MICROBIOME MOVEMENT DRUG DEVELOPMENT

CELEBRATING OUR 4th YEAR

June 26-28, 2019 | Revere Hotel Boston Common, Boston, MA

Pursuing Disease Causation to Foster the Creation of Targeted Microbiome-Based Therapeutics, Biomarkers & Diagnostics

Eric Shaff
CEO
Seres Therapeutics

Mike Romanos
CEO
Microbiotica

Esi Lamousé
Director, Immunology
Translational Medicine
Janssen Pharmaceuticals

Bernat Olle
CEO
Vedanta Biosciences

Cathryn Nagler
Bunning Food Allergy
Professor
University of Chicago

Alison Lawton
CEO
Kaleido Biosciences

Ken Blount
CSO
Rebiotix

Ulrich Thienel
Chief Medical Officer
Finch Therapeutics Group

EXPERTISE PARTNERS

Diversigen

COSMOSID® Unlocking The Microbiome

CoreBiome Powering Microbiome Science with Big Data™

Boston Analytical

WELCOME TO THE MICROBIOME MOVEMENT

A LETTER FROM OUR PROGRAM DIRECTOR & CO-FOUNDER

Dear Microbiome Enthusiasts,

The study of the human microbiome remains one of the most exciting frontiers in modern medicine that if targeted correctly, has the potential to benefit millions of patients suffering from numerous diseases. However, the potential for disease treatment through the human microbiome is matched by the challenges in developing them. As such, academic and pharmaceutical researchers must continue to **pursue the causal role of the human microbiome in human disease, to help bring a new generation of targeted treatments to market that demonstrate consistent clinical outcomes and predictable molecular mechanisms of action.**

Part of the globally recognised *Microbiome Movement,* and returning for the fourth year, the ***Microbiome Movement*** **- Drug Development Summit** remains the industry-leading forum to help a growing community of pharmaceutical, biotech and academic researchers pave through unknown territory, and translate complex microbiome science into effective therapeutic, biomarker and diagnostic candidates of the future.

If you are or want to become a player in the microbiome arena, this is the conference you should attend to both stay up to date with the most cutting pre-clinical and clinical microbiome case-studies across multiple product modalities and disease phenotypes but make valuable connections to drive your microbiome development forward and help translate the potential of the microbiome into a reality for patients. It is with great pleasure and enthusiasm that I invite you to *join the Microbiome Movement* and I look forward to seeing you all in Boston.

Sincerely,

Alexander Puttick

Program Director & Co-Founder
Microbiome Movement

KEY BENEFITS OF ATTENDING

INVESTIGATE THE CRITICAL MICROBIOME THERAPEUTIC MODALITIES ACROSS VARIOUS DISEASE PHENOTYPES – With case-studies on LBPs, microbial-derived bioactives, genetically engineered strains and subtractive approaches, to stay up to date with the most important microbiome approaches being applied in the pharmaceutical industry.

OVERCOME REGULATORY UNCERTAINTY AND CLINICAL DEVELOPMENT CHALLENGES – As the microbiome industry accelerates towards market approval, learn how organizations are working alongside regulatory agencies to select patient populations, measure therapeutic dose and establish clinical end points across early and late stage trial development.

IMPLEMENT SCALABLE & COST-EFFECTIVE MANUFACTURING PRACTICES FOR LBPS – With perspectives from leading CDMO's and drug developers, learn how to scale up LBPs through cutting-edge GMP formulation and manufacturing protocols in order to achieve stability and consistency of therapeutic candidates.

NEW FOR 2019 DISCOVER MICROBIOME-DERIVED BIOMARKERS THAT SUPPORT CLINICAL DEVELOPMENT AND PREDICT THERAPEUTIC RESPONSE – As biomarkers continue to be a critical tool in de-risking drug discovery efforts, learn how forward thinking researchers are developing microbiome-derived biomarkers in IBD & Oncology.

MEET THE MICROBIOME PIONEERS, JOIN THE COMMUNITY AND BE PART OF THE *MOVEMENT* – With an exclusive focus on the microbiome's role in drug development, this is your chance to network with fellow microbiome enthusiasts from the pharma, biotech and academic community and define the future of microbiome-based therapeutic and biomarker development.

3 DEDICATED TRACKS OF CONTENT

60+
Expert Speakers

Discovery & Pre-Clinical Development of Microbiome-Based Therapeutics

Learn how the leaders in the field are defining host microbiome interactions, identifying new targets and addressing the current challenges in the pre-clinical development of microbiome-based therapeutics across a broad range of modalities and disease phenotypes

3
Interactive Deep-Dive Workshops

Manufacturing & Clinical Development of Microbiome-Based Therapeutics

Navigate through the evolving translational, clinical, regulatory and manufacturing challenges of microbiome-based therapeutics to help improve clinical outcomes and bring these products to a commercial scale

Microbiome Biomarkers, Bioinformatics & Therapeutic Response

Outlining research into the identification of microbiome-derived biomarkers and better understanding their application to help guide clinical development, and as an important patient stratification tool for predetermining therapeutic response across multiple disease phenotypes

12+
Hours of Networking & Collaboration

WHAT THE MICROBIOME COMMUNITY SAYS:

"This meeting is possibly the best in the microbiome field for a biotech company, for networking and hearing the latest developments."

Mike Romanos, CEO, **Microbiotica**

"An extremely important forum if one wishes to gain a broad, yet in-depth, understanding of the most recent advances globally in microbiome-based therapies."

Jim Brown, Director of Computational Biology & Senior Fellow, **GSK**

"The microbiome is one of the most emerging fields right now and at this meeting we have the group leaders and industry pioneers in the field of microbiome science sharing their experience in knowledge."

Yogesh Mudalier, Researcher Investigator – Formulation Development, **Takeda**

"As a newcomer to the microbiome field, this conference provided an excellent overview."

Richard Shanksky, Executive Director, Regulatory Affairs-CMC, **Seres Therapeutics**

"It was a great conference to effectively learn the current trends in microbiome drug development around the world."

Nanae Izumi, Senior Researcher, **Daiichi Sankyo**

AGENDA AT A GLANCE

PRE-CONFERENCE WORKSHOP DAY
WEDNESDAY, JUNE 26

WORKSHOP A
11:30 - 14:00

Metagenomics Masterclass –
Your Comprehensive Guide to Microbiome Data Analysis

WORKSHOP B
14:30 – 17:00

Leveraging the Role of the Human Microbiome
to Improve Immunotherapy Outcomes

Lunch & Networking

WORKSHOP C: START-UP FOCUS EVENING
17:30 – 19:30

How Can Academic Promise Translate
into Commercial Success?

CONFERENCE DAY ONE
THURSDAY, JUNE 27

MICROBIOME LEADER'S PERSPECTIVES

Speed Networking

PRE-CLINICAL & DISCOVERY	MANUFACTURING, CLINICAL & COMMERCIALIZATION	BIOMARKERS, BIOINFORMATICS & RESPONSE
Livebiotherapeutic Discovery & Development	Manufacturing the Microbiome	Microbiome Biomarker Discovery & Development in IBD

Lunch & Networking

Microbiome-Derived Molecule/ Metabolite Discovery & Development	Early Stage Clinical Design & Development	Microbiome Biomarker Discovery & Development in IBD

Afternoon Refreshments & Networking

STREAMLINING REGULATORY GUIDANCE

Drinks Reception & Poster Session

CONFERENCE DAY TWO
FRIDAY, JUNE 28

STANDARDS IN MICROBIOME RESEARCH

Morning Refreshments & Networking

PRE-CLINICAL & DISCOVERY	MANUFACTURING, CLINICAL & COMMERCIALIZATION	BIOMARKERS, BIOINFORMATICS & RESPONSE
Subtractive Microbiome Approaches Discovery & Development	Measuring Engraftment	Using Artificial Intelligence to Tackle Microbiome Data
	Pharmaceutical Perspectives & Partnerships	

