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Cambridge Healthtech Institute's *10th Annual*

June 7 - 9, 2011



# WPC

Promising Assays and Technologies for  
**Better Pre-Clinical Predictions**

## World Pharma Congress

Sheraton Philadelphia City Center  
Philadelphia, PA

### WPC SHORT COURSES



Monday, June 6

- Animal Models of Pain: Progress and Challenges
- Use of Stem Cells for Safety Screening
- Advanced Topics in Drug Metabolism
- Translating Safety Biomarkers from the Lab to the Clinic
- Addressing Safety Concerns for Biological Drugs
- Practical Application of Plate-Based Label-Free Biosensors: Getting the Basics & Details You Need for Decision Making

Wednesday, June 8

- Molecular Imaging in Drug Discovery and Development: Back to Basics
- Mechanistic Insights into Hepatotoxicity

**10**  
CELEBRATING  
**A DECADE**

## Drug Safety Summit

- Monitoring Cardiotoxicity
- Predicting Hepatotoxicity
- Detecting Nephrotoxicity
- Early ADME/DMPK Predictions

## Drug Discovery Summit

- Targeting Pain with Novel Therapeutics
- In Vivo* Molecular Imaging
- Targeting Alzheimer's Disease
- Targeting Parkinson's Disease

## Screening Summit

- Tools & Technologies for HTS
- Novel Technologies for Cell-Based Screening

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CHI's **World Pharma Congress 2011** encompasses a broad spectrum of topics that are very important and relevant to scientists in academia as well as those in the pharmaceutical and biotechnology industry. Building on last year's focus on the pre-clinical aspects of drug discovery and development, the congress has now expanded the coverage of each of its three summits by adding two new conferences to the program. The conferences all offer informative and pragmatic viewpoints for tackling issues relevant to chemists, biologists, pharmacologists, toxicologists and clinicians alike. Each conference features presentations, interactive panels and technology talks that cover the very latest on the topic, both on the scientific and the technical side. The World Pharma Congress continues to offer attendees and exhibitors ample opportunity to network, brain-storm and collaborate on various fronts.

### CONFERENCE-AT-A-GLANCE

	DRUG SAFETY SUMMIT		DRUG DISCOVERY SUMMIT		SCREENING SUMMIT
Monday June 6	Pre-Conference Short Courses*				
Tuesday June 7	Innovative Approaches for Monitoring Cardiotoxicity	Detecting Nephrotoxicity Using Early Markers and Imaging Tools	Targeting Pain with Novel Therapeutics	Successful Targeting of Alzheimer's Disease	Tools & Technologies for HTS
Wednesday June 8	Innovative Approaches for Monitoring Cardiotoxicity	Detecting Nephrotoxicity Using Early Markers and Imaging Tools	Targeting Pain with Novel Therapeutics	Successful Targeting of Alzheimer's Disease	Tools & Technologies for HTS
	New Assays and Tools for Predicting Hepatotoxicity	Early ADME and DMPK Predictions for Better Lead Optimization	<i>In Vivo</i> Molecular Imaging in Drug Discovery & Development	Targeting Parkinson's Disease	Evaluating Novel Technologies for Cell-Based Screening
Dinner Short Courses*					
Thursday June 9	New Assays and Tools for Predicting Hepatotoxicity	Early ADME and DMPK Predictions for Better Lead Optimization	<i>In Vivo</i> Molecular Imaging in Drug Discovery & Development	Targeting Parkinson's Disease	Evaluating Novel Technologies for Cell-Based Screening

\*Separate registration required, please see page 3 for details

### What people are saying about World Pharma Congress:

"The speakers gave excellent, in-depth presentations on timely issues that are extremely relevant to the pharma community."

WPC 2010 attendee, Roche

"An excellent spectrum of speakers with great depth of knowledge and plenty of opportunity for Q&A led to an outstanding forum for learning."

WPC 2010 attendee, BioClinica

STAY CONNECTED

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**MONDAY, JUNE 6 (9 AM - 12 PM)****ANIMAL MODELS OF PAIN: PROGRESS AND CHALLENGES**

Due to frustration with translational progress, animal models of pain are currently being reconsidered. This course will cover:

- Implementation of classical models of acute, tonic and chronic pain
- Limitations of these classical models
- Refinement of classical models via a consideration of modulatory factors (sex, genetics, testing environment, social modulation)
- Development of new animal models (e.g., operant methods, spontaneous behaviors)

Course Instructor:

Jeffrey S. Mogil, Ph.D., E.P. Taylor Professor of Pain Studies, McGill University

**USE OF STEM CELLS FOR SAFETY SCREENING**

The course provides new insights into the use of embryonic and pluripotent stem cells for drug safety testing, especially cardiac safety.

- Differentiation of human stem cells into cardiac myocytes
- Comparison of electrophysiology and pharmacology
- Overcoming technical challenges related to working with stem cells
- Methodologies to maintain and use stem cells for predictive safety testing

Course Instructor:

Emile Nuwaysir, VP and COO, Cellular Dynamic Intl.

**ADVANCED TOPICS IN DRUG METABOLISM**

The purpose of this course is to cover advanced topics related to drug metabolism with a focus on newer developments in the field.

- *In vitro* tools to study drug metabolism
- New biotransformation pathways including some that lead to reactive metabolites
- Evidence linking reactive metabolites and idiosyncratic drug toxicity
- *In silico* tools to predict metabolism

Course Instructor:

John C. Erve, Ph.D., Investigator III, Analytical Sciences, Novartis Institutes for Biomedical Research

**WEDNESDAY, JUNE 8 (6 PM - 9 PM)****MOLECULAR IMAGING IN DRUG DISCOVERY AND DEVELOPMENT: BACK TO BASICS.**

This course will provide knowledge needed to choose the appropriate imaging modality for a pre-clinical study and the basic requirements for generation of imaging agents for optical, MR, and nuclear imaging. It will consist of two parts:

- Strengths and limitations of imaging modalities
- Imaging agent design and synthesis

Chairperson: Dr. Matthew Leevy, Carestream Molecular Imaging

Course instructors:

Thomas Krucker, Ph.D., Head, Molecular Imaging, Global Imaging Group, Novartis Institutes for Biomedical Research, Inc.

Hisataka Kobayashi, M.D., Ph.D., Chief Scientist, Molecular Imaging Program, NCI/NIH

Vania Kenanova, Ph.D., Head, Pre-clinical PET/SPECT/CT Imaging Laboratory, Novartis Institutes for Biomedical Research, Inc.

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**MONDAY, JUNE 6 (2 PM - 5 PM)****TRANSLATING SAFETY BIOMARKERS FROM THE LAB TO THE CLINIC**

The course offers a unique and practical perspective for successfully translating the pre-clinical work done for testing and validating safety biomarkers to the clinic.

- Design and implementation of studies to identify new biomarkers
- Designing clinical studies to test and validate biomarkers
- Clinical methodologies for cost-effective and reliable decision-making
- Bridging the gap between pre-clinical and clinical findings
- Practical considerations when using biomarkers in the clinic
- Points to consider for a successful transfer from the lab to the clinic

Course Instructors:

Stephen Furlong, Ph.D., Safety Science Lead, U.S., Patient Safety, AstraZeneca

William B. Mattes, Ph.D., DABT, Independent Consultant, PharmPoint Consulting

**ADDRESSING SAFETY CONCERNS FOR BIOLOGICAL DRUGS**

The course offers guidance from experts in the field on what is being used and looked at for early safety assessments for biological molecules, and how these early predictions are then being applied for clinical testing.

- Overview of challenges pertaining to the safety of biologics
- Tools, markers and assays for early safety predictions
- Assessing immunogenicity and off-target effects
- Regulatory guidelines and their interpretations
- Criteria for determining what needs to be tested and when

Course Instructors:

Lisa M. Plitnick, Ph.D., Senior Investigator, Safety Assessment, Merck & Co., Inc.

Noël Dybdal, Ph.D., D.V.M., Associate Director, Principal Scientist, Safety Assessment, Genentech, Inc.

Vivek Kadambi, Ph.D., Senior Director, Drug Safety Evaluation, Millennium, The Takeda Oncology Company

Lauren E. Black, Ph.D., Senior Scientific Advisor, Navigators, Charles River Laboratories

**MECHANISTIC INSIGHTS INTO HEPATOTOXICITY**

The course is designed for both pre-clinical and clinical scientists looking to better understand the mechanisms underlying drug-induced liver injury or DILI, to help in the development of early predictive technologies for hepatotoxicity including mechanism-based assays. It provides an overview of cellular pathways involved in:

- Mitochondrial dysfunction and oxidative stress
- Inflammation
- Excessive generation of reactive metabolites
- Inhibition of bile salt efflux protein and involvement of hepatic transporters in drug-induced hepatotoxicity

Course Instructors:

Dylan P. Hartley, Ph.D., Senior Scientist, Investigative Toxicology, Genentech, Inc.

