PHAGE FUTURES CONGRESS

29-30TH JANUARY 2019 | WASHINGTON D.C, USA

Translating phage-based applications into clinically and commercially viable therapeutics

- **Regulatory guidance** to achieve clinical data from Cara Fiore, FDA
- **Strategies to access the market** via the veterinary, personalized medicine and traditional pharmaceutical routes
- **Insights into investment drivers** for phage therapy from NIH and Merck
- **Facts on how to manufacture GMP phage**
- **Applications to overcome multi-drug resistance** with combined approaches such as phage therapy and antibiotics

SPEAKERS TO INCLUDE:

Steffanie Strathdee & Tom Patterson
University of California San Diego

Carl Merril
CSO and Founder
Adaptive Phage Therapeutics

Scott Stibitz
Microbiologist, Center for Biologics Evaluation and Research
FDA

Martha Clokie
Professor of Microbiology
University of Leicester

Biswajit Biswas
Chief, Division of Bacteriophage Science, Biological Defense Research Directorate
US Naval Medical Research Center

Joe Campbell
Research Resources Project Officer
NIH (NIAID)

INSTITUTIONS PRESENT INCLUDE:

NIH · FDA · Naval Medical Research Center · AmpliPhi Biosciences Corporation · Locus Biosciences · Adaptive Phage Therapeutics · Merck · Massachusetts Institute of Technology · UC San Diego

WELCOME

With antimicrobial resistance an ongoing worldwide issue, there is now a renewed interest in phage therapy as an alternative to antibiotics. There has been uncertainty as to whether phage therapy can be a commercially viable and FDA/EMA approved product. However, the highly positive results of compassionate use cases since 2016 and knowledge gained recently from microbiome research have been key catalysts to progress the field within western medicine. Successful phase II clinical trials are on the horizon!

The Phage Futures Congress will bring together peers from biotech companies and academia, along with experts from regulatory bodies, pharmaceutical companies and government institutions, to discuss how to actively progress clinical science and viable phage application routes to market. The conference will cover key industry trends including:

- Regulatory guidance to achieve clinical data and market approval
- Use of phage in chronic indications such as IBD
- How to manufacture GMP compliant phage
- Opportunities within the personalized medicine model and veterinary market
- Combined therapy approach of phage and antibiotics to alleviate MDR
- Investment drivers

> The Phage Futures Congress has the potential to act as a catalyst to further cooperative and collaborative efforts to develop alternate Phage based approaches to the antibiotic crisis.
>
> In addition, the location in the Washington DC area will facilitate an opportunity for Government Agencies, responsible for public health, such as the NIH, FDA, USDA and DOD to participate and interact with educational research groups and biotechnology companies developing phage therapies and initiating clinical testing.
>
> **Carl Merril,**
> **Adaptive Phage Therapeutics**

EVENT PARTNERS

Phagelux | Proteon Pharmaceuticals | Cellexus | Clean Cells

THE ROADMAP TO COMMERCIAL PHAGE THERAPY MEDICINE

SCIENCE

What does the sequencing of the microbiome mean for phage therapy?

Nick Conley, Locus Biosciences – offering insights into utilising bacteriophages to deliver precision microbiome engineering to eradicate bacterial targets.

IMPLEMENTATION

Translational skills are crucial for progressing phage in human health.

Magda Barbu, C3J Therapeutics – Sharing how to transfer drug development knowledge to phage therapy clinical studies.

REGULATION

What are the phage therapy regulatory considerations for clinical studies

Cara Fiore, FDA – on the required regulatory input for phage, INDs and compassionate case long term validity.

DELIVERY

Antibiotics have a broad spectrum, how can phages compete?

Kevin Yehl, MIT – presenting the importance of engineered phage and next-generation scaffolds to efficiently broaden host range and suppress MDR

APPLICATION

Route to market in phage involves many parameters including disease, host and phage source selections.

Biswajit Biswas, Naval Medical Research Center - discussing a route to market, personalised medicine model and the importance of phage synergy for maximum efficacy.

COLLABORATION

Infectious disease groups with pharma are watching the phage field.

