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August 21-23 | Boston, USA

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3rd Annual PREDICT:3D Models

Enhancing the Predictive Confidence of Models-Based Discovery & Development

38 Expert Speakers Including:

Silva Krause
Senior Scientist - Translational Medicine
Momenta Pharmaceuticals

Brian Berridge
Associate Director
National Institute of Environmental Health Sciences – (NIEHS)

William Mattes
Director, Division of Systems Biology, National Center for Toxicological Research
U.S. Food and Drug Administration

Kristin Fabre
Microphysiological Systems Lead, IMED Biotech Unit
AstraZeneca

Terry R. Van Vleet
Head of Molecular and Computational Toxicology
AbbVie

EXPERTISE PARTNERS:

DRAPER

StemoniX

PROGRAM PARTNER:

SYNVIVO

MatTek CORPORATION

INNOVATION PARTNERS:

epistem

TARA

EXHIBITION PARTNERS:

AxoSim Human Data, Faster.

eastriver biosolutions

OLYMPUS

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3D Tissue Models: Drug Discovery & Development

hansonwade

ABOUT

Exploring The Utility Of 3D Models Across Discovery And Development

The 3rd PREDiCT: 3D Models (Previously "3D Tissue Models") remains committed to providing a forum that unites multidisciplinary stakeholders in overcoming the remaining translational, organizational and developmental barriers to 3D model-use.

Driven by case studies from biopharma, PREDiCT: 3D Models looks beyond the science of tissue engineering. It will reveal how 3D models can and are being successfully deployed to expedite discovery and translation to clinical research.

So whether you've already established 3D models into your efforts or are just about to, tap into a ready-made network of peers who continue to redefine this area, solving the biggest barriers to model use.

I really do hope you can join a truly diverse group of professionals from biopharmaceutical, technology and academic institutions in redefiing the use of early stage and preclinical in-vitro models.

Adam Cohen
Senior Conference Director
PREDiCT Event Series

Key Case Studies Not to Miss

1. **Sanofi** establishing organotypic models informing hepatotoxicity and safety assessments to mitigate early stage safety concerns

2. **Bristol-Myers Squibb and UWash** highlighting strategies incorporating translational 3D models to guide metabolite identification, in-vivo clearance and enzyme inducibility

3. **Resonant Therapeutics** pioneering the development of HTP high fidelity phenotypic screens combined with machine learning strategies to accelerate anti-tumor antibody ID and selection

4. **Momenta Pharmaceuticals** demonstrating how 3D systems are being adapted towards demanding conditions of biological relevance to optimize mechanistic investigations and biomarker discovery

5. **Hemoshear Therapeutics and Takeda** showcasing advances in the screening capabilities of organotypic models (from simple to complex) and their impact on guiding compound discovery, selection and target assessment

6. **Syracuse and Boston University** exploring the development of platforms integrating hiPSC biology, tissue engineering and gene editing technologies to lead the development of next generation disease-specific organoid and chip systems

WHY PAST ATTENDEES ARE RETURNING

130+ Attendees
38 Expert Speakers
30+ Case Studies
4 Deep Dives
8+ Hours Networking

"The two previous 3D Model meetings have been highly successful and key contributions to the growth of this field and community of interest. The result has been a growing alignment on opportunities, challenges and strategies to building internal confidence in the applicability of these new capabilities"

Brian R. Berridge, Associate Director, National Toxicology Program, Scientific Director, NIEHS

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"The 2017 Predict:3D Models conference was excellent. I came away feeling that I had been brought up to date on the latest technologies, by an impressive group of leaders in the pharmaceutical, academic and technology development industries. 3D models are developing rapidly, so I am excited to attend this year's conference, to learn of the progress that has been made over the last year and share my own experiences with these models as a speaker. Highly recommended!"

James Morelli, Research Investigator, Sanofi

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"I appreciated the very focused topic and the format of the meeting, which allowed for significant one-one discussions with other delegates and speakers"

John Westwick CEO, Resonant

.....

"I thought the conference was very focused. It was time well spent. I learned a lot and had productive networking sessions"

Hicham Alaoui, Senior Vice President, Discovery Biology, Symic Biomedical

.....

"The upcoming meeting really does feel like one of those 'can't miss' opportunities. Once again, it will bring together champions and users across industry, academia and government to define the applicability, and explore successes in utilizing more physiologically relevant systems to better identify therapeutic targets and predict drug toxicities"

Yvonne Will, Senior Director, WRD Technology Strategy and Innovation, Pfizer Inc

YOUR EXPERT SPEAKERS

Adrian Roth
Head of Mechanistic Safety & Non-Clinical Safety
Roche

Ajamete Kaykas
Senior Investigator
Novartis

Alejandro Amador
Scientific Leader
GlaxoSmithKline

Andreas R. Baudy
Associate Principal Scientist, Safety Assessment
Merck & Co.