José E. Manautou, Ph.D., Associate Professor of Toxicology, Department of Pharmaceutical Sciences, University of Connecticut

Robert A. Roth, Ph.D., DABT, Professor, Pharmacology and Toxicology, Director, Graduate Program in Environmental and Integrative Toxicological Sciences, Michigan State University

Yvonne Will, Ph.D., Associate Research Fellow, Compound Safety Prediction, Pfizer Global R&D

\*Separate Registration Required

**TUESDAY, JUNE 7**

**7:45 am Registration and Morning Coffee**

**EARLY *IN VITRO* MODELS AND MARKERS FOR CARDIAC SAFETY PREDICTIONS**

**8:45 Chairperson's Opening Remarks**

*Peter Hoffmann, M.D., Ph.D., Executive Director, Pre-Clinical Safety, Novartis Institutes for BioMedical Research*

**8:55 Expanding *in vitro* Biochemical and Cellular Models for Earlier Drug Safety Assessment**

*Mary Ellen Cvjic, Ph.D., Principal Scientist, Lead Evaluation, Molecular Sciences and Candidate Optimization, Bristol-Myers Squibb Co.*

**9:25 Stem Cell Cardiomyocyte Screening**

*Craig T. January, M.D., Ph.D., Professor, Medicine and Physiology, Division of Cardiovascular Medicine, University of Wisconsin, Madison*

**9:55 Networking Coffee Break**

**10:25 Development of Translatable Biomarkers for Cardiovascular Safety**

*Jennifer Colangelo, Ph.D., Associate Director, Drug Safety R&D, Pfizer Global Research and Development*

**10:55 Pre-Clinical Strategies for De-Risking the Potential of Cardiovascular Toxicity**

*Peter Hoffmann, M.D., Ph.D., Executive Director, Pre-Clinical Safety and Co-Chair, Translational Cardiovascular Advisory Team, Novartis Institutes for BioMedical Research*

**11:25 Biologicals and Cardiac Toxicity Risk: Relating Toxicity to Mechanism of Action**

*Noël Dybdal, Ph.D., D.V.M., D.A.C.V.P., Associate Director, Principal Scientist, Safety Assessment, Genentech, Inc.*

**11:55 Multiplex Biomarker Assays for Kidney and Liver Toxicity**

*Pankaj Oberoi Ph.D., Director of Scientific Services & Director of Qualified Kit Development, Meso Scale Discovery*



**12:25 Luncheon Presentation II**

(Sponsorship Opportunity Available)

**CHALLENGES CORRELATING *IN VITRO* AND *IN VIVO* DATA**

**1:30 pm Chairperson's Remarks**

*Vivek Kadambi, Ph.D., Senior Director, Drug Safety Evaluation, Millennium, The Takeda Oncology Company*

**1:35 Evolving Trends in Pre-Clinical Cardiac Safety: Gazing into the Crystal Ball**

*Gary Gintant, Ph.D., Senior Group Leader, Integrative Pharmacology, Global Pharmaceutical Research & Development, Abbott Laboratories*

**2:05 Does it Help or Hurt to Know Cardiovascular Biology?**

*Douglas B. Sawyer, M.D., Ph.D., Lisa M. Jacobson Professor of Medicine and Chief, Cardiovascular Division, Vanderbilt University Medical Center*

**2:35 You Don't Give Drugs to Normal People, so Why Search for Toxicity in Normal Animals?**

*Robert Hamlin, Ph.D., Professor, Veterinary Biosciences, Ohio State University*

**3:05 Innovative Approaches for Monitoring Cardiotoxicity**

*Abdel-Ilah El Amrani, Ph.D., Head, Safety and General Pharmacology, CiT-Safety & Health Research Laboratories*

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**3:20 Sponsored Presentation (Opportunity Available)**

**3:35 Grand Opening Refreshment Break in the Exhibit Hall**

**4:35 FEATURED PRESENTATION: Pre-Clinical Strategies for Predicting and Preventing Cardiotoxicity**

*Thomas Force, M.D., Professor of Medicine and Clinical Director of the Center for Translational Medicine, Thomas Jefferson University*

**5:05 PANEL DISCUSSION: Minimizing the Disconnect Between the *In Vitro* and *In Vivo* Worlds**

*Moderator: Vivek Kadambi, Ph.D., Senior Director, Drug Safety Evaluation, Millennium, The Takeda Oncology Company*

**5:35 - 6:30 Happy Hour in the Exhibit Hall**

**WEDNESDAY, JUNE 8**

**7:30 am Continental Breakfast Breakout Discussions**

*Breakout Discussion Topics:*

- Trends in Safety Screening for Small Molecule Drugs Versus Biologics
- New Approaches and Insights for Early Pre-Clinical Safety Testing

**MITOCHONDRIAL INVOLVEMENT IN CARDIAC, RENAL AND LIVER TOXICITY**

**8:30 Chairperson's Remarks**

*Yvonne Will, Ph.D., Associate Research Fellow, Compound Safety Prediction, Pfizer Global R&D*

**8:40 Introduction to Mitochondrial Function and Drug-Induced Dysfunction**

*James Dykens, Ph.D., CEO, EyeCyte Therapeutics*

**9:10 Tales of Broken Mitochondria: Drug-Induced Cardiac Mitochondrionopathy**

*Paulo Oliveira, Ph.D., Group Leader, Mitochondrial Toxicology and Disease, Center for Neuroscience and Cell Biology, University of Coimbra, Portugal and Visiting Research Associate, University of Minnesota Medical School*

**9:40 Automate the Detection and Quantitative Characterization of Pathological Changes - Benefits of Digital Pathology in Drug Development**

*Curtis Adams, Ph.D., Senior Product Manager, Life Sciences, Aperio*

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4<sup>th</sup> Annual

# Innovative Approaches for Monitoring Cardiotoxicity

**10:10 Networking Coffee Break in the Exhibit Hall**

**10:50 Mitochondrial Homeostasis in Acute Kidney Injury**

*Rick Schnellmann, Ph.D., Professor, Chair, Pharmaceutical and Biomedical Sciences, South Carolina College of Pharmacy*

**11:20 Mechanistic Insights into Mitochondrial-Based Organ Toxicity**

*Yvonne Will, Ph.D., Associate Research Fellow, Compound Safety Prediction, Pfizer Global R&D*

**11:50 PANEL DISCUSSION: Strategies for Assessing Mitochondrial Involvement in Drug-Induced Organ Toxicities**

*Moderator: Yvonne Will, Ph.D., Associate Research Fellow, Compound Safety Prediction, Pfizer Global R&D*

**12:20 pm End of Conference**

CHI's  
**INTRONET**  
Networking at its Best

## Maximize your experience on-site at World Pharma Congress 2011 with CHI's IntroNet!

The Intro-Net offers you the opportunity to set up meetings with selected attendees before, during and after this conference, allowing you to connect to the key people you want to meet. This online system was designed with your privacy in mind and is available only to registered session attendees of this event.

Registered conference attendees will receive more information on accessing the Intro-Net in the weeks leading up to the event!

