

# SESSIONS

DAY 1 - 14/03/2018

Microbiome Therapeutics Europe

14 - 15 March 2018  
Novotel Amsterdam City  
Amsterdam

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## Registration

08:00 - 08:50

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## Chairperson's Opening Remarks

08:50 - 09:00

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## Microbiome Drug Development with Whole Communities and Defined Consortia

09:00 - 09:30

Microbiome Therapeutics Europe

### Participants

**Joseph Maxwell** - IBD Program Director, Finch Therapeutics

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## Designed Microbiome Therapies Targeting the Microbes and Beyond

09:30 - 09:45

Microbiome Therapeutics Europe

Altered microbial communities (dysbiosis) has been observed in many inflammatory disorders but it is not clear whether it is a cause or a consequence of the diseases. A healthy gut microbiota exists in an equilibrium with the gut barrier and the immune system. The importance and design of multiple-target drug cocktails comprising commensal bacteria will be discussed. The bacterial library, screening technologies will be presented with particular focus on successful products that treat Irritable Bowel Syndrome and Clostridium difficile infection.

### Participants

**Shahram Lavasani** - Founder and CEO, ImmuneBiotech AB

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## Microbiome and Skin Aging: An Example of Applicable Dysbiosis

09:45 - 10:00

Microbiome Therapeutics Europe

As published in a recent Scientist Report by l'Oreal and Tokyo University, comparative display of skin microbiome during age in women shows a specific dysbiosis.

This dysbiosis characterized by an increase of diversity during age associated with a decrease of a strain "gatekeeper" of healthy skin in young people associated with an increase of bacteria living usually in the mouth, during age.

### Participants

**Lionel Breton** - Scientific Director, Advanced Research, L'Oréal

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## Morning Coffee and Networking

10:00 - 10:30

Microbiome Therapeutics Europe

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## Transforming the Therapeutic Landscape of Allergic Asthma

10:30 - 11:00

Microbiome Therapeutics Europe

Siolta Therapeutics, a San Francisco based biotech company, is designing next generation microbial therapeutics aimed at the prevention and treatment of inflammatory diseases. Our current focus is on the rational design of a mixed-species microbial consortium for the prevention and treatment of allergic asthma. We are concurrently working towards a future in which the microbiome can help drive patient stratification and tailored microbial therapeutics.

\* We have combined a human-first strategy with a multi-omics approach in order to develop an efficacious microbial therapeutic for allergic asthma.

### Participants

**Nikole Kimes** - Founder/Vice President, Siolta Therapeutics

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## Advancing Microbiome Therapeutics R&D through Application of Omics Technologies

11:00 - 11:30

Microbiome Therapeutics Europe

### Participants

**Chris Howerton** - Head of Microbiome Discovery Platform, Assembly Biosciences, Inc.

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## Measurement Assurance for Innovation in Microbiome Science

11:30 - 12:00

Microbiome Therapeutics Europe

Appreciation for the role of microbes in our lives has been growing rapidly, but the measurement science needed to understand and fully exploit microbial systems has developed at a much slower pace than the industries dependent on them demand. In all applications involving complex microbial communities, the research is hampered by the lack of standards, protocols, and technical infrastructure to allow confidence in the data and comparability. At NIST, we are developing methodologies to enable measurement assurance of complex microbial systems for applications in antimicrobial resistance, in vitro diagnostics, and characterization of microbiomes and biofilms.

### Participants

**Scott Jackson** - Leader - Complex Microbial Systems Group, Biosystems and Biomaterials Division, National Institute of Standards and Technology

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## Standardizing Microbiomics – Removing Bias in Collection, Purification and Analyses

12:00 - 12:30

Microbiome Therapeutics Europe

- The rapid growth of Microbiomics has increased the demand for standard methods to improve the reproducibility and quality of the data being generated.
- To address these fundamental challenges, the scientists at Zymo Research have created reference materials for the development of the most accurate and unbiased workflows from sample collection to analyses.