Anita Seshire
Head of Laboratory Cellular Pharmacology & Translational Innovation Platform Oncology
Merck KGgA

Anna M Sitarski
Post Doctoral Scientist
Cyteir Therapeutics

B. Prabhakar Pandian
Chief Technology Officer
SynVivo Inc.

Bhushan Mahadik
Assistant Director NIH/NIBIB Center for Engineering Complex Tissues (CECT)
University of Maryland

Brian R. Berridge
Associate Director, National Toxicology Program, Scientific Director
NIEHS

Brian Wamhoff
Co-founder and Head of Innovation
HemoShear Therapeutics

Darrell Kotton
Seldin Professor of Medicine & Director, Center for Regenerative Medicine (CReM)
Boston University and Medical Center

Dik C. van Gent
Associate Professor
Erasmus MC

Dominic Williams
Associate Director - Preclinical Hepatic Safety
AstraZeneca

Edward Kelly
Associate Professor
University of Washington

Eric McDuffie
Scientific Director & Head of Investigative & Mechanistic Toxicology
Janssen Pharmaceuticals

Fabian Zanella
Director of R&D
StemoniX

Graham Marsh
Scientist I - Translational Sciences
Biogen

Hicham Alaoui
Senior Vice President, Discovery Biology
Symic Biomedical

James Morelli
Research Investigator
Sanofi

Jinping Gan
Senior Principal Scientist
Bristol-Myers Squibb

John K. Westwick
President and CEO
Resonant Therapeutics, Inc.

John Wikswo
Gordon A. Cain Professor & Director
VIIBRE

Joseph Charest
Program Manager
Draper Laboratory

Kristin Fabre
Microphysiological Systems Lead, IMED Biotech Unit
AstraZeneca

Matthew Wagoner
Associate Director - Investigative Toxicology
Takeda

Misti Ushio
CEO
TARA Biosystems

Piyush Bajaj
Scientist II, Drug Safety Research and Evaluation
Takeda

Rhiannon Hardwick
Research Scientist - Nonclinical Safety Assessment
Theravance Biopharma

Sarah Hoyle
Senior Research Scientist
Epistem Ltd

Silva Krause
Senior Scientist - Translational Medicine
Momenta Pharmaceuticals

Swati Gupta
Director, Immunology Non-Clinical and Translational Sciences
Allergan

Seyoum Ayehunie
Vice President of Immunological Systems
MatTek Corporation

Szczepan Baran
Global Head of Animal Welfare Compliance Training
Novartis

Terry R. Van Vleet
Head of Molecular and Computational Toxicology
AbbVie

Thomas Knudsen
Researcher
US Environmental Protection Agency

William Mattes
Director, Division of Systems Biology, National Center for Toxicological Research
U.S. Food and Drug Administration

Yvonne Will
Senior Director, WRD Technology Strategy and Innovation
Pfizer Inc

Zhen Ma
Assistant Professor
Syracuse University

"I really enjoyed the conference, and I learned a lot, both from presentations and informal interactions. Presentations were well balanced between science and technical innovation, and speakers focused on highlighting pros and cons of each application, which is helpful for someone just starting to explore the field of 3D models"

Monica Gostissa, 3D Tissue Models: Oncology 2018 Attendee

AGENDA AT A GLANCE

8am

10am

12pm

2pm

4pm

6pm

8pm

Deep Dives
August 21st, 9am-4pm

Organs-on-Chips: A Developer's Masterclass

3D Printing & Bioprinting for Complex Tissue Engineering

3D Models for ADME Tox Studies

Stem Cell Organoid Models for Drug Screening

Presenting Organizations Include:

Vanderbilt University

University of Washington

University of Maryland

Syracuse University

Conference Day 1
August 22nd, 8.20am-7pm

3D Systems Informing Disease Biology

Accelerating Target & Phenotypic Discovery

Enhancing the Confidence of Safety Assessments

Optimising Lead Selection

Predicting Safety Liabilities In Vitro

Overcoming Core Challenges with 3D Models

23 Presenting Organizations Include:

AstraZeneca, gsk, Roche, Sanofi, HEMOSHEAR THERAPEUTICS, Takeda

Conference Day 2
August 23rd, 8.30am-3.30pm

Guiding Indication Selection & Biomarker Discovery

Informing Your Early Stage Discovery

Key Design Criteria for Safety Testing

Towards In-Vivo Outcomes

Advancing DMPK Profiling

Engineering Future Success

12 Presenting Organizations Include:

janssen, NOVARTIS, Biogen, Bristol-Myers Squibb, MERCK, MOMENTA

Pre-Conference Workshop Day | August 21st

Workshop A

Organs-on-Chips: A Developer's Masterclass

9.00am - 12.00pm

Following the success and overwhelming feedback from the session in the last two event iterations. This workshop will be back once more to provide an in depth analysis of how to approach and develop microfluidic devices with a focus on interconnected systems and their use within industry.