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3<sup>rd</sup> Annual

# New Assays and Tools for Predicting Hepatotoxicity

## WEDNESDAY, JUNE 8

**12:30 pm Registration**

### **IDIOSYNCRATIC DILI: TRANSITIONING FROM PRE-CLINICAL TO CLINICAL**

**1:55 Chairperson's Opening Remarks**

*Arie Regev, M.D., Hepatology Consultant and Chair, Liver and GI Safety Committee, Global Patient Safety, Eli Lilly and Company*

**2:00 How Good are Currently Available Biomarkers for Idiosyncratic DILI, and Which New Biomarkers Should We Look for?**

*Arie Regev, M.D., Chair, Liver and GI Safety Advisory Committee, Global Patient Safety, Eli Lilly and Company; Adjunct Associate Professor of Medicine, Indiana University School of Medicine*

» **2:30 FEATURED PRESENTATION: Genetic Basis of Susceptibility to DILI**

*Paul B. Watkins, M.D., Director, Hamner-UNC Institute for Drug Safety Sciences, Verne S. Caviness Distinguished Professor of Medicine, University of North Carolina at Chapel Hill*

**3:00 Development of a New High Content Methodology for Predicting Hepatotoxicity** Sponsored by **FLUOFARMA**

*Marion Zanese, Ph.D., Group Leader, Predictive Toxicology, Fluofarma*

**4:30 Pediatric Drug Induced Liver Injury- Children Are Not Just Small Adults**

*William Salminen, Ph.D., DABT, Director, Center for Hepatotoxicity, U.S. FDA, National Center for Toxicological Research*

**5:00 PANEL DISCUSSION: Early Prediction of Idiosyncratic DILI: Recent Progress and Interesting Trends**

*Moderator: Arie Regev, M.D., Hepatology Consultant and Chair, Liver and GI Safety Committee, Global Patient Safety, Eli Lilly and Company*

**5:30 End of Day**

## THURSDAY, JUNE 9

**7:20 am Continental Breakfast Breakout Discussions**

Breakout Discussion Topics:

- Utilization of Appropriate Models and Markers for Predicting Liver Injury
- Promising *in vitro* Tools for Early Pre-Clinical Testing
- Challenges with Predicting and Monitoring Liver Injury in the Clinic

### **EFFECTIVE USE OF MODELS AND BIOMARKERS FOR PREDICTING LIVER INJURY**

**8:20 Chairperson's Remarks**

*Robert A. Roth, Ph.D., DABT, Professor, Pharmacology and Toxicology, Director, Graduate Program in Environmental and Integrative Toxicological Sciences, Michigan State University*

**8:30 DILI-sim: An *in silico* Approach to Understanding and Predicting Drug-Induced Liver Injury**

*Brett A. Howell, Ph.D., Research Scientist, The Hamner-University of North Carolina Institute for Drug Safety Sciences*

**9:00 Virtual Liver: Integrating *in vitro* and *in vivo* Data to Predict Chemical-induced Toxicity**

*Imran Shah, Ph.D., Head, Computational Systems Biology, Natl. Ctr. for Computational Toxicology, U.S. Environmental Protection Agency*

**9:30 Inflammatory Stress Responses and Animal Models for Idiosyncratic DILI**

*Robert A. Roth, Ph.D., DABT, Professor, Pharmacology and Toxicology, Director, Graduate Program in Environmental and Integrative Toxicological Sciences, Michigan State University*

**10:00 Networking Coffee Break in the Exhibit Hall**

### **MECHANISMS UNDERLYING HEPATOTOXICITY**

**10:45 Prediction of Immune-Mediated Drug-Induced Liver Injury in Pre-Clinical Drug Development**

*Tsuyoshi Yokoi, Ph.D., Professor, Drug Metabolism and Toxicology, Kanazawa University*

**11:15 Hepatoprotective Effect of Peroxisome Proliferators is Associated with Induction of Vanin-1 Gene Expression**

*José E. Manautou, Ph.D., Associate Professor of Toxicology, Pharmaceutical Sciences, University of Connecticut*

**11:45 pm Luncheon Presentations** (Sponsorship Opportunities Available) **or Lunch on Your Own**

### **EARLY PRE-CLINICAL PREDICTIONS OF LIVER INJURY**

**1:15 Chairperson's Remarks**

*Eric Blomme, D.V.M., Ph.D., DACVP, Senior Project Leader, Abbott Laboratories*

**1:25 Current Toolbox for the Prediction of Hepatotoxicity**

*Eric Blomme, D.V.M., Ph.D., DACVP, Senior Project Leader, Abbott Laboratories*

**1:55 *In vitro* Strategies: High Content Mechanistic Screening, Mitochondrial Toxicity, and Transporter Assessment**

*Yvonne Will, Ph.D., Associate Research Fellow, Compound Safety Prediction, Pfizer Global R&D*

**2:25 Ice Cream Refreshment Break in the Exhibit Hall**

**3:05 Approaching Hepatotoxicity in Drug Discovery as a Lead Optimization Problem**

*Dylan P. Hartley, Ph.D., Senior Scientist, Investigative Toxicology, Genentech, Inc.*

**3:35 The Utility of Emerging Biomarkers of Liver Injury in Pre-Clinical and Clinical Drug Development**

*Shelli Schomaker, Principal Scientist, Drug Safety Research & Development, Pfizer, Inc.*

**4:05 From Mild Pre-Clinical Transaminase Elevations to Idiosyncratic Liver Injury in One Easy Lesson**

*Paul Vancutsem, D.V.M., Ph.D., Director, Pre-Clinical Safety; Senior Member, Novartis Internal Liver Experts Team, Novartis Pharmaceuticals*

**4:35 End of Conference**

2<sup>nd</sup> Annual

# Detecting Nephrotoxicity Using Early Markers and Imaging Tools

## **TUESDAY, JUNE 7**

**7:45 am Registration and Morning Coffee**

### **UNDERSTANDING MECHANISMS OF NEPHROTOXICITY**

**8:45 Chairperson's Opening Remarks**

*Stephen Furlong, Ph.D., Safety Science Lead, U.S., Patient Safety, AstraZeneca*

**8:55 Cisplatin Nephrotoxicity and Renal Protective Strategies**

*Navjotsingh Pabla, Ph.D., Postdoctoral Fellow, Department of Cellular Biology and Anatomy, Medical College of Georgia/Georgia Health Sciences University*

**9:25 Primary Cell Cultures from Human and Rat Proximal Tubule as Models to Study Mechanisms of Acute Kidney Injury**

*Lawrence H. Lash, Ph.D., Professor and Associate Chair, Department of Pharmacology, School of Medicine, Wayne State University*

**9:55 Networking Coffee Break**

### **MONITORING AND ASSESSING KIDNEY INJURY**

**10:25 Current Use of Renal Biomarkers in Early Drug Development**

*Diann Weddle, Ph.D., D.V.M., Senior Pathologist, Department of Pathology, Pre-clinical Safety, Abbott Laboratories*

**10:55 Pre-Clinical Biomarkers of Nephrotoxicity: Applications in Drug Discovery and Development**

*Eric Blomme, D.V.M., Ph.D., D.A.C.V.P., Senior Project Leader, Abbott Laboratories*

**11:25 Integrative Assessment of Drug-Induced Kidney Function Changes and Acute Injury Using an Automated Blood Sampling and Telemetry (ABST) System**

*Yafei Chen, M.D., M.S., Scientist Safety Pharmacology, Global Safety Assessment, AstraZeneca Pharmaceuticals*

**11:55 Luncheon Presentations (Sponsorship Opportunities Available) or Lunch on Your Own**

### **KIDNEY MARKERS: FROM BENCH TO BEDSIDE**

**1:30 pm Chairperson's Remarks**

*W. Brian Reeves, M.D., F.A.C.P., Chief, Division of Nephrology, Professor and Vice Chair, Department of Medicine, Penn State College of Medicine*

#### **» 1:35 FEATURED PRESENTATION: Establishing the Context for Introducing New Safety Biomarkers into Clinical Trials**

*Stephen Furlong, Ph.D., Safety Science Lead, U.S., Patient Safety, AstraZeneca*

**2:05 Clinical Evaluation and Qualification of Kidney Safety Biomarkers: A Collaboration between Two Consortia**

*Maria Vassileva, Ph.D., Scientific Program Manager, The Biomarkers Consortium, Foundation for the NIH*

**2:35 Urinary Cytokines as Biomarkers of Nephrotoxicity**

*W. Brian Reeves, M.D., F.A.C.P., Chief, Division of Nephrology,*

*Professor and Vice Chair, Medicine, Penn State College of Medicine*

**3:05 Sponsored Presentations** (Opportunities Available)

**3:35 Grand Opening Refreshment Break in the Exhibit Hall**

**4:35 Rapid Point-of-Care GFR: Technique, Diagnostic and Therapeutic Advantages**

*Bruce A. Molitoris, M.D., Director, Division of Nephrology and Professor of Medicine, Indiana University*

**5:05 PANEL DISCUSSION: Renal Injury Markers and How Effectively Can They Be Used?**

*Moderator: W. Brian Reeves, M.D., F.A.C.P., Chief, Division of Nephrology; Professor and Vice Chair, Department of Medicine, Penn State College of Medicine*

**5:35 - 6:30 Happy Hour in the Exhibit Hall**

## **WEDNESDAY, JUNE 8**

**7:30 am Continental Breakfast Breakout Discussions**

Breakout Discussion Topics:

- Biomarkers for Organ Toxicity and Their Effective Use in Pre-Clinical and Clinical Development
- Monitoring Mitochondria and Their Impact on Organ Toxicities