### Participants

**Thomas Kuri** - Scientific Director, Zymo Research Europe GmbH

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## Lunch and Networking

12:30 - 13:45

Microbiome Therapeutics Europe

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## Harnessing the Microbiome: A New Continuum for Therapeutics

13:45 - 14:15

Microbiome Therapeutics Europe

- Microbiome-based therapeutics will span the health continuum, crossing from treatment into disease interception and prevention
- The microbiome has already shown clinical success in GI disorders, but there is promising research demonstrating its potential in immunology, metabolic and auto-immune disorders.
- Despite the high-perceived risk, less conventional approaches to product development, including microbial cocktails and precision microbiota editing, have lower actual risk and greater commercial opportunities.
  - In-human discovery allows us to more quickly understand the microbiome's role in health and disease, while de-risking the development process
- Improved and standardized computational data analysis tools are necessary to accelerate therapeutic development
  - Collaboration between industry and academia will help translate data into actionable insights

### Participants

**Dirk Gevers** - Global Head, Janssen Human Microbiome Institute

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## Thought Leaders Discussion: Big Pharma's Perspective on Microbiome Therapeutics

14:15 - 14:45

Microbiome Therapeutics Europe

- What are big pharma' view on microbiome therapeutics potential?
- What are the challenges and strategies to overcome these to enter the microbiome sector?

### Participants

**Oliver Chao** - Head, Emerging Biomedical Sciences, Sanofi

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## Defining the Mechanism of Action of Microbiome Therapeutics

14:45 - 15:15

Microbiome Therapeutics Europe

### Participants

**John Hambor** - Director, Research Beyond Borders, Boehringer Ingelheim

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## The Metabolome as a Potential Key Player in Inflammatory Bowel Diseases and Functional Bowel Disease

15:15 - 15:45

Microbiome Therapeutics Europe

- Normal human intestines contain hundreds of bacteria and fungi species (known as the microbiome), which help digest food and protect against disease-causing germs
- FMT -and other studies show an association between bacteria, fungus, and their metabolites, in IBD and functional bowel disorders. Cell based assays show
- Metabolites can cause harmful effects to intestinal epithelia and barrier function; nutritional intervention studies may allow efficacy for treatment by adapting metabolite composition

### Participants

**Wouter De Jonge** - Professor of NeuroGastroenterology, AMC Amsterdam

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## Afternoon Coffee

15:45 - 16:15

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## Spotlight Presentation: Improving Preclinical Models for Predictive Drug Development and Translation to the Clinic

16:15 - 16:45

Microbiome Therapeutics Europe

If you are interested in giving this talk please contact [perri.lucatello@knect365.com](mailto:perri.lucatello@knect365.com)

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## Translating Microbiome R&D into the Clinic

16:45 - 17:15

Microbiome Therapeutics Europe

### Participants

**Outi Vaarala** - VP, Head of Lung Immunity, AstraZeneca

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## End of Conference Day 1

17:15 - 17:20

# SCHEDULE

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<b>TIME</b>	<b>MICROBIOME THERAPEUTICS EUROPE</b>
<b>08:00</b>	<b>08:00</b> - Registration <b>08:50</b> - Chairperson's Opening Remarks
<b>09:00</b>	<b>09:00</b> - Microbiome Drug Development with Whole Communities and Defined Consortia <b>09:30</b> - Designed Microbiome Therapies Targeting the Microbes and Beyond <b>09:45</b> - Microbiome and Skin Aging: An Example of Applicable Dysbiosis
<b>10:00</b>	<b>10:00</b> - Morning Coffee and Networking <b>10:30</b> - Transforming the Therapeutic Landscape of Allergic Asthma
<b>11:00</b>	<b>11:00</b> - Advancing Microbiome Therapeutics R&D through Application of Omics Technologies <b>11:30</b> - Measurement Assurance for Innovation in Microbiome Science
<b>12:00</b>	<b>12:00</b> - Standardizing Microbiomics – Removing Bias in Collection, Purification and Analyses <b>12:30</b> - Lunch and Networking
<b>13:00</b>	<b>13:45</b> - Harnessing the Microbiome: A New Continuum for Therapeutics
<b>14:00</b>	<b>14:15</b> - Thought Leaders Discussion: Big Pharma's Perspective on Microbiome Therapeutics <b>14:45</b> - Defining the Mechanism of Action of Microbiome Therapeutics
<b>15:00</b>	<b>15:15</b> - The Metabolome as a Potential Key Player in Inflammatory Bowel Diseases and Functional Bowel Disease <b>15:45</b> - Afternoon Coffee
<b>16:00</b>	<b>16:15</b> - Spotlight Presentation: Improving Preclinical Models for Predictive Drug Development and Translation to the Clinic <b>16:45</b> - Translating Microbiome R&D into the Clinic
<b>17:00</b>	<b>17:15</b> - End of Conference Day 1