This workshop will help you realize the unlimited potential of engineered tissue models for replicating organ system signaling and dynamics.

Leave this workshop with:

- A greater understanding of the key challenges facing the development of microfluidic systems and how to overcome them
- An in depth insight into how to model, interconnect, test, and control these biological systems consistent with allometric, biochemical and/or functional scaling
- Knowledge of how best to achieve non-invasive readouts with the latest advances in imaging, sensor, and multi-omic technologies

Workshop Leader
John Wikswo
Gordon A. Cain Professor & Director
VIIBRE

"I really enjoyed the conference, and I learned a lot, both from presentations and informal interactions. Presentations were well balanced between science and technical innovation, and speakers focused on highlighting pros and cons of each application, which is helpful for someone just starting to explore the field of 3D models"

Monica Gostissa, 3D Tissue Models: Oncology 2018 Attendee

OR

Workshop B

3D Printing & Bioprinting for Complex Tissue Engineering

9.00am - 12.00pm

Bioprinted tissue constructs have great potential as platforms to improve our understanding of cell and tissue-level biology for various applications. However, numerous challenges exist in adopting and utilizing the variety of technologies and approaches within development workflows. The objective of this workshop is to introduce tools and techniques related to 3D Printing and Bioprinting in order to fabricate complex tissue architecture that can serve as in vitro models capable of recapitulating native biology.

Leave this workshop with:

- An in-depth insight into a variety of tools and techniques in additive manufacturing for generating tissue models
- Exploration into issues and strategies to mitigate material selection and printability
- A greater understanding of 3D printing and Bioprinting principles for getting started with complex in vitro models developed

Workshop Leader
Bhushan Mahadik
Assistant Director NIH/NIBIB Center for Engineering Complex Tissues (CECT)
University of Maryland

Workshop C

Leveraging 3D In-vitro Models for ADME-Tox Studies

1.00pm - 4.00pm

Active drug metabolites and drug-drug interactions are attributed for a large percentage of drug failures. As such, representative ADME studies are essential to the drug discovery process and yet current models fall short on their pharmacokinetic profile, largely due to their over simplicity and lack of physiological relevance.

Better recapitulating the physiological and metabolic properties of the in vivo environment, 3D models represent significant advantages for detection of drug induced toxicities.

This workshop will review current advances in 3D model development and use for ADME-tox with reference to single and coupled 3D microfluidic systems

Leave this workshop with:

- Novel approaches utilizing chip based models for metabolite identification and enzyme mapping
- Strategies utilizing 3d microtissues in the clearance prediction of low turnover compounds

Workshop Leader
Edward Kelly
Associate Professor
University of Washington

"This was a great scientific meeting and networking opportunity. It brought together key players in the field to discuss important strategic issues of mutual interest"

Brian R. Berridge, Associate Director, National Toxicology Program, Scientific Director, NIEHS, PREDiCT:3D Models 2016, 2017 & 2018 Meeting Chair

OR

Workshop D

Development of Stem Cell Organoid Models for Drug Screening Applications

1.00pm - 4.00pm

Human in vitro cardiac models predictive of human drug response would be a significant advancement for understanding and developing new drugs. Recent technical advances in human iPSC-derived 3D organoids have presented huge opportunities to bridge the in vitro and in vivo gap. Providing insights, beyond basic descriptors at the cellular level, these models are offering new insights into complex organ development and have vast applications within pharmaceutical research. With specific reference to 3D hiSPC cardiac organoids, this session will look to explore the technical advances in designing these models, applications within the basic and pharmaceutical setting as well as strategies for overcoming remaining issues to use.

Leave this workshop having:

- Envisioned the integration of hiPSC biology, tissue engineering and gene editing technologies to develop next-gen 3D tissue models and organ-on-chip systems
- Reviewed current biofabrication technologies for creating 3D tissue models for high-throughput and high-content preclinical drug evaluation
- Highlights on the integration of in vitro model with in silicon model for multifaceted data analysis and drug toxicity prediction.