### **MITOCHONDRIAL INVOLVEMENT IN CARDIAC, RENAL AND LIVER TOXICITY**

**8:30 am Chairperson's Remarks**

*Yvonne Will, Ph.D., Associate Research Fellow, Compound Safety Prediction, Pfizer Global R&D*

**8:40 Introduction to Mitochondrial Function and Drug-Induced Dysfunction**

*James Dykens, Ph.D., CEO, EyeCyte Therapeutics*

**9:10 Tales of Broken Mitochondria: Drug-Induced Cardiac Mitochondrionopathy**

*Paulo Oliveira, Ph.D., Group Leader, Mitochondrial Toxicology and Disease, Center for Neuroscience and Cell Biology, University of Coimbra, Portugal and Visiting Research Associate, University of Minnesota Medical School*

**9:40 Sponsored Presentations** (Opportunities Available)

**10:10 Networking Coffee Break in the Exhibit Hall**

**10:50 Mitochondrial Homeostasis in Acute Kidney Injury**

*Rick Schnellmann, Ph.D., Professor, Chair, Pharmaceutical and Biomedical Sciences, South Carolina College of Pharmacy*

**11:20 Mechanistic Insights into Mitochondrial-Based Organ Toxicity**

*Yvonne Will, Ph.D., Associate Research Fellow, Compound Safety Prediction, Pfizer Global R&D*

**11:50 PANEL: Strategies for Assessing Mitochondrial Involvement in Drug-Induced Organ Toxicities**

*Moderator: Yvonne Will, Ph.D., Associate Research Fellow, Compound Safety Prediction, Pfizer Global R&D*

**12:20 pm End of Conference**

Inaugural  
**Early ADME and DMPK Predictions for Better Lead Optimization**

**WEDNESDAY, JUNE 8**

**12:30 pm Registration**

**PREDICTIVE ADME AND DMPK ASSESSMENTS**

**1:55 Chairperson's Opening Remarks**

*Alan G.E. Wilson, Ph.D., Vice President, Drug Metabolism, Pharmacokinetics, Toxicology and Pathology, Lexicon Pharmaceuticals*

**2:00 Transforming Drug Discovery and Development: The Strategic Role of ADME, PK and Toxicology**

*Alan G.E. Wilson, Ph.D., Vice President, Drug Metabolism, Pharmacokinetics, Toxicology and Pathology, Lexicon Pharmaceuticals*

**2:30 Pharmacokinetic Drivers of Toxicity for Small Molecules**

*Dolores Diaz, Ph.D., DABT, Investigative Toxicology, Genentech, Inc.*

**3:00 Sponsored Presentation** (Opportunity Available)

**3:30 Networking Refreshment Break in the Exhibit Hall**

**4:30 Strategies for Transporter Studies in Discovery and Development**

*Praveen Balimane, Ph.D., Senior Research Investigator, Metabolism and Pharmacokinetics Group, Bristol-Myers Squibb Co.*

**5:00 Predicting *in vivo* Drug Interactions From *in vitro* Data**

*Jan Wahlstrom, Ph.D., Principal Scientist, Pharmacokinetics and Drug Metabolism, Amgen, Inc.*

**5:30 End of Day**

**THURSDAY, JUNE 9**

**7:20 am Continental Breakfast Breakout Discussions**

Breakout Discussion Topics:

- Utilization of Genotoxic Data for Effective Risk Assessments
- Emerging Trends in ADME/DMPK Testing

**TACKLING GENOTOXICITY ISSUES**

**8:20 Chairperson's Remarks**

*Martha Moore, Ph.D., Director, Division of Genetic and Molecular Toxicology, U.S. FDA, National Center for Toxicological Research*

**8:30 Genetic Toxicity Concepts and Strategies for Small Molecule Lead Optimization**

*Dolores Diaz, Ph.D., DABT, Investigative Toxicology, Genentech, Inc.*

**9:00 Early Genotoxicity Assessment: From HTS to Regulatory Testing**

*Stephan Kirchner, Ph.D., Predictive Toxicology & Emerging Technologies, Lab Head, Genotoxicology, Phototoxicity, F. Hoffmann-La Roche Ltd.*

**9:30 Going Beyond the Standard Genetic Toxicology Battery**

*Pamela L. Heard, Ph.D., Principal Scientist, Drug Safety R&D, Genetic Toxicology CoE, Pfizer Global Research & Development*

**10:00 Networking Coffee Break in the Exhibit Hall**

**» 10:45 FEATURED PRESENTATION**

**Weight of the Evidence Integration of Genetic Toxicology Data for Risk Assessment**

*Martha Moore, Ph.D., Director, Division of Genetic and Molecular Toxicology, U.S. FDA, National Center for Toxicological Research*

**11:15 PANEL DISCUSSION: New Strategies for Genotoxic Risk Assessments**

*Moderator: Martha Moore, Ph.D., Director, Division of Genetic and Molecular Toxicology, U.S. FDA, National Center for Toxicological Research*

**11:45 Luncheon Presentations** (Sponsorship Opportunities Available) **or Lunch on Your Own**

**EARLY PRE-CLINICAL PREDICTIONS OF LIVER INJURY**

**1:15 pm Chairperson's Remarks**

*Eric Blomme, D.V.M., Ph.D., D.A.C.V.P., Senior Project Leader, Abbott Laboratories*

**1:25 Current Toolbox for the Prediction of Hepatotoxicity**

*Eric Blomme, D.V.M., Ph.D., D.A.C.V.P., Senior Project Leader, Abbott Laboratories*

**1:55 *In vitro* Strategies: High Content Mechanistic Screening, Mitochondrial Toxicity, and Transporter Assessment**

*Yvonne Will, Ph.D., Associate Research Fellow, Compound Safety Prediction, Pfizer Global R&D*

**2:25 Ice Cream Refreshment Break in the Exhibit Hall**

**3:05 Approaching Hepatotoxicity in Drug Discovery as a Lead Optimization Problem**

*Dylan P. Hartley, Ph.D., Senior Scientist, Investigative Toxicology, Genentech, Inc.*

**3:35 The Utility of Emerging Biomarkers of Liver Injury in Pre-Clinical and Clinical Drug Development**

*Shelli Schomaker, Principal Scientist, Drug Safety R&D, Pfizer, Inc.*

**4:05 From Mild Pre-Clinical Transaminase Elevations to Idiosyncratic Liver Injury in One Easy Lesson**

*Paul Vancutsem, D.V.M., Ph.D., Director, Pre-Clinical Safety and Senior Member of Novartis Internal Liver Experts Team, Novartis Pharmaceuticals*

**4:35 End of Conference**



4<sup>th</sup> Annual

# Targeting Pain with Novel Therapeutics

## **TUESDAY, JUNE 7**

**7:45 am Registration and Morning Coffee**

**8:45 Chairperson's Opening Remarks**

» **8:55 KEYNOTE PRESENTATION**

*Frank Porreca, Ph.D., Professor of Pharmacology and Anesthesiology, University of Arizona*

### **ANIMAL MODELS OF PAIN**

» **9:25 KEYNOTE PRESENTATION: PHARMACODYNAMIC CORRELATIONS IN THE TRANSLATION OF EFFICACY FROM ANIMAL PAIN MODELS**

*Garth Whiteside, Ph.D., Director, Discovery, Purdue Pharma*

**9:55 Networking Coffee Break**

**10:25 Animal Models of Pain: Back Translating from Veterinary and Human Clinical Pain States**

*Edward Bilsky, Ph.D., Professor of Pharmacology & Director, Center of Excellence in the Neurosciences, University of New England*

**10:55 ED50s, Responder Rates and Number Needed to Treat: Can Animal Studies and Clinical Trials Speak the Same Language?**

*Jim Pomonis, Ph.D., Director, Technical Development, Algos Preclinical Services*

**11:25 PANEL DISCUSSION: Animal Models of Pain**

Panelists to include:

*Edward Bilsky, Ph.D., Professor of Pharmacology & Director, Center of Excellence in the Neurosciences, University of New England*

*Jeffrey D. Kennedy, Ph.D., Senior Research Fellow, Neuroscience Discovery Research, Eli Lilly and Company*

*Jeffrey S. Mogil, Ph.D., E.P. Taylor Professor of Pain Studies, McGill University*

*Jim Pomonis, Ph.D., Director, Technical Development, Algos Preclinical Services*

