Cambridge Healthtech Institute 2nd Annual

WORLD PHARMA WEEK

DRIVING INNOVATION IN DRUG R&D

June 2-4, 2020 • Boston, MA

Preclinical Program

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Featured Speakers

Barbara Sosnowski,
Vice President and Global Head, Emerging Science & Innovation Leads, WWRDM, Pfizer

Hans Clevers, MD, PhD,
Principal Investigator of Hubrecht Institute and Princess Máxima Center, CSO of HUB Organoids Technology

Stephen Fesik, PhD,
Chair in Cancer Research, Vanderbilt University School of Medicine

Dmitri Wiederschain, PhD,
Global Head, Immuno-Oncology Research Therapeutic Area, Sanofi

Anthony Philippakis,
Chief Data Officer, Broad Institute; Venture Partner, GV

Hua Gong, MD, PhD,
Senior Director, Head of Genomics Biomarker Development, Navigate Biopharma

PharmaWeek.com

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3D Cellular Modeling • iPSCs • Bioengineered Models

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Preclinical Strategies Models and Tools in Oncology

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View Agenda

Advances in Drug Metabolism & Safety Testing

Lead Optimization • Predicting Toxicity • Safety for New Modalities

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Plenary Keynote Sessions

JUNE 2 - 4

DAY 1

TUESDAY, JUNE 2, 4:25 - 6:05 PM

The life sciences community has an unprecedented scientific arsenal to discovery, develop and implement treatments, cures and preventions that enhance human healthcare. Scientific innovation and opportunity continues to stimulate a surge in entrepreneurship to deliver life-changing therapeutics to patients and their caregivers.

PANEL DISCUSSION: Driving Entrepreneurial Innovation To Accelerate Therapeutic Discoveries

Investing in drug discovery and development continues to face inherent challenges:

- Scale and duration of investment required;
- Risk and attrition in drug discovery and development;
- Uncertainties around pricing and reimbursement of new medicines;
- Leveraging the intersection of life-sciences and technology

Several novel business and investment models have been explored, and continue to be developed, to meet these challenges, and ensure medical breakthroughs continue to be delivered to address unmet patient needs. This session will explore such models, and potential new opportunities, with leaders within the biopharma, investment and related sectors who are at the cutting-edge of driving entrepreneurial innovation for therapeutic discovery.

Moderator: Nadeem Sarwar, PhD, Founder & President, Eisai Center for Genetics Guided Dementia Discovery (G2D2), Eisai, Inc.

Panelists: Anthony Philippakis, Chief Data Officer, Broad Institute; Venture Partner, GV

Barbara Sosnowski, Vice President and Global Head, Emerging Science & Innovation Leads, WWRDM, Pfizer

John Hallinan, Chief Business Officer, Massachusetts Biotechnology Council




This panel discussion will focus on novel collaborative business models in biopharma. The purpose of this panel will be to highlight examples of innovative investment and collaborative models being used to accelerate the discovery and development of game-changing new medicines, and discuss future opportunities in this space.

DAY 2

WEDNESDAY, JUNE 3, 1:45 - 3:15 PM

Wednesday's Plenary Keynote session focuses on the innovative science spurring new drugs to market. Advances in stem cell and 3D cell culture for better disease modeling will be covered. Another topic focuses on new approaches that are 'breaking the barrier' to finding compounds against a common cancer-causing molecule, the mutant form of KRAS, that is notoriously difficult to inhibit because of its structure.

Keynote Introduction: *Speaker to be Announced, Reprints Desk, Inc*

Lgr5 Stem Cell-Based Organoids in Human Disease

Hans Clevers, MD, PhD, Principal Investigator of Hubrecht Institute and Princess Máxima Center, CSO of HUB Organoids Technology

Bio: Hans Clevers obtained his MD degree in 1984 and his PhD degree in 1985 from the University Utrecht, the Netherlands. His postdoctoral work (1986-1989) was done with Cox Terhorst at the Dana-Farber Cancer Institute of the Harvard University, Boston, USA. From 1991-2002 Hans Clevers was Professor in Immunology at the University Utrecht and, since 2002, Professor in Molecular Genetics. From 2002-2012 he was director of the Hubrecht Institute in Utrecht. From 2012-2015 he was President of the Royal Netherlands Academy of Arts and Sciences (KNAW). From June 2015-2019 he was director Research of the Princess Máxima Center for Pediatric Oncology.

Systematically Drugging Ras

Stephen Fesik, PhD, Professor of Biochemistry, Pharmacology, and Chemistry; Orrin H. Ingram II Chair in Cancer Research, Vanderbilt University School of Medicine

Bio: Dr. Fesik's research focus is on cancer drug discovery using fragment-based approaches and structure-based drug design. Prior to joining Vanderbilt in May 2009, Dr. Fesik was the Divisional Vice President of Cancer Research at Abbott (2000-2009) where he built a pipeline of compounds that are showing promising anti-cancer activities in early stage clinical trials. While at Abbott, he also developed new NMR methods, determined the three-dimensional structures of several proteins and protein/ligand complexes, pioneered a method for drug discovery called SAR by NMR, and applied this method to identify and optimize ligands for binding to many protein drug targets. Dr. Fesik has published more than 285 papers, trained 59 postdoctoral fellows, has been a reviewer for several government funding agencies and has served as a member of the Editorial Boards of many peer-reviewed journals. He won numerous awards including the Life Time Achievement Award in Nuclear Magnetic Resonance from Eastern Analytical Society (2003), the NIH Director's Pioneer Award (2010), and the AACR Award for Outstanding Achievement in Chemistry in Cancer Research (2012).

Plenary Keynote Sessions

JUNE 2 - 4

DAY 3

THURSDAY, JUNE 4, 8:30 - 9:40 AM

Digital innovations, especially Artificial Intelligence (AI) is coming out as disruptive technology for the faster discovery and development of innovative therapies. There is a lot of excitement about the opportunities associated with the application of AI, but at the same time, a gap exists in understanding these possibilities and applying them to drug discovery and development processes. Thursday's plenary session aims to discuss how AI and digitization can supercharge the pharma R&D and also delve into the practical considerations and challenges in its adoption and implementation.

Applications of Artificial Intelligence in Drug Discovery – Separating Hype from Utility

Patrick Walters, PhD, Senior Vice President, Computation, Relay Therapeutics

Over the last few years, there has been tremendous interest in the application of artificial intelligence and machine learning in drug discovery. Ultimately, the success of any predictive model comes down to three factors: data, representation, and algorithms. This presentation will provide an overview of these factors and how they are critical to the successful implementation and deployment of AI methods.

Bio: Pat Walters heads the Computation & Informatics group at Relay Therapeutics in Cambridge, MA. His group focuses on novel applications of computational methods that integrate computer simulations and experimental data to provide insights that drive drug discovery programs. Pat is co-author of the book "Deep Learning for the Life Sciences", published by O'Reilly and Associates. His work in AI began with expert systems in the late 1980s, moved to machine learning in the 1990s, and has continued through 25 years in the pharmaceutical industry. Prior to joining Relay, Pat spent more than 20 years at Vertex Pharmaceuticals where he was Global Head of Modeling & Informatics.

women in PHARMA

Join the conversation. Be inspired.

The World Pharma Week team is proud to recognize the importance of Women in Pharma. We are delighted to announce a NEW event at World Pharma Week 2020 to honor women in pharma and STEM programs.

THURSDAY, JUNE 4, 12:00 - 1:00 PM

On Thursday, June 4 from 12:00 – 1:00 pm join your peers for a Women in Pharma Luncheon Panel Discussion. This session will create a forum to share thought-provoking questions, inspiring stories, practical advice, and networking opportunities with influencers in the field.

INNOVATION STATION

WEDNESDAY, JUNE 3, 5:45 - 6:45

Life science researchers in Massachusetts, and especially the Boston/Cambridge areas, are world renown for their ability to revolutionize drug discovery and development. Come and visit the Innovation Station, now a part of World Pharma Week on Wednesday, June 3 from 5:45 – 6:45 pm to chat with local venture capitalists, accelerators, entrepreneurs, start-ups and small companies to see what new ideas are brewing in this thriving ecosystem.

Disease Modeling

3D Cellular Modeling • iPSCs • Bioengineered Models

Recommended Short Course*

SC7: Intro to OOAC and Bioprinting for Disease Modeling

**Separate registration required.*

TUESDAY, JUNE 2

3D CELLULAR MODELS

In the past decade, a lot of momentum has been gaining for three-dimensional (3D) cell culture; proponents state that this is more physiologically relevant, but admit that we still need to discuss standardization, validity, scalability and more. Join us on Day 1 of the Disease Modeling conference at World Pharma Week as we discuss innovations, specific-use cases of 3D-oids (organoids, spheroids or tumoroids), and applications for drug discovery and development.

10:00 am Main Conference Registration Open

MOVING TOWARDS A 3D PHYSIOLOGICALLY RELEVANT CELLULAR MODEL

11:15 Chairperson's Remarks

Virneliz Fernandez Vega, Scientific Associate, Molecular Medicine, Scripps Research

11:20 Combining 3D Models and Functional Genomics in Preclinical Drug Development

Alejandro Amador, PhD, Scientific Leader, Platform Biology Automation, GSK

The current preclinical oncology drug discovery paradigm involves lengthy and costly optimization/lead discovery campaigns, often using cellular or *in vivo* tumor models with weak translational relevance that don't closely resemble human solid tumors. I will highlight opportunities/challenges in implementing 3D solid tumor models. I will outline key components that should be considered when developing, validating, scaling, and automating 3D solid tumor models that are more physiologically relevant.

11:40 Adult Stem Cell Organoids: A Patient in the Lab

Robert Vries, PhD, CEO, Hubrecht Organoid Technology (HUB)

Key to the development of the HUB Organoid Technology was the discovery of adult stem cells by Hans Clevers. Provided with the appropriate growth factors, the adult stem cells form a polarized epithelium in which stem cells and their differentiated offspring maintain their natural hierarchy and function. In addition, the organoids are genetically stable during prolonged culture. Subsequently, we developed Organoid technology for most other epithelia. High-establishment efficiency means that we can use the Organoid Technology to generate disease models from virtually all patients.