# SESSIONS

DAY 2 - 15/03/2018

Microbiome Therapeutics Europe

14 - 15 March 2018  
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Amsterdam

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## Chairperson's Opening Remarks

08:50 - 09:00

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## Notes from the Underground -The Dirt on Clinical Development of a Soil Bacteria

09:00 - 09:30

Microbiome Therapeutics Europe

### Participants

**Larry Weiss** - Chief Medical Officer, AOBiome

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## Feedback from Seres Therapeutics, Inc. - Lessons Learnt from Microbiome Therapeutics in Clinical Development

09:30 - 10:00

Microbiome Therapeutics Europe

### Participants

**Michelle Trucksis** - Executive Vice-President and Chief Medical Officer, Seres Therapeutics, Inc.

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## Lessons Learnt from Microbiome Therapeutics in Clinical Development

10:00 - 10:30

Microbiome Therapeutics Europe

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## Morning Coffee and Networking

10:30 - 11:00

Microbiome Therapeutics Europe

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## Clinical Development of Microbiome Therapeutics for Cardio-Metabolic Disorders

11:00 - 11:30

Microbiome Therapeutics Europe

The presentation will address the challenges in the design and evaluation of clinical trials of microbiome therapeutics. Main points to be covered include:

- Study design – key objectives in T2DM and Metabolic Syndrome
- Study preparation – choice of formulation and challenges in manufacturing
- Study conduct in subjects with Metabolic Syndrome
- Evaluation of results – data mining – value of metagenomics

### Participants

**Luc Sterkman** - CEO, Caelus Health B.V.

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## Business, Regulatory, and Clinical Strategies to Develop New Microbiome-Directed Therapeutics

11:30 - 12:00

Microbiome Therapeutics Europe

Research and business around the microbiome continues to rapidly expand. There are currently many institutions and companies looking at various ways to utilize bugs as drugs. More science and quality parameters are being developed to create, manufacture and commercialize these new and unique medicines to treat various diseases of the microbiome. Microbiota Restoration Therapy (MRT) is one example of a new and novel way to provide bugs as drugs utilizing Science and Quality.

### Participants

**Ken Blount** - Head of External Research, Rebiotix, Inc.

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## Lunch and Networking

12:00 - 13:00

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## Designing Scale Up and Manufacturing Processes for Microbiome Therapeutics

13:00 - 13:30

Microbiome Therapeutics Europe

Live Biotherapeutic Products (LBPs) have great potential to treat diseases related to the dysbiosis of the gut microbiota. Designing scale up processes for LBPs presents its own unique challenges. This presentation will discuss the considerations necessary when performing process development, scale up, and manufacturing for multiple anaerobic microbial cultures for a rationally designed CGMP LBP.

### Participants

**Scott Michonski** - Manager of Process Development, Vedanta Biosciences, Inc.

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## Formulation Technologies to Ensure Consistent Stable Product Production

13:30 - 14:00

Microbiome Therapeutics Europe

### Participants

**Sejal Ranmal** - Director of Formulation, Intract Pharma Limited

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## Regulation of Fecal Microbiota Transfer Products – The German Perspective

14:00 - 14:30

Microbiome Therapeutics Europe

German authorities classify fecal microbiota transfer (FMT) products as drugs to be manufactured in a GMP facility, regulated under the German Medicines Act. The University Hospital Cologne is creating a GMP-certified national stool bank to assure supply with high quality FMT products for the purpose of clinical care and clinical trials.

