

SCIENCE AND REGULATION OF BACTERIOPHAGE THERAPY
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (FDA)
AND NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIH)
AUGUST 30-SEPTEMBER 1, 2021

Note: All times are US Eastern Daylight Time
General Meeting Link:



Day One: Monday, August 30, 2021

- 9:30-9:40 am** Welcoming remarks
Marion Gruber, CBER; and Emily Erbeling, NIAID
- 9:40-10:00 am Workshop background and goals
Jane Knisely, NIAID; and Roger Plaut, CBER
- 10:00-10:20 am Regulatory framework for the development and use of bacteriophage therapy in the US
Cara Fiore, CBER
- Session 1: Choosing and characterizing bacteriophages for therapy**
Moderator: Roger Plaut, CBER
- 10:20-10:40 am Regulatory considerations for characterization of bacteriophages for therapy
Roger Plaut, CBER
- 10:40-11:00 am Bioinformatic approaches for determining phage properties
Jason Gill, Texas A&M University
- Break**
- 11:10-11:30 am Phage-host interactions in biofilm communities: challenges and limitations
Luís Melo, Centre of Biological Engineering, Portugal
- 11:30-11:50 am The consequences of phage resistance evolution for the virulence levels of bacterial pathogens
Edze R. Westra, University of Exeter, UK
- 11:50 am-12:10 pm Phage assessment and phage selection: infectivity, efficacy, quality, and standardization using the virulence index
Dominic Sauvageau, University of Alberta, Canada
- 12:10-12:40 pm Panel discussion
Moderator: Roger Plaut, CBER
- 12:40-1:10 pm** **Lunch**
- Session 2: Manufacturing phages for stability and clinical use**
Moderator: Susan Lehman, CBER
- 1:10-1:30 pm Considerations for choosing and developing QA/QC test methods
Susan Lehman, CBER

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|-------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1:30-1:50 pm | Using advanced metrology tools for phage manufacturing and formulation
Danish Malik, Loughborough University, UK |
| 1:50-2:10 pm | Manufacturing aspects of phage-based product development from early steps to production of clinical trial material
Frenk Smrekar, JAFRAL, Slovenia |
| 2:10-2:30 pm | A cell-free platform for production, modification, and engineering of bacteriophages for therapeutic use
Kilian Voegelé, Invitris, Germany |
| Session 3: | Breakout sessions: Putting the pieces together |
| 2:30-2:40 pm | Breakout session instructions
Erica Bizzell, NIAID |
| 2:40-3:25 pm | Focused Session 1: Links at the end of the agenda
Room A: Patentability of phage therapeutics—IP challenges
Michele Wales, Adaptive Phage Therapeutics
Room B: Single-patient INDs—Step by Step
Cara Fiore, CBER
Room C: Preclinical services at NIAID
Erica Raterman, NIAID; and Erin Zeituni, NIAID
Room D: Funding for clinical trials
Jane Knisely, NIAID; Richard Alm, CARB-X; and Anna Jacobs, BARDA |

Day Two: Tuesday, August 31, 2021

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| Session 4: | Clinical Use of Bacteriophage Therapeutics
Moderator: Chip Schooley, University of California San Diego |
| 10:00-10:20 am | Early clinical experience with phage therapy
Saima Aslam, University of California San Diego |
| 10:20-10:40 am | Clinical development of bacteriophage therapy products
Rebecca Reindel, CBER |
| Break | |
| 10:50-11:10 am | An overview of adaptive clinical trial design
John Scott, CBER |
| 11:10-11:30 am | Phage susceptibility testing in support of phage clinical trials
Robin Patel, Mayo Clinic |

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- 11:30-11:50 am Phase 1b experience with LBP-EC01, a CRISPR-Cas3 engineered bacteriophage cocktail targeting *E. coli*
 Dave Ousterout, Locus Biosciences
- 11:50 am -12:20 pm Lunch**
- 12:20-12:40 pm Addressing emerging antimicrobial resistance with an adaptive library of bacteriophage: PhageBank
 Robert Hopkins, Adaptive Phage Therapeutics
- 12:40-1:00 pm Phage therapy for managing *Shigella* infections
 Jennifer Schwartz, Intralytix
- 1:00-1:20 pm Phages for all: developing phage prophylaxis for cholera
 Minmin Yen, PhagePro
- 1:20-2:00 pm Panel discussion
 Moderator: Chip Schooley, University of California San Diego
- Session 5: Breakout sessions: Putting the pieces together**
- 2:00-2:05 pm Instructions for breakout sessions
 Erica Bizzell, NIAID
- 2:05-2:50 pm **Focused Session 2: Links at the end of the agenda**
 Room A: eCTD Details—What Goes Where?
 Sheila Dreher-Lesnick, CBER
 Room B: Meetings with FDA—What is Expected?
 Susan Lehman, CBER
 Room C: Grants/SBIR/STTR
 Ryan Ranallo, NIAID; and Nancy Ernst, NIAID
 Room D: Clinical Trial Design—Details:
 Rebecca Reindel, CBER

Day Three: Wednesday, September 1, 2021

- Session 6: Research Gaps**
Moderator: Jane Knisely, NIAID; and Joe Campbell, NIAID
- 10:00-10:20 am Bacteriophage research updates from NIH Preclinical Services
 Erica Bizzell, NIAID

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10:20-10:40 am CRISPR-assisted engineering of *Staphylococcal* phages to combat antibiotic-resistant infections

Asma Hatoum-Aslan, University of Illinois Urbana-Champaign

Break

10:50-11:10 am Respiratory delivery of bacteriophages
Reinhard Vehring, University of Alberta, Canada

11:10-11:30 am Optimizing bacteriophage regimens to treat pulmonary infections
Laurent Debarbieux, Institut Pasteur, France

11:30 am-12:00 pm Panel discussion
Moderator: Jane Knisely, NIAID

12:00-12:30 pm Lunch

12:30-12:50 pm Four-dimensional therapeutics
Anthony Maresso, Baylor College of Medicine

12:50-1:10 pm Opportunities and challenges for phage therapy of *M. abscessus* infections
Rebekah Dedrick, University of Pittsburgh

1:10-1:30 pm Development of a bacteriophage host immune response in a lung transplant recipient receiving phage therapy for MDR *Pseudomonas aeruginosa* pneumonia
Jennifer Dan, University of California San Diego

1:30-1:50 pm Phage selection for reduced virulence in bacterial pathogens
Paul Turner, Yale University

1:50-2:20 pm Panel discussion
Moderator: Joe Campbell, NIAID

Session 7:

2:20-2:50 pm Workshop wrap-up
Graham Hatfull, University of Pittsburgh

2:50-2:55 pm Closing remarks
Scott Stibitz, CBER



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Zoom Links:

General sessions:

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Webinar ID:
Passcode:

Focused sessions:

Room A:

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Meeting ID:
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Room B:

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Room C:

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Room D:

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