12:00 pm Understanding Donor-to-Donor Variability in Healthy Human Gut-Derived Organoids

Linda Lieberman, PhD, Principal Scientist, Merck Exploratory Science Center

Primary organotypic cultures need to be robust and reproducible with limited donor-to-donor variability to advance discovery research toward complex functional tissue biology, yet donor-to-donor variability has not been characterized systematically for many human organoid systems. We established intestinal organoid cultures from adult stem cells of healthy donors and characterized inter- and intra-culture variability. We found that differentiation patterns were consistent among cultures and passages, producing all expected intestinal cell types.

12:20 *In vitro* Generation of Cancer-Associated Fibroblasts for 3D Culture Modeling of Immune-Excluded Tumors

Joanna Lee, PhD, Scientist, Genentech

The transcriptional regulator YAP is considered a universal mechanotransducer, based largely on 2D culture studies. We show a lack of YAP activity in cells in 3D culture and *in vivo*, which is associated with drastic changes in nuclear morphology relative to cells in 2D culture. This work highlights the context-dependent role of YAP in mechanotransduction, and establishes that YAP does not mediate mechanotransduction in breast cancer.

12:55 Transition to Lunch

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:30 Session Break

Disease Modeling

3D Cellular Modeling • iPSCs • Bioengineered Models

HOW TO SCALE UP 3D MODELS FOR HTS OR UHTS

2:00 Chairperson's Remarks

Virneliz Fernandez Vega, Scientific Associate, Molecular Medicine, Scripps Research

2:05 3D Enteroid-Derived "Gut-in-a-Dish" Model for Developing Personalized Therapies for Chronic Inflammatory Diseases

Soumita Das, PhD, Associate Professor, Department of Pathology, Chief Scientific Director, HUMANOID Center of Research Excellence (CoRE), University of California, San Diego

We have developed a Gut-in-a-dish model from 3D organoids isolated from the intestinal specimens of healthy and diseased patients. This model consisting of epithelial cells, immune cells, and microbes could be utilized to investigate mechanisms for gastrointestinal inflammatory diseases, both oncogenic and non-oncogenic. A semi-HTP format of the model can be useful for the identification of new diagnostic and therapeutic targets, personalization of therapies through Phase "0" human trials, and much more.

2:35 3D Models of Brain Cancer for Precision Medicine Therapeutic Profiling

Virneliz Fernandez Vega, Scientific Associate, Molecular Medicine, Scripps Research

Our goal is to develop and validate a precision medicine therapeutic profiling technology by implementing rapid, cost-effective, physiologically relevant, functional 3D models of brain cancer for phenotypic evaluation of anti-cancer drugs. This combined with molecular pathology has been implemented into clinically pertinent information, which will improve the quality and speed of a physician's decision-making for drug selection in treating cancer in a patient-specific manner.

3:05 Development of a Miniaturized 3D Organoid Culture Platform for Ultra-High-Throughput Screening (uHTS)

Yuhong Du, PhD, Associate Professor, Department of Pharmacology and Chemical Biology, Associate Director, Emory Chemical Biology Discovery Center (ECBDC), Emory University School of Medicine

"Organoids" with an extracellular matrix to support 3D architecture offer a new approach for drug discovery. However, it has been challenging for high-throughput screening (HTS)-based drug discovery due to technical difficulties. We have developed such a 3D organoid culture with an extracellular matrix in high-density, 1536-well plate for ultra-HTS (uHTS), and validated its application for large-scale primary compound screening. Our miniaturized platform provides an enabling technology to accelerate organoid-based drug discovery.

3:35 Methods and Media for the Differentiation of Human Intestinal Organoids and Organoid-Derived Monolayers

Sponsored by STEMCELL™ TECHNOLOGIES

Martin Stahl, Scientist, R&D Intestinal, Stemcell Technologies Inc.

Organoid cultures have redefined the limits of biological data that can be obtained *in vitro*. Learn about how IntestiCult™ Organoid Differentiation Medium drives the differentiation of organoids and organoid-derived monolayer cultures into a more functional, differentiated epithelium that better recapitulates the cellular composition and function of the human intestinal epithelium.

3:50 CO-PRESENTATION: Advanced Peptide Hydrogels for 3D Models, Lab-on-Chip, and hiPSCs

Sponsored by PepGel

Susan Sun, CTO, PepGel LLC

Todd Ringhouse, General Manager, PepGel LLC

PGmatrix 3D Models for cells, spheroids, and organoids from a variety of cells, stimulate the secretion of *in vivo*-like extracellular vesicles (exosomes). Biologically formed stem cell spheroids in PGmatrix demonstrate high pluripotency and differentiation potential at molecular levels. PGmatrix system is affordable, scalable, injectable, bioprintable, microfluidable and beyond.

4:05 Networking Refreshment Break and Transition to Keynote

PLENARY KEYNOTE SESSION
4:25 - 6:05

Driving Entrepreneurial Innovation to Accelerate Therapeutic Discoveries

The life sciences community has an unprecedented scientific arsenal to discovery, develop and implement treatments, cures and preventions that enhance human healthcare.

Moderator: Nadeem Sarwar, President, Eisai Center for Genetics Guided Dementia Discovery (G2D2), Eisai Inc.

Panelists: Anthony Philippakis, Chief Data Officer, Broad Institute; Venture Partner, GV

Barbara Sosnowski, Vice President and Global Head, Emerging Science & Innovation Leads, WWRDM, Pfizer

John Hallinan, Chief Business Officer, Massachusetts Biotechnology Council

See Plenary Keynotes Page for More Information.

6:05 Welcome Reception in the Exhibit Hall with Poster Viewing

7:10 Close of Day

Disease Modeling

3D Cellular Modeling • iPSCs • Bioengineered Models

WEDNESDAY, JUNE 3

iPSC-BASED MODELS

With advances in reprogramming and differentiation technologies, as well as with the recent availability of gene editing approaches, we are finally able to create more complex and phenotypically accurate cellular models based on pluripotent cell technology. This opens new and exciting opportunities for pluripotent stem cell utilization in early discovery, preclinical, and translational research. Day 2 of the Disease Modeling conference at World Pharma Week is designed to bring together experts and bench scientists working with induced pluripotent cells, end-users of their services, and researchers working on finding cures for specific diseases and disorders.

7:30 am Registration Open and Morning Coffee

UTILIZING iPSC TO MODEL DISEASES AND EXPLORE TOMORROW'S THERAPEUTICS

8:10 Chairperson's Remarks
Stefan Braam, PhD, CEO, Ncardia

8:15 FEATURED PRESENTATION: Generation, Validation & Application of iPSC Models in Early Discovery
Lisa Mohamet, PhD, Scientific Leader, Drug Design & Selection, GSK
This presentation will focus on the use of iPSC-derived platforms, complex *in vitro* models to improve disease relevance in phenotypic screening, and target engagement.

8:45 Using "Brains-in-a-Dish" to Investigate Developmental Features of Huntington Disease
Mahmoud Pouladi, PhD, Principal Investigator, Agency for Science, Technology and Research (A*STAR) and National University of Singapore (NUS)
Cerebral organoids grown from human embryonic and pluripotent stem cells can be used to perform detailed studies on brain development and to understand cellular mechanisms underlying Huntington's disease. Details of these findings and other possible applications will be discussed.

9:15 Development of Patient-Derived iPSC Models and Phenotypic Assays for Early Drug Discovery in Neuroscience
Yoshiyuki Tsujihata, PhD, Director, Phenotypic Reverse Translation Lab, Neuroscience Drug Discovery Unit, Takeda Pharmaceutical Company Limited
Phenotypic assay/screening, with patient iPSC-derived models and quantitative image analysis, is an attractive strategy to develop innovative drugs in neurological disorders. Our strategy is to create simple and complex assay systems comprised of iPSC-derived neurons and glial cells and quantitatively capture pathological events, such as synapse plasticity and mitochondrial dysfunction. Those are being developed with a robustness that not only supports initial screening, but also downstream pharmacological and mechanistic evaluations.

Sponsored by StemoniX

9:45 Talk Title to be Announced
Blake Anson, PhD, Vice President, Business Operations, StemoniX

10:00 Presentation to be Announced

Sponsored by maxwell BIOSYSTEMS

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

BIOENGINEERED BLOOD-BRAIN BARRIER MODELS

11:00 Reconstruction of the Human Blood-Brain Barrier *in vitro* Reveals the Pathogenic Mechanisms of APOE4 in Cerebral Amyloid Angiopathy
Joel Blanchard, PhD, Postdoctoral Fellow, Picower Institute for Learning and Memory, MIT
Alzheimer's disease leads to amyloid deposits along cerebral vasculature which impair the function of the blood-brain barrier (BBB) and accelerate cognitive degeneration. APOE4 is the strongest risk factor for cerebrovascular amyloid pathology (CAA) and Alzheimer's disease (AD); however, the underlying pathogenic mechanisms are unknown. We developed an *in vitro* model of the human BBB that revealed the mechanisms through which APOE4 predisposes amyloid deposition, and uncovered new therapeutic opportunities for CAA and AD.

11:30 3D Alzheimer's Disease (AD) Model for Studying the Blood-Brain Barrier Dysfunctions in AD
Yoojin Shin, PhD, Postdoctural Fellow, Mechanical Engineering, Roger Kamm's Lab, MIT
We have developed a physiologically relevant three-dimensional (3D) Alzheimer's disease (AD) model with a neurovascular unit (blood-brain barrier, BBB) including human neurons, astrocytes, pericytes, and brain endothelial cells in a microfluidic system. Using this model, we have investigated BBB dysfunction, such as the increase in permeability and abnormal angiogenesis in AD, and explored whether Aβ and/or toxic molecules disrupt normal BBB function.