Workshop Leader
Zhen Ma
Assistant Professor
Syracuse University

TURN THE PAGE TO VIEW THE MAIN AGENDA

Conference Day One | August 22nd 2018

Brian R. Berridge
Associate Director, National Toxicology Program, Scientific Director
NIEHS

8.20 Chairs Opening Remarks

Terry R. Van Vleet
Head of Molecular and Computational Toxicology
AbbVie

8.30 IQ Consortium Microphysiological Systems Working Group: History & Updates
- Describing the consortium and key past contributions
- Reviewing current changes and insights into ongoing activities of the consortium
- Highlighting future direction & objectives

Adding Human Relevancy into the Pipeline – 3D Systems Informing Disease Biology

Joseph Charest
Program Manager
Draper Laboratory

9.00 Leveraging Microfabrication for Tissue Models with a Path to Validation
- Highlighting how microfabricated models can influence and quantify tissue or function
- Illustrating two examples of microfabricated models:
  - A complex in vitro model to culture and evaluate tissues or functions with barrier function
  - A system to quantify and evaluate interactions between patient-derived tissues and immune components

Darrell Kotton
Seldin Professor of Medicine & Director, Center for Regenerative Medicine (CReM)
Boston University and Medical Center

9.30 Pluripotent Stem Cell Models of Lung Disease in 3D
- Review the state-of-the-art methods in using patient specific iPSC's for lung epithelial differentiation in 3D
- Application of these models for understanding airway and alveolar lung diseases
- Developing drug screens and precision medicine approaches using iPSC lung cell models

Fabian Zanella
Director of R&D
StemoniX

10.00 Adding Structure to HTP hiPSC-Derived Cardiac and Neuronal Models for Improved Physiological Relevance and Performance.
- microBrain 3D and microHeart are iPSC-based screening platforms that have been structurally engineered with greater physiological relevance aimed to elevate performance in drug discovery and development applications
- Both platforms are tested and validated for performance in screening and safety applications
- Case studies are provided for the successful implementation of these platforms in screening and safety applications

10.30 Speed Networking

11.00 Morning Refreshments

Discovery Track

Accelerating Target & Phenotypic Based Discovery

11.30 Creating Physiological Disease Models for Drug Discovery
- Utilizing a novel disease relevant 3D model to interrogate disease pathways and identify new targets for rare metabolic diseases
- Highlighting the use of parallel in-silico models to generate rationally driven hypotheses and drive the discovery of more relevant data
- Exploring concepts and methods applied for model validation

Brian Wamhoff, Co-founder and Head of Innovation, **HemoShear Therapeutics**

Development Track

Enhancing the Predictive Confidence of Preclinical Safety Assessments

11.30 Application of 3D Hepatic Cultures for Risk Assessment of Drug Induced Liver Injury
- Recapitulating healthy and disease liver states-engineering models to identify patient specific toxicities
- Exploring the capabilities of model-incorporated cell types and their impact on therapeutic and DILI assessment
- Demonstrating cross validated platforms utilized within AstraZeneca's pipeline and its potential implications for DILI assessment of novel therapeutic modalities

Dominic Williams, Associate Director - Preclinical Hepatic Safety, **AstraZeneca**

12.00 Advancing Drug Discovery Through the Technological Convergence of Organs-On-Chips & Mass Spectrometric Multi-Omics
- Exploring how microfluidics and untargeted multi-omic reconstruction of drug MoA, through advanced mass spectrometry and machine learning, are set to revolutionise discovery
- Highlighting its potential impact in revealing problematic human haplotypes and drug-drug interactions for small molecules
- Demonstrating its utility in the discovery of novel mechanisms of human diseases, identification of novel compounds, and the discovery of on- and off-target of drug candidate MoAs

John Wikswo, Gordon A. Cain Professor & Director, **VIIBRE**

12.30 Active-Learning Strategies for High Content Screening of 3D Tumor Cell Models
- Introducing novel 3D tumor in vitro models, high content imaging and cell-based screening technologies improving clinical relevance in the testing of oncology drugs
- Showcasing the design and build of an intelligent, automated platform to accelerate the identification of high value small molecule leads, and the delivery of quality candidates into clinical development
- Discussing computational active-learning approaches used in high content screenings of a large number of 3D tumor spheroid images

Alejandro Amador, Scientific Leader, **GlaxoSmithKline**

12.00 Intestinal 3D organoids – A Predictive Model of Intestinal Toxicity
- Brief history and description of intestinal organoids and how they compare to in vivo structures
- Overview of the species from which organoids have been made
- Examples of toxicity studies in different species