Lunch & Networking

Genetically Engineered Bacteria Discovery & Development	Clinical Design & Development Continued	Microbiome Biomarker Discovery & Development in Cancer
Translating Animal Studies to Human		Challenges in Bioinformatics & Data Integration
Microbiome Leaders of Tomorrow		

Close of Conference

WORLD-CLASS SPEAKER FACULTY

Lothar Steidler
Chief Technology Officer
ActoBio Therapeutics

Nathan Magarvey
Founder
Adapsyn Bioscience

Micah Mackinson
SVP, Corporate Development & Strategy, **Assembly Biosciences**

Nigel Titford
CEO
BioGaia Pharma

Adrien Nivoliez
CEO
biose industrie

Ross Youngs
CEO & Founder
Biosortia Pharmaceuticals

Assaf Oron
Chief Business Officer
BiomX

Chris Reyes
Co-Founder & CEO
Bloom Science

Jeffrey Heiser
Director Microbiology
Boston Analytical

Patrick Thiaville
Senior R&D Supervisor
Captozyme

Mark Pimentel MD
Director of MAST Program
Cedars-Sinai

Ben Bradley
Head of Partnerships & Licensing
CHAIN Biotech

Suguna Rachakonda
Senior Director, Product Development
Cleveland Clinic

John Colson
Director of Operations
ClostraBio

Greg Mckenzie
Chief Scientific Officer
ConsortiaTX

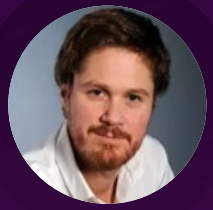
Nur Hasan
Chief Scientific Officer
CosmosID

Dan Knights
CEO
CoreBiome

Gerard Honig
Translational Research Manager
Crohn's & Colitis Foundation

Julia Cope
Director of Scientific Operations
Diversigen

James McIlroy
Founder & Chief Business Officer
Enterobiotix



Rodolphe Clerval
Chief Business Officer - VP US Operations
Enterome

Romain Daillere
Co-Founder & Head of Preclinical Research
EverImmune

Edna Termilus
Medical Officer
FDA

Mark Smith
CEO
Finch Therapeutics Group

WORLD-CLASS SPEAKER FACULTY

Ulrich Thienel
Chief Medical Officer
Finch Therapeutics Group

Jim Sigler
EVP, CMC & Site Head
Finch Therapeutics Group

Bharat Dixit
VP Bioprocess & Analytical Development, **Finch Therapeutics Group**

Molly Gibson
Senior Associate
Flagship Pioneering

Daniel van der Lelie
Chief Scientific Officer
Gusto Global

Esi Lamousé
Director, Immunology Translational Medicine, **Janssen Pharmaceuticals**

Melissa Marko
Senior Clinical Research Scientist, **Janssen Pharmaceuticals**

Fyza Shaikh
Postdoctoral Fellow
John Hopkins Hospital

Katharine Knobil MD
Chief Medical Officer & Head of R&D
Kaleido Biosciences

Alison Lawton
CEO
Kaleido Biosciences

Susan Stewart
SVP, Regulatory Affairs & Quality
Kaleido Biosciences

Stacy Burns-Guydish
VP, Biotherapeutics Development & Manufacturing
List Laboratories

Tuval Ben-Yehezkel
CEO
Loop Genomics

Jason Ryan
Head of Upstream
LuinaBio

Mark Wilson
President & CEO
MatriSys Bioscience

Ashwin Ananthakrishnan MD
Associate Professor of Medicine
Massachusetts General Hospital

Lynn Bry MD
Director
Massachusetts Host-Microbiome Center

Dario Gutierrez
Head of Investigational Biology
Merck ESC

Malcolm Kendall
CEO
Microbiome Insights

Mike Romanos
CEO
Microbiotica

Simon Harris
CHead of Bioinformatics
Microbiotica

Scott Jackson
Leader - Complex Microbial Systems Group
NIST

Herwig Bachmann
Group Leader Fermentation
NIZO

WORLD-CLASS SPEAKER FACULTY

Wes Whitaker
Co-Founder and CSO
Novome Biotechnologies

Liz Shepherd
Co-Founder
Novome Biotechnologies

Arpita Maiti
Sr Director, ES&I, I&I & Microbiome
Pfizer

Aurelien Baudot
International Business Developer
ProDigest

Mike Frodsham
Pharmaceutical Development Manager
Quay Pharma

Edward Burd
Head of Regulatory Affairs
Rebiotix

Ken Blount
Chief Scientific Officer
Rebiotix

Julius Goepp
CEO
Scaled Microbiomics

Matthew Henn
Chief Scientific Officer
Seres Therapeutics

Jim Weston
SVP Regulatory Affairs
Seres Therapeutics

Jennifer Wortman
Senior Director Bioinformatics
Seres Therapeutics

Eric Shaff
CEO
Seres Therapeutics

Thomas J. DesRosier
Chief Legal Officer & Secretary
Seres Therapeutics

Nikole Kimes
Founder & Chief Scientific Officer
Siolta Therapeutics

Glennda Smithson
Director, Translational Biomarker Research (Immunology)
Takeda

Gregory Lambert
CEO
TargEDys

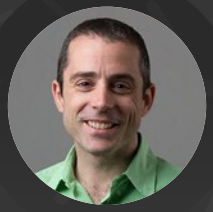
Cathryn Nagler
Bunning Food Allergy Professor
University of Chicago

Matt Martin
Microbiome Lead Technology Commercialization,
University of Chicago

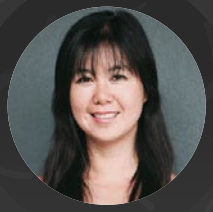
Betty Theriault DVM, DACLAM
Associate Professor & Director, Gnotobiotic Research Animal Facility
University of Chicago

Rita Colwell
Distinguished University Professor
University of Maryland

Alexander Khoruts MD, Medical Director
University of Minnesota Microbiota Therapeutics



Bernat Olle
CEO
Vedanta Biosciences



Colleen Cutcliffe
Co-Founder & Chief Executive Officer
Whole Biome

Andrew Goodman
Associate Professor
Yale University

PRE-CONFERENCE WORKSHOP DAY - WEDNESDAY, JUNE 26

WORKSHOP A

11:30 - 14:00

Metagenomics Masterclass – Your Comprehensive Guide to Microbiome Data Analysis

As emerging research continues to uncover the important relationship between the human microbiome across a variety of critical disease phenotypes, the ongoing challenge of correctly identifying function and the causative role of microbial dysbiosis in disease remains. To help tackle this complex challenge, sophisticated sequencing tools including shotgun metagonomics are becoming widely adopted. This workshop will focus on the current challenges when undergoing metagenomics studies during microbiome research.

Join this session to:

- Understand the importance of metagenomics studies when conducting microbiome research for therapeutic and biomarker development
- Appreciate the current limitations when characterizing microbial composition and function across multiple sample types
- Effectively use shotgun sequencing and bioinformatics analysis to assemble metagenomes and create accurate community and functional analyses
- Discuss the ongoing challenges of metagnomic analysis and the growing importance of conducting holistic microbiome analysis including metatranscriptomics, metabolomics and meta-analysis

Workshop Leader:
Rita Colwell
Distinguished University Professor
University of Maryland

WORKSHOP B

14:30 – 17:00

Leveraging the Role of the Human Microbiome to Improve Immunotherapy Outcomes

Cancer immunotherapy has revolutionized cancer treatment, improving overall survival in comparison to standard of care treatments such as chemotherapy. In recent years, ongoing partnerships, promising in-vivo results and emerging clinical studies that link the gut microbiome, immune response regulation and ICI therapies have begun to elucidate the microbiome's potential impact on predicting immunotherapy response.

