AGENDA

FDA-IDSA-NIH-Pew Public Workshop

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

Day 1: November 18, 2019

FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Great Room, Silver Spring, MD 20993.

Goals of the Workshop: This workshop will bring together a diverse array of subject matter experts in the fields of infectious diseases (ID), from academia, industry and other government agencies to better understand the current state of U.S. based antibacterial drug development and to consider some potential strategies to enhance antibacterial drug development:

- Review current state of antibacterial drug development
- Obtain stakeholder perspectives on what data would be informative from development programs for new antibacterial drugs
- Evaluation of strategies to support generation of the desired data from antibacterial drug development programs
    - The role of novel endpoints
    - The role of novel statistical methods (e.g., Bayesian analytical techniques)
    - Ways to facilitate clinical trial conduct (e.g., enhancing enrollment, clinical trial networks)
    - Role of scientific journals in the dissemination of information/publication of data
    - Timely and regular updates of guidelines as new data emerge

Time	***Topic***	***Speaker(s) and Affiliation***
7:30 AM-8:30 AM	Registration	
8:30 AM-8:40 AM	Welcome and Panel Introduction	John Farley, FDA
Session 1: Antibacterial Trials: Current State and Resources **Session Chair and Co-Chair: John Farley (Chair), Erin Duffy (Co-Chair)**		

8:40 AM-9:15 AM	Overview of Antibacterial Trials Geographic Shifts in Antibacterial Drug Trial Enrollment: Implications for Generalizability	Sumathi Nambiar, FDA Stephen Bart, FDA
9:15 AM-9:30 AM	Current Constraints in Antibacterial Drug Development: Clinician's Perspective	Helen Boucher, Tufts University
9:30 AM-9:45 AM	Role of Antibiotic Stewardship Programs in Utilization of Antibacterial Drugs	Sara Cosgrove, Johns Hopkins University
9:45 AM-10:00 AM	Patient Perspective on Clinical Trial Participation	Amy Leitman, NTM Info and Research
10:00 AM-10:15 AM	Review of Antibiotics in Clinical Development Pipeline	Wes Kim, PEW
10:15 AM-10:30 AM	**BREAK**	
10:30 AM-11:15 AM	Current Federal Efforts to Support Antibacterial Drug Development	Dennis Dixon, NIAID Erin Duffy, Carb-X Mark Albrecht, BARDA
11:15 AM-11:30 AM	Economic Challenges and Considerations in Antibacterial Drug Development	Kevin Outterson, CARB-X
11:30 AM-11:50 PM	Clarifying Questions	
11:50-12:50 PM	**LUNCH**	
Session 1 (cont.): Industry Roundtable on Needs and Challenges Around Antibacterial Trials **Session Chair and Co-Chair: Kevin Outterson (Chair), Amanda Jezek (Co-Chair)**		

12:50 PM-2:40 PM	**Moderated Session: Industry Perspective on Current Challenges of Antibacterial Clinical Trials** 12:50 PM-1:25 PM: Company Talks 1:25 PM-2:40 PM: Roundtable Discussion (Moderator: Kevin Outterson)	Ryan Cirz, Achaogen Manos Perros, Entasis Nick Kartsonis, Merck David Melnick, Spero Rienk Pypstra, Pfizer Sue Cammarata, Melinta
2:40 PM-3:00 PM	Formal Public Comments	
3:00 PM-3:15 PM	**BREAK**	
Session 2A: Antibacterial Clinical Trial Innovation: What Are the Realistic Options for Enhancing the Antibacterial Clinical Trial Enterprise? **Session Chair and Co-Chair: Sumathi Nambiar (Chair), Helen Boucher (Co-Chair)**		
3:15 PM-3:30 PM	Impact of Publications on Clinical Care and Research of Antibacterial Drugs	Lindsey Baden, Harvard University
3:30 PM-3:45 PM	Updating Professional Society Guidelines for Bacterial Infections	Cynthia Sears, Johns Hopkins University
3:45 PM-5:10 PM	**Moderated Panel Discussion (with Audience Q&A)** 1. What are some serious infections (e.g. S. aureus bacteremia, prosthetic joint infections, DFI) for which there is a clinical need for new therapies? What are some feasible approaches to obtaining clinical trial data in patients with these types of infections?	All Panelists