Sponsored by CORNING

12:00 pm Presentation to be Announced

12:15 Sponsored Presentation *(Opportunity Available)*

12:30 Transition to Lunch

Sponsored by NANOSURFACE BIOMEDICAL

12:35 LUNCHEON PRESENTATION: Structural Maturation in the Development of hiPSC-Cardiomyocyte Models for Preclinical Safety, Efficacy, and Discovery
Nicholas Geisse, PhD, CSO, NanoSurface Biomedical
HiPSC-CM maturation is sensitive to structural cues from the extracellular matrix (ECM). Failure to reproduce these signals *in vitro* can hamper experimental reproducibility and fidelity. Engineering approaches to address this gap typically trade off complexity with throughput, making them difficult to deploy in the modern development paradigm. NanoSurface technology leverages scalable engineering approaches in a cell-, assay-, and instrument-agnostic manner. It can be employed non-disruptively in nearly any workflow to enhance an assay's predictive power.

1:05 Session Break

Disease Modeling

3D Cellular Modeling • iPSCs • Bioengineered Models

PLENARY KEYNOTE SESSION
1:45 - 3:15

Lgr5 Stem Cell-Based Organoids in Human Disease
Hans Clevers, MD, PhD, Principal Investigator of Hubrecht Institute and Princess Máxima Center, CSO of HUB Organoids Technology

Systematically Drugging Ras
Stephen Fesik, PhD, Professor of Biochemistry, Pharmacology, and Chemistry, Orrin H. Ingram II Chair in Cancer Research, Vanderbilt University School of Medicine
See Plenary Keynotes Page for More Information.

3:15 Refreshment Break in the Exhibit Hall with Poster Viewing

iPSC FOR TISSUE-CHIPS

4:00 Chairperson's Remarks
Chairperson to be Announced, Maxwell Biosystems

4:05 HiPSC-Based Disease Modeling and Taking iPSC Derivatives to the Clinic
Dhruv Sareen, PhD, Executive Director, Cedars-Sinai Biomanufacturing Center, Director, iPSC Core and Assistant Professor, Departments of Biomedical Sciences and BOG Regenerative Medicine Institute, Cedars-Sinai
This presentation will discuss modeling neurological, metabolic, and pancreatic diseases using iPSCs in different formats *in vitro*, including Tissue-Chips. Then it will discuss a pathway for taking iPSC-derived cells to the clinic describing processes used for cGMP manufacturing, including Cedars-Sinai's new biomanufacturing center.

4:35 Neuromuscular Junction-on-a-Chip Model
Graham Marsh, PhD, Scientist II, Biogen
Modeling the complex physiology of the human NMJ is essential to building our understanding of the underlying biology of diseases. We have developed a 3D co-culture model of the NMJ, including iPSC-derived motor neurons and skeletal muscle cells with physiological and translatable readouts that recapitulate a patient phenotype *in vitro*.

5:05 Find Your Table, Meet Your Moderator

5:10 Roundtable Breakout Discussions

TABLE: Organoids – Is It a Fad or an Enduring Technology?
Moderator: Angela Zhang, PhD, Product Manager, Epithelial Cell Biology, Research & Development, Stemcell Technologies

TABLE: Developing Organs-on-a-Chip/Microphysiological Systems for Drug Discovery
Moderator to be Announced

5:45 Reception in the Exhibit Hall with Poster Viewing

6:45 Close of Day

THURSDAY, JUNE 4

MPS, ORGANS-ON-A-CHIP, BIOPRINTING

Day 3 of the Disease Modeling conference at World Pharma Week will focus on cellular and tissue engineering and will explore a variety of approaches, including microfluidic engineering methods like organ-on-a-chip, as well as bioprinting. This day will also discuss the applications of such approaches for disease modeling and drug testing.

8:00 am Registration Open and Morning Coffee

PLENARY KEYNOTE SESSION
8:30 - 9:40

Applications of Artificial Intelligence in Drug Discovery – Separating Hype from Utility
Patrick Walters, PhD, Senior Vice President, Computation, Relay Therapeutics
See Plenary Keynotes Page for More Information.

9:40 Coffee Break in the Exhibit Hall with Poster Viewing

BIOENGINEERED MODELS FOR DRUG DISCOVERY AND DEVELOPMENT

10:25 Chairperson's Remarks
Roger Kamm, PhD, Cecil and Ida Green Distinguished Professor of Mechanical and Biological Engineering, Departments of Mechanical Engineering and Biological Engineering, Massachusetts Institute of Technology

10:30 KEYNOTE PRESENTATION: PhysioMimetics: Integration of Systems Biology with Organs-on-Chips for Drug Development
Linda Griffith, PhD, School of Engineering Professor of Teaching Innovation, Biological Engineering, and Mechanical Engineering, Massachusetts Institute of Technology

11:00 IQ MPS Consortium Update

Szczepan Baran, Head, Emerging Technologies, LAS, SO, Novartis

The International Consortium for Innovation and Quality in Pharmaceutical Development (IQ) is a technically-focused organization of pharmaceutical and biotechnology companies with a mission of advancing science and technology to augment the capability of member companies to develop transformational solutions that benefit patients, regulators, and the broader R&D community.

11:30 Biofabrication of 3D Tissues for Disease Modeling and Drug Screening

Marc Ferrer, PhD, Leader, Biomolecular Screening and Probe Development, Division of Pre-Clinical Innovation, National Center for Advancing Translational Sciences, National Institutes of Health (NIH)

The NCATS 3D Tissue Bioprinting Laboratory is using biofabrication techniques together with quantitative assay technologies to produce architecturally and physiologically validated normal and diseased 3D tissue models in multi-well plate format to create an in-tissue assay platform for drug discovery and development that will be more clinically predicative than current *in vitro* cellular models. The presentation will describe the approach used at NCATS to create a portfolio of biofabricated 3D tissue models of the retina, skin, ometum and brain, as in tissue assay platforms for disease modeling, including age-related macular degeneration, atopic dermatitis and several cancers, and for pharmacological testing of toxicity and efficacy effects.

12:00 pm Sponsored Presentation *(Opportunity Available)*

12:30 Transition to Lunch

12:35 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:05 Dessert and Coffee Break in the Exhibit Hall with Poster Viewing

MODELS TO INFORM DRUG SAFETY AND TOXICITY

2:00 Chairperson's Remarks

Madhu Lal-Nag, PhD, Program Lead, Research Governance Council, Office of Translational Sciences, Center for Drug Evaluation & Research, U.S. Food and Drug Administration

2:05 Emerging Microphysiological Systems for Drug Safety Testing: A Regulatory Perspective

Madhu Lal-Nag, PhD, Program Lead, Research Governance Council, Office of Translational Sciences, Center for Drug Evaluation & Research, U.S. Food and Drug Administration

There is a great need to understand the synergy between the areas of translational and regulatory science research as they pertain to microphysiological systems and their application in evaluating safety and efficacy for therapeutic indications for different disease areas. My presentation will focus on identifying these areas of synergy and focus on the development of microphysiological systems that are a best fit for different applications.

2:35 Microphysiological Systems: Tissues on Chip for Safety, Toxicity, and Efficacy Tools in Precision Medicine

Danilo Tagle, PhD, Associate Director for Special Initiatives, National Center for Advancing Translational Sciences, National Institutes of Health

Microphysiological systems are bioengineered *in vitro* tools that mimic the 3D structure and function of human organ systems and have been developed to improve the predictive assessment of the safety and efficacy of promising therapeutics. The use of human-derived cells and tissues have increased the utility of tissue chips towards modeling diseases and for clinical trials on chips to inform human trial design. This presentation will focus on the latest advances in this promising technology.

3:05 Of Microtissues and Men: Applications of Advanced *in vitro* Systems in Toxicology

Matthew Wagoner, PhD, Director, Investigative Toxicology, Takeda Pharmaceutical

Advanced in vitro cell culture systems are transforming the way we design safer medicines. Here we share case studies of how neural, hepatic, and intestinal organoids are allowing us to more effectively detect and de-risk toxicity, while reducing a reliance on animal models.

3:35 Close of Conference

Preclinical Strategies Models and Tools in Oncology

Platforms and Combinations • Novel Therapeutics • Tumor Models

Recommended Short Course*

SC1: *In vitro* and *in vivo* Modeling for Cancer Research

**Separate registration required.*

TUESDAY, JUNE 2

PLATFORMS AND COMBINATIONS

Immunotherapeutic strategies have changed the way cancers are being treated, providing significant benefit to patients. Despite success, a large fraction of patients does not respond to single-agent therapy. Combination approaches may be the key to improving response rates in these patients. Preclinical immuno-oncology models provide tremendous value for shaping clinical strategies, given that countless potential combinations exist with other immunotherapies, radiation, and/or standard of care.

10:00 am Main Conference Registration Open

MULTI-TARGETED PLATFORMS AND EXTERNAL COLLABORATIONS

11:15 Chairperson's Remarks

Michael Woo, PharmD, Head, Search & Evaluation, Immuno-Oncology, Business Development & Licensing, Novartis Institutes for BioMedical Research, Inc

11:25 KEYNOTE PRESENTATION: Leveraging Multi-Targeting for More Effective Cancer Immunotherapy

Dmitri Wiederschain, PhD, Global Head, Immuno-Oncology Research Therapeutic Area, Sanofi

Cancer immunotherapies with anti-PD-1/PD-L1 checkpoint blockers have revolutionized the treatment of a wide variety of malignancies. However, immunotherapy is ineffective in a significant subset of cancer patients or eventually results in the development of resistance with relapsed disease. Therefore, the future of immuno-oncology is identification of new multi-targeted agents that can elicit robust anti-tumor immunity as single agents and/or be combined with PD1/PDL1 inhibitors to increase the duration and durability of clinical responses. Sanofi is leveraging its rich internal toolbox of therapeutic modalities, including multispecific antibodies, nanobodies and ADCs, to reduce the concept of multi-targeting to practice and convert "cold" non-immunogenic tumors into "hot" tumors with rich and functionally active immune infiltrate.