Join this session to:

- Review the recent academic and commercial case-studies that link the influence of the gut microbiota on the efficacy of checkpoint inhibitors for more targeted and effective cancer treatment
- Gain insights into developing microbiome-based therapeutics as chemotherapy adjuvants for improved response to emerging immunotherapy options, including immune checkpoint inhibitors
- Understand the challenges of interpreting human clinical samples and mouse models of cancer when linking microbiome composition with response to immunotherapy

Workshop Leaders:
Dario Gutierrez
Head of Investigational Biology
Merck ESC

Fyza Shaikh
Postdoctoral Fellow
John Hopkins Hospital

WORKSHOP C
START-UP FOCUS EVENING
17:30 – 19:30

PLUS ADDITIONAL CONFERENCE OPPORTUNITIES

POSTER SESSION

Share your work with the community and gain feedback on your latest microbiome research. Open to all attendees, the scientific poster session is an invaluable opportunity for you to review and discuss breakthrough microbiome research being carried out by your peers, as well as presenting your own findings. All posters are subject to approval by the *Microbiome Movement* team.

SPEED NETWORKING

A *Microbiome Movement* tradition, this unique networking session will enable you to engage with a large proportion of your fellow attendees early on in the conference, to rapidly establish the relationships you want to forge over the rest of the conference.

How Can Academic Promise Translate into Commercial Success? Reviewing Microbiome Business Models for Successful Therapeutic Development

What challenges have emerging start-up organizations in this field faced and how have they overcome them? This dedicated focus evening will enable you to understand how organizations are establishing themselves in this rapidly-evolving field. Join this intimate evening of case-study led presentations and open, frank discussions to learn from experts who have experienced the reality of establishing successful microbiome initiatives from early academic insights first-hand.

Confirmed Speakers

(More Speakers To Be Announced Soon):

Molly Gibson
Senior Associate
Flagship Pioneering

Cathryn Nagler
Bunning Food Allergy Professor
University of Chicago & ClostraBio

Suguna Rachakonda
Senior Director, Product Development
Cleveland Clinic

Matt Martin
Microbiome Lead, Technology Commercialization
University of Chicago

Arpita Maiti
Sr Director, ES&I, I&I & Microbiome
Pfizer

AGENDA

17:30 **Chair's Opening Remarks**

17:45 **Clostrabio - A Microbiome Start-Up Founded by UChicago Scientists**

18:00 **Commercializing Microbiome Research at the Cleveland Clinic**

18:15 **Commercializing Microbiome Research at UChicago**

18:30 **Flagship Pioneering - Establishing a Novel Approach to Microbiome Venture Creation**

18:45 **Closing Panel Discussion**

19:30 **End of Pre-Conference Focus Evening**

CONFERENCE DAY ONE - THURSDAY, JUNE 27

TRANSLATING CAUSATION TO TREATMENT – REVIEWING THE MICROBIOME'S ROLE IN DRUG DEVELOPMENT

The gut microbiome continues to be at the fore front of medical research and both the industrial and academic communities expect that insights gained from microorganisms will soon become a critical component of health management across a gamut of critical indications. However, the biggest hurdle in translating promising gut microbiome research into effective therapeutic candidates is demonstrating the causative role of human microbiome in disease pathology. Although there are a growing number of microbiome-based candidates showing promising results in both pre-clinical and clinical settings, the approaches that are likely to have well-validated mechanisms of action are limited. The purpose of this theme will be to review the current thinking in approaching the human microbiome mechanistically and understanding both the academic and industrial perspectives on this important topic.

8.30 **Microbiome Industry Leaders Panel Discussion**

- Reviewing the ongoing scientific AND product-development orientated challenges of developing safe, effective and commercially-viable microbiome-based therapeutics - understanding MoAs, identifying microbiome-relevant targets, modelling host-microbiome interactions, the value of engraftment, clinical development, IP, regulatory guidance, scale-up
- Plotting the road to commercialization and defining the rules of the microbiome - addressing uncertainties after Rx approval
- Looking at the rising trends we've seen gather pace in the last two years - including the rise of IO, discovering microbiome-derived biomarkers to predict response, the growing role of microbiome diagnostics and targeting diseases beyond GI
- Ensuring that consistent standards are implemented throughout development
- The role of big institutions to support a complex and unpredictable science - reviewing recent pharmaceutical deals and wide scale government iniatives
- If we could change one thing today, what would it be?

Moderator:

Mike Romanos
CEO
Microbiotica

Panellists:

Bernat Olle
CEO
Vedanta Biosciences

Colleen Cutcliffe
CEO
Whole Biome

Ken Blount
Chief Scientific Officer
Rebiotix

Eric Shaff
CEO
Seres Therapeutics

Alison Lawton
CEO
Kaleido Biosciences

9.30 **Healthy Infants Harbour Intestinal Bacteria That Protect Against Food Allergy**

- Germ free mice colonized with bacteria from healthy, but not cow's milk allergic (CMA), infants are protected against anaphylactic responses to a cow's milk allergen
- Healthy and CMA colonized mice also exhibit unique transciptome signatures in the ileal epithelium
- Correlation of ileal bacteria with genes upregulated in the ileum of healthy or CMA colonized mice identified a butyrate producing Clostridial species, Anaerostipes caccae, that protects against an allergic response to food
- Intestinal bacteria are critical for regulating allergic responses to dietary antigens, suggesting that interventions that modulate bacterial communities may be therapeutically relevant for food allergy

Cathryn Nagler
Bunning Food Allergy Professor
University of Chicago

10.00 **Microbiome Tools & Trends for the Pharmaceutical Industry**

Julia Cope
Director of Scientific Operations
Diversigen

10.30 **Shotgun Sequencing & Strain-Level Analysis: Study Design for Pre-Clinical & Clinical Development**

Nur Hasan
Chief Scientific Officer
CosmosID

11.00 **Morning Refreshments & Speed Networking**

CONFERENCE DAY ONE - THURSDAY, JUNE 27

TRACK A: DISCOVERY PLATFORMS & PRE-CLINICAL DEVELOPMENT OF MICROBIOME-BASED THERAPEUTICS

Introduction & Purpose: Prior to clinical validation, translational microbiome researchers look to leverage cutting edge pre-clinical models to identify microbiome-derived targets that can be pursued for therapeutic development. The purpose of this stream will be to explore the discovery and pre-clinical assessment of microbiome-based therapeutics across the critical product modalities and disease phenotypes.

LIVEBIOTHERAPEUTIC DISCOVERY & DEVELOPMENT

12.00 **A Preclinical Assessment of a Rationally Designed LBP**

Esi Lamouse-Smith, Director Early Development Translational Medicine in Immunology, **Janssen Pharmaceuticals**

12.30 **Translating Probiotic Research into LBP Drug Programs**

- The BioGaia group of companies covers all regulatory categories of the probiotic/ LBP/ microbiome industry. Within the probiotic sector it is an integrated business from discovery to branded products
- BioGaia Pharma AB is a subsidiary analyzing early stage research for drug development opportunities and taking candidates into next stage development
- Discussing challenges with translating to a drug program from probiotic discovery research

Nigel Titford, Chief Executive Officer, **BioGaia Pharma**

TRACK B: MANUFACTURING, CLINICAL DEVELOPMENT & COMMERCIALIZATION OF MICROBIOME-BASED THERAPEUTICS

Introduction & Purpose: Although there has been significant progress both commercially and academically, there is still much we do not know about the microbiome and its role in disease causation. The purpose of this stream will be to review the critical product development challenges when bringing a microbiome-based therapeutic candidate to market.

MANUFACTURING THE MICROBIOME & FORMULATION AND DELIVERY

12.00 **Panel Discussion - Manufacturing and Scaling LBPs**

- Addressing the common challenges when manufacturing LBPs and outlining ways in which organizations are overcoming those
- Understand how to interact with global regulatory agencies to meet guidelines and optimize production
- Effectively scaling LBP development as organizations progress from early stage discovery to clinical development
- Reviewing the most successful case-studies in the microbiome space that organizations can learn from

Adrien Nivoliez, Chief Executive Officer, **biose industrie**
Bharat Dixit, VP Bioprocess & Analytical Development, **Finch Therapeutics Group**
Chris Reyes, CSO, **Bloom Science**

12.30 **CMC Development for a Full Spectrum Microbiota Product**

Jim Sigler, EVP, CMC & Site Head, **Finch Therapeutics Group**

TRACK C: MICROBIOME BIOMARKERS, BIOINFORMATICS & THERAPEUTIC RESPONSE

Introduction & Purpose: As molecular biomarkers continue to become an important component to diagnosing disease and predicting response to treatment, the human microbiome has become a rich source for biomarker discovery across a broad range of disease phenotypes. The purpose of this stream will be to review efforts in biomarker discovery and applications within the drug development and diagnostic industry.