Joe Campbell, NIH – presenting the importance of collaboration and investment in phage therapy to facilitate successful bacteriophage efficacy trials.

PHAGE FUTURES CONGRESS | Kisaco Research

ANSWERING THE CRITICAL QUESTIONS TO BUILD A PHAGE FUTURE

TALK TO OUR SPEAKERS ABOUT...

- Addressing future antimicrobial resistance with phage evolution
- Key translational skills
- The applications of phage therapy
- How to produce GMP compliant phage
- The key considerations for designing clinical trials
- Benefits of expanded access cases versus a full clinical trial
- How microbiome related applications are opening up the field
- How to target an appropriate host range
- Why phage therapy is important for industry & where they see it going
- Commercial pathways for phage therapies

MEDIA PARTNERS

viruses an Open Access Journal by MDPI

IDSA Infectious Diseases Society of America

Phage Directory

SPEAKERS

Dr Steffanie Strathdee
Associate Dean of Global Health Sciences
University of California San Diego

Professor Thomas Patterson
University of California San Diego School of Medicine

Dr Carl Merril
CSO and founder
Adaptive Phage Therapeutics

Scott Stibitz
Microbiologist
Center for Biologics Evaluation and Research FDA

Professor Martha Clokie
Professor of Microbiology
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Senior Director, Synthetic Biology
C3J therapeutics

Dr Shawna McCallin
Project Leader
PhageForward

Xavier Duportet
CEO
Eligo Bioscience

Dr Brian Varnum
Chief Development Officer
C3J therapeutics

Dr David Harper
CEO and CSO
Evolution Biotechnologies

Dr Tobi Nagel
Founder & President
Phages for Global Health

Greg Merril
CEO and founder
Adaptive Phage Therapeutics

Dr Betty Kutter
Head of Bacteriophage Lab
Evergreen State College

Dr Breck Duerkop
Assistant Professor of Immunology & Microbiology
University of Colorado School of Medicine

Dr Catherine Loc-Carrillo
Internal Medicine - Research Assistant Professor
University of Utah

Dr Derek Holman
Stanford University

Dr Nick Conley
Principal Scientist
Locus Biosciences

Dr Benjamin Chan
Yale University

Dr Chandrabali Ghose
Founder and CEO
Bioharmony Therapeutics

Dr Taylor Wallace
George Mason University

Dr Kevin Yehl
Lead Phage Researcher
MIT

Dr Carrie-Lynn Langlais Furr
VP of Regulatory Affairs
AmpliPhi Biosciences

Dr Jarek Dastych,
CEO
Proteon Pharmaceuticals

Dr Mark Engel,
CEO
Phagelux

Dr Laurent Bretaudeau
Head of R&D
Clean Cells

Dr Carl Balibar
Principal Scientist
Merck

AGENDA DAY 1

8:00 am REGISTRATION OPENS

PLENARY SESSION: CURRENT OUTLOOK

8:50am **Chairperson's opening remarks**

9:00 am **KEYNOTE: The success of phage therapy in the US: A patient's view of receiving phage therapy**

- Hear the sequence of events which saved Tom Patterson's life from a multi-drug resistant bacterial infection
- Gain a patient's perspective on receiving phage therapy

Professor Thomas Patterson, University of California San Diego

Dr Steffanie Strathdee, Associate Dean of Global Health Sciences, University of California San Diego

9:30 am **KEYNOTE: The evolutionary necessity for the development and uses of phage libraries for the individualized therapy of bacterial infections**

- Explore how bacteria, phage and humans evolve and how their subsequent interactions affect the potential use of phage as a therapeutic antibacterial agent
- Address the need for ever expanding clinically relevant and safe phage libraries, touching upon methods to rapidly screen such libraries for effective phage based therapeutic applications

Dr Carl Merril, CSO and Founder, Adaptive Phage Therapeutics

10:00 am **KEYNOTE: Rational analysis of why phase II clinical trials have been failing**

- Discuss the science and structure of past clinical trials, including an in-depth view of previous trials such as Nestle and Phagoburn trials
- Explore what was different for the successful Biocontrol efficacy trial