11:55 Exploring Novel Immunotherapy Combinations to Overcome Resistance to PD-1 Blockade

Russell Jenkins, MD, PhD, Assistant Professor, Medicine, Center for Cancer Research, Massachusetts General Hospital

Cancer immunotherapy with immune checkpoint blockade has transformed the treatment of patients with advanced melanoma, but strategies to overcome resistance are limited. Using molecular and pharmacologic tools, we have confirmed TANK-binding kinase 1 (TBK1) as a novel target to overcome resistance to PD-1 blockade, further supporting the preclinical and clinical development of this novel combination strategy.

12:25 pm External Collaboration in Immuno-Oncology: New Approaches and Business Models

Michael Woo, PharmD, Head, Search & Evaluation, Immuno-Oncology, Business Development & Licensing, Novartis Institutes for BioMedical Research, Inc

The rapid expansion of the field of immune-oncology provoked a spike of venture capital activity and increased the level of external collaboration among pharmaceutical and biotechnology companies. This presentation will focus on strategic consequences of the IO wave for pharma, biotech, and the venture ecosystem.

12:55 Transition to Lunch

Sponsored by

1:00 Advances in Patient Derived *in vitro* and *in vivo* Models for Hematology, Solid Tumors and Immuno-Oncology

Amy Wesa, PhD, Director of Immuno-Oncology Research, Champions Oncology

Patient-derived models that can be used both *in vivo* and *ex vivo* represent a new mechanism for streamlining testing of therapeutic agents through preclinical development. Innovative translationally relevant models for Immuno-Oncology and hematology that span both *in vitro* and *in vivo* applications will be presented to highlight advances beyond traditional cancer models.

1:30 Session Break

TRANSLATIONAL APPROACHES AND NOVEL TARGETS

2:00 Chairperson's Remarks

Viviana Cremasco, PhD, Investigator III, Exploratory Immuno-Oncology, Novartis

2:05 *In vivo* Imaging Techniques for Model Characterization and Guiding Combination Strategies

Tapan Nayak, PhD, Director, Translational Imaging Biomarkers, Merck & Co., Inc.

The success rate of experimental therapy is difficult to predict, as its efficacy often depends upon the characteristics of the preclinical animal models. The presentation will cover different non-invasive imaging techniques to characterize animal models and the information used to guide combination therapies in animal models.

2:25 TGFβ-Blockade Uncovers Stromal Plasticity in Tumors by Revealing the Existence of a Novel Subset of Interferon-Licensed Fibroblasts

Viviana Cremasco, PhD, Investigator III, Exploratory Immuno-Oncology, Novartis

By performing an unbiased interrogation of tumor mesenchymal cells, our study shows that TGFβ-neutralization leads to a profound remodeling of CAF dynamics, greatly reducing the frequency and activity of myofibroblasts, while promoting the formation of a novel fibroblast population characterized by strong response to interferon and heightened immunomodulatory properties. These changes are sufficient to drive productive anti-tumor immunity, laying the foundation for future investigations aimed at defining strategies to reprogram CAF composition for cancer therapy.

2:45 Driving Clinical Decisions about Indications and Combination Partners Using Patient-Derived Xenograft Models
Anderson Clark, PhD, Director, Translational in vivo Pharmacology, Translational Innovation Platform, Oncology, EMD Serono
Small Cell Lung Cancer (SCLC) is characterized by rapid tumor growth and currently, there are few therapeutic options or predictive biomarkers. In a Phase I clinical trial of the p70S6K/AKT1/3 inhibitor M2698, one SCLC patient had prolonged stable disease while on treatment. A follow-up screen in 45 preclinical *in vivo* patient-derived xenograft (PDX) models resulted in a tumor control rate of roughly 27%.

3:05 TAC Development for the Treatment of Solid and Liquid Tumors
Christopher Helsen, PhD, Director, R&D and Head, Platform Development, Triumvira Immunologics Inc.
Triumvira is a clinical-stage company developing T-cell therapies engineered with the proprietary T-cell antigen coupler (TAC). TAC is designed to co-opt the natural TCR independent of MHC showing safe and effective tumor rejection in mouse models of solid and liquid tumors. Triumvira successfully cleared IND/CTA submission for TAC01-CD19 to treat LBCL with a second solid tumor program in preclinical development.

3:35 Presentation to be Announced

Sponsored by Ocello

3:50 Using Quantitative Super-Resolution Imaging to Design Safe and Effective Therapies
Valerio Pereno, Business Development, ONI

Sponsored by ONi

4:05 Networking Refreshment Break and Transition to Keynote

PLENARY KEYNOTE SESSION
4:25 - 6:05

Driving Entrepreneurial Innovation to Accelerate Therapeutic Discoveries
The life sciences community has an unprecedented scientific arsenal to discovery, develop and implement treatments, cures and preventions that enhance human healthcare.
Moderator: Nadeem Sarwar, President, Eisai Center for Genetics Guided Dementia Discovery (G2D2), Eisai Inc.
Panelists: Anthony Philippakis, Chief Data Officer, Broad Institute; Venture Partner, GV
Barbara Sosnowski, Vice President and Global Head, Emerging Science & Innovation Leads, WWRDM, Pfizer
John Hallinan, Chief Business Officer, Massachusetts Biotechnology Council
See Plenary Keynotes Page for More Information.

6:05 Welcome Reception in the Exhibit Hall with Poster Viewing

7:10 Close of Day

WEDNESDAY, JUNE 3

NOVEL THERAPEUTICS

Cancer immunotherapy remains the fastest growing field in oncology, with immune checkpoint inhibitors and T cell therapy as the backbone of current advances in oncology. However, in the form of monotherapy, none of the therapies work as a magic bullet; the quest for effective combination regimens and novel therapies is underway.

7:30 am Registration Open and Morning Coffee

COMBINATION REGIMENS AND NOVEL THERAPEUTICS

8:10 Chairperson's Remarks
Benno Rattel, PhD, Executive Director Research Amgen, CBSS, Amgen

8:15 KEYNOTE PRESENTATION: Rational Development of Immuno-Therapy Combination Regimens
Roy Baynes, MD, PhD, Senior Vice President and Head, Global Clinical Development, CMO, Merck Research Laboratories
After initially defining the breadth and depth of PD-1 antibody (pembrolizumab) monotherapy activity and deploying precision medicine tools across the program, certain biological leads led to the exploration of many combination therapeutic approaches. These included company-owned products, as well as a broad array of external collaborations. Broadly, the approach has encompassed combinations with anti-proliferative agents, targeted therapies, other immuno-therapeutic agents and those addressing specific resistance biology.

8:45 Development of a T-Cell Redirecting CD3 Bispecific Antibody for the Treatment of Gastrointestinal Tumors
Lindsay King, PhD, Associate Research Fellow, Biomedicines Design, Pfizer
PF-07062119 is a novel T-cell redirecting bispecific against tumors expressing Guanylate Cyclase 2C (GUCY2C), a target expressed in more than 90% of CRC, and in other gastrointestinal cancers. We demonstrate tumor selective and potent *in vitro* and *in vivo* efficacy with PF-07062119 in human xenograft models with T-cell adoptive transfer, as well as in an

immunocompetent syngeneic model. PF-07062119 shows combination benefits with checkpoint inhibitors and with chemo- and anti-VEGF-therapy.

9:15 Bispecific T Cell Engagers: Overview of Amgen's BiTE® Pipeline

Benno Rattel, PhD, Executive Director Research Amgen, CBSS, Amgen

Bispecific T cell engagers, commonly referred to as BiTE® antibody constructs, can transiently link tumor cells with resting polyclonal T cells for induction of a surface target antigen-dependent redirected lysis of tumor cells. Blinatumomab (BLINCYTO®) is directed against CD19 and is the first approved T cell engaging antibody. The nonclinical characterizations of blinatumomab, as well as of various BiTE® antibody constructs, and their translation into the clinic will be presented.

9:45 Sponsored Presentation *(Opportunity Available)*

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

TARGETING INFLAMMATORY MICROENVIRONMENTS AND INFLAMMASOMES

11:00 Friends & Enemies: Spatial Mapping of Regulatory T Lymphocytes in Inflammatory Microenvironments

Shawn O'Neill, DVM, PhD, Senior Director, Global Pathology & Investigative Toxicology, Global Microscopic Imaging Lead, Drug Safety Research & Development, Pfizer Worldwide Research & Development

Tregs are CD4+ T lymphocytes that are central to peripheral immune tolerance, actively inhibiting inflammation upon antigenic stimulation. Tregs thus play a conflicting dual role: as endogenous suppressors of inflammation in autoimmune diseases, while also inhibiting effector CTL from killing tumor cells. In this presentation. we will localize Tregs and CTL by multiplex immunofluorescence and demonstrate spatial mapping of these cells in inflammatory microenvironments by digital pathology using artificial intelligence.

11:30 Targeting Tumor-Promoting Inflammation via the Inflammasome Pathway – Lessons Learned

Pushpa Jayaraman, PhD, Senior Investigator I, Exploratory Immuno Oncology, Novartis Institutes for Biomedical Research

Chronic inflammation via the inflammasome pathway plays a key role in carcinogenesis by accelerating tumor invasiveness, growth, and metastatic spread by promoting an immunosuppressive tumor microenvironment. Our work highlights the pathophysiological role of inflammasome mediator, IL-1b in tumor immunomodulation and that IL-1b blockade might have important consequences on T cell function and checkpoint blockade in cancer.

12:00 pm Sponsored Presentation *(Opportunity Available)*

12:30 Transition to Lunch

12:35 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:05 Session Break

PLENARY KEYNOTE SESSION
1:45 - 3:15

Lgr5 Stem Cell-Based Organoids in Human Disease

Hans Clevers, MD, PhD, Principal Investigator of Hubrecht Institute and Princess Máxima Center, CSO of HUB Organoids Technology

Systematically Drugging Ras

Stephen Fesik, PhD, Professor of Biochemistry, Pharmacology, and Chemistry, Orrin H. Ingram II Chair in Cancer Research, Vanderbilt University School of Medicine

See Plenary Keynotes Page for More Information.