MICROBIOME BIOMARKER DISCOVERY & DEVELOPMENT IN IBD

12.00 **Microbiome-based Biomarkers for Inflammatory Bowel Diseases: Opportunities to Accelerate Drug Development and Improve Clinical Outcomes**

- Biomarker selection criteria for impact in drug development and clinical practice
- Regulatory, development & commercialization paths for biomarkers
- Why biomarkers are a critical priority in the IBD and microbiome fields
- Findings from recent working groups focused on gaps & opportunities in the IBD biomarker space

Gerard Honig, Translational Research Manager, **Crohn's & Colitis Foundation**

12.30 **Utilizing Microbiome-Derived Biomarker to Assess PK/PD and Support the Development of Rationally Designed LBPs**

- How do we think about PK/PD in a microbiome setting to support a proposed MoA for microbiome-based therapeutics?
- Reviewing changes in the composition of the microbiome post treatment and corresponding alterations in microbial metabolites and host biomarkers

CONFERENCE DAY ONE - THURSDAY, JUNE 27

13.00 **Developing Microbial Therapies to Prevent and Treat Human Disease and Allergies**

- Identifying human-origin commensal bacteria that promote tolerant responses in the immune system to reverse food allergies
- Development updates of two protective consortia therapeutics, including CTX-944, a first in-kind allergen-independent therapeutic
- Outlining microbiome-related biomarkers and mechanistic understandings of dysbiosis that contributes to food allergies

Greg Mckenzie, Chief Scientific Officer, **ConsortiaTX**

13.30 **Delivery, Survival, Engraftment & Activity of LBPs in the GI Tract**

- Sharing how validated in-vitro technology platforms are a key tool for the pre-clinical work in LBPs development
- Exploring how the SHIME system enables integrated simulation of the full GI track, including lumen, mucosa and host
- Investigating the MoAs of LBPs in areas of the gut, which are not easily accessible, generating data complementary to in vivo studies

Massimo Marzorati, Chief Executive Officer, **ProDigest**

13.00 **Development of Oral LBPs – a CDMOs Perspective**

- Key CMC considerations for the development of an LBP
- Understanding critical factors affecting timelines when outsourcing GMP manufacturing activities of LBPs
- Incorporating quality systems and regulations into early phase dosage from design of LBPs

Mike Frodsham, Pharmaceutical Development Manager, **Quay Pharma**

13.30 **Scale Up & GMP Manufacture of LBPs**

- Consideration for technology transfer and development of LBPs prior to GMP
- Assessing the scale-up considerations and challenges associated with LBPs in early clinical trial material
- Outlining viability and yield considerations throughout the manufacturing process to bulk drug product

Jason Ryan, Head of Upstream, **LuinaBio**

- Update from Seres – SER-287

Matthew Henn, Chief Scientific Officer, **Seres Therapeutics**

13.00 **Microbiome-derived Biomarker Initiatives at Janssen Pharmaceuticals to Evaluate the Success of VE202**

Melissa Marko, Senior Clinical Research Scientist, **Janssen Pharmaceuticals**

13.30 **Commercial Speaking Position Reserved for Solution/Service Provider -** Please Contact adam.haras-gummer@hansonwade.com for Further Details

13.40 **Lunch & Networking**

14.40 **Improving Cancer Treatment Through Oncobax-Based Therapeutics**

- Intestinal commensals dictate our systemic and anticancer immunity
- Harnessing the microbiome for the discovery of diagnosis and therapeutic tools in cancer is key for modulating the clinical outcome of anticancer regimens
- EverImmune is developing oncobax-based therapeutics to improve the efficacy of anticancer treatments

Romain Daillere, Co-Founder & Head of Preclinical Research, **EverImmune**

EARLY STAGE CLINICAL DESIGN & DEVELOPMENT

14.40 **Clinical Development and Scale-Up Considerations for a Microbiome-based Therapeutic for the Treatment of Metabolic Disease**

- Characterizing a microbiome-based mechanism in appetite regulation
- Developing a food supplement, ProbioSatys, based on strain industrialization that can guide further therapeutic efforts

14.40 **Applying Microbiotica's Platform to Identify Bacterial Biomarkers & Medicines**

Simon Harris, Head of Bioinformatics, **Microbiotica**

15.10 **Commercial Speaking Position Reserved for Solution/Service Provider -** Please Contact adam.haras-gummer@hansonwade.com for Further Details

CONFERENCE DAY ONE - THURSDAY, JUNE 27

SMALL MOLECULE/METABOLITE DISCOVERY & DEVELOPMENT

15.10 **Commercial Speaking Position Reserved for Solution/Service Provider -** Please Contact adam.haras-gummer@hansonwade.com for Further Details

15.40 **Microbiota-Derived Metabolites to Treat Food Allergy and Prevent Food Allergen Sensitivity**

- Outlining a novel approach to treat food allergies using polymer-modified bacterially-derived metabolites
- Developing polymers that are locally-acting and induce a barrier protective response in the ileum
- In the context of dysbiosis and food allergy, ClostraBio's polymer are disease modifying and show potential to prevent allergic sensitization

John Colson, Director of Operations, **ClostraBio**

16.10 **A Chemistry-Driven Approach to Leveraging the Potential of the Microbiome Organ to Treat Disease and Improve Human Health**

Katharine Knobil MD, Chief Medical Officer and Head of R&D, **Kaleido Biosciences**

16.40 **From Sample to Data - Considerations for Designing Microbiome Studies**

Malcolm Kendall, Chief Executive Officer, **Microbiome Insights**

- Design of a double blind, placebo-controlled clinical study to evaluate the benefit of ProbioSatys on weight reduction in overweight subjects

Gregory Lambert, Chief Executive Officer, **TargEDys**

15.10 **Clinical Validation for Microbiome Modulators**

Herwig Bachmann, Group Leader Fermentation, **NIZO**

15.40 **Reverse Translation for Therapeutic Development in the Human Microbiome**

- Interpreting correlations observed in human cohort studies
- Developing therapeutic insights from clinical observations
- Observing patterns of microbial engraftment to develop a new generation of rationally selected

Ulrich Thienel, Chief Medical Officer, **Finch Therapeutics Group**

16.10 **Developing Microbiome-based Therapeutics for the Prevention and Treatment of Inflammatory Diseases**

- Collecting and analyzing longitudinal microbiome data from infants to identify communities of microbes with immunomodulatory capacity
- Isolating and characterizing keystone species that function by interrupting the cascade of asthma symptoms, as both a treatment and preventative measure
- Overview of Phase 1b trial for consortia

Nikole Kimes, Founder & Chief Scientific Officer, **Siolta Therapeutics**

16.40 **Overcoming Hurdles in the Development of Live Biotherapeutic Products**

Stacy Burns-Guydish, VP, Biotherapeutics Development & Manufacturing, **List Laboratories**

15.40 **A Novel Machine Learning Approach to Microbiome Based Biomarker Discovery**

- The need and challenges in microbiome-based biomarker discovery
- Using a novel cloud based computational approach utilizing machine learning to identify biomarkers
- Sharing examples of biomarker discovery

Assaf Oron, Chief Business Officer, **BiomX**

16.10 **The Growing Role of the Gut Microbiome in Drug Metabolism**

- Disentangling host and microbiome contributions to drug PK and toxicity, focusing on cases where host and microbiome produce a chemically identical metabolite
- Quantitative understanding of host microbiome-encoded metabolic activities will clarify how the microbiome impacts drug metabolism
- Revealing new insights for tailored interventions strategies to improve drug responses

Andrew Goodman, Associate Professor, **Yale University**

16.40 **Commercial Speaking Position Reserved for Solution/Service Provider -** Please Contact adam.haras-gummer@hansonwade.com for Further Details

CONFERENCE DAY ONE - THURSDAY, JUNE 27

16.50 **Afternoon Refreshments and Networking**

STREAMLINING REGULATORY APPROVAL OF MICROBIOME-BASED THERAPEUTICS

As microbiome therapies constitute a novel paradigm in modern medicine, a robust regulatory framework that addresses key safety and biocontainment issues should be evaluated for safe implementation of these treatments. Despite the rise in notoriety across the pharmaceutical industry, only a few regulatory agencies have provided clarity over the regulatory hurdles when developing a microbiome-based therapeutic. The purpose of this theme will be to outline how leading regulatory bodies currently review microbiome candidates whilst highlighting successful IND applications for emerging and well established microbiome companies.