Dr Shawna McCallin, Project Leader, PhageForward

10:30 am **KEYNOTE: Regulatory and manufacturing compliance of phage therapy products**

- From a pharmaceutical classification point of view, phages fall in the categories of anti-infectious products and of biological products, given the intended use and their live nature. At the production steps, the compliance to the Good Manufacturing Practices (GMP) is a requirement for any medicinal product, with the objective to ensure the quality, safety and efficacy of both investigational and approved drugs.
- The EU-funded PhagoBurn's project was conducted with the objective to set the standards from the regulatory and manufacturing points of view. This experience and other projects with natural and genetically modified phages open the way for future developments of phage therapy

Dr Laurent Bretaudeau, Head of R&D, Clean Cells

11:00am NETWORKING BREAK

DEVELOPING PHAGE THERAPIES TO MINIMIZE ANTIMICROBIAL RESISTANCE

11:30 am **Combining bacteriophages and antibiotics for wound infections**

- Assess the feasibility and efficacy of locally delivering a phage and antibiotic combination (PAC) therapy to treat polymicrobial wound infections
- Present case studies detailing how to develop reproducible infected rat models to test the efficacy of antimicrobials, which rely on non-invasive monitoring techniques to allow the infection to be tracked in 'real-time'
- Determine if a combination of phage and antibiotic is more effective at reducing the bacterial load of S. aureus compared to either individual treatment in vitro on biofilms
- Develop novel ways to locally deliver antimicrobials to the infected site and reduce undesirable side effects.

Dr Catherine Loc-Carrillo, Internal Medicine, University of Utah

AGENDA DAY 1

11:55 am **The importance of phage evolution: phage therapy in three cases of MDR Pseudomonas aeruginosa infection**

- Present case studies detailing three distinct trials of MDR Pseudomonas aeruginosa infection: 1. a contaminated prosthetic graft; 2. a lung infection associated with cystic fibrosis; and, 3. a lung abscess following radiation therapy.
- Explain the clinical course of the cases and approach to phage therapy with the findings that suggest clinical application of phage can be highly effective at eradication and/or re-sensitization of P. aeruginosa to antibiotics

Dr Benjamin Chan, Yale University

12:20 pm **Sequence-specific antimicrobials: CRISPR-Cas delivery via engineered phages**

- Discuss engineering the broad host range of phage capsids which demonstrating targeted killing of pathogenic gut bacterial strains and efficient packaging of large DNA circuits in phage capsids

Xavier Duportet, CEO, Eligo Biosciences

12:45 pm NETWORKING LUNCH

PHAGE BIOLOGY AND MICROBIOME INDICATIONS

2:00 pm **The assembly of intestinal bacteriophage communities during inflammation**

- Explore how phages associate with the intestinal mucosa and phage abundances are altered during inflammatory bowel disease (IBD)
- Assess how experimental murine colitis, characterized by inflammation of the colon, promotes stochastic changes in the phage community that reflect dysbiosis
- Discuss how murine colitis serves as a model to better understand the role of phages during human IBD

Dr Breck Duerkop, Assistant Professor of Immunology & Microbiology, University of Colorado

2:25 pm **Moving from vitro to vivo: Key characteristics and maximising efficacy by optimising the bacteriophage depth**

- Discuss C. difficile-phage interactions in biofilm, insect, epithelial cell lines and artificial gut models
- Explore C. difficile adsorption, tail fibers, and resistance

Professor Martha Clokie, Professor of Microbiology, University of Leicester

AGENDA DAY 1

2:50 pm **Precision microbiome engineering with CRISPR-weaponized phages**

- Discover how weaponizing phages with CRISPR/Cas3 and integrating high-throughput automation, next-generation sequencing, and machine learning can bridge the gap at producing a scalable phage drug product that fits within the pharma paradigm.

