



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)
9:00 AM-9:10 AM	Pharmacokinetic Considerations in Advancing Animal Models for Antibacterial Drug Development	Abhay Joshi, FDA
9:10 AM-9:20 AM	Preclinical Services by NIAID	Judith Hewitt, NIH/NIAID
9:20 AM-9:30 AM	CARB-X Portfolio	Tina Guina, BARDA
9:30 AM-9:45 AM	Break	
<i>Session 1: Advancing Development of Murine Animal Models</i>		
Session Co-Chairs: Yuliya Yasinskaya (Chair), Jennifer Hoover (Co-Chair)		
9:45 AM-10:05 AM	Development of Murine Lung Infection Models	Lynn Miesel, Eurofins Scientific
10:05 AM-10:35 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
10:35 AM-11:00 AM	Development and PK challenges of a Murine Model for <i>Pseudomonas aeruginosa</i>	Matthew Lawrenz, University of Louisville Alexander Lepak, University of Wisconsin
11:00 AM-11:45 AM	Moderated Panel Discussion <ol style="list-style-type: none">1. What are the drug development community perspectives on the use and development of murine animal models?2. How can these murine animal models be further refined to be more relevant to human disease?3. What are the panel's thoughts with respect to achieving humanized exposures in plasma for murine animal models and other pharmacokinetic related aspects discussed in the AM Session presentations?	All Panelists
11:45 AM-12:00 PM	Open Public Comments	
12:00 PM-1:00 PM	LUNCH	
Session 2: Advancing Development of Larger Animal Models		
Session Co-Chairs: John Farley (Chair), Marina Kozak (Co-Chair)		
1:00 PM-1:20 PM	Development and PK Challenges of a Rabbit Meningoencephalitis Model	William Hope, University of Liverpool

1:20 PM-1:40 PM	Development and Challenges of a Rabbit Model System of Pneumonia Infection	Thomas Walsh, Weill Cornell Medical College, Cornell University
1:40 PM-2:10 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
2:10 PM-2:30 PM	Porcine Animal Model of Ventilator-Associated Bacterial Pneumonia Caused by <i>Pseudomonas aeruginosa</i> or <i>Acinetobacter baumannii</i>	Andrew Phipps, Tunnell Government Services - BARDA
2:30 PM-2:45 PM	BREAK	
2:45 PM-3:45 PM	<p>Moderated Panel Discussion</p> <ol style="list-style-type: none"> 1. What are the drug development community perspectives on the use and development of larger animal models? 2. How can these larger animal models be further refined to be more relevant to human disease? 3. What are the panel’s thoughts with respect to pharmacokinetic related aspects discussed in the PM Session presentations ? 4. Are there foreseeable issues or barriers that would make the use of certain animal models, in specific circumstances, either desirable or impractical? 	All Panelists
3:45 PM-4:00 PM	Summaries and Closing Remarks	Edward Weinstein, FDA



Panelists (Includes Speakers):

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

External:

Tina Guina	BARDA
Judith Hewitt	NIAID
Marina Kozak	BARDA
Andrew Phipps	Tunnell Government Services supporting BARDA
Jürgen Bulitta	University of Florida
Binh Diep	University of California San Francisco
William Hope	University of Liverpool
Matthew Lawrenz	University of Louisville
Alexander Lepak	University of Wisconsin
Brian Luna	University of Southern California
Eric Nuermberger	Johns Hopkins University
Brad Spellberg	University of Southern California
Thomas Walsh	Weill Cornell Medical College
William Weiss	University of North Texas
Cara Cassino	ContraFect
Jennifer Hoover	GlaxoSmithKline
Lynn Miesel	Eurofins Scientific
Achim Wach	Polyphor

Workshop materials can be found at:

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

Federal Register Notice and Docket Information:

Docket Number: FDA-2019-N-6046

Accepting Public Comments Until: April 6, 2020

<https://www.regulations.gov/document?D=FDA-2019-N-6046-0001>

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