	2. As there are some approved therapies to treat CRE infections (and others in development), future NI trials could enrich for such organisms. For a future new agent targeting Gram-negative pathogens that retains activity in the presence of certain resistance mechanisms, what should the design of clinical trials look like to get interpretable data? Please comment on the choice of comparator, patient population and enrichment strategies. 3. What are some feasible approaches to updating treatment guidelines for serious bacterial infections more frequently?	
5:10 PM-5:15 PM	Closing Remarks	

Day 2: November 19, 2019

FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Great Room, Silver Spring, MD 20993.

Time	***Topic***	***Speaker(s) and Affiliation***
7:30 AM-8:30 AM	Registration	
Session 2B: Strategies to Better Support Antibacterial Clinical Trials **Session Chair and Co-Chair: Dan Rubin (Chair), Jane Knisely (Co-Chair)**		
8:30 AM-8:45 AM	What Do We Need, What Should We Be Doing, Who Should be Doing It?	John Rex, F2G
8:45 AM-9:00 AM	Pitfalls and Progress in Getting Clinicians the Trials They Need	Vance Fowler, Duke University
9:00 AM-9:15 AM	Enhancing Clinical Trial Enrollment Strategies	Pamela Tenaerts, CTTI
9:15 AM-9:30 AM	International Clinical Trial Networks	Chibuzor Uchea, Wellcome Trust
9:30 AM-9:45 AM	**BREAK**	
9:45 AM-11:15 AM	**Statistical Considerations for Conducting Antibacterial Clinical Trials** FDA Statistical Perspective (15 min) Statistical Approaches for Antibiotic Trials (20 min) Radical Pragmatism: DOOR and SMART COMPASS for the Evaluation of Antibiotics (20 min)	 Dan Rubin, FDA Roger Lewis, Berry Consultants Scott Evans, George Washington University

	An Alternative Design for Trials of Patients with Rare Pathogens: Conducting Trials with Difficult to Find Cases (20 min) Q&A (15 min)	Aaron Dane, DaneStat Consulting Limited
11:15 AM-12:15 PM	**Moderated Panel Discussion (with Audience Q&A)** 1. What innovations, to make clinical trials of new antibacterial drugs more feasible or interpretable, should be prioritized for adoption? 2. What might be some considerations to facilitate drug development for the difficult to study conditions, (e.g., trial design, endpoint development for serious infectious/unmet need, who develops the endpoints, etc)? 3. How could a clinical trial network to support antibacterial drug development be designed to maximize impact?	All Panelists
12:15 PM-12:45 PM	Summary of Days 1 and Days 2	John Rex, F2G TBD
12:45 PM-1:00 PM	Closing Remarks	

Panelists (Includes Speakers):

FDA: John Farley, Sumathi Nambiar, Dan Rubin, Rebecca Reindel

External:

Dennis Dixon	NIAID
Jane Knisely	NIAID
Kevin Outterson	CARB-X (Day 1)
Erin Duffy	CARB-X
Mark Albrecht	BARDA
Aaron Dane	DaneStat Consulting
Roger Lewis	Berry Consultants
Pamela Tenaerts	CTTI
Chibuzor Uchea	Wellcome Trust
Amanda Jezek	IDSA
Wes Kim	Pew Trusts
Manos Perros	Entasis Therapeutics
Ryan Cirz	Achaogen
Sue Cammarata	Melinta
David Melnick	Spero Therapeutics
Rienk Pypstra	Pfizer
Nick Kartsonis	Merck
John Rex	F2G
Helen Boucher	Tufts University School of Medicine
Scott Evans	George Washington University (Day 2)
Amy Leitman	NTM Info & Research, Patient Representative
Lindsey Baden	Harvard Medical School
Cindy Sears	Johns Hopkins University
Vance Fowler	Duke University
Sarah Cosgrove	Johns Hopkins

Speaker slides and other workshop material can be found at: https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/enhancing-clinical-trial-enterprise-antibacterial-drug-development-united-states-11182019-11192019

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