Dr Nick Conley, Principal Scientist, Locus Biosciences

3:15 pm **Importance of understanding phage-host interactions under potential treatment conditions in selecting therapeutic phages**

- Choose a suitable breadth of phage to effectively eradicate target pathogens

Dr Betty Kutter, Head of Bacteriophage Lab, Evergreen State College

3:40pm NETWORKING BREAK & POSTER SESSION

PLENARY SESSION: ROUTES TO MARKET

4:10pm **KEYNOTE: Utilizing Bacteriophages to Prevent Infections**

- Commercial realties of therapies vs. preventatives
- Phagelux Solutions: Sustained release sprays and patches
- Pricing of Phagelux Solutions and Projected Use of the Products

Dr Mark Engel, CEO, Phagelux

4:40pm **KEYNOTE: Personalized medicine model: The benefits and science considerations in expanded access cases.**

- Discuss the parameters and practicalities for developing effective phage library to overcome phage resistant bacteria during phage therapy
- Evaluate a precision or personalized phage therapy approach for successfully treating multi drug resistant (MDR) bacterial infections
- Assess the implementation of Biolog based system for compounding effective phage cocktails to maximize the therapeutic efficacy of phwage treatment.
- Assess the phage antibiotic synergy to overcome MDR bacterial infections

Dr Biswajit Biswas, Chief, Division of Bacteriophage Science, Biological Defense Research Directorate, US Naval Medical Research Center

5:10pm **KEYNOTE: Toward phage clinical trials for emerging markets**

- Since approximately 90% of the expected AMR deaths will occur in the developing world, these countries represent significant emerging markets for future phage products
- Details of projects in the developing world that suggests there is an openness to pursuing phage research and regulatory approval in those countries

Dr Tobi Nagel, Founder & President, Phages for Global Health

5:40 pm **KEYNOTE: Commercial viability of precision phage therapy**

- Assess phage library manufacturing and regulatory considerations such as high through-put phage-bacteria matching assays
- Explain efforts to reduce the time needed to deliver a precision targeted phage therapy
- Explore future opportunities for phage therapy as 2nd and 1st line anti-infective agents

Greg Merril, CEO and Founder, Adaptive Phage Therapeutics

6:10 pm **Closing remarks**

6:15 pm END OF DAY ONE

AGENDA DAY 2

8:00 am REGISTRATION OPENS

PLENARY SESSION: COLLABORATION AND INVESTMENT

8:50 am **Chairperson's Opening remarks**

9:00 am **KEYNOTE: Encouraging investment: NIAID perspective on and support for bacteriophage therapy**

- Learn about the DMID/NIAID pre-clinical services are used to explore the efficacy of bacteriophages in vivo and in vitro
- Details of biopharmaceutical products therapeutic development services-task orders are used to craft product development plans
- Discover how DMID/NIAID genomic services are used to analyse bacteriophage genomes.
- Details of funding of solicited and un-solicited grants to explore and develop the therapeutic bacteriophages and their gene products

Dr Joe Campbell, Research Resources Project Officer, NIH

9:30 am **KEYNOTE: Big Pharma View on the clinical utility and commercial opportunity for Phage therapy**

- From a big pharma perspective, having clear clinical, regulatory, and commercial paths are paramount to bringing a phage-based product forward
- Discuss the main challenges including narrow-spectrum activity, incomplete host range coverage within a species, and the ability to design appropriate and efficient clinical trials.
- Defining the optimal means to utilize phage therapy to address AMR beyond compassionate care will be vital to derive an ultimate target product profile and value proposition in respect to risk/benefit profiles for the patient.

Dr Carl Balibar, Principal Scientist, Merck

PLENARY SESSION: REGULATION

10:00 am **KEYNOTE: Obtaining phage therapy pharmacokinetic data via radiolabelled phage**

- Discuss the advantages of using radiolabelling for addressing pharmacokinetics regulatory requirements: phage-patient or phage-model organism interactions
- Details of radiolabelling imaging/BioD data from multiple routes of administration (IV, IP, aerosol)
- Assess the practical considerations associated with phage radiolabelling

Dr Derek Holman, Stanford university

10:30 am NETWORKING BREAK

11:00 am **PANEL: Clinical trial vs compassionate use**

- Discover the FDA's position on both approaches in phage therapy
- Asses if there is a business case to commercialise the compassionate use long term
- Debate the benefits and challenges of each model