17.15 **Regulatory and Clinical Considerations for LBPs**

- Understanding the IND process
- Discussing current FDA review of LBPs and other microbiome based biologics
- Reviewing the current FDA review on clinical development of LBPs

Edna Termilus
Medical Officer
FDA

17.45 **Gut Microbiome Endgame: Ramping up cGMP Program Design to Ensure Regulatory Preparedness for Microbiome Products**

- Implementing program design approaches in order to ensure regulatory approval for IND filings
- Evaluation of successful clean room commissioning, release testing characterization and stability testing approaches
- Providing an in-depth evaluation of the expertise required in order to successfully bring a microbiome-based product into the next phase of a program's lifescycle

Jeffrey Heiser
Director Microbiology
Boston Analytical

18.15 **Panel Discussion – Building Clear Regulatory Guidelines for Microbiome-based Therapeutics**

- How does modality of a microbiome-based therapeutic impact regulatory thinking and strategy?
- Addressing the common regulatory opinion on donor screening and reducing overall variability of samples used for the development of LBPs
- Discussing the regulatory guidelines underpinning product characterization criteria
- Reviewing international perspectives on microbiome-based therapeutics and ways in which regulatory strategy is being harmonised on a global scale

Edna Termilus
Medical Officer
FDA

Jim Weston
SVP Regulatory Affairs
Seres Therapeutics

Susan Stewart
SVP, Regulatory Affairs & Quality, **Kaleido Biosciences**

Edward Burd
Head of Regulatory Affairs
Rebiotix

19.00 **Evening Drinks Reception & Poster Session Hosted by *the Microbiome Movement***

20.00 **Close of Conference Day One**

CHATHAM HOUSE RULES C-LEVEL ROUNDTABLE (INVITE ONLY)

17.15 – 18.45
This theme will be an invite only session that will look to unite the leaders of the translational microbiome space to discuss the long term challenges and opportunities that still lie within this ever-growing field.

CONFERENCE DAY TWO - FRIDAY, JUNE 28

ADVANCING STANDARDS FOR TRANSLATIONAL MICROBIOME RESEARCH IN THERAPEUTIC DEVELOPMENT

As the vast quantity of microbiome research continues to be translated into therapeutic, biomarker and diagnostic applications, the development of standard operating procedures continues to be crucial to ensure the reproducibility and regulatory approval of these products. The purpose of this theme will be to review the importance of creating standards to ensure the long-term viability of microbiome-based products within the pharmaceutical industry to allow for greater comparability and reproducibility between studies without dampening cutting edge scientific innovation.

8:30 **Introducing the Microbiome Therapeutics Innovation Group – Building a Collective Voice to Enhance the Regulatory, Investment and Commercial Success of Microbiome-Based Therapeutics**

- Working with the FDA to streamline the regulatory process and decrease the amount of time needed for new microbiome-based therapeutics to reach the market, including obtaining regulatory clarity on clinical trial design, endpoint selection and biomarker selection, use of expedited review pathways, and product nomenclature
- Mobilizing legislators, policymakers, clinicians, patients and the public to support efforts aimed at advancing research and development of microbiome-based therapeutics addressing serious unmet medical needs

Thomas J. DesRosier
Chief Legal Officer & Secretary
Seres Therapeutics

9.00 **Improving Microbiome Work Flow Standards to Overcome Regulatory Hurdles and Accelerate Product Development**

- Analyzing the growing need to clarify and improve microbiome research measurements
- Reviewing the greatest complexitites in measuring and analysing complex microbial data when pursuing therapeutic goals
- Outlining measurement tools to ensure maximum purity, identity, stability and potency of microbiome-based therapeutics

Scott Jackson
Leader - Complex Microbial Systems Group
NIST

9.30 **Panel Discussion - Establishing Industry Standards for Microbiome-Based Therapeutics**

- Discussing the importance and need for creating reference materials and methodologies when conducting microbiome-specific research
- Addressing the challenges of standardising the various stages of microbiome workflow including sample handling, DNA extraction, sequencing and bioinformatics analysis
- Looking at how pharmaceutical organizations, standards and regulatory agencies can collaborate to accelerate the adoption of industry-wide standards for translational microbiome research
- Identifying gaps on harmonising our understanding of the human microbiome and their relative function in disease causation
- Reviewing the ongoing efforts today in making microbiome standards a reality

Panellists to be Confirmed Shortly - Please Check Back with Us Soon

10.00 **Powering Microbiome Discovery with Big Data**

Dan Knights
Chief Executive Officer
CoreBiome

10.30 **Morning Refreshments & Networking**

CONFERENCE DAY TWO - FRIDAY, JUNE 28

TRACK A: DISCOVERY PLATFORMS & PRE-CLINICAL DEVELOPMENT OF MICROBIOME-BASED THERAPEUTICS

SUBTRACTIVE MICROBIOME APPROACHES DISCOVERY & DEVELOPMENT

11.30 **Immunotherapeutic Approaches to Selective Modulation of Microbiomes**

- Addressing a major opportunity for disease interception through the human microbiome
- Introducing IgY, a non-mammalian immunoglobulin as a targeted approach to subtractive microbiome interventions
- SMB-19-001: Valentix, an exciting therapeutic designed to intercept and treat colorectal cancer

Julius Goepp, Chief Executive Officer, **Scaled Microbiomics**

12.00 **Customized Phage Therapies for Chronic Disease**

Assaf Oron, Chief Business Officer, **BiomX**

GENETICALLY ENGINEERED BACTERIA DISCOVERY & DEVELOPMENT

12.30 **Development of a Novel IBD Therapeutic Using Engineered Clostridium**

- CHAINs microbiome therapeutics approach using genetically engineered clostridium butyricum
- Summary of strain engineering and scale-up manufacturing for clostridium spores
- Summary of in vitro and in vivo pre-clinical work for a (R)-3-hydroxybutyrate producing strain, under evaluation as a novel therapeutic to treat ulcerative colitis

Ben Bradley, Head of Partnerships & Licensing, **CHAIN Biotech**

TRACK B: MANUFACTURING, CLINICAL DEVELOPMENT & COMMERCIALIZATION OF MICROBIOME-BASED THERAPEUTICS

MEASURING THE IMPORTANCE OF ENGRAFTMENT FOR MICROBIOME-BASED THERAPEUTICS

11.30 **An Exclusive Metabolic Niche Enables Strain Engraftment in the Gut Microbiota**

- Addressing the unpredictable fate of exogenous commensal and probiotic strains applied to an established microbiota
- Generating an exclusive metabolic niche in mice via administration of a marine polysaccharide, porphyran, and an exogenous Bacteriodes strain harbouring a rare gene cluster for porphyran utilization
- Reviewing the influences of nutrient availability in shaping microbiota membership, overcoming priority exclusion by isogenic strains and designing cell-based therapeutic strategies in the gut

Liz Shepherd, Co-Founder, **Novome Biotechnologies**

PHARMACEUTICAL PERSPECTIVES & PARTNERSHIP STRATEGIES FOR MICROBIOME-BASED THERAPEUTICS

12..00 **Panel Discussion – New Perspectives On Pharmaceutical & Biotech Partnerships In The Microbiome**

- Reviewing the trends of collaborations that have occurred in the microbiome space between cutting-edge biotechs and large pharmaceutical organizations
- Addressing the selection criteria pharmaceutical organizations use when assessing potential partnerships in field that hasn't been validated by advanced clinical results or approved therapeutics
- Choosing partnerships that are a right fit for

