



## Public Workshop—Facilitating Antibacterial Drug Development for Patients With Unmet Need and Developing Antibacterial Drugs That Target a Single Species

<b>Day 1: Monday July 18<sup>th</sup>, 2016</b>		
<b>Time</b>	<b>Topic</b>	<b>Presenter</b>
7:30 AM-8:30 AM	Registration	
	<b>Session 1: General Considerations for Unmet Need Programs</b>	
8:30 AM-8:50 AM	Effectiveness Standards Including Orphan Products	Ed Cox
8:50 AM-9:10 AM	Trial Considerations for Unmet Need	Sumathi Nambiar
9:10 AM-9:30 AM	Regulatory Pathways and Approaches to Unmet Need	Marco Cavaleri
9:30 AM-9:50 AM	Developing Antibacterial Drugs for Unmet Need and So That We Stay Ahead of the Epidemic: Points to Consider for Developers	John Rex
9:50 AM-10:10 AM	Pharmacokinetic Considerations in Unmet Need Programs	Paul Ambrose
10:10 AM-10:30 AM	BARDA's Market Research for a Clinical Trial Network for Antibiotics	Joe Larsen
10:30 AM-11:00 AM	Break 1	
11:00 AM-11:30 AM	Clarifying Questions (Panelists and Audience)	
	<b>Session 2: Real World Experiences in Conducting such Trials</b>	
11:30 AM-11:45 AM	Developing Antibacterial Drugs for Patients with Unmet Need: Experience and Recommendations	Ian Friedland
11:45 AM-12:00 PM	Planning and Executing a Carbapenem/Beta-Lactamase Inhibitor Program Focused on Treatment of KPC-Producing CRE	Mike Dudley
12:00 PM-12:15 PM	Clarifying Questions (Panelists and Audience)	
<b>12:15 PM-1:00 PM</b>	<b>Lunch</b>	
1:00 PM-2:00 PM	Panel Discussion 1	
	<b>Session 3: Statistical Considerations</b>	
2:00 PM-2:20 PM	Evaluating Antibacterial Drugs in Unmet Need Settings	Dan Rubin
2:20 PM-2:40 PM	Innovative Trial Designs	Kert Viele
2:40 PM-3:10 PM	Clarifying Questions (Panelists and Audience)	
3:10 PM-3:30 PM	Break 2	
3:30 PM-4:00 PM	Public Comments	
4:00 PM-5:00 PM	Panel Discussion 2 (Covering All Topics)	



**Sessions 1-3 Moderators:** Ed Cox, Lynn Marks

**Panel Members:** Paul Ambrose, Luciana Borio, Helen Boucher, Samuel Bozzette, Marco Cavaleri, Aaron Dane, Dennis Dixon, Michael Dudley, Ian Friedland, Nick Kartsonis, Joe Larsen, Thomas Louis, John Rex, Dan Rubin, Sumathi Nambiar, John Powers, Kert Viele

Speaker slides and other workshop material can be found at:

<http://www.fda.gov/Drugs/NewsEvents/ucm497650.htm>

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