Panellists: Scott Stibitz, Microbiologist, FDA

Brian Varnum, Chief Development Officer, C3J Therapeutics

David Harper, CEO, Evolution Biotechnologies

Carrie-Lynn Langlais Furr, VP of Regulatory Affairs, AmpliPhi Biosciences

Moderator: Shawna McCallin, Project Leader, PhageForward

AGENDA DAY 2

PHAGE FUTURES CONGRESS | Kisaco Research

11:50 am **KEYNOTE: Regulatory Considerations in the Development of Bacteriophage for Clinical Use**

- The U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Vaccines Research and Review (OVRR) regulates bacteriophage (phage) therapy when used for infectious disease indications.
- Discuss the Investigational New Drug (IND) regulatory review process and phage therapy development for studies under IND. Regulatory considerations for clinical studies and the chemistry, manufacturing and control (CMC) information will be reviewed, which may aid in preparation of an Investigational New Drug Application (IND) that is designed to collect clinical data to support marketing approval in the U.S.

Cara Fiore, Microbiologist, FDA

SESSION 1: APPLICATION ROUTES TO CLINICAL DATA

12:20 pm **Effective usage of bacteriophage in industrial poultry farming: Importance of the delivery mechanism**

- Discussion of a Bacteriophage cocktail can be effectively delivered in large industrial poultry farms
- Multiple delivery formats can deliver phages in stable and economically attractive ways
- Selection of the delivery format is critical for commercial feasibility of phage-based products

Dr Jarek Dastych, CEO, Proteon Pharmaceuticals

12:50 pm NETWORKING LUNCH

2:00 pm **Applying the veterinary model as a route to market**

- Discuss how progressing a veterinary therapeutic to market, in the high-value companion animal sector, will provide proof of concept for both regulatory progression and commercialisation, while also providing valuable data on safety and efficacy for phage therapy in general
- Assess field trial data in canine otitis, as then undertaken provided useful data. for progression into clinical trials against otitis in humans but could also lead directly into pre-market trials for a veterinary therapeutic and low-cost model.

Dr David Harper, CEO, Evolution Biotechnologies

2:25 pm **Bacteriophage lysins: novel non-traditional antimicrobial treatments for MDR pathogens**

- Explore the principles and applications of Lysins which are enzymes capable of cleaving bonds in the peptidoglycan layer of bacterial cell walls, resulting in rapid hypotonic lysis and bacterial death within seconds after contact
- Details of data that supports the resistance to these molecules are orders of magnitude less likely than traditional antibiotics, making lysins an ideal antimicrobial for the treatment of MDR pathogens such as MRSA, Carbapenem resistant Acinetobacter and others

Chandra Ghose, Bioharmony Therapeutics

AGENDA DAY 2

PHAGE FUTURES CONGRESS | Kisaco Research

2:50 pm **Engineering bacteriophage to combat infectious disease and remodel the microbiome**

- Learn about engineering phage as sequence-specific antimicrobials
- Explore assembling and editing phage genomes using a yeast-based platform and suppressing bacterial resistance through tail fiber mutagenesis
- Discover the next-generation therapeutic phage scaffolds

Dr Kevin Yehl, Lead Phage Researcher (Timothy's Lu group), MIT

3:15 pm **Can bacteriophages improve the microbiome and human health?**

- Assess how the consumption of therapeutic doses of bacteriophages are safe and tolerable in human populations, at least in the short-term
- Explore how bacteriophages may have the ability to influence microbiome-related disease biomarkers (e.g., LDL cholesterol)
- Discus the future therapeutic utility of bacteriophages may include prophylactic effects against ingested enteric pathogens, which are largely responsible for nutritional deficiencies derived from chronic diarrhoea in the developing world

Dr Taylor Wallace, George Mason University

3:40 pm NETWORKING BREAK

SESSION 2: FACILITATING CLINICAL STUDY AND MARKET APPROVAL

4:10 pm **Applying traditional drug development approaches to phage therapy**

- Explore phage discovery and engineering (broadened host range and improved antimicrobial activity)
- Details of GMP manufacturing: fermentation, purification, formulation
- Assess IND-enabling studies for engineered phage candidate