*Garth Whiteside, Ph.D., Director, Discovery, Purdue Pharma*

**11:55 pm Luncheon Presentations (Sponsorship Opportunities Available) or Lunch on Your Own**

### **BIOMARKERS**

**1:30 Chairperson's Remarks**

*Mark R. Bowlby, Ph.D., Neurophysiology & Pain Lead, Merck Research Labs*

**1:35 Translational Models and Biomarkers for Pain Therapeutic Development**

*Mark R. Bowlby, Ph.D., Neurophysiology & Pain Lead, Merck Research Labs*

**2:05 microRNA as Biomarkers in Pain**

*Seena K. Ajit, Ph.D., Assistant Professor, Pharmacology and Physiology, Drexel University College of Medicine*

### **IDENTIFYING NOVEL TARGETS**

**2:35 Imaging Pain and Analgesics: Going the Distance to the Clinic**

*David Borsook, M.D., Ph.D., Director, Center for Pain and the Brain, Harvard Medical School*

**3:05 Sponsored Presentations (Opportunities Available)**

**3:35 Grand Opening Refreshment Break in the Exhibit Hall**

### **BIOLOGICS & THE IMMUNE SYSTEM**

**4:35 The Promise of Biologic Drugs for the Treatment of Pain**

*Iain Chessell, Ph.D., Head, Neuroscience Centre of Excellence, MedImmune*

*5:05 Roles for Innate Alarmins, Cytokines and Chemokines in Neuropathic Pain*

*Fletcher White, Ph.D., V.K. Stoelting Professor, Anesthesia, Indiana University School of Medicine*

**5:35 Happy Hour in the Exhibit Hall**

**6:30 End of Day**

4<sup>th</sup> Annual

# Targeting Pain with Novel Therapeutics

**WEDNESDAY, JUNE 8**

**7:30 am Continental Breakfast Breakout Discussions**

Breakout Discussion Topics:

- | Animal Models
- | Biologics for Pain
- | Peripherally Restricted Therapeutics

## THE ENDOCANNABINOID SYSTEM & PERIPHERALLY RESTRICTED TARGETS

**8:30 Chairperson’s Remarks**

*Tim Young, Ph.D., Associate Research Fellow, Pfizer*

**8:40 Discovery and Clinical Development of PF-04457845, an Irreversible Inhibitor of Fatty Acid Amide Hydrolase**

*Tim Young, Ph.D., Associate Research Fellow, Pfizer*

**9:10 Peripheral CB1/CB2 Agonist for the Treatment of Pain and Inflammation**

*Robert Spencer, Ph.D., Senior Director, Pre-Clinical Development, Cara Therapeutics*

**9:40 Targeting Low Brain Penetrant CB1 Receptor Agonists for the Treatment of Chronic Neuropathic Pain**

*Paul Ratcliffe, Ph.D., Director, Global Drug Discovery & Head, Medicinal Chemistry 1, Grünenthal*

**10:10 Networking Coffee Break in the Exhibit Hall**

## TARGETING ION CHANNELS

**10:50 Sodium Channels as Therapeutic Targets in Pain: Many Isoforms, Many Actions, Many Opportunities**

*Stephen G. Waxman, M.D., Ph.D., Bridget Marie Flaherty Professor of Neurology, Neurobiology and Pharmacology, Yale University School of Medicine*

**11:20 Design and Pre-Clinical Development of Novel T-Type and N-Type Calcium Channel Blockers for Pain Intervention**

*Terrance P. Snutch, Ph.D., FCAHS, FRSC, Vice President & CSO, Zalicus, Inc.*

**11:50 Talk Title to be Announced**

*Nuria A. Tamayo, Ph.D., Principal Scientist, Small Molecule Drug Discovery, Amgen, Inc.*

**12:20 pm End of Conference**

2<sup>nd</sup> Annual

# In Vivo Molecular Imaging in Drug Discovery and Development

## WEDNESDAY, JUNE 8

12:30 pm Registration

### IN VIVO MOLECULAR IMAGING AS AN ESSENTIAL TOOL IN DRUG DISCOVERY AND DEVELOPMENT

1:55 Chairperson's Opening Remarks

Thomas Krucker, Ph.D., Head, Molecular Imaging, Global Imaging Group, Novartis Institutes for Biomedical Research, Inc.

» **2:00 KEYNOTE PRESENTATION: Imaging Biomarkers in Drug Development**

Jeffrey Evelhoch, Ph.D., Vice President, Exploratory & Translational Sciences; Head, Imaging, Merck Research Laboratories

**2:30 Successfully Integrating Molecular Imaging into Drug Discovery and Development**

Thomas Krucker, Ph.D., Head, Molecular Imaging, Global Imaging Group, Novartis Institutes for Biomedical Research, Inc.

**3:00 NanoSPECT/CT Imaging of Bispecific Molecular Liver Targeting for Treatment of Hepatitis C**

Stephen Mather, Ph.D., Professor, Centre for Molecular Oncology, Barts Cancer Institute

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**3:30 Networking Refreshment Break in the Exhibit Hall**

**4:30 The Expanding Role of Imaging for Assessment of Proof-of-Concept in Pharma- and Bio-Therapeutic Drug Discovery and Development**

Thomas Bocan, Ph.D., Senior Director & Head, Pre-Clinical BioImaging Center, Worldwide Research and Development, Pfizer, Inc.

**5:00 Multiplexed Molecular Imaging; Rational Design of the Next Generation of Informative Molecular Imaging Probes**

Hisataka Kobayashi, M.D., Ph.D., Chief Scientist, Molecular Imaging Program, NCI/NIH

5:30 End of Day

## THURSDAY, JUNE 9

7:20 am Continental Breakfast Breakout Discussions

**Topic: In vivo Molecular Imaging in Cancer Drug Development**

Moderator: Juri G. Gelovani, M.D., Ph.D., President, Academy of Molecular Imaging; Professor and Chairman, Experimental Diagnostic Imaging; Director, Center for Advanced Biomedical Imaging Research, University of Texas MD Anderson Cancer Center

- What type of *in vivo* molecular imaging agents and approaches are useful for pre-clinical and clinical phases in cancer drug development?
- How should the development drug and molecular imaging agent or approaches be coordinated?
- What impedes the utilization of molecular imaging agents and approaches in early phase clinical studies of novel cancer drugs?

**Topic: Internal vs Outsourced Preclinical In Vivo Molecular Imaging**

Moderator: Thomas Bocan, Ph.D., Senior Director & Head, Pre-Clinical BioImaging Center, Worldwide Research and Development, Pfizer, Inc.

- The scope and need for preclinical imaging outsourcing vendors.
- Barriers and impediments for establishing a preclinical imaging outsourcing service, e.g., cost, qualified technical staff, infrastructure and regulatory issues.
- Design of a preclinical imaging outsource vendor. What types of hardware and infrastructure are needed to meet the needs of Pharma and BioTech?
- Advantages and disadvantages of internal and outsourced preclinical imaging.

**Topic: Challenges in collaboration and teamwork between imaging specialists and research scientists**

Moderator: Scott Malstrom, Ph.D., Head, Applied Therapeutics & Whole Animal Imaging Core Facility, Koch Institute for Integrative Cancer Research, MIT

### TRANSLATIONAL APPROACHES IN PRE-CLINICAL IN VIVO MOLECULAR IMAGING RESEARCH

8:20 Chairperson's Opening Remarks

Peter Conti, M.D., Ph.D., Professor of Radiology, Biomedical Engineering and Pharmacy, University of Southern California

» **8:30 KEYNOTE PRESENTATION: Molecular Imaging for Selection and Monitoring of Therapies in Oncology**

Juri G. Gelovani, M.D., Ph.D., President, Academy of Molecular Imaging; Professor and Chairman, Experimental Diagnostic Imaging; Director, Center for Advanced Biomedical Imaging Research, University of Texas MD Anderson Cancer Center

**9:00 Molecular Imaging in Clinical Trials: Advancing Drug Development**

2<sup>nd</sup> Annual

# In Vivo Molecular Imaging in Drug Discovery and Development

*Peter Conti, M.D., Ph.D., Professor of Radiology, Biomedical Engineering and Pharmacy, University of Southern California*

## 9:30 Translational Imaging: Applications in Oncology Drug Development

*Patrick Chow, Ph.D., Principal Scientist, Research & Development Clinical Biomarkers – Imaging, Bristol-Myers Squibb*

## 10:00 Networking Coffee Break in the Exhibit Hall

## 10:45 Novel PET Tracers as Translational Tools in Drug Discovery and Development

*Dennis McCarthy, Ph.D., Director, Early Development, AstraZeneca R&D*

## 11:15 PANEL DISCUSSION

### Translating Molecular Imaging from Pre-Clinical to Clinical Stages of Drug Development: Success Rate, Constraints, and Ways to Improve Efficiency