Sarah Hoyle, Senior Research Scientist, **Epistem Ltd**

12.10 Exploring the Utility of Spheroids for Improving the Prediction of Hepatotoxicity Studies
- Describing an alternative method of spheroid culture that results in more spheroid micro-tissues per well, compared to hanging drop or single well methods
- Presenting data comparing rat and human hepatic spheroids, allowing for species-specific comparisons of hepatotoxicity in vitro to known outcomes in vivo
- Reviewing this methodology in comparison with others, giving a brief review of best practices, and the predictive power of 3D hepatic models over traditional models

James Morelli, Research Investigator, **Sanofi**

12.40 Primary Human Endothelial Cells-Based 3D Models & Assays for Detection of Innate Immune Responses
- Comparing models and assays to monitor inflammation responses following interactions with host proteins and impurities.
- Developing vascularized environments for investigation of immune cell behaviour
- Demonstrating the ability for real-time visualization and quantitation of vascular leakiness

Swati Gupta, Director, Immunology Non-Clinical and Translational Sciences, **Allergan**

12.50 iPSC Derived Mature Cardiac Tissue for Drug Development
- Description of BiowireTM II Platform
- Characteristics of Cardiac Tissue Maturity
- Applications for Drug Development

Misti Ushio, CEO, **TARA Biosystems**

1.00 Lunch

Novel Screening Applications to Optimise Lead Selection

2.00 Bringing 3D Cell Culture into Cancer Drug Development & High Throughput Drug Screening
- High throughput assays in 3D drug screening
- Spheroids as a next step from 2D to 3D in assay development in chemotherapeutics
- Scaffolds (biomaterials) into the high throughput world
- Challenges in characterizing a system, measurements, reproducibility and expense

Anna M Sitarski, Post Doctoral Scientist, **Cyteir Therapeutics**

Improving In-Vitro Prediction of Safety Liabilities

2.00 Adapting 3D Microtissues for The Detection & Mechanistic Evaluation of Drug-Induced Toxicity
- Exploring how to model clinically relevant tissue responses through the generation of a 3D liver model with architecture closely resembling that of in vivo human tissue
- Confirming viability and functionality over prolonged culture periods as well as recapitulation of clinical liver toxicity not detected in conventional models
- Demonstrating how 3D liver tissues can both effectively model DILI and distinguish between highly related compounds with differential profiles

Adrian Roth, Head of Mechanistic Safety & Non-Clinical Safety, **Roche**

2.30 High-Throughput Antibody Identification Based On the Tumor Microenvironment

- Highlighting the development of novel tumor microenvironment models, and Resonant's approach linking target and therapeutic candidate identification and functional validation
- Combining high-throughput fidelity phenotypic screens and machine learning strategies to accelerate the process, and result in unprecedented speed in the identification of novel, efficacious anti-tumor monoclonal antibodies
- Explore case studies demonstrating the process and resultant therapeutic candidates currently in development

John K. Westwick, President and CEO, **Resonant Therapeutics, Inc.**

2.30 Novel 3-D Primary Human Gut Model to Predict Drug Toxicity and Host-Microbe Interaction

- Drug toxicity results from 3D-Intestinal tissues correlate better to human responses compared to standard preclinical animal models.
- 3D intestinal tissues showed adhesion and invasion by symbionts and pathogenic microorganisms.
- Microbes or microbial components initiate innate immune responses in of 3D intestinal tissue model that mimic human responses.

Seyoum Ayehunie, Vice President of Immunological Systems, **MatTek Corporation**

3.00 Utilising Multicellular 3D Models for Preclinical Drug Discovery

- Developing primary 3D cell cultures from patient material
- Addition of monocytes or fibroblasts to identify a potential trophic role
- Transplantation of multicellular spheres to create tumours with microenvironments and enable the exploration of the influence of the TME on stemness

Anita Seshire, Head of Laboratory Cellular Pharmacology & Translational Innovation Platform Oncology, **Merck KGgA**

3.00 Microphysiological Systems in Drug Discovery: Advances in CNS & Immune-mediated Liver Injury

- Sharing our ongoing efforts to validate microbrain and minibrain models with clinical data from 100 medicines.
- Presenting data on our novel medium throughput model of immune DILI complete with lymphocytes, Kupffer cells, endothelial cells & hepatocytes.
- Deficiencies in our current immunotoxicity models will also be presented in the hopes that someone in the audience has a solution to what seems to be a universal problem