3:15 Refreshment Break in the Exhibit Hall with Poster Viewing

NEW MODALITIES

4:00 Chairperson's Remarks

Aaron Goldman, PhD, Faculty and Principal Investigator, Goldman Laboratory Drug Resistance Group, Harvard Medical School

4:05 Targeting Immune Checkpoint TIM-3 for Cancer Immunotherapy

Xiaomo Jiang, PhD, Principal Scientist II, Immuno-Oncology, Novartis Institutes for BioMedical Research

TIM-3 has critical roles in tumor-induced immune suppression. Blockade of TIM-3, alone or in combination with PD-1 pathway blockade, has shown anti-tumor efficacy in several preclinical cancer models and in clinical trials. TIM-3 blockade to activate immune response and control tumor growth could reflect the combined effects on modulating multiple cell types in the complex interactions between cancer and the immune system.

4:25 Novel Fully Synthetic Bicyclic Peptides as Tumor Targeted Immune Cell Modulators

Sailaja Battula, PhD, Associate Director, Immuno-Oncology, Bicycle Therapeutics

CD137 is a validated target for cancer immunotherapy, but antibody approaches targeting CD137 thus far had limited success, likely due to systemic immune activation. We demonstrated that Bicycle's tumor targeted immune cell agonists (TICATM) showed tumor target-dependent immune activation localized to tumor with superior anti-tumor activity in pre-clinical models.

4:45 'Smart' Release Therapeutics Target Multi-Drug Resistance in Solid Cancers

Aaron Goldman, PhD, Faculty and Principal Investigator, Goldman Laboratory Drug Resistance Group, Harvard Medical School

The ability for cancer cells to phenotypically switch and survive under drug pressure, referred to as drug-induced resistance or tolerance, is an emerging, yet poorly understood, mechanism of anticancer therapy failure. We discovered a novel metabolic pathway induced by the first drug in a standard chemotherapy combination leads to multi-drug resistance. To target this mechanism, we engineered small molecule inhibitors of upstream glucose metabolism with anthracyclines using a 'smart' release mechanism, which improves response to therapy *in vivo*.

5:05 Find Your Table, Meet Your Moderator

5:10 Roundtable Breakout Discussions

TABLE: Preclinical Strategies for T Cell Therapy
Moderator: Lindsay King, PhD, Associate Research Fellow, Biomedicines Design, Pfizer

TABLE: Targeting Inflammasome in Cancer & Beyond
Moderator: Pushpa Jayaraman, PhD, Senior Investigator I, Exploratory Immuno Oncology, Novartis Institutes for Biomedical Research

5:45 **Reception in the Exhibit Hall with Poster Viewing**

6:45 **Close of Day**

THURSDAY, JUNE 4

TUMOR MODELS

Preclinical tumor models are key tools to evaluate the activity of cancer therapies. They are instrumental to understanding the mechanism of action of tested compounds and help with identifying rational combination partners for best anti-tumor efficacy. Next-generation tumor models, preclinical imaging, and translational strategies will be featured at Day 3 of this conference.

8:00 am **Registration Open and Morning Coffee**

PLENARY KEYNOTE SESSION
8:30 - 9:40

Applications of Artificial Intelligence in Drug Discovery – Separating Hype from Utility
Patrick Walters, PhD, Senior Vice President, Computation, Relay Therapeutics
See Plenary Keynotes Page for More Information.

9:40 **Coffee Break in the Exhibit Hall with Poster Viewing**

NEXT-GENERATION MODELING SYSTEMS AND WHAT WE CAN LEARN WITH THEIR HELP

10:25 **Chairperson's Remarks**
Christopher Kemball, PhD, Scientist, Biochemical & Cellular Pharmacology, Genentech

10:30 **Preclinical Modeling Using Human Cancer Xenografts Grown in Immune-Deficient Zebrafish**
David Langenau, PhD, Associate Chief of Research and Director of Molecular Pathology, Massachusetts General Hospital; Associate Professor, Pathology, Harvard Medical School

We have generated immune-compromised zebrafish that lack T-, B- and NK-cells that robustly engraft human cancers. Capitalizing on the optical clarity of zebrafish and facile imaging approaches, we have documented small-molecule therapy responses and dynamic cell killing by CAR T cell- and bispecific T cell-engager antibodies (BITES) at single-cell resolution. Our studies credential the immune-deficient zebrafish as a new platform for preclinical drug studies.

11:00 **CD34+ Stem Cell-Derived Human Dendritic Cells Provide a Physiologically Relevant System to Evaluate the Pharmacology of Therapeutic Molecules**
Christopher Kemball, PhD, Scientist, Biochemical & Cellular Pharmacology, Genentech
Anti-tumor immunity may be enhanced by therapeutic agents that promote dendritic cell expansion and differentiation. To better characterize the pharmacology of these therapies, *in vitro* models are needed that recapitulate physiologically relevant human DC subsets. DCs generated *in vitro* from human CD34+ progenitor cells closely resemble primary blood DCs. We show that CD34-derived DCs can be used to characterize the potency of a therapeutic molecule to drive cDC1 differentiation.

11:30 **Is There a Key Node in the TME to Tip the Balance?**
Zhao Chen, PhD, Investigator III, Exploratory Immuno-Oncology, Novartis Institutes for BioMedical Research, Inc.
The efficacy of the host immune response against cancer largely

depends on the behavior of the tumor microenvironment (TME). Many TME components were shown to impact different aspect of cancer immunity, ranging from T cell priming, effector function, exhaustion to memory. However, the highly heterogeneous TME is often a big hurdle for the clinical translation of TME targets. We are interested in the interplay between components of the TME and the key node that can truly perturb the TME balance.

12:00 pm Sponsored Presentation *(Opportunity Available)*

12:30 Transition to Lunch

12:35 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:05 Dessert and Coffee Break in the Exhibit Hall with Poster Viewing

2:00 Chairperson's Remarks

Virna Cortez-Retamozo, PhD, Lab Head, Senior Principal Scientist, Oncology-Pharmacology, Sanofi

2:05 Transplanted Syngeneic Metastasis Models for Preclinical Applications

Viswanathan Muthusamy, PhD, Research Scientist; Executive Director, Center for Precision Cancer Modeling, Yale School of Medicine

There is a great need for robust *in vivo* preclinical models for evaluation of drugs interfering with metastasis. We have developed several transplantable, syngeneic metastasis models and used these to assess: 1) interventions to prevent colonization and growth in distant organs; and 2) treatment-induced abscopal effects on distant metastases. In preliminary studies, an immune-targeting, intratumorally injected drug candidate reduced metastatic burden and improved survival in one such model.

2:35 Using Humanized Mouse Models to Evaluate T Cell Engagers

Virna Cortez-Retamozo, PhD, Lab Head, Senior Principal Scientist, Oncology-Pharmacology, Sanofi

The success of early cancer immunotherapies has led to the development of several new therapeutic approaches, including T cell engagers. T cell engagers are typically bispecific Abs directed against the T cell and a tumor-associated antigen, whose therapeutic strategy is to: 1) engage T cells; 2) activate the T cells; and 3) engage tumor cells and induce tumor cell killing. Preclinical evaluation relies on development of models that mirror some properties of a human setting to assess the therapeutic properties of T cell engagers.

3:05 PANEL DISCUSSION: Next-Generation Modeling Systems and What We Can Learn with Their Help

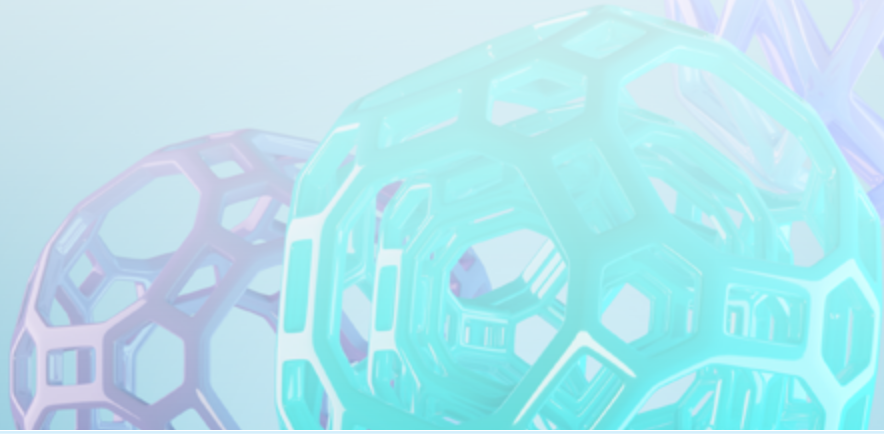
Moderator: Zhao Chen, PhD, Investigator III, Exploratory Immuno-Oncology, Novartis Institutes for BioMedical Research, Inc.

Panelists: Speakers of the Session

3:35 Close of Conference

"WPW is a must-attend event to better understand how the pharma industry is moving forward. We will definitely return next year. "

-Director, Marketing, NanoSurface Biomedical



Advances in Drug Metabolism & Safety Testing

Lead Optimization • Predicting Toxicity • Safety for New Modalities

Recommended Short Course*

SC4: Optimizing Drug Metabolism, Drug Clearance and Drug-Drug Interactions
**Separate registration required.*

TUESDAY, JUNE 2

OPTIMIZING DRUG METABOLISM

Lead compounds need to be optimized for metabolism and safety early in the drug development process. Day 1 in the Advances in Drug Metabolism & Safety Testing conference looks at some innovative tools and strategies that are being utilized for lead optimization, particularly for drug metabolism, dosing, and drug-drug interactions. How to utilize these tools for evaluating and optimizing new drug modalities will also be discussed.

10:00 am Main Conference Registration Open

EARLY METABOLISM & SAFETY ASSESSMENTS

11:15 Chairperson's Remarks
Li Di, PhD, Research Fellow, Pharmacokinetics, Dynamics and Metabolism, Pfizer

11:25 The Impact of Intracellular Free-Drug Concentration on Prediction of Clearance and Drug-Drug Interaction
Li Di, PhD, Research Fellow, Pharmacokinetics, Dynamics and Metabolism, Pfizer
A novel *in vitro* method has been developed to estimate *in vivo* live-to-plasma unbound partition coefficient (Kpuu). The method uses hepatocytes in 4% bovine serum albumin (BSA). BSA plays an important role in maintaining transporter functional activities, similar to *in vivo*. *In vitro-in vivo* correlation (IVIVE) has been established for liver Kpuu and clearance-mediated by both enzymes and transporters. Applications of the method to predict human clearance and drug-drug interaction (DDI) will be discussed.

