



AGENDA

FDA Public Workshop

Advancing Animal Models for Antibacterial Drug Development

March 5, 2020

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

<i>Time</i>	<i>Topic</i>	<i>Speaker(s) and Affiliation</i>
7:30-8:30 AM	Registration	
8:30 AM-8:45 AM	Introductory Remarks and Panel Introduction	John Farley, FDA
8:45 AM-9:00 AM	Assessing Animal Models of Bacterial Pneumonia Used in Investigational New Drug Applications for the Treatment of Bacterial Pneumonia	Ursula Waack, FDA ORISE Fellow
9:15 AM-9:25 AM	Humanizing Animal Models – An Overview	Abhay Joshi, FDA
9:25 AM-9:35 AM	Preclinical Services by NIAID	Judith Hewitt, NIH/NIAID
9:35 AM-9:45 AM	CARB-X Clinical Portfolio	Tina Guina, BARDA
9:45 AM-10:00 AM	Break	
Session 1: Advancing Development of Murine Animal Models		
Session Co-Chairs: TBD		
10:00 AM-10:20 AM	Eurofin’s Development of Murine Model	Lynn Miesel, Pharmacology Discovery Services (PDS)
10:20 AM-10:50 AM	Development and PK Challenges of a Murine Model for <i>Acinetobacter baumannii</i> infection	Brian Luna, University of Southern California Jürgen Bulitta, University of Florida

10:50 AM-11:15 AM	Development and PK challenges of a Murine Model for <i>Pseudomonas aeruginosa</i>	Matthew Lawrenz, University of Louisville Alexander Lepak, University of Wisconsin
11:15 AM-12:00 PM	Moderated Panel Discussion TBD	All Panelists
12:00 PM-12:15 PM	Open Public Comments	
12:15 PM-1:15 PM	LUNCH	
Session 2: Advancing Development of Larger Animal Models		
Session Co-Chairs: TBD		
1:15 PM-1:35 PM	Development and PK Challenges of a Rabbit Meningoencephalitis Model	William Hope, University of Liverpool
1:35 PM-1:55 PM	Development and Challenges of a Rabbit Model System of Pneumonia Infection	Thomas Walsh, Weill Cornell Medical College, Cornell University
1:55 PM-2:25 PM	Development and PK Challenges of an Acute Pneumonia and Ventilator-Associated Pneumonia Model in Rabbits	Binh Diep, University of California – San Francisco William Weiss, University of North Texas
2:25 PM-2:45 PM	Advancement of a Porcine Ventilator-Associated Pneumonia Model	Andrew Phipps, Tunnell Government Services - BARDA
2:45 PM-3:00 PM	<i>BREAK</i>	
3:00 PM-3:45 PM	Moderated Panel Discussion TBD	All Panelists
3:45 PM-4:00 PM	Summaries and Closing Remarks	Edward Weinstein, FDA



Panelists:

External: Jürgen Bulitta, Cara Cassino, Binh Diep, Tina Guina, Judith Hewitt, Jennifer Hoover, William Hope, Marina Kozak, Matthew Lawrenz, Alexander Lepak, Brian Luna, Lynn Miesel, Eric Nuermberger, Andrew Phipps, Brad Spellberg, Thomas Walsh, William Weiss

FDA: John Farley, Abhay Joshi, Sumathi Nambiar, Kellie Reynolds, Simone Shurland, Ursula Waack (CDER ORISE Fellow), Edward Weinstein

Speaker slides and other workshop material can be found at:

<https://www.fda.gov/drugs/news-events-human-drugs/advancing-animal-models-antibacterial-drug-development-03052020-03052020>

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