



# 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, MD, MPH, 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, MS, PhD, FDA ORISE Fellow
9:15 AM-9:25 AM	Humanizing Animal Models – An Overview	Abhay Joshi, PhD, FDA
9:25 AM-9:35 AM	Preclinical Services by NIAID	Judith Hewitt, PhD, NIH/NIAID
9:35 AM-9:45 AM	CARB-X Clinical Portfolio	Tina Guina, PhD, BARDA
<b>Session 1: Advancing Development of Murine Animal Models</b>		
<b>Session Co-Chairs:</b> TBD (FDA), TBD (Non-FDA)		
9:45 AM – 10:05 AM	<b>Eurofin’s Development of the Murine Model</b>	Lynn Miesel, PhD, Pharmacology Discovery Services (PDS)
10:05 AM-10:35 AM	Development and (PK) Challenges of a Murine Model for <i>Acinetobacter baumannii</i> infection	Brian Luna, PhD, University of Southern California  Jürgen Bulitta PhD, University of Florida



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



**Panelists:**

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

**FDA:** John Farley, Abhay Joshi, John Lazor, Sumathi Nambiar, 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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