11:55 Incorporating Complex *in vitro* Models in Drug Safety Assessment
Terry Van Vleet, PhD, DABT, Director, Investigative Toxicology, Department of Preclinical Safety, AbbVie
This talk will discuss some example applications of complex *in vitro* models in early drug safety assessments. A comparison of 2D and 3D model outcomes will be presented as well for perspective.

12:25 pm Complex *In vitro* Models for ADME Applications: Current Status and Future Perspectives
Jinping Gan, PhD, Senior Principal Scientist, Pharmaceutical Candidate Optimization, Research & Early Development, Bristol-Myers Squibb
The evolving landscape of biopharmaceutical R&D demands more predictive and flexible models for many aspects of preclinical sciences, including ADME applications. Complex *in vitro* models, typically of more physiological nature, hold promise to improve translation from preclinical to clinical or from *in vitro* to *in vivo*. In this talk, key gaps in ADME translation will be reviewed, examples of progress will be shared, along with future perspectives.

12:55 Transition to Lunch

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:30 Session Break

ASSESSING NEW DRUG MODALITIES

2:00 Chairperson's Remarks
Donglu Zhang, PhD, Principal Scientist, Drug Metabolism and Pharmacokinetics, Genentech, Inc.

2:05 Local Metabolism Leads to Better Understanding of Tissue Drug Concentration for New Modalities
Donglu Zhang, PhD, Principal Scientist, Drug Metabolism and Pharmacokinetics, Genentech, Inc.
For small-molecule drugs, the liver is the major organ for drug clearance. Liver *in vitro* systems can be used to predict *in vivo* PK. Plasma drug concentration is a good surrogate for tissue concentrations. For new modalities, especially drug conjugates, there is a universal lysosomal degradation of proteins for clearance and generation of active drugs. The efficacy and toxicity is supported by the drug that is released locally in the right form and concentration from a conjugate. This talk discusses the importance of tissue metabolism.

2:35 CRISPR Screens Identify Regulators of Antibody-Drug Conjugate Toxicity
Kimberly Tsui, PhD, Postdoctoral Fellow, Laboratory of Dr. Andrew Dillin, Department of Molecular and Cell Biology, University of California, Berkeley
Using CRISPR-Cas9 screens, we have uncovered many known and novel endolysosomal regulators as modulators of Antibody-drug conjugate (ADC) toxicity. Through comparative analysis of screens with ADCs bearing different linkers, we show that a subset of late endolysosomal regulators selectively influence toxicity of non-cleavable linker ADCs. These results reveal new regulators of endolysosomal trafficking, provide important insights for ADC design and identify candidate combination therapy targets.

3:05 Developing and Embedding an *in vitro* Capability to De-Risk Translational *in vivo* Attributes of Therapeutic Antibody Panels
Daniel Rycroft, Antibody Pharmacology Team Leader and GSK Associate Fellow, Biopharm Molecular Discovery, GSK
While it is well established that small sequence differences between therapeutic monoclonal antibodies cause a range of biophysical attributes which can affect the manufacturability potential of drug candidates, it is now becoming increasingly understood that these same properties can impact *in vivo* suitability. By using a panel of orthogonal *in vitro* methods, it is however possible to de-risk antibody panels for *in vivo* properties without the need for iterative *in vivo* studies.

3:35 Sponsored Presentation *(Opportunity Available)*

4:05 Networking Refreshment Break and Transition to Keynote

PLENARY KEYNOTE SESSION
4:25 - 6:05

Driving Entrepreneurial Innovation to Accelerate Therapeutic Discoveries
The life sciences community has an unprecedented scientific arsenal to discovery, develop and implement treatments, cures and preventions that enhance human healthcare.
Moderator: Nadeem Sarwar, President, Eisai Center for Genetics Guided Dementia Discovery (G2D2), Eisai Inc.
Panelists: Anthony Philippakis, Chief Data Officer, Broad Institute; Venture Partner, GV
Barbara Sosnowski, Vice President and Global Head, Emerging Science & Innovation Leads, WWRDM, Pfizer
John Hallinan, Chief Business Officer, Massachusetts Biotechnology Council
See Plenary Keynotes Page for More Information.

6:05 Welcome Reception in the Exhibit Hall with Poster Viewing

7:10 Close of Day

WEDNESDAY, JUNE 3

PREDICTING DRUG TOXICITY

Day 2 in the Advances in Drug Metabolism & Safety Testing conference focuses on innovative use of screening assays, computational and machine learning tools for better assessing and predicting drug-related toxicities. The talks highlight ways to use CRISPR screening, quantitative modeling, AI/ML algorithms, and high-performance computing to make better and more accurate drug safety predictions early in the drug development process.

7:30 am Registration Open and Morning Coffee

IDENTIFYING OFF-TARGET DRUG TOXICITY

8:10 Chairperson's Remarks
Jason Sheltzer, PhD, Principal Investigator, Cold Spring Harbor Laboratory

8:15 Off-Target Toxicity is a Common Mechanism of Action of Cancer Drugs Undergoing Clinical Trials
Jason Sheltzer, PhD, Principal Investigator, Cold Spring Harbor Laboratory
We have recently applied CRISPR mutagenesis to demonstrate that many putative targeted inhibitors in clinical trials kill cancer cells independently of their reported targets. This off-target toxicity raises significant safety concerns and may contribute to the frequent failure of new anti-cancer drugs. We discuss multiple genetic strategies to ensure on-target drug activity and to minimize potentially harmful off-target interactions.

8:45 Novel Microbiome-Targeting Drugs to Improve the Therapeutic Window of Prescription Medicines
Ward Peterson, PhD, President & CEO, Symberix Inc.
The use of various classes of prescription medicines are frequently associated with dose-limiting intestinal sequelae. These drugs undergo glucuronidation by liver UDP-glucuronosyltransferases and subsequent de-glucuronidation by gut bacterial b-glucuronidases (GUS), resulting in the production of toxic drug catabolites in the intestinal lumen. Symberix's approach for ameliorating these toxicities is to selectively inhibit bacterial GUS with microbiome-targeting "symbiotic drugs" that do not damage the endogenous microbiota.

9:15 Application of Tox21 qHTS Data in Predicting Drug Toxicity
Ruili Huang, PhD, Group Leader, Tox21 Informatics, National Center for Advancing Translational Sciences, National Institutes of Health
Target-specific, mechanism-oriented *in vitro* assays post a promising alternative to traditional animal toxicology studies. The Tox21 program, a large-scale *in vitro* chemical toxicity screening effort, has tested ~10K drugs and environmental chemicals in quantitative high-throughput screening (qHTS) format against a panel of ~70 assays, producing more than 100 million data points to date. Strategies will be discussed on applying this rich set of *in vitro* activity profiles to assess potential drug toxicity.

9:45 Sponsored Presentation *(Opportunity Available)*

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

Advances in Drug Metabolism & Safety Testing

Lead Optimization • Predicting Toxicity • Safety for New Modalities

STRATEGIES FOR EARLY RISK ASSESSMENTS

11:00 Using DILIsym to Predict Hepatotoxicity Risk during Preclinical Development

Paul Michalski, PhD, Investigator, Systems Modeling and Translational Biology, GlaxoSmithKline

DILIsym is a quantitative systems toxicology (QST) model of drug-induced liver injury (DILI) developed primarily to provide mechanistic understanding of clinically observed hepatotoxicity. We recently evaluated DILIsym as a screening tool for preclinical development. Here we will give an overview of DILIsym and discuss the results of our evaluation, highlighting where DILIsym can provide value in early development. We also provide practical advice on the steps required to industrialize DILIsym as an in-house screening tool.

11:30 Accelerating Drug Discovery through Accurate Safety Predictions: One Goal of The ATOM Consortium

Sarine Markossian, PhD, Specialist, Department of Pharmaceutical Chemistry, University of California San Francisco

The Accelerating Therapeutics for Opportunities in Medicine (ATOM) consortium is an academia, industry, and government partnership with the goal of rapidly accelerating drug discovery by integrating high-performance computing and diverse biological data. One of our goals in ATOM is to optimize preclinical safety predictions, so we can incorporate predictive toxicology early in the drug discovery process. Here we present our strategy and efforts towards reliably measuring and predicting drug-induced liver injury (DILI).

12:00 pm Sponsored Presentation *(Opportunity Available)*

12:30 Transition to Lunch

12:35 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:05 Session Break

PLENARY KEYNOTE SESSION
1:45 - 3:15

Lgr5 Stem Cell-Based Organoids in Human Disease

Hans Clevers, MD, PhD, Principal Investigator of Hubrecht Institute and Princess Máxima Center, CSO of HUB Organoids Technology

Systematically Drugging Ras

Stephen Fesik, PhD, Professor of Biochemistry, Pharmacology, and Chemistry, Orrin H. Ingram II Chair in Cancer Research, Vanderbilt University School of Medicine

See Plenary Keynotes Page for More Information.

3:15 Refreshment Break in the Exhibit Hall with Poster Viewing

USE OF AI/ML FOR ADME/Tox PREDICTIONS

4:00 Chairperson's Remarks

Barun Bhhatarai, PhD, Investigator, Novartis Institute for Biomedical Research

4:05 ML and AI on ADME/Tox Accelerating Drug Discovery

Barun Bhhatarai, PhD, Investigator, Novartis Institute for Biomedical Research

ML- and AI-related approaches have been tested and applied in various areas within Novartis. In ADMETox, ML approaches are serving intended purposes and complementing experimental methods. With the advent of AI, ingenious deep learning algorithms, and powerful micro-processors, we have explored its anticipated benefit in preclinical and clinical programs. Our various efforts on data digitization, ML and AI implementation, and collaborations will be discussed with specific examples from ADMETox.

