

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 <i>Enterococcus</i>	↓ 33% Carbapenem-resistant <i>Acinetobacter</i>
↓ 29% Multidrug-resistant <i>Pseudomonas aeruginosa</i>	↓ 25% Drug-resistant <i>Candida</i>
↓ 21% Methicillin-resistant <i>Staphylococcus aureus</i> (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 <i>Neisseria gonorrhoeae</i>	↑ 50% ESBL-producing Enterobacteriaceae
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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