*Moderator: Dennis McCarthy, Ph.D., AstraZeneca R&D*

### 11:45 pm Luncheon Presentations (Sponsorship Opportunities Available) or Lunch on Your Own

## MOLECULAR IMAGING UTILIZATION IN VARIOUS THERAPEUTIC AREAS

### 1:15 Chairperson's Remarks

*Paul D. Acton, Ph.D., Team Leader, Molecular Imaging, Johnson & Johnson Pharmaceutical Research and Development*

### 1:25 Role of Molecular Imaging in Large Molecule and Biologic Drug Development

*Paul D. Acton, Ph.D., Team Leader, Molecular Imaging, Johnson & Johnson Pharmaceutical Research and Development*

### 1:55 Pre-Clinical Biomarkers for Translational Neuroscience: Examples from Drug Discovery

*Donna L. Maier, Ph.D., Associate Director, Biology, BrainCells, Inc.*

### 2:25 Ice Cream Refreshment Break in the Exhibit Hall

### 3:05 Use of Functional, Structural and Molecular *in vivo* Imaging as Translational Tools to Assess Joint Disease: Efficacy of a Potent FMS-Kinase Inhibitor in a Rat Model of Rheumatoid Arthritis

*Lawrence de Garavilla, Ms.S., Ph.D., Research Fellow, ImmunoPharmacology, Johnson & Johnson*

### 3:35 Characterization of a Water Soluble Z DEVD Aminoluciferin Probe for the Non Invasive Bioluminescent Imaging of Apoptosis *in vivo*

*Jonathan A. Hickson, Ph.D., Senior Scientist II, Pharmacology, Cancer Research, Global Pharmaceutical R & D, Abbott Laboratories*

### 4:05 Integration of Molecular Imaging with Basic Research in the Diagnosis, Monitoring and Treatment of Cancer

*Scott Malstrom, Ph.D., Head, Applied Therapeutics & Whole Animal Imaging Core Facility, Koch Institute for Integrative Cancer Research, MIT*

### 4:35 End of Conference



3<sup>rd</sup> Annual

**Successful Targeting of Alzheimer's Disease**

**TUESDAY, JUNE 7**

**7:45 am Registration and Morning Coffee**

**8:20 Chairperson's Opening Remarks**

**» 8:25 OPENING KEYNOTE: Impact of Pre-Competitive Collaboration on Alzheimer's Disease Drug Development in Europe**

*Olivier Blin, M.D., Ph.D., M.B.A., Head CIC-CPCT, Clinical Pharmacology, Timone University Hospital, Marseille, France*

**8:55 Anti-Abeta Immunotherapy for the Treatment of Alzheimer's Disease**

*Gene Kinney, Ph.D., Vice President, Head of Research, Janssen Alzheimer Immunotherapy*

**9:25 New Criteria for AD**

*Bruno Dubois, Ph.D., Director, Institut de la Mémoire et de la Maladie d'Alzheimer (IMMA), Director, INSERM Group (ICM), Hôpital La Salpêtrière, France*

**9:55 Networking Coffee Break**

**HUMAN GENETICS**

**10:25 What can Recent Genetic Findings Teach us About Novel Therapeutics for Alzheimer's Disease?**

*Rudolph E. Tanzi, Ph.D., Joseph P. and Rose F. Kennedy, Professor of Neurology, Harvard Medical School; Director, Genetics and Aging Research Unit, MassGeneral Institute for Neurodegenerative Disease*

**10:55 A TOMM-40 Variable Length Polyt Repeat Polymorphism, Inherited through Evolution, Determines the Age of Onset Distribution of Late-Onset Alzheimer's Disease**

*Allen D. Roses, M.D., Director, Deane Drug Discovery Institute, Duke University*

**11:25 Genome-Wide Association Analyses of Alzheimer's Disease in Cohorts: Will it Change AD Prevention and Treatment?**

*Sudha Seshadri, M.D., Associate Professor of Neurology, Co-Director of Medical Education for the Residency Program, Boston University School of Medicine, Senior Investigator, The Framingham Study*

**11:55 Luncheon Presentations (Sponsorship Opportunities Available) or Lunch on Your Own**

**IMAGING & BIOMARKERS**

**1:30 pm Chairperson's Remarks**

**1:35 The Impact of the ADNI on Drug Discovery & Development**

*William Potter, Ph.D., former Vice President, Translational Neuroscience, Merck Research Laboratories*

**2:05 Early Detection of Alzheimer's Disease: Are CSF Biomarkers Ready for the Challenge?**

*Leslie Shaw, Ph.D., Director, Toxicology Laboratory, Biomarker Research Laboratory, Pathology & Laboratory Medicine, University of Pennsylvania Medical Center*

**2:35 Neuroimaging Predictors of Cognitive Change: Findings from the Baltimore Longitudinal Study of Aging**

*Susan M. Resnick, Ph.D., Senior Investigator, Cognition Section, Laboratory of Personality and Cognition, NIA/NIH*

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**3:05 Novel Tissue and CSF Biomarkers Targeting Causal Pathways and Network Dynamics in Neurodegenerative Disease**

*Mahalakshmi "Shubha" Shankaran, Ph.D., Director, Neurobiology, Kinemed, Inc.*

**3:35 Grand Opening Refreshment Break in the Exhibit Hall**

**4:35 ASL Perfusion MRI as a Biomarker of Disease Progression and Therapeutic Response in AD**

*John A. Detre, M.D., Professor, Neurology and Radiology, Director, Center for Functional Neuroimaging, University of Pennsylvania*

**5:05 A Novel Blood Based Biomarker Assay for Alzheimer's Disease**

*Muralidhar Reddy Moola, Ph.D., Associate Professor, Department of Chemistry, The Scripps Research Institute*

**5:35 - 6:30 Happy Hour in the Exhibit Hall**

**WEDNESDAY, JUNE 8**

**7:30 am Continental Breakfast Breakout Discussions**

**ANIMAL MODELS**

**8:30 Chairperson's Remarks**

**8:40 A Canine Model for Evaluating Gamma Secretase Modulators and Inhibitors**

*Herman Borghys, Ph.D., Neuroscience, Janssen Pharmaceutica, a division of Johnson & Johnson Pharmaceutical R&D*

**9:10 Aging Dogs as a Pre-Clinical Model to Test Therapeutics or Preventative Approaches for Alzheimer's Disease**

*Elizabeth Head, M.A., Ph.D., Associate Professor, Molecular and Biomedical Pharmacology, Sanders-Brown Center on Aging, University of Kentucky*

**9:40 Aged Nonhuman Primate Models of Alzheimer-like Proteopathy**

*Lary C. Walker, Ph.D., Research Professor, Yerkes Center, Neurology, Emory University*

**10:10 Networking Coffee Break in the Exhibit Hall**

**TARGETS**

**10:50 Synaptic Zinc as a Pharmacological Target in Alzheimer's Disease**

*Ashley I. Bush, M.D., Ph.D., Director, Oxidation Biology Lab., Mental Health Research Institute, Victoria; Professor of Pathology, University of Melbourne; Lecturer in Psychiatry, Harvard Medical School, MGH; Adjunct Professor of Neuroscience, Cornell University Medical Center*

**11:20 Potential for the Treatment and Prevention of Alzheimer's Disease with Liver X Receptor Agonist**

*Celina Zerbinatti, Ph.D., Team Lead, Cognitive Disorders, Neuro-symptomatic Disorders, Merck & Co., Inc.*

**11:50 Studies Probing the Mechanism of Action of Allosteric  $\gamma$ -Secretase Inhibitors and Modulators**

*Douglas S. Johnson, Ph.D., Senior Principal Scientist, Medicinal Chemistry, Pfizer, Inc.*

**12:20 pm End of Conference**



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Inaugural  
Targeting Parkinson's Disease

**WEDNESDAY, JUNE 8**

**12:30 pm Registration**

**1:55 Chairperson's Opening Remarks**

» **2:00 KEYNOTE PRESENTATION**

*David Weiner, M.D., Vice President, Head, Early Clinical Development & Neurology Global Clinical Development Unit; U.S. Site Head, Medical Science and Innovation, EMD Serono, Inc.*

**MOUSE MODELS**

**2:30 Mitopark Mice: A Model of Progressive Dopamine Depletion and Parkinsonism**

*Susan E. Browne, Ph.D., Director, Neuropharmacology, Merck Research Labs*

**3:00 Alpha-synuclein Overexpressing Mouse Models of Parkinson's Disease**

*Anita Sidhu, Ph.D., Professor & Head, Laboratory of Molecular Neurochemistry, Georgetown University*

**3:30 Networking Refreshment Break in the Exhibit Hall**

**4:30 The Rotenone Model of Parkinson's Disease**

*J. Timothy Greenamyre, M.D., Ph.D., Professor & Vice-Chair of Neurology; Director, Pittsburgh Institute for Neurodegenerative Diseases; UPMC Endowed Chair & Chief, Movement Disorders, University of Pittsburgh*

**5:00 LRRK2 Parkinson's Mouse Model**

*Youren Tong, Ph.D., Instructor in Neurology, Center for Neurologic Diseases, Brigham and Women's Hospital, Harvard Medical School*

**5:30 End of Day**

**THURSDAY, JUNE 9**

**7:20 am Continental Breakfast Breakout Discussions**

Breakout Discussion Topics:

- Impact of Using Induced vs. Transgenic Models
- Biomarker Discovery: How Close are we?
- Concomitant Drugs: Will the Next PD Drug be Drugs...?