### Participants

**Maria Vehreschild** - Clinical Microbiome Research Group and Clinical Trials Unit II Infectious Diseases, University Hospital Cologne

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## Spotlight Presentation: CMO Perspective: Optimising Anaerobic Manufacturing for Large Scale Production of Microbiome Therapeutics

14:30 - 15:00

Microbiome Therapeutics Europe

- Evaluating CMO's with capability to manufacture microbiome therapeutics
- Scale up strategies for anaerobic microbial organisms for phase III production volumes
- Anaerobic culturing methods
- Downstream purification processes
- Developing testing methods to ensure GMP quality control, product stability and potency

If you are interested in giving this presentation please contact [perri.lucatello@knect365.com](mailto:perri.lucatello@knect365.com)

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## Afternoon Coffee

15:00 - 15:30

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## Commercialisation Strategies for Microbiome Therapeutics

15:30 - 16:00

Microbiome Therapeutics Europe

### Participants

**Jonathan Gilbert** - Global Commercial Lead  
Microbiome GI Health, Nestlé Health Science

# SESSIONS

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## Near Extinction of a Keystone Commensal in the Infant Gut Microbiome

16:00 - 16:30

Microbiome Therapeutics Europe

Human milk has been the sole source of nutrition for infants for millions of years, and is rich in specific oligosaccharides (HMOs). The natural infant gut microbiome is dominated by a single species of Bifidobacteria that is exceptionally competitive at consuming HMOs. Through the unintended consequences of formula feeding, antibiotic use, and C-Section deliveries, a keystone commensal in this natural microbiome has been lost in the developed world. We have rescued the natural microbiome from the present dysbiosis through an early remodeling that returns the colonic microenvironment to its natural state.

### Participants

David Kyle - Chairman and CSO, Evolve Biosystems Inc.

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## Panel Discussion: Funding and Investment Opportunities for Microbiome Therapeutics

16:30 - 17:00

Microbiome Therapeutics Europe

- What is the outlook for microbiome therapeutics?
- Evaluating new projects and upcoming investments in microbiome therapeutics: What do you look for investment?
- Expectations of partnerships/ financing of biotechs and pharma in this space – What stage of product development / idea development is required for investment?
- Realistic expectations for early exploratory studies compared to phase II studies

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## End of Conference Day 2

17:00 - 17:05

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<b>12:00</b>	<b>12:00</b> - Lunch and Networking
<b>13:00</b>	<b>13:00</b> - Designing Scale Up and Manufacturing Processes for Microbiome Therapeutics <b>13:30</b> - Formulation Technologies to Ensure Consistent Stable Product Production
<b>14:00</b>	<b>14:00</b> - Regulation of Fecal Microbiota Transfer Products – The German Perspective <b>14:30</b> - Spotlight Presentation: CMO Perspective: Optimising Anaerobic Manufacturing for Large Scale Production of Microbiome Therapeutics
<b>15:00</b>	<b>15:00</b> - Afternoon Coffee <b>15:30</b> - Commercialisation Strategies for Microbiome Therapeutics
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<b>17:00</b>	<b>17:00</b> - End of Conference Day 2

# SESSIONS

POST CONFERENCE WORKSHOP - 16/03/2018

Microbiome Therapeutics Europe

14 - 15 March 2018  
Novotel Amsterdam City  
Amsterdam

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## Registration

08:30 - 09:00

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## Establishing a Regulatory Framework for Microbiome Therapeutics

09:00 - 15:00

- What are the regulatory requirements to license a microbiome drug?
- Expectations for different microbiome treatment modalities e.g. single strain vs. consortia
- Expectations for clinical trials, CMC, quality, GMP production
- Differences between EU and USA requirements

## Participants

**Peter Embley** - Senior Director Regulatory & Health Economic Science, VCLS

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## End of Post Conference Workshop

15:00 - 15:05

# SCHEDULE

POST CONFERENCE WORKSHOP - 16/03/2018

Microbiome Therapeutics Europe

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TIME	
08:00	08:30 - Registration
09:00	09:00 - Establishing a Regulatory Framework for Microbiome Therapeutics
10:00	
11:00	
12:00	
13:00	
14:00	
15:00	15:00 - End of Post Conference Workshop