4:35 Artificial Intelligence and Small-Molecule Drug Metabolism

Joshua Swamidass, MD, PhD, Assistant Professor, Immunology and Pathology, Laboratory and Genomic Medicine; Faculty Lead, Translational Informatics, Institute for Informatics, Washington University

We have been building artificial intelligence (AI) models of metabolism and reactivity. Metabolism can both render toxic molecules safe and safe molecules toxic. The AI models we use quantitatively summarize the knowledge from thousands of published studies. The hope is that we could more accurately model the properties of medicines to determine whether metabolism renders drugs toxic or safe. This is one of many places where artificial intelligence could give traction on the difficult questions facing the industry.

5:05 Find Your Table, Meet Your Moderator

5:10 Roundtable Breakout Discussions

TABLE: Impact of Artificial Intelligence and Machine Learning on Drug Safety Assessments

Moderators: Barun Bhhatarai, PhD, Investigator, Novartis Institute for Biomedical Research

Joshua Swamidass, MD, PhD, Assistant Professor, Immunology and Pathology, Laboratory and Genomic Medicine; Faculty Lead, Translational Informatics, Institute for Informatics, Washington University

TABLE: Traditional and Advanced Models and Strategies for Early Risk Assessments

Moderators: Terry Van Vleet, PhD, DABT, Director, Investigative Toxicology, Department of Preclinical Safety, AbbVie

Paul Michalski, PhD, Investigator, Systems Modeling and Translational Biology, GlaxoSmithKline

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5:45 Reception in the Exhibit Hall with Poster Viewing

6:45 Close of Day

Advances in Drug Metabolism & Safety Testing

Lead Optimization • Predicting Toxicity • Safety for New Modalities

THURSDAY, JUNE 4

IMPROVING TRANSLATION INTO CLINIC

Translation of preclinical findings to the clinical setting remains a formidable challenge in drug development. Day 3 in the Advances in Drug Metabolism & Safety Testing conference focuses on attempts being made to reduce those gaps in translation and to find better ways to accurately predict clinical outcomes. The talks will highlight scientific and technical innovations and applications that are making this possible.

8:00 am Registration Open and Morning Coffee

PLENARY KEYNOTE SESSION
8:30 - 9:40

Applications of Artificial Intelligence in Drug Discovery – Separating Hype from Utility
Patrick Walters, PhD, Senior Vice President, Computation, Relay Therapeutics
See Plenary Keynotes Page for More Information.

9:40 Coffee Break in the Exhibit Hall with Poster Viewing

OVERCOMING TRANSLATIONAL CHALLENGES

10:25 Chairperson's Remarks
James Hickman, PhD, Founding Director, NanoScience Technology Center and Professor, Nanoscience Technology, Chemistry, Biomolecular Science, Material Science and Electrical Engineering, University of Central Florida

10:30 Lost in Translation: Challenges in Interpreting *in vitro* Studies Using Human-Derived Tissues
Gary Gintant, PhD, Senior Research Fellow, Department of Integrative Pharmacology, Integrated Science and Technology, AbbVie
With the advent of human-derived cells and tissues has come newfound challenges for the translation of *in vitro* study findings to guide drug development. This presentation will focus on biological and platform-related challenges (and potential solutions) for nonclinical safety studies with human-derived tissues.

11:00 Human Heart Slices as a Reliable Platform for Predicting Cardiotoxicity
Tamer Mohamed, PhD, Assistant Professor of Medicine, Institute of Molecular Cardiology, University of Louisville
Culturing human heart slices is a promising model of intact human myocardium. This technology provides access to the complete 3D multicellular system that is similar to the human heart tissue that reflects the human myocardium in physiological or pathological conditions, both functionally and structurally. Recently, we have developed a novel biomimetic culture system that maintains full viability and functionality of human and pig heart slices (300 µm thickness) for 6 days in culture.

11:30 Human-on-a-Chip Applications in ADME/Tox to Predict Clinical Outcomes
James Hickman, PhD, Founding Director, NanoScience Technology Center and Professor, Nanoscience Technology, Chemistry, Biomolecular Science, Material Science and Electrical Engineering, University of Central Florida
Multi-organ human-on-a-chip platforms have been used to demonstrate concurrent measurement of efficacy and toxicity for therapeutic index estimation. Evaluation of drugs and compounds has shown similar responses to results seen from clinical data, as well as demonstrated long-term (28-day) function. Applications for ALS, Alzheimer's, rare diseases, diabetes, and cardiac mechanistic toxicity will be reviewed. The development of *in vitro* PDPK models that are being used to predict *in vivo* results will also be presented.

12:00 pm Sponsored Presentation *(Opportunity Available)*

12:30 Transition to Lunch

12:35 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:05 Dessert and Coffee Break in the Exhibit Hall with Poster Viewing

2:00 Chairperson's Remarks
Madhu Lal-Nag, PhD, Program Lead, Research Governance Council, Office of Translational Sciences, Center for Drug Evaluation & Research, U.S. Food and Drug Administration

2:05 Emerging Microphysiological Systems for Drug Safety Testing: A Regulatory Perspective
Madhu Lal-Nag, PhD, Program Lead, Research Governance Council, Office of Translational Sciences, Center for Drug Evaluation & Research, U.S. Food and Drug Administration
There is a great need to understand the synergy between the areas of translational and regulatory science research as they pertain to microphysiological systems and their application in evaluating safety and efficacy for therapeutic indications for different disease areas. My presentation will focus on identifying these areas of synergy and focus on the development of microphysiological systems that are a best fit for different applications.

Advances in Drug Metabolism & Safety Testing

Lead Optimization • Predicting Toxicity • Safety for New Modalities

2:35 Microphysiological Systems: Tissues on Chip for Safety, Toxicity, and Efficacy Tools in Precision Medicine

Danilo Tagle, PhD, Associate Director, Special Initiatives, National Center for Advancing Translational Sciences, National Institutes of Health

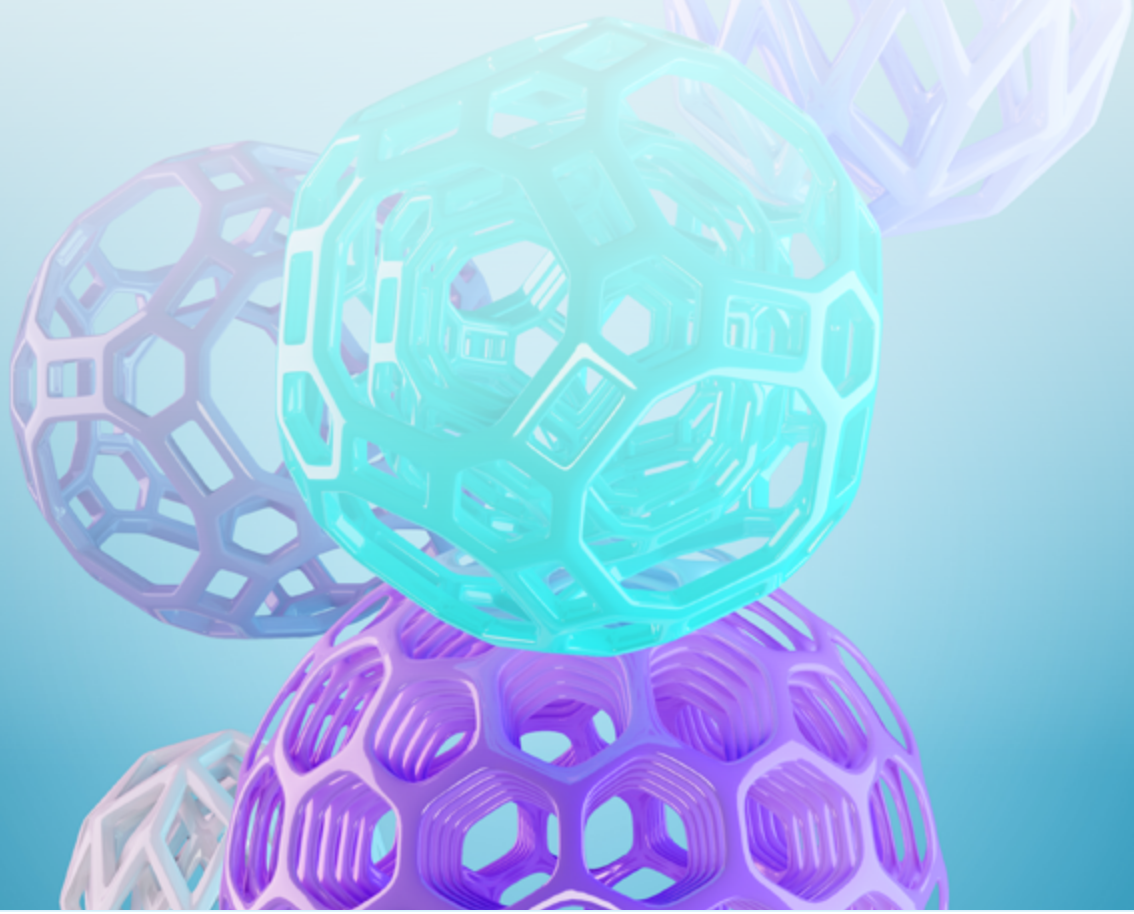
Microphysiological systems are bioengineered *in vitro* tools that mimic the 3D structure and function of human organ systems and have been developed to improve the predictive assessment of the safety and efficacy of promising therapeutics. The use of human-derived cells and tissues have increased the utility of tissue chips towards modeling diseases and for clinical trials on chips to inform human trial design. The presentation will focus on the latest advances in this promising technology.

3:05 Of Microtissues and Men: Applications of Advanced *in vitro* Systems in Toxicology

Matthew Wagoner, PhD, Director, Investigative Toxicology, Takeda Pharmaceutical

Advanced *in vitro* cell culture systems are transforming the way we design safer medicines. Here we share case studies of how neural, hepatic, and intestinal organoids are allowing us to more effectively detect and de-risk toxicity, while reducing a reliance on animal models.

