AGENDA

Drug Development Considerations for the Prevention of Healthcare-Associated Infections—Virtual Public Workshop

August 30, 2022

Goals of the Workshop: FDA and CDC are holding a virtual public workshop to discuss drug development considerations for the prevention of health-care associated infections

Topics will include:

- Current state of development of pathogen-directed products used to prevent healthcare-associated infections
- Evidence supporting decolonization and pathogen reduction (in colonized patients) as a strategy to prevent infection and transmission of antimicrobial-resistant healthcare-associated pathogens
- Antimicrobial resistance threats as potential targets for decolonization and pathogen reduction
- Challenges and potential approaches to drug development and registration of products for the prevention of healthcare-associated infections

Time	***Topic***	***Speaker(s) and Affiliation***
8:30 AM-8:45 AM	Introductory Remarks	John Farley, FDA Michael Craig, CDC
Session 1: Background and Epidemiology Session Co-Chairs: Heidi Smith (FDA), Katy Capers (CDC)		
8:45 AM – 8:55 AM	Prioritize Prevention and Diversify Our Patient Safety Toolbox: Decolonization Is a Missing Tool We Need	Michael Craig, CDC
8:55 AM-9:15 AM	Rationale for Decolonization as a Strategy for Preventing Antimicrobial-Resistant Infections	John Jernigan, CDC
9:15 AM- 9:35 AM	Decolonizing Approaches: Current State and Future Needs	L. Clifford McDonald, CDC
9:35 AM – 9:55 AM	Multidrug-Resistant Gram-Negative Bacilli – Epidemiology and Decolonization Considerations	Maroya Walters, CDC
9:55 AM – 10:15 AM	Gram Positives: *Staphylococcus aureus* and Vancomycin-resistant Enterococci	Cal Ham, CDC

10:15 AM-10:25 AM	**BREAK**	
10:25 AM – 10:45 AM	*C. auris* Colonization and Implications for Public Health	Joe Sexton, CDC
10:45 AM - 11:05 AM	*Clostridioides difficile:* Epidemiologic Risks and Decolonization Strategies	Alice Guh, CDC
11:05 AM – 11:25 AM	Patient Impact and Perspective The Impact of Infection on the Lives of People with Cystic Fibrosis The Aftermath of Living with Having an HAI	 A. Whitney Brown, Cystic Fibrosis Foundation Jeanine Thomas, MRSA Survivors Network
11:25 AM-11:55 PM	Formal Public Comments Microbiome Approaches to Treat Colonization with Antibiotic Resistant Bacteria Preventing Biofilm Fouling of Indwelling Medical Devices to Reduce HAIs and AMR Microbiome, Liver Transplant, and Hospital Acquired Infections	 Michael Woodworth, Emory University Carl Genberg, N8 Medical, LLC Christopher Lehmann, University of Chicago
11:55 AM-12:30 PM	**LUNCH**	
Session 2: Regulatory Perspective and Trial Design Challenges and Considerations Session Co-Chairs: Dan Rubin (FDA), John Jernigan (CDC)		
12:30 PM-12:50 PM	Regulatory Considerations for the Registration of Products for Prevention or Reduction in the Incidence of Healthcare-Associated Infections	Heidi Smith, FDA
12:50 PM-1:10 PM	Regulation of Healthcare Antiseptics	Theresa Michele, FDA
1:10 PM-1:30 PM	Regulatory Considerations for Microbiome Based Therapeutics	Paul Carlson, FDA

1:30 PM-1:50 PM	Clinical Considerations and Operational Challenges for Prevention Trials	Susan Huang, University of California Irvine
1:50 PM-2:10 PM	Statistical Considerations for Prevention Trials	Ed Bein, FDA
2:10 PM-2:30 PM	Controlling Pathogens in Healthcare: A Way Forward	Robert Weinstein, Rush University
2:30 PM-2:50 PM	Updates on Hand Antiseptics, Cleaning and Disinfectant Products Current Status of ACI's Topical Antiseptics Research and Future Directions Development of Efficacious Cleaning and Disinfecting Products in Healthcare Settings	 James Kim, American Cleaning Institute Nicholas Georges, Household and Commercial Products Association
2:50 PM-3:00 PM 3:00 PM-3:40 PM	Considerations in the Development of Non-Traditional Therapeutics: A CARB-X Perspective Industry Perspective(s): Challenges and Lessons Learned Challenges and Lessons Learned Developing DAV132, A Novel Therapy Protecting the Gut Microbiota from Antibiotic-Induced Dysbiosis Lessons Learned in Developing SYN-004: a Potential Point-of-Care Preventative for CDI	Erin Duffy, CARB-X Florence Sejourne, Da Volterra—BEAM Alliance Vince Wacher, Synthetic Biologics

	Defined Bacterial Consortia, a Novel Approach to Tackle Healthcare-Associated Infections Microbiome Therapeutics to Transform the Treatment of Antimicrobial Resistant Infections	Silvia Caballero, Vedanta Matt Henn, Seres Therapeutics
3:40 PM-3:50 PM	**BREAK**	
3:50 PM-5:05 PM	**Moderated Panel Discussion** Panel Moderators: Peter Kim (FDA), Michael Craig (CDC) 1. Please discuss the greatest needs for drug product development for prevention of healthcare-associated infections. (*30 minutes*) 2. Please discuss ideas for study designs that could provide evidence of the contribution of a new therapeutic for prevention of healthcare-associated infections on the background of existing infection-prevention measures including, but not limited to: (*25 minutes*) • Pros and cons of cluster randomized study designs • Enrichment strategies for populations at greatest risk 3. Please discuss clinical endpoints (effects on how a patient feels, functions, survives) that would be most relevant for evaluating the efficacy of a new therapeutic for prevention of healthcare-associated	All Panelists (Listed Below, Page 5). See Affiliations/Disclosures document for panelist affiliations.

	infections including, but not limited to: (*20 minutes*) • Possible differences in endpoints used in trials randomized at the unit level vs. the patient level • Defining endpoints for pathogen-specific vs. broader spectrum therapeutics • Handling of deaths during the study in endpoint analyses	
5:05 PM-5:20 PM	Summary and Closing Remarks	Michael Craig, CDC, and Peter Kim, FDA

All Panelists:

FDA: Edward Bein, Timothy Bensman, Paul Carlson, Dmitri Iarikov, Caroline Jjingo, Peter Kim, Theresa Michele, Dan Rubin, Heidi Smith

CDC: Michael Craig, Christopher Elkins, Alice Guh, Cal Ham, John Jernigan, Lawrence Mcdonald, Joe Sexton, Maroya Walters

External: Lilian Abbo (University of Miami), A. Whitney Brown (Cystic Fibrosis Foundation), Silvia Caballero (Vedanta), Erin Duffy (CARB-X), Vance Fowler (Duke University), Nicholas Georges (Household and Commercial Products Association), Matt Henn (Seres Therapeutics), Susan Huang (University of California, Irvine), James Kim (American Cleaning Institute), Florence Sejourne (Da Volterra—BEAM Alliance), Jeanine Thomas (MRSA Survivors Network), Vince Wacher (Synthetic Biologics), Robert Weinstein (Rush University), Sharon Wright (Beth Israel Lahey Health)

Speaker slides and other workshop materials will be posted before/after workshop at:

https://info.rescueagency.com/en-us/drug-development-consideration-virtual-public-workshop-cdc-fda