Welcome!

Enhancing the Clinical Trial Enterprise for Antibacterial Drug Development in the United States

FDA-IDSA-Pew Public Workshop

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CDC’s 2019 AR Threats Report:
PREVENTION WORKS.

- **18%** fewer deaths from antibiotic resistance overall since 2013 report
- **28%** fewer deaths from antibiotic resistance in hospitals since 2013 report

DECREASES IN INFECTIONS CAUSED BY:

- **41%** Vancomycin-resistant Enterococcus
- **33%** Carbapenem-resistant Acinetobacter
- **29%** Multidrug-resistant Pseudomonas aeruginosa
- **25%** Drug-resistant Candida
- **21%** Methicillin-resistant Staphylococcus aureus (MRSA)

STABLE
- Carbapenem-resistant Enterobacteriaceae (CRE) & drug-resistant tuberculosis (TB disease cases)

Despite these gains, CDC’s 2019 AR Threats Report shows additional actions are needed to protect people.

- **2.8M+** antibiotic-resistant infections each year
- **35k+** deaths from antibiotic resistance each year

Plus: 223,900 cases and 12,800 deaths from Clostridioides difficile

INCREASES IN INFECTIONS CAUSED BY:

- **315%** Erythromycin-resistant invasive group A strep
- **124%** Drug-resistant Neisseria gonorrhoeae
- **50%** ESBL-producing Enterobacteriaceae
Agenda for the Workshop

Day 1
• Antibacterial trials – current state and resources
• Industry roundtable – needs and challenges
• Realistic options for enhancing the enterprise

Day 2
• Strategies and new approaches to better support the enterprise
Discussion Topics

• Serious infections in need of feasible approaches to obtaining clinical trial data
• Trial designs of the future for new agents targeting Gram-negative pathogens
• Feasible approaches to updating treatment guidelines
• A clinical trial network that would maximize impact
• Innovations in statistical approaches, design, and endpoints to prioritize