3:35 Close of Conference



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CORNING

hub Hubrecht Organoid Technology

The Jackson Laboratory

lipotype
Lipidomics for a better life

maxwell BIOSYSTEMS

NANOSURFACE BIOMEDICAL

NeuCyte
Translatable Neuroscience

OcellO

ONI

PELAGO BIOSCIENCE

PepGel

RESEARCH SOLUTIONS REPRINTS DESK

STEMCELL™ TECHNOLOGIES

StemoniX

TRANS-HIT BIO
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ULTIVUE
ILLUMINATING BIOLOGY

XYLYX

Corporate Support Sponsors:

Biopticon
Discovery through imaging

CYTEK
TRANSCEND THE CONVENTIONAL

HITALIM

Lonza

Mispro
Biotech Services

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Stem cell experts

OLYMPUS
Your Vision, Our Future

SYNVIVO

TOXIKON
RIGHT. FROM THE START.℠

Sponsorship, Exhibit & Lead Gen Information

Comprehensive sponsorship packages allow you to achieve your objectives before, during, and long after the event. Signing on earlier will allow you to maximize exposure to hard-to-reach decision-makers.

Podium Presentations - Available within Main Agenda!

Showcase your solutions to a guaranteed, targeted audience through a 15- or 30-minute presentation during a specific conference program, breakfast, or lunch. Package includes exhibit space, on-site branding, and access to cooperative marketing efforts by CHI. For the luncheon option, lunches are delivered to attendees already seated in the main session room. Presentations do sell out early

One-on-One Meetings

Select your top prospects from the pre-conference registration list. CHI will reach out to your prospects and arrange the meeting for you. A minimum number of meetings will be guaranteed, depending on your marketing objectives and needs. A very limited number of these packages will be sold.

Reception / VIP Dinner

Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or local venue. CHI will extend invitations and deliver prospects, helping you to make the most out of this invaluable opportunity. Evening will be customized according to sponsor's objectives (i.e.: purely social, focus group, reception style, plated dinner with specific conversation focus).

Exhibit

Exhibitors will enjoy facilitated networking opportunities with qualified delegates, making it the perfect platform to launch a new product, collect feedback, and generate new leads. Exhibit space sells out quickly, so reserve yours today!

Additional Branding Opportunities include:

- Double-Sided Meter Boards
- Solutions Theatre Presentation
- Notepads
- Product Launch
- Lanyards
- Seating Area Sponsorship
- Foot Trails
- Aisle Sign (wherein booth located)
- Keynote Chair Drop
- Staircase Wrap
- Tote Bag Exclusive Sponsorship
- Tote Bag Insert
- Chair Drop in Session Roo
- Water Bottles
- Hotel Room Key Cards

EXHIBIT FLOOR PLAN

PAST ATTENDEE LIST

TO SPONSOR & EXHIBIT, CONTACT:

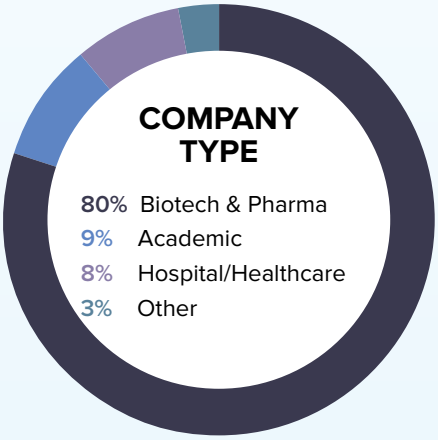
Companies A-K

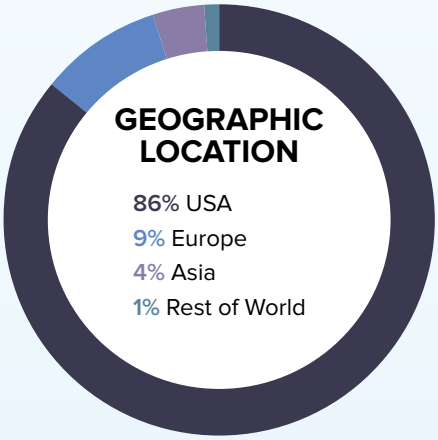
Rod Eymael
Manager, Business Development
781-247-6268
reymael@healthtech.com

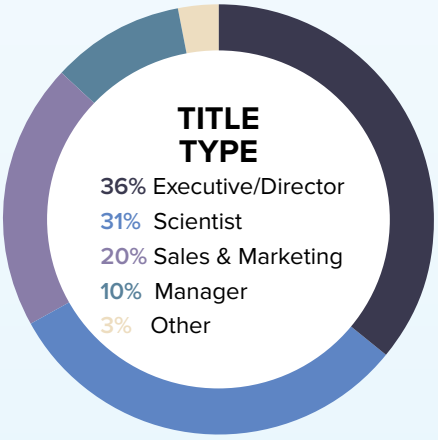
Companies L-Z

Joseph Vacca, MS
Director, Business Development
781-972-5431
jvacca@healthtech.com

2019 Attendee Demographics







Hotel & Travel

Conference Venue:
Hynes Convention Center
900 Boylston Street
Boston, MA 02115

Host Hotel:
Sheraton Boston Hotel
39 Dalton Street
Boston, MA 02199
Phone: 1-617-236-2000

Visit PharmaWeek.com/Travel for additional information.

Discounted Room Rate: $329 s/d

Discounted Room Rate Cut-off Date: May 4, 2020

25 for 25

Special Offer

If you are an employee of the following TOP 25 Pharmaceutical Companies as cited by Pharmaceutical Executive* you may attend this meeting at a 25% discount off the current rate. **Enter Keycode PH25** upon checkout when registering World Pharma Week on-line.

Group registrations are encouraged and we suggest calling:

Jeff Knight
T: (+1) 781-247-6264
E: jknight@healthtech.com

1. Pfizer
2. Roche
3. Novartis
4. Johnson & Johnson
5. Merck & Co.
6. Sanofi
7. AbbVie
8. GlaxoSmithKline
9. Amgen
10. Gilead Sciences
11. Bristol-Myers Squibb
12. AstraZeneca
13. Eli Lilly
14. Bayer
15. Novo Nordisk
16. Takeda
17. Celgene
18. Shire
19. Boehringer Ingelheim
20. Allergan
21. Teva Pharmaceuticals
22. Mylan
23. Astellas Pharma
24. Biogen
25. CSL

** http://www.pharmexec.com/pharm-execs-top-50-companies-2019*

MEDIA PARTNERS

Official Event Publications

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Diagnostics World

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The Scientist — Exploring Life, Inspiring Innovation

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American Pharmaceutical Review

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Big4Bio

Biocompare — The Buyer's Guide for Life Scientists

BioSpace

labcompare

Pricing and Registration Information

CONFERENCE PRICING

STANDARD PACKAGE (Includes access to 1 conference, excludes short courses)	**Commercial**	**Academic, Government, Hospital-affiliated**	**Student ***
Early - Registration Rate until March 20, 2020	$2,199	$1,149	$495
Advance - Registration Rate until April 24, 2020	$2,399	$1,199	$495
Registrations after April 24, 2020 and On-Site	$2,499	$1,299	$495

C1: Accelerating Target Discovery	C7: Preclinical Strategies, Models & Tools in Oncology
C2: Expanding Chemical & Druggable Space	C8: Advances in Drug Metabolism & Safety Testing
C3: New Small Molecule Drug Targets	C9: Immuno-Oncology Biomarkers
C4: Emerging Indications & Modalities	C10: Clinical and Translational Biomarkers
C5: Immuno-Oncology Advances	C11: AI for Drug Discovery & Development
C6: Disease Modeling	C12: Drug Discovery Technologies (Included with your complete registration)

PRE-CONFERENCE SHORT COURSES

One short course (Short courses run concurrently)	$549	$329	$149

SC1: In vitro and in vivo Modeling for Cancer Research	SC5: Chemoproteomics Enabling Drug Discovery
SC2: Immunology Basics: Focusing on Autoimmunity and Cancer	SC6: An ML/AI Tutorial: From Basics to Advanced
SC3: Fit-for-Purpose Biomarker Assay Development – Performance Characterization and Validation to "Context of Use"	SC7: Intro to OOAC and Bioprinting for Disease Modeling
SC4: Optimizing Drug Metabolism, Drug Clearance and Drug-Drug Interactions	

CONFERENCE DISCOUNTS

Poster Submission - **Discount ($50 Off)**: Poster abstracts are due by April 24, 2020. Once your registration has been fully processed, we will send an email containing a unique link allowing you to submit your poster abstract. If you do not receive your link within 5 business days, please contact jring@healthtech.com.

** CHI reserves the right to publish your poster title and abstract in various marketing materials and products.*

REGISTER 3 - 4th IS FREE: Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply.

Alumni Discount: Cambridge Healthtech Institute (CHI) appreciates your past participation at this event. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.

Group Discounts: Special rates are available for multiple attendees from the same organization. For more information on group discounts contact Jeff Knight at 781-247-6264 or jknight@healthtech.com.

** Full time graduate students and PhD candidates qualify for the student rate. Students are encouraged to present a research poster and receive an additional $50 off their registration fee. Student rate cannot be combined with any other discount offers, except poster discount. Students must present a valid/current student ID to qualify for the student rate. Limited to the first 100 students that apply.*

If you are unable to attend but would like to purchase the World Pharma Week CD for $750 (plus shipping), please visit PharmaWeek.com. Massachusetts delivery will include sales tax.

ADDITIONAL REGISTRATION DETAILS

Each registration includes all conference sessions, posters and exhibits, food functions, and access to the conference proceedings link.

Handicapped Equal Access: In accordance with the ADA, Cambridge Healthtech Institute is pleased to arrange special accommodations for attendees with special needs. All requests for such assistance must be submitted in writing to CHI at least 30 days prior to the start of the meeting.

To view our Substitutions/Cancellations Policy, go to healthtech.com/regdetails

Video and or audio recording of any kind is prohibited onsite at all CHI events.

How to Register: **PharmaWeek.com**

reg@healthtech.com • P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode **WPWPCL** when registering!