TRACK C: MICROBIOME BIOMARKERS, BIOINFORMATICS & THERAPEUTIC RESPONSE

USING ARTIFICIAL INTELLIGENCE TO TACKLE THE COMPLEXITY OF MICROBIOME DATA

11.30 **Incorporating Microbiome and Clinical Data to Develop Predictive Algorithms as a Marker of Response to IBD Treatment**

Ashwin Ananthakrishnan MD, Associate Professor of Medicine, **Massachusetts General Hospital**

12.00 **Combining Genomic, Metabolomic Data with Machine Learning to Identify New Targets from the Human Microbiome**

Nathan Magarvey, Founder, **Adapsyn Bioscience**

12.30 **A Prototype Biomarker for Microbiome Rehabilitation in Patients with Clostridium Difficile Infections: Application to a Clinical Trial of a Lyophilized, Non-Frozen, Oral, Microbiota-Based Drug rbx7455**

- Introducing the Microbiome Health Index (MHI), a unidimensional algorithm which captures changes in the relative abundance of taxonomic classes known to have relevance to microbiome health and colonization resistance
- Reviewing the role of the MHI in assessing the clinical efficacy of RBX7455 and RBX2660
- Evaluating the role of the MHI as a clinical trial endpoint to confirm the robustness of the metric

Ken Blount, Chief Scientific Officer, **Rebiotix**

CONFERENCE DAY TWO - FRIDAY, JUNE 28

13:00 **Next Generation Microbiome Profiling**

- LoopSeq™ microbiome profiling is the first long-read, high-resolution microbiome sequencing technology that uses existing Illumina sequencers
- LoopSeq™ technology introduces single-molecule counting for improved microbiome species abundance quantification
- LoopSeq™ simplifies microbiome sequencing workflows by enabling 'one pot', multiplexed sample preparation of up to 96 samples

Tuval Ben-Yehezkel, CEO, **Loop Genomics**

both sides (strategic, cultural and organizational factors)
- Learning how to trust each party's strengths/ weaknesses and communicate expertise openly for long-lasting relationships to speed R&D efforts and increase chances of drug approval

Micah Mackinson, SVP, Corporate Development & Strategy, **Assembly Biosciences**
Rodolphe Clerval, Chief Business Officer - VP US Operations, **Enterome**
Mark Smith, Chief Executive Officer, **Finch Therapeutics Group**
Mike Romanos, Chief Executive Officer, **Microbiotica**
Arpita Maiti, Sr Director, ES&I, I&I & Microbiome, **Pfizer**

13:00 **ALIVE: The 5 Key Drivers to Developing & Manufacturing Successful LBPs**

Patrick Thiaville, Senior R&D Supervisor, **Captozyme**

13.10 **Lunch & Networking**

14.50 **Engineering Therapeutic Bacteria to Robustly Colonize the Gut**

- New genetic tools for Bacteroides enable modification of the most abundant gut genus
- Creating an exclusive niche via rare carbohydrate utilization enables robust and controllable gut colonization
- Engineered therapeutic activities modulate host physiology

Wes Whitaker, Co-Founder and CSO, **Novome Biotechnologies**

GENERATING & TRANSLATING ANIMAL STUDIES TO HUMANS

15.20 **Panel Discussion: Exploring the Utility of In-Vivo Models for Translational Microbiome Research**

- What should look we for when choosing the right animal model for microbiome research?
- Analysing the function and mechanism of microbial communities on disease using in vivo models

CLINICAL DESIGN & DEVELOPMENT CONTINUED

14.50 **Clinical Trial Design Challenges & Considerations for a Novel Synbiotic in Patients with Type 2 Diabetes**

- Highlighting the key challenges of designing clinical trials in the microbiome space (timeline of trial, dosing considerations, engraftment considerations, stool collection etc.) and how we overcame them
- Outlining a discovery platform to successfully identify microbiome targets for T2D
- Looking at the manufacturing and QC challenges unique to microbiome products

Colleen Cutcliffe, Co-Founder & Chief Executive Officer, **Whole Biome**

15.20 **Matrisys Bio – Phase 2 Clinical Updates and New Developments**

- Commensal bacteria make potent antimicrobial peptides

MICROBIOME BIOMARKER DISCOVERY & DEVELOPMENT IN CANCER

14.50 **Leveraging Gut Microbiota Networks for Impacting Tumor Immunotherapy**

Jennifer Wortman, Senior Director, Bioinformatics, **Seres Therapeutics**

15.20 **Panel Discussion: Reviewing the Role of the Human Microbiome in Biomarker Discovery & Development**

- When we think about PK, what does that mean for the different microbiome-based drug modalities (LBPs, small molecules, GMO, Natural products etc.)?
- Highlighting the importance of dosing and dosing strategies and how that relates to PK/PD
- Discussing how regulatory agencies look at IBD biomarkers when assessing the relative efficacy of microbiome-based therapeutics
- When looking at cancer specifically, which pathways in the cancer cycles are companies trying to

- Reviewing the predictability, reproducibility and translatability of preclinical microbiome studies when preparing for clinical development
- Discussing the challenges and limitations when conducting translational microbiome research with gnotobiotic mouse models
- Assessing pre-clinical systems beyond in vivo models and their applicability to microbiome studies

Esi Lamouse-Smith, Director Early Development Translational Medicine in Immunology, **Janssen Pharmaceuticals**
Lynn Bry MD, Director, **Massachusetts Host-Microbiome Center**
Betty Theriault DVM, DACLAM, Associate Professor & Director, Gnotobiotic Research Animal Facility,**University of Chicago**

MICROBIOME LEADERS OF TOMORROW – LATE BREAKING ABSTRACTS

15.50 **Actobiotics®, Lactococcus-Based Biopharmaceuticals for Expression and Local Delivery of Therapeutics at Target Sites**
Lothar Steidler, Chief Technology Officer, **ActoBio Therapeutics**

16.05 **Harnessing Whole Community Microbiome Transfer to Develop and Advance Novel Medicinal Products**
James McIlroy, Founder & Chief Business Officer, **Enterobiotix**

16.20 **Obtaining Hidden & Novel Small Molecules of the Microbiome**
Ross Youngs, CEO, **Biosortia Pharmaceuticals**

16.35 **Presentation Title TBC, Please Check Back With us Soon**

- The skin surface is not flat
- Microbiome therapeutics are commercially viable

Mark Wilson, President & Chief Executive Officer, **MatriSys Bioscience**

15.50 **The Human Microbiome and IBS**
Mark Pimentel MD, Director of MAST Program, **Cedars-Sinai**

16.20 **Standardising the Process of Clinical Trial Design and Capsule Development for Microbiome-Based Therapeutics**

- Addressing the current pitfalls when undergoing clinical studies for LBPs, with a focus on C.Difficile
- Outlining strategies to preserve and deliver microbiota for therapeutic development
- Sharing the only academic program that is manufacturing encapsulated microbiome products for disease treatment

Alexander Khoruts MD, Medical Director, **University of Minnesota Microbiota Therapeutics**

impact (immune responses, increased trafficking to tumours). How will product modality impact this?
Jennifer Wortman, Senior Director, Bioinformatics, **Seres Therapeutics**
Matthew Henn, Chief Scientific Officer, **Seres Therapeutics**
Gerard Honig, Translational Research Manager, **Crohn's & Colitis Foundation**
Glennda Smithson, Director, Translational Biomarker Research (Immunology), **Takeda**

CHALLENGES IN MICROBIOME BIOINFORMATICS & DATA INTEGRATION

15.50 **Bioinformatic Analysis of Microbial Communities for Novel LBP Discovery and Patient Stratification**

- Short-comings of customary approaches for metagenome comparison and functional analysis
- GUST+, an improved bioinformatics platform for biomarker discovery and patient stratification
- Rational design of novel LBPs around functional redundancies and metabolic interdependencies

Daniel van der Lelie, Chief Scientific Officer, **Gusto Global**

16.20 **Understanding Precision Metagnomics to Assess Human Biology, Disease and Diagnostics**
Rita Colwell, Distinguished University Professor, **University of Maryland**

16.50 **Close of 4th *Microbiome Movement* - Drug Development Summit 2019**

WHO WILL YOU MEET?