Matthew Wagoner, Associate Director - Investigative Toxicology, **Takeda**

3.30 Extended Q&A

3.30 Physiologically Relevant 3D Tissue Models for Translational Studies

- Utilizing vascularized tumor microenvironment to evaluate cancer-stromal-immuneendothelium interactions
- Showcasing a blood brain barrier model for real-time visualization and quantitation of cellular interactions and barrier functionality
- Using an integrated assay for mechanistic understanding of vascular-immune-tissue interactions
- Assessing the use of layered multi-cellular architecture for complex organ physiology and toxicology

B. Prabhakar Pandian, Chief Technology Officer, **SynVivo Inc.**

4.00 Afternoon Refreshments

Thomas Knudsen
Researcher
US Environmental Protection Agency

4.30 Computer Modeling & Simulation to Reconstruct the Basis of Developmental Toxicity

5.00 Round Challenge Tables

Building Confidence in the Utility of 3D

- When can studies from 3D models be considered critical path?
- How should we most effectively be demonstrating the internal business case?
- Does 3D always mean more predictive? How should we define the context of use to address this?
- How should we be working with external collaborators for PoC studies?
- How should we address issues of robustness and reproducibility across lab environments?

Hicham Alaoui, Senior Vice President, Discovery Biology, **Symic Biomedical**

Overcoming the Analytical Hurdles for Testing Endpoints In Organotypic Cultures

- How can we best adapt the low volumes to analytical techniques such as transcriptomics and proteomics?
- How can we best optimise readout methods for sensitivity?
- What technologies can we apply?

Szczepan Baran, Global Head of Animal Welfare Compliance Training, **Novartis**

Strategies to Mitigate Cell Sourcing and Maturity Issues

- What are the benefits/risks of isolating key cell types within your organization versus commercial sourcing?
- New opportunities to acquire "hard to isolate" or unavailable cell types.
- How do "mature" cells need to be before incorporation into a model, and what are the opportunities for cell maturation within a system?
- Setting clear and manageable cell acceptance criteria to drive reproducibility.

Rhiannon Hardwick, Research Scientist - Nonclinical Safety Assessment, **Theravance Biopharma**

Human Based vs Animal Models for Decision-Making: Pros And Cons

Brian Wamhoff, Co-founder and Head of Innovation, **HemoShear Therapeutics**

What Constitutes a Validated Model: An Industry Perspective

- How should define the standards for these
- Can we develop set compound libraries to testmodels against?
- Where can we establish confidence in both specificity and sensitivity to identify relevant endpoints
- What key components should be considered when developing a predictive 3D model

Yvonne Will, Senior Director, WRD Technology Strategy and Innovation, **Pfizer Inc**

6.00 Round Table Moderator Feedback Panel

6.15 Close of Conference Day One

Poster Session

After the formal presentations have finished, the learning and networking carries on. The Poster Session is an informal part of the conference agenda, allowing you to connect with your peers in a relaxed atmosphere and continue to forge new and existing relationships. During this session scientific posters will be presented on 3D models validating innovative targets, disease models highlighting novel mechanisms, systems that are informing investigative toxicology and safety assessments.

Conference Day Two | August 23rd 2018

Brian R. Berridge
Associate Director, National Toxicology Program, Scientific Director
NIEHS

8.25 Chairs Opening Remarks

3D Models Guiding Indication Selection & Biomarker Discovery

Silva Krause
Senior Scientist - Translational Medicine
Momenta Pharmaceuticals

8.30 Utilizing a 3D Tissue Platform from Bench to Bedside for Mechanistic Studies & Identifying Translational Biomarkers

- Demonstrating the use of a 3D model for understanding the MoA of a multi-targeted drug
- Highlighting comparative similarities/differences and validation of animal models
- Revealing the potential utility of the system in biomarker ID by referencing how protein alterations within the system were representative of changes observed in patient plasma samples

Dik C. van Gent
Associate Professor
Erasmus MC

9.00 Predicting Clinical Outcomes Through the Development 3D Assays on Tumor Biopsies

- Revealing how 3D tumor tissue slices can be cultured and treated as *ex-vivo* as a predictive model for therapy response
- Clinical validation of *ex-vivo* assays on tumor biopsies is ongoing
- Exploring how the miniaturization and standardization in a cancer-on-chip set up may enable truly personalized medicine (testing multiple treatments, co-clinical trial)

