressing the post-market economic challenges to diagnostics development**

**Opening presentation:**
- Hui-Hsing Wong, Office of the Assistant Secretary for Planning and Evaluation (ASPE)
- Andrew Fish, AdvaMedDX

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

**Panelists:**
- Hui-Hsing Wong, ASPE
- Andrew Fish, AdvaMedDX
- Louis Jacques, ADVI

3:15pm  
**Break**

3:30pm  
**Session V: Prioritizing actions to incentivize the development of rapid diagnostics for bacterial infection**

**Panelists:**
- Angela Caliendo, Alpert Medical School of Brown University
- Ed Cox, FDA
- Steve Gitterman, FDA
- John McInnes, Division of Outpatient Care, Hospital and Ambulatory Policy Group, Center for Medicare, Centers for Medicare and Medicaid Services

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

4:20 – 4:30pm  
**Next steps and closing remarks**

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