"This is a tremendous event, everyone who's important in this field, we're seeing them here and it's helping stimulate innovation in our own programs."

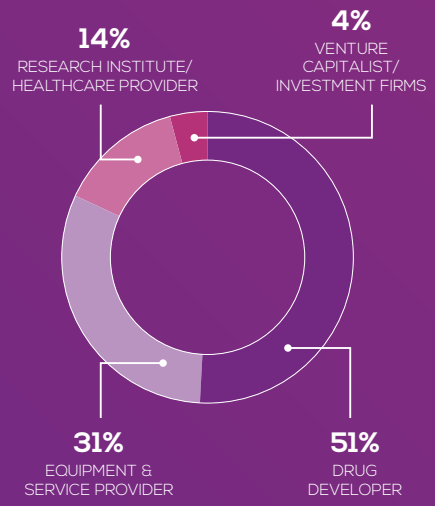
Ken Blount, Chief Scientific Officer, **Rebiotix**

60+ SPEAKERS

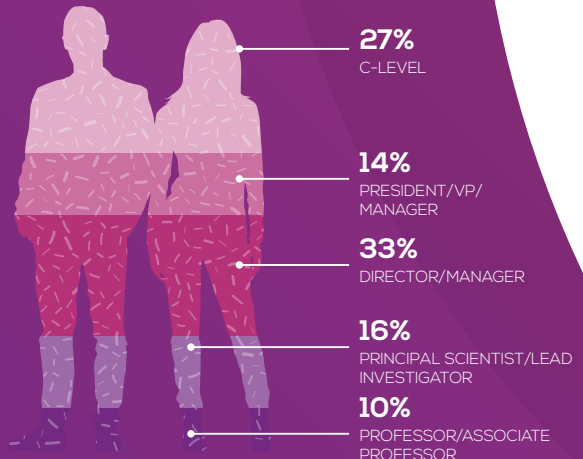
250+ ATTENDEES

200+ COMPANIES

COMPANY TYPE*



SENIORITY*



* Based on the last two years of the *Microbiome Movement* - Drug Development Series in Boston and Paris.

SNAPSHOT OF PREVIOUS ATTENDEES*

PHARMACEUTICALS

Allergan, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Daiichi-Sankyo, Lilly, Ferring Pharmaceuticals, GlaxoSmithKline, Janssen, Merck, Novartis, Pfizer, Sanofi, Shionogi Inc., Takeda

BIOTECH

AOBiome, assembly biosciences, Axial, enterome, Evelo, Gusto Global, microbiotica, OpenBiome, 4D pharma plc, Rebiotix, Ritter Pharmaceuticals, Second Genome, Seres Therapeutics, Synthetic Biologics, Vedanta Biosciences, Whole Biome

ACADEMICS, GOVERNMENT & INVESTORS

Baylor University, Bill & Melinda Gates Foundation, Caltech, Cleveland Clinic, FDA, INRA, Karolinska Institutet, MIT, NIST, Seventure, Flagship Pioneering

PROUD TO PARTNER WITH

"The *Microbiome Movement* has proven to deliver a superior conference where scientific content is consistently emphasized concurrently with business relationship building opportunity. CosmosID has found each event to be an excellent platform for advancement of the microbiome industry, no matter which facet of the field was being promoted."

Manoj Dadlani, CEO, CosmosID

EXPERTISE PARTNER

CosmosID®, based in Rockville, MD, provides award-winning Next-Generation Sequencing & Bioinformatics solutions for unlocking the microbiome through rapid identification and characterization of microorganisms for pharmaceutical R&D, molecular diagnostics, public health, food safety, agriculture, and environmental applications. CosmosID's CLIA-certified laboratories offer end-to-end solutions; from study design to sample collection, extraction, library preparation, sequencing, data analysis and publication support. Lastly, CosmosID's user-friendly and independently validated cloud-based application returns strain-level metagenomic analyses with industry-leading sensitivity & precision along with access to the world's largest database for microbial genomics.

www.cosmosid.com

EXPERTISE PARTNER

CoreBiome is a genomics platform company focused on accelerating discovery for customers in the pharmaceutical, agriculture, and research communities, to unleash the translational potential of the microbiome. The Company's proprietary BenchMark™, BoosterShot™, and Core Analysis™ platforms provide a rapid and highresolution measurement and interpretation of microbial diversity. The recently launched BoostArray™platform provides an ideal method for the characterization of strain libraries. CoreBiome was founded in 2016 based on intellectual property originating from the University of Minnesota. The founding team has collective experience processing and analyzing hundreds of thousands of microbiome samples.

www.corebiome.com

EXPERTISE PARTNER

Boston Analytical, the Life Sciences Division of Alpha Analytical, is a cGMP compliant, FDA/DEA registered, ISO/IEC-17025:2005 certified analytical laboratory located in Salem, NH. We can provide all of the identity, purity and potency analyses necessary to characterize your microbiome product. Boston Analytical has a proven track record with sponsors on a variety of Microbiome programs including both Spore Fraction and Defined Drug Product manufacturing processes. We employ Labware Inc's™ LIMS & ELN software with on-line data access for your convenience.

www.bostonanalytical.com

EXPERTISE PARTNER

Accelerate and transform your research across the entire project lifecycle and capitalize on the diverse opportunities of the microbome. Diversigen provides comprehensive microbiome, metagenomics, host genetic services, customized study design, and complex data analysis - all focused on solutions to improve human and animal health, environmental conditions, and agriculture production worldwide.

ww.diversigen.com

PROGRAM PARTNER

Quay Pharma is experienced in formulation development and is one of very few companies licensed to provide clinical manufacturing materials containing live bacterial strains being targeted for delivery to, and in, the digestive, urogenital, otorhinologic and pulmonary tracts. Understanding the client dosing requirements for the live biotherapeutic, Quay can prepare a formulation development strategy to bring your live bacterial strain rapidly and effectively to First in Man studies aiming to provide a formulation with the best chance of clinical success.

www.quaypharma.com

PROGRAM PARTNER

Biose Industrie is a Contract Development and Manufacturing Organization (CDMO), specialised in Live Biotherapeutic Products. Founded in 1951 by pharmacists and microbiologists, Biose Industrie has been manufacturing drug substance and drug products based on microorganisms for 60 years. Company, with 10 000m² of GMP facilty, offers product development at laboratory and pilot scale specialised in microbiology for aerobie and anaerobie strains and is Drug GMP certified for the manufacturing of API, clinical batches and commercial products.

www.biose.com/en/cdmo

PROGRAM PARTNER

NIZO is world leading in contract research for better food and health. We believe food and health are closely connected. Moreover we are convinced that working closely with our customers, leading food and health companies, is the only road to success. For pharma, (functional)ingredient, nutraceutical and personal care companies we perform discovery, development programmes and clinical trials related to gut health, oral health and skin health with a specific focus on microbiome modulation.

www.nizo.com

INDUSTRY PARTNER

Microbiotica is transforming personalised medicine with leading microbiome science, identifying gut bacteria linked to patient phenotype with unprecedented precision for the discovery of novel microbiome-based medicines and biomarkers of drug response. Microbiotica was spun out of Trevor Lawley's Lab at the Wellcome Sanger Institute and is founded on a unique pipeline for culturing and genomically characterising the entirety of the bacteria in the human gut for the first time. It has the world's largest microbiome genome database and culture collection, a suite of translational in vitro and animal models, and state of the art bioinformatics and AI. The company has a focus on IBD and Immuno-Oncology, and a program in C. difficile which is spearheading innovation in development of live bacterial products.