**LRRK2**

**8:20 Chairperson's Remarks**

**8:30 The Biochemistry of LRRK2 Reveals New Opportunities for Regulating Its Activity**

*Matthew J. LaVoie, Ph.D., Assistant Professor of Neurology, Brigham and Women's Hospital and Harvard Medical School*

**9:00 LRRK2 Genetics and the Impact on Parkinson's Drug Development**

*Alastair D. Reith, Ph.D., Director, External Alliances & Development, R&D China, Medicines Research Centre, GlaxoSmithKline (INVITED)*

**9:30 LRRK2 cell biology: Basic Research Towards Parkinson's Disease Therapeutics**

*Wanli W. Smith, M.D., Ph.D., Assistant Professor, Head, Molecular Neuroscience Laboratory, Pharmaceutical Sciences, University of Maryland School of Pharmacy*

**10:00 Networking Coffee Break in the Exhibit Hall**

**TARGETS**

**10:45 The Inhibition of a-Synuclein by Regulating its Translation Level**

*Maria Maccacchini, Ph.D., President & CEO, QR Pharma*

**11:15 Targeting Nuclear Hormone Receptors to Treat Neurodegenerative Disease**

*Ethan S. Burstein, Ph.D., Director, Biosciences, ACADIA Pharmaceuticals*

**11:45 Luncheon Presentations** (Sponsorship Opportunities Available) **or Lunch on Your Own**

**1:15 pm Chairperson's Remarks**

**1:25 Novel mGluR4 Positive Allosteric Modulators in Parkinson's Disease**

*Ian J. Reynolds, Ph.D., Senior Director, Neuroscience, Merck Research Laboratories*

**1:55 The Discovery and Development of Positive Allosteric Modulators of MGlur4 for the Treatment of Parkinson's Disease**

*Corey R. Hopkins, Ph.D., Research Assistant Professor, Associate Director of Medicinal Chemistry, Drug Discovery Program, Vanderbilt Program*

**2:25 Ice Cream Refreshment Break in the Exhibit Hall**

**3:05 Iron, Tau and DJ-1: Insights into the Mechanism of Action of PBT-434 in Parkinson's Disease Mouse Models**

*Ashley I. Bush, M.D., Ph.D., Director, Oxidation Biology Laboratory, Mental Health Research Institute, Victoria, Australia; Professor of Pathology, University of Melbourne; Lecturer in Psychiatry, Harvard Medical School, Massachusetts General Hospital; Adjunct Professor of Neuroscience, Cornell University Medical Center, New York*

**BIOMARKERS & IMAGING**

**3:35 Is Modulating Synuclein Phosphorylation a Potential Disease Modifying Approach for Parkinson's Disease?**

*Marcelle Bergeron, Ph.D., Director, Neuropharmacology, Elan Pharmaceuticals, Inc.*

**4:05 Animal Model of Presymptomatic Parkinson's Diseases**

*Craig Ferris, Ph.D., Professor, Psychology and Pharmaceutical Sciences, Director, Center for Translational NeuroImaging, Northeastern University*

**4:35 End of Conference**

7<sup>th</sup> Annual  
Tools & Technologies for HTS

**TUESDAY, JUNE 7**

7:45 am Registration and Morning Coffee

**KEYNOTE SESSION****8:45 Chairperson's Opening Remarks**

Daniel G. Sipes, Director of Advanced Automation Technologies, Genomics Institute of the Novartis Research Foundation

**8:55 Strategies for Uncorking the Drug Discovery Process**

Rathnam Chaguturu, Ph.D., Director, High-Throughput Screening Laboratories, University of Kansas; Editor-in-Chief, Combinatorial Chemistry and High-Throughput Screening

**9:25 Improving Drug Candidate Optimization by Streamlining Processes and Harnessing Advanced Discovery Platforms**

Litao Zhang, Ph.D., Executive Director, Applied Biotechnology, Lead Evaluation and Mechanistic Biochemistry, Bristol-Myers Squibb

9:55 Networking Coffee Break

**HIT TRIAGE****10:25 Integrated Lead Finding**

Peter Fekkes, Ph.D., Head, Open Access Medium Throughput Screening Center, Center for Proteomic Chemistry Lead Finding Platform, Novartis Institutes for BioMedical Research

**10:55 Application of Label Free Technologies for Mechanistic-Based Assessment to Accelerate Hit Triage**

William Metzler, Ph.D., Associate Director, Mechanistic Biochemistry, Bristol-Myers Squibb

**11:25 Strategies for Improving Hit Triage**

Matthew Todd, Ph.D., Team Leader, Research Fellow, Lead Generation Biology, Johnson & Johnson

**11:55 Luncheon Presentations** (Sponsorship Opportunities Available) or **Lunch on Your Own**

**ION CHANNELS & ELECTROPHYSIOLOGY****1:30 pm Chairperson's Remarks**

Michael F.A. Finley, Ph.D., Assay Development Team Lead, Small Molecule Screening, Exploratory & Translational Sciences, Merck & Co.

**1:35 Inter-Assay Correlation for Ion Channel Screening**

Michael F.A. Finley, Ph.D., Assay Development Team Lead, Small Molecule Screening, Exploratory & Translational Sciences, Merck & Co.

**2:05 Changing the Game in Ion Channels: Ultra High-Throughput Automated Electrophysiology**

Adam Hendricson, Ph.D., Applied Biotechnology & Lead Evaluation, Bristol-Myers Squibb

**2:35 High-Throughput Voltage-Clamp Assays of Ligand-Gated Ion Channels**

Glenn E. Kirsch, Ph.D., Senior Director, Pharmacology and Program Management, ChanTest Corporation

**HT-MASS SPECTROSCOPY**

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**3:05 Optimizing Lead Optimization Assays: Case Studies Using LC/MS**

Lynn Abell, Ph.D., Senior Principal Scientist, Bristol-Myers Squibb

**3:35 Grand Opening Refreshment Break in the Exhibit Hall****4:35 HTMS - From *in vitro* to *ex vivo*: 5-Lipoxygenase and Beyond**

Robert Hills, Ph.D., Senior Scientist, Lead Discovery, East Coast RCO, Janssen Pharmaceutical Companies of Johnson & Johnson

**5:05 EXPERT PANEL: Translating Technologies Outside the HTS Lab**

Moderator : Litao Zhang, Ph.D., Executive Director, Applied Biotechnology, Lead Evaluation and Mechanistic Biochemistry, Bristol-Myers Squibb

- The push for translational medicine
- ADME/Tox screening
- Biomarker discovery

**5:35 Happy Hour in the Exhibit Hall**

6:30 End of Day

**WEDNESDAY, JUNE 8**

7:30 am Continental Breakfast Breakout Discussions

**LABEL FREE METHODS****8:30 Chairperson's Remarks**

Lance Laing, Ph.D., Executive Director, Business Development, Therapeutics and Platform Technologies, ACEA Biosciences

**8:40 Applications of Cell-Based Label-Free Technologies to 7TM Receptor Studies in Drug Discovery**

Ralph Garippa, Ph.D., Research Leader, Roche Discovery Technologies

**9:10 Characterization of Allosteric Modulators Using Label Free Technology**

Patricia McDonald, Ph.D., Associate Scientific Director, Translational Research Institute, Scripps Florida

**9:40 Use of Stem-Cell Derived Cardiomyocytes to Predict Drug-Induced Cardiotoxicity**

Kyle L. Kolaja, Ph.D., D.A.B.T., Fellow, A.T.S., Director, Global Head, Predictive Toxicology Screens, Mechanistic Toxicology-USA, Nonclinical Safety, Hoffmann-LaRoche

**10:10 Networking Coffee Break in the Exhibit Hall****10:50 Combining Label Free Assay Platforms to Support both Large and Small Molecule Drug Discovery**

Robin Barbour, Director, Antibody Technology, Neotope Biosciences, a Division of Elan Pharmaceuticals, Inc.