9.30 Morning Refreshments Networking

Discovery Track

In Vitro Platforms Informing Early Stage Discovery Efforts

10.30 Interrogating Phenotypic Changes of 3D Neural Models to Discover & Validate Biomarker Candidates

- Exploring contemporary microphysiological models to generate discovery compound safety profiles
- Leveraging imaging technologies and in vitro models to inform target assessment
- Presenting case studies: Monitoring for translational safety biomarker changes in vitro

Eric McDuffie, Scientific Director & Head of Investigative & Mechanistic Toxicology, **Johnson & Johnson**

11.00 Using Stem Cells for Neuroscience Target Discovery

- Discussing the generation of a large bank of iPSC lines from schizophrenic and autistic patients
- Highlighting strategies for the large-scale differentiation of these patient lines into cortical excitatory neurons
- Exploring the characterization of the progenitors and neurons with omics-based technology, one which being single cell RNA-seq

Ajamete Kaykas, Senior Investigator, **Novartis**

11.30 Microfluidic Models of the Blood Brain Barrier

- Exploring how researchers are building neuronal models with the goal of increasing the complexity and physiological relevance of the microphysiological models we are developing
- Reviewing novel platform technologies that are being developed to increase the throughput and scalability of our models

Graham Marsh, Scientist I – Translational Cell Sciences, **Biogen**

Development Track

Design Criteria for Optimised Safety Efficacy Testing

10.30 Key Criteria of Advanced 3D Human Liver Models for the Improvement of Safety Testing and Widespread Adoption

- Demonstrating how in-vivo human biological metrics must be taken into account when building an advanced in vitro model
- For liver, rates of albumin production and urea synthesis are important first considerations
- More complex is not always best. Showcasing how models that can answer key scientific questions while maintaining reasonable throughput will be at the forefront of future research

Andreas R. Baudy, Associate Principal Scientist, Safety Assessment, **Merck & Co**

11.00 Designing iPSC Derived Organoids for Cardiac Safety Efficacy Testing

- Highlighting the progress and promise human iPSCs with 3D models hold for precision medicine and companion diagnostics applications
- Demonstrating the development of a 3D cardiac organoid model mimicking early human heart development
- Showcasing its utility as a drug testing platform to evaluate the embryotoxicity of pregnancy medication to fetal development
- Engineering a fiber-based human cardiac tissue model to recapitulate more adult-like cardiac tissue structure for drug screening and disease modelling purposes

Zhen Ma, Assistant Professor, **Syracuse University**

11.30 Extended Q&A

12.00 Lunch

Enhancing The Fidelity of In-Vitro Models Towards In-Vivo Outcomes

1.00 Microfluidic Technologies Impacting how AstraZeneca Optimizes Drug Scheduling

- Understanding how we are "scheduling discovery" to optimize dosing regimens for efficacy and safety
- Exploring the use of dynamic in vitro systems can allow us to better understand efficacy and safety for drug combination studies
- Innovating capabilities to maximize output from MPS studies

Kristin Fabre, Microphysiological Systems Lead, IMED Biotech Unit, **AstraZeneca**

1.30 Advanced Predictive In-Vitro Liver & Kidney Models for Drug Discovery

- Opportunities for advanced predictive 3D models to address some of the challenges faced by the pharma industry
- Impact examples of advanced liver and kidney models over conventional 2D static culture platforms

Piyush Bajaj, Scientist II, Drug Safety Research and Evaluation, **Takeda**

Advancing Drug Metabolism & Pharmacokinetic Profiling

1.00 Recent Advances in DMPK Applications of 3D Tissue Models

- Highlighting the real advances in the development and application of 3D models for DMPK during the last few years
- Showcasing areas of application including PK prediction of low clearance compounds, and complex metabolism and transport of drugs in multiple organs of interest
- Emerging trends for modular, higher throughput, and imaging compatible tissue models

Jinping Gan, Senior Principal Scientist, **Bristol-Myers Squibb**

1.30 ADMET Modeling Via Linked Microphysiological Systems

- HUnderstanding the role of multi-step processes in druginduced toxicities
- Revealing insights into gene X environment interactions and inter-individual susceptibility

Edward Kelly, Associate Professor, **University of Washington**

2.00 Afternoon Refreshments

2.30 Mastermind Summary Panel: Engineering Future Success for 3D Models

Kristin Fabre
Microphysiological Systems Lead, IMED Biotech Unit
AstraZeneca

Szczepan Baran
Global Head of Animal Welfare Compliance Training
Novartis

Matthew Wagoner
Associate Director - Investigative Toxicology
Takeda

3.00 Mastermind Discussion Groups - Collaborating To Advance Model Uptake

Following the conclusion of the summary panel the room will split into smaller groups to individually discuss and define the below points. The key aim of this session is to facilitate in-depth discussions between participants in an informal environment. Responses from each group will be collated and shared following the event.