www.microbiotica.com

INNOVATION PARTNER

Captozyme is a vertically integrated manufacturer and distributor of health care products, offering contract development and manufacturing services focused on personalized gut health. Using sound scientific principles and expert knowledge, Captozyme is a dependable extension of our clients' teams, offering full-service development and manufacturing with a focus on live biologics and enzymes. From discovery, to R&D, product development and manufacturing for Phase 1 clinical studies, Captozyme takes pride in helping their partners succeed.

www.captozyme.com

INNOVATION PARTNER

LuinaBio is Australia's most experienced biopharmaceutical CDMO's with 20 years' experience in our field. More specifically Luina carries out microbial aerobic and anaerobic fermentation, yeast fermentation, cell banking, vaccine production, process development, analytical services, stability studies, storage and distribution of investigative material for clinical studies.

www.luinabio.com.au

INNOVATION PARTNER

Since 1978 List Biological Laboratories, Inc. has been the leading manufacturer of bacterial products for research. Leveraging decades of experience growing microorganisms, List Labs offers GMP manufacturing of Live Biotherapeutic Products (LBP) for clinical trials. We have developed products for many microbiome companies from technology transfer through GMP production, including cultivation of aerobic, anaerobic and spore-forming bacteria. List Labs is your ideal full service CDMO, with the flexibility and expertise to customize a successful development path for your microbiome product.

www.listlabs.com

INNOVATION PARTNER

ProDigest is a product leader in the development of unique laboratory models of the human and animal gastrointestinal tract (SHIME®). These models allow to obtain unique insight in gut processes associated to the intestinal fate of actives and to study the complete gut microbiome under controlled conditions. ProDigest is globally active as a service provider for food and pharmaceutical companies and installs its technology in selected R&D facilities around the world. Furthermore, ProDigest has set up a number of product development projects in relation to the gut microbiota management and novel biotherapeutics.

www.prodigest.eu

INNOVATION PARTNER

Microbiome Insights provides state-of-the art microbiome analysis and bioinformatics. Our end-to-end service starts from experimental design and sample collection to data analysis and bioinformatics interpretation. Microbiome Insights is focused on providing our clients a deeper understanding of functions and interactions of microbial communities across a range of human, animal, agricultural and environmental research applications.

www.microbiomeinsights.com

INNOVATION PARTNER

Loop Genomics is a DNA sequencing company with a vision to provide products that deliver the most complete and accurate human microbiome data. Loop technology meets the critical need for high-resolution phylogenetic data using long-read sequencing and single molecule abundance quantification, with an innovative approach that transforms existing short-read sequencing machines. Our long-read single molecule microbiome sequencing products enable drug R&D pipelines to discover previously inaccessible metagenomics information at unprecedented scale, while leveraging their existing sequencing systems and workflows.

www.loopgenomics.com

INNOVATION PARTNER

Based on its pioneering research on the role of tissue microbiota inthe initiation of the inflammatory cascade leading to metabolic disorders, Vaiomer vocation is to contribute to the studies of disease mechanism, in clinical and basic research to discover innovative biomarkers, therapeutic targets and products. Vaiomer offers a unique platform to study the microbiome of low bacterial load samples (human or animal: blood, liver, brain, adipose tissue, muscle, bone marrow, MLN, bile, ascites and more).

www.vaiomer.com

EXHIBITION PARTNER

With more than 20 years' experience, Wacker Biotech is "THE MICROBIAL Contract Development and Manufacturing Organization" (CDMO) – the partner of choice for the manufacturing of therapeutic proteins, vaccines and live microbial products. Wacker Biotech`s sites in Jena, Halle (Germany) and Amsterdam (Netherlands) provide a complete range of services for the development and GMP-compliant manufacture of biopharmaceuticals. The service portfolio covers process & analytical development and the GMP manufacturing of biologics for clinical trials and commercial supply.

www.wacker.com/biologics

EXHIBITION PARTNER

Anaerobe Systems has over 40 years of experience specializing in manufacturing pre-reduced anaerobic culture media, anaerobic transport media, and anaerobic chambers for the cultivation and transport of anaerobic organisms. We specialize in producing customized media formulations to meet our customer's unique requirements and have a range of standard products that support the growth of human microbiota. Anaerobe Systems manufactures and sells anaerobic chambers which provide an oxygen free environment for manipulation and growth of anaerobic organisms.

www.anaerobesystems.com

EXHIBITION PARTNER

Microbiology International specializes in laboratory automation by providing advanced instruments and custom media solutions to the modern laboratory. Our advanced Whitley Anaerobic Workstations provide a strict anaerobic atmosphere for gut microbiota applications. Features include no-bake catalyst, glove-free operation, maintenance-free humidity control, electronic anaerobic conditions monitoring, touchscreen interface, transfer airlock, and more. Whatever your application, we can tailor the Whitley Anaerobic Workstation to your requirements. Stop by our booth for a demonstration.

www.800ezmicro.com

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For more information on group rates and eligibility criteria, please email info@microbiome-movement.com or visit the website. Full T&Cs apply.

Top 3 Reasons to Attend

1. **SAVE** valuable time and resources by learning how leading companies have optimized regulatory, clinical and manufacturing strategies
2. **GAIN** first-hand insights from the movers and shakers in the microbiome space
3. **FORM** lasting connections by engaging directly with colleagues from cutting-edge pharma and biotech companies actively development microbiome-based solutions in an intimate environment

Package Details	Register & Pay By Friday, May 10	Standard Rate
Drug Developer: Pharma & Biotech		
Full Access: Conference + Workshop Day	$4096 (SAVE $500)	$4296 (SAVE $300)
Conference + 2 Workshops	$3597 (SAVE $400)	$3797 (SAVE $200)
Conference + 1 Workshop	$3098 (SAVE $300)	$3298 (SAVE $100)
Conference Only	$2599 (SAVE $200)	$2799
Solution & Service Provider		
Full Access: Conference + Workshop Day	$5096 (SAVE $500)	$5296 (SAVE $300)
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Conference + 1 Workshop	$4098 (SAVE $300)	$4298 (SAVE $100)
Conference Only	$3599 (SAVE $200)	$3799

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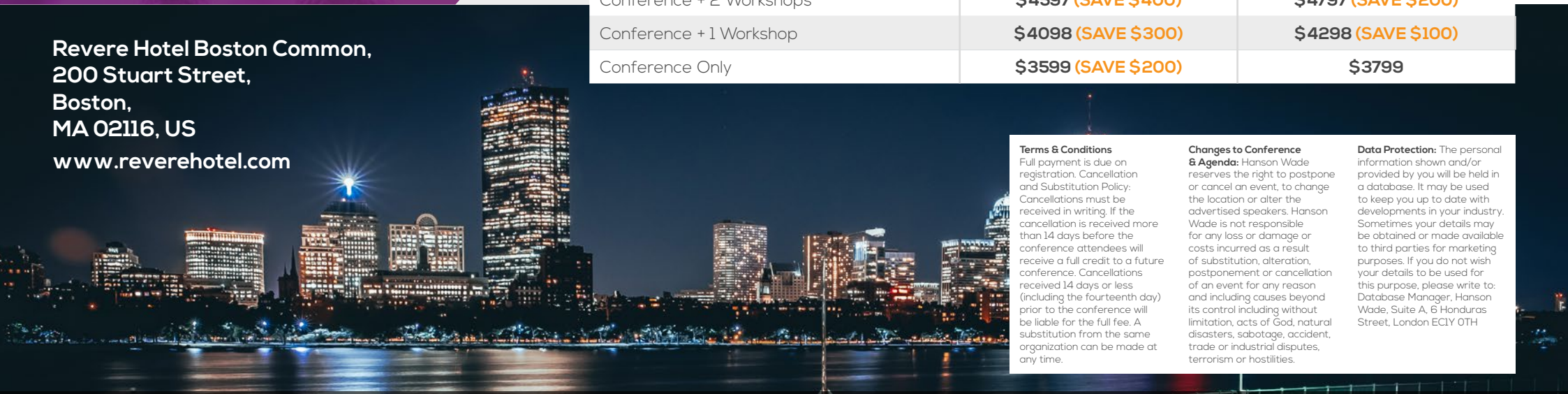

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3 Easy Ways To Book

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