Dr Magda Barbu, Senior Director, Synthetic Biology, C3J Therapeutics

4:35 pm **Achieving approval: proving your product is safe, pure and potent in the biologics license application**

- Discuss how to incorporate data obtained during the development of the phage product into the required format of FDA CBER's Biologics License Application
- Evaluate the players needed to author, compile, submit, and guide the BLA through the review process to approval,
- Learn when to start preparing the BLA and what the FDA review process entails

Dr Carrie-Lynn Langlais Furr, VP of Regulatory Affairs, AmpliPhi Biosciences

5:00 pm **Commercial Considerations for Implementing Phage Therapy in Western Hospitals: Pricing and Access Implications**

- Therapeutic utilization in the hospital setting is highly influenced by health system access and reimbursement
- Driving access and adoption in this setting is increasingly challenging for innovative therapeutic technology
- Understanding the reimbursement structure, key decision-makers and their incentives will inform commercial strategy and influence value for phage therapeutics

Kate Kitsopoulos, Partner, Triangle Insights Group

5:25 pm **Closing remarks**

5:30 pm END OF DAY TWO

WHO WILL YOU MEET?

This congress will bring together international delegates and stakeholders across all disciplines related to phage including:

Biotechnology companies
Build relationships, partner, gain regulatory knowledge and discover recent advancements

Pharmaceutical companies
Learn about the current applications in phage, innovations from microbiome research and improve current antimicrobial resistance alternatives through collaboration

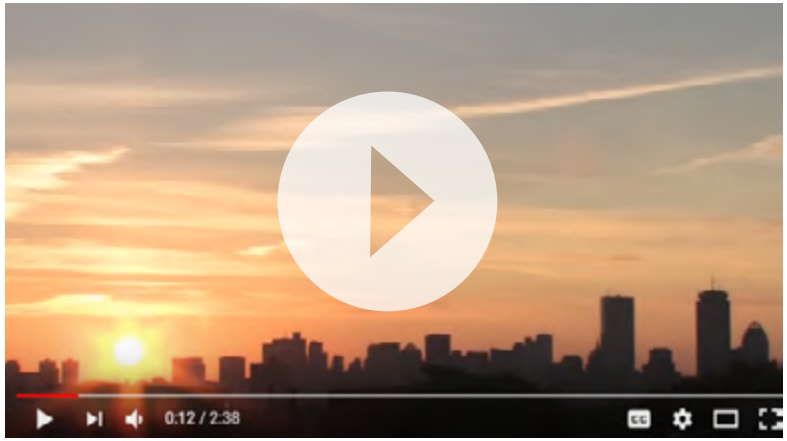
Physicians/clinicians
Understand how your patients can benefit from phage in various disease indications, more about the therapy in a clinical setting & how to improve patient outcomes

Service Providers
Meet the people who need your services, better understand their needs in the context of phage therapy

Academics
Improve industry know how, build partnerships, collaborate, discuss work

Regulatory Bodies
Interact and provide regulatory guidance to educational research groups and biotechnology companies developing phage therapies

THE ONSITE EXPERIENCE



Human Biotech & Animal Health, Boston 2018

3rd Annual European Microbiome Congress

BE A PART OF PHAGE FUTURES

POSTER PRESENTATION

Our dedicated poster session is the perfect way to get your research noticed. In order to present a poster at the forum you need to be registered as a delegate. Please note that there is limited space available and poster space is assigned on a first come first served basis (subject to checks and successful registration).

At the Congress, your presentation will be displayed in a dedicated poster area. The poster presentation session will take place at the afternoon networking break on day one.

SUBMISSIONS ARE NOW CLOSED

Poster abstract submission deadline is on 17th December 2018.

Abstracts received after this time may not be accepted so please submit your abstract as soon as possible!

Posters should be sized A0 (841mm x 1189mm) in portrait orientation.