- What is the best way to establish effective communication strategies to advise model use in discovery and development?
- How can different disciplines interact more effectivelyto leverage advances and lessons learned from early successes e.g tox to discovery?
- What is the most effective way to collaborate and advance the field?
- How should we be working external providers to facilitate model use and development within the pharma setting?

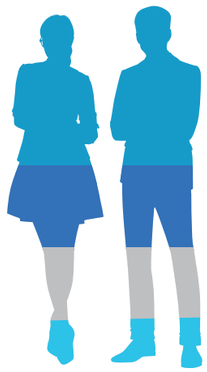
3.30 Chairs Closing Remarks

3.35 Close of Conference

WHO ATTENDS?

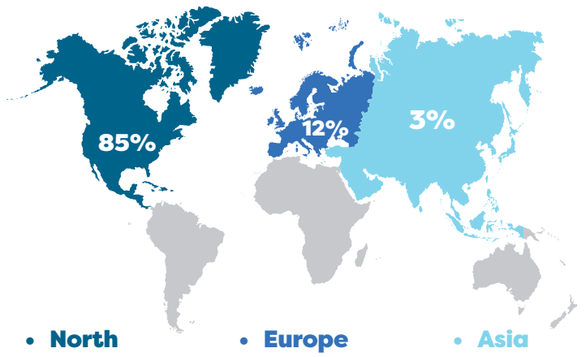
PREVIOUS ATTENDEES INCLUDE

COMPANIES BY TYPE*



- **Drug Developer: 44%**
- **Model and Service Providers: 27%**
- **Research Institute: 26%**
- **Other: 3%**

BREAKDOWN BY REGION*



- **North America**
- **Europe**
- **Asia**

*Expected attendance figures based on actual attendance from past PREDiCT: 3D Models events (2016-18)

> There was a diverse set of presentations, covering multiple aspects of challenges and opportunities setting up and using 3D models. A lot of attention was given to time for networking and exchanging experiences. All in all, a very efficient and useful conference

Marleen van Loenen, Director Non Clinical Development, Gadeta Bv 3D Tissue Models: Oncology Attendee

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Partnerships Director
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- **10% discount – 2-3 delegates**
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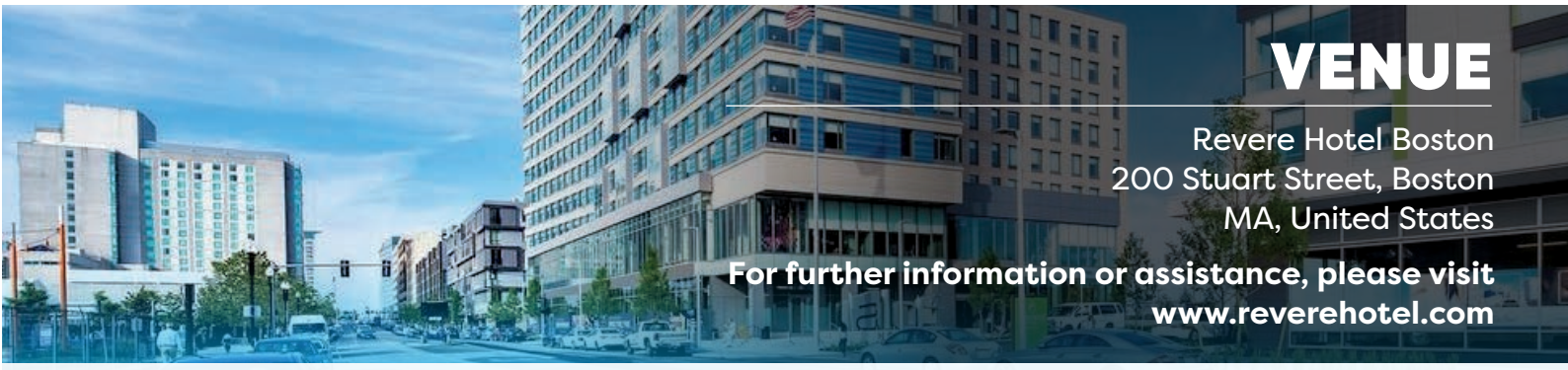
Please note that discounts are only valid when three or more delegates from one company book and pay at the same time. Contact: register@hansonwade.com

"The 3D Tissue Models conference was a fantastic platform for industry and academics to come together and discuss how this field should and will move forward"

Moody Suliman, Nortis
3D Tissue Models 2016/2017 Attendee



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