STUDENTS

Phage Futures is calling all students! As the congress looks to the future of phage therapy, we are encouraging young researchers to get involved. Progressing phage therapy is dependent on collaboration and innovative thinking so input from rising stars is key! Join the congress with our special student price, you'll have the opportunity to:

- Engage with industry as well as academia to expand your network and career opportunities
- Get involved in the debate about approaching the clinic
- Showcase your innovations through the poster session

STUDENT PASSES ARE NOW SOLD OUT

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Academic	$899
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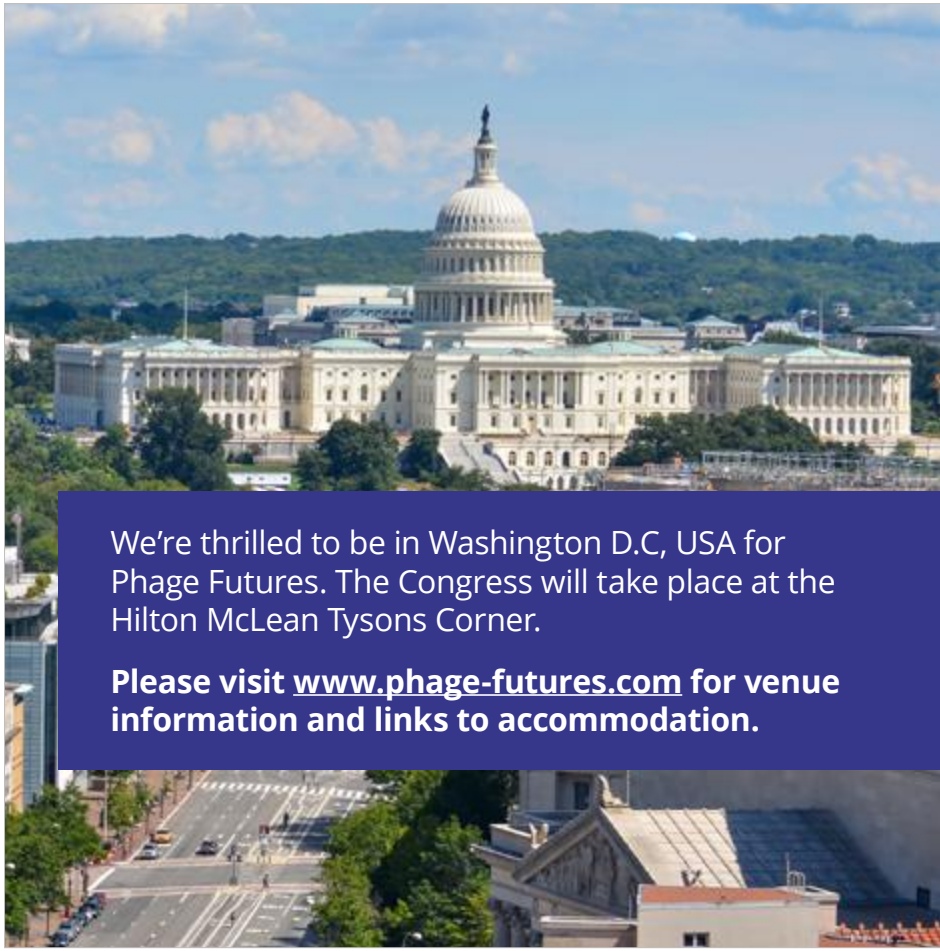
VENUE & ACCOMMODATION



We're thrilled to be in Washington D.C, USA for Phage Futures. The Congress will take place at the Hilton McLean Tysons Corner.

Please visit www.phage-futures.com for venue information and links to accommodation.

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Animal Microbiome Congress USA
19-20 March, 2019

ANIMAL HEALTH INVESTMENT Europe

Animal Health Investment Europe
London, UK
26-27 February, 2019

WHAT OUR ATTENDEES SAY

'The event had an adequate mix of topics revolving microbiome, be it from a scientific, commercial or regulatory point of view'
– Eva Mong, Jennewein Biotech

'Good conference overall, very good talks, nice ambiance for discussions and good contacts made during the two days'
- Cordaillat Simmons, Pharmabiotic

'Excellent introduction to the needs and opportunities in animal health for the human health world'
- Alan Schneyer, Fairbanks Pharma