**11:20 Expediting Kinetic Characterization, Epitope Binning and Epitope Mapping of Antibodies Using Label-Free Biosensors**

Kevin Lindquist, M.S., Principal Scientist, Protein Engineering, Rinat Pfizer

**11:50 Leveraging Label-free Technology for Development of a Compound Annotation Database for Off-Target Prediction**

Keith R. Olson, Ph.D., Corning Incorporated

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12:20 pm End of Conference

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7<sup>th</sup> Annual

## Evaluating Novel Technologies for Cell-Based Screening

**WEDNESDAY, JUNE 8**

12:30 pm Registration

**PRIMARY & STEM CELLS**

1:55 Chairperson's Opening Remarks

*Paul Kassner, Ph.D., Director, Research, Amgen, Inc.***2:00 The Challenges of Using Primary Cells in Drug Discovery***Marcie Glicksman, Ph.D., Co-Director, Laboratory for Drug Discovery, Harvard NeuroDiscovery Center, Partners Center for Drug Discovery; Assistant Professor, Neurology, Brigham and Women's Hospital***2:30 Partially Reprogrammed Cells Exhibit Marked Variation in Gene Expression, Epigenetic State, and Differentiation Potential***Kelvin Lam, Ph.D., Director, High-Throughput Screening of the Harvard Stem Cells Institute, Department of Stem Cell and Regenerative Biology at Harvard University***3:00 Sponsored Presentations** (Opportunities Available)**3:30 Networking Refreshment Break in the Exhibit Hall****4:30 Identifying Compound Leads for Breast Cancer Stem Cells***Leigh C. Carmody, Ph.D., Research Scientist/Project Lead, Assay Development, Broad Institute of Harvard and MIT***5:00 Phenotypic Primary Cell Screening with Non-Traditional Label Free Technology***Craig C. Beeson, Ph.D., Associate Professor, Pharmaceutical & Biomedical Sciences, Medical University of South Carolina***5:30 End of Day****THURSDAY, JUNE 9****7:20 am Continental Breakfast Breakout Discussions**

Breakout Discussion Topics:

- How Low is Too Low? Miniaturization at the Risk of Data Quality
- When to Say "No Go"

**CUTTING EDGE TOOLS****8:20 Chairperson's Remarks****8:30 Reverse Phase Arrays***Gavin MacBeath, Ph.D., Senior Director & Head, Translational Research, Merrimack Pharmaceuticals; Lecturer, Department of Systems Biology, Harvard Medical School***9:00 BacMam-Enabled High Throughput Cell-Based Assay Development***Hu Li, Ph.D., Manager, Biological Reagents and Assay Development in Molecular Discovery Research, GlaxoSmithKline***9:30 Using Combination Ultra High-Throughput Screening (cuHTS) to Address Efficacious Drug Combinations to Responsive Tumor Genotypes***Glenn Short, Ph.D., Director, Discovery Sciences, Zalicus, Inc.***10:00 Networking Coffee Break in the Exhibit Hall****10:45 Application of a Real Time Informatics Platform to High Content Analysis of Cell-Based Assays***Sunita J. Shukla, M.P.H., Ph.D., Postdoctoral Fellow, Genomic Assay Technologies, NIH Chemical Genomics Center, National Human Genome Research Institute, National Institutes of Health***11:15 High-Throughput Vertebrate Screening at Cellular Resolution***Mehmet Fatih Yanik, Ph.D., Associate Professor, Massachusetts Institute of Technology***11:45 pm Advantages of Bioluminescence Assays for GPCR Studies in Drug Discovery***Mei Cong, Ph.D., Research Manager, Research, Promega Corporation*

Promega has developed multiple sensitive assays for GPCR studies that offer flexibility in the approach to experimental design. We will present data on reporter and second messenger assays, both lytic and live-cell, as well as multiplexed options.

**12:00 Luncheon Presentations** (Sponsorship Opportunities Available) **or Lunch on Your Own****1:25 Implementation of Micro Bioreactors for Nanoscale HTS and HCS Screening***Anthony Davies, Ph.D., Director, High Content Research Facility (Trinity HCA), Department of Clinical Medicine, Trinity College, Dublin***1:55 Drug Discovery Using *C. elegans****Stephen C. Pak, Ph.D., Assistant Professor, University of Pittsburgh School of Medicine***2:25 Ice Cream Refreshment Break in the Exhibit Hall****HT-FLOW CYTOMETRY****3:05 High Dimensional Single-Cell Mass Cytometry of Differential Immune and Drug Responses Across Healthy Human Hematopoiesis and Related Malignancies***Garry P. Nolan, Ph.D., Professor, Microbiology and Immunology, Baxter Laboratory for Stem Cell Biology, Center for Clinical Science Research, Stanford University***3:35 A High-Throughput Flow Cytometry Method Capable of Screening >500,000 Wells for Intracellular Phosphorylation***Mark Sandberg, Ph.D., Senior Scientist, Lead Discovery, Amgen, Inc.***4:05 Single Cell Analysis Techniques: Primary Cells, Imaging and High-Throughput Flow Cytometry***Robert X. Eagle, Senior Scientist, Screening and Compound Profiling, GlaxoSmith Kline***4:35 End of Conference**

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**Promega**



## SPONSOR INFORMATION

CHI offers comprehensive sponsorship packages which include presentation opportunities, exhibit space, branding, as well as the use of the pre and post show delegate list.

Sponsorships allow you to achieve your objectives before, during, and long after the event. Any sponsorship can be customized to meet with your company's needs and budget.

### Opportunities Include:

#### Sponsored Presentations

Speak to a captive audience about your latest technology. Sponsorship includes a 15 minute podium presentation within the scientific agenda, exhibit space, onsite branding, and access to cooperative marketing efforts by CHI.

#### Breakfast & Luncheon Presentations

Invite session attendees to enjoy breakfast or lunch on your company's behalf while you give your talk. Includes a 30-minute presentation and concludes with a 15-minute Q&A session.

#### Invitation-Only VIP Dinner/Hospitality Suite

Sponsor will select invitees from the conference pre-registration list for an evening of networking at the hotel or a top local venue. CHI will extend invitations, conduct follow-up and monitor responses. Reminder cards will be placed in the badges of those delegates who will be attending.

#### CHI's Co-Operative Marketing Program

CHI is pleased to help market to your prospect list at a shared cost. We will offer your prospects a discounted rate to attend the conference on your behalf via mailing or email. CHI's marketing manager will customize a specific message to your target audience.

#### Focus Groups

CHI will gladly provide you the opportunity to host a focus group on-site at the conference. This exclusive gathering can be useful to conduct market research, gather feedback on a new product idea and gather marketing intelligence from industry experts on a specific topic.

#### Other Networking and Promotional Opportunities:

- Badge Lanyards Sponsor (exclusive)
- Exhibit Hall Reception
- Hotel Room Door Hanger (1 night exclusive)
- Hotel Room Drop
- Keynote Chair Drop
- Specific Conference Chair Drop
- Padfolio Sponsor
- Refreshment Break
- Tote Bag Sponsor
- Tote Bag Insert
- Program & Exhibit Guide Sponsor (exclusive)

#### Exhibits

Exhibitors at the World Pharmaceutical Congress will enjoy facilitated networking opportunities with over 500 high-level decision-makers. Speak face to face with prospective clients and showcase your latest product, service or solution.

## Sponsors & Exhibitors will have the opportunity to network with 500 attendees.

The World Pharmaceutical Congress presents your company with the opportunity to network with decision-makers and leading professionals from all aspects of the biopharmaceutical community.

Become a sponsor and exhibitor and get the opportunity to network, influence, and interact with over 500 highly qualified, targeted delegates.

### Benefits of Sponsorship and Exhibiting at CHI Events

- Intimate, targeted events that allow you to meet and influence senior level scientists, executives, and decision makers
- Develop new business leads via our networking events and participation in our Break-out Sessions (specific to event content)
- Revisit existing customers, support & strengthen the relationship for future growth
- Brand your company name and generate awareness of your corporate image
- Typical CHI event attendees include; C-Level Executives, Directors, Research Scientists, and Managers/Senior Scientists from Biotech, Pharmaceutical, Academia, and Hospitals

### For information, contact:

**Suzanne Carroll, Manager, Business Development**  
781-972-5452 • [scarroll@healthtech.com](mailto:scarroll@healthtech.com)

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**BioSpace.com**  
Global Hub for the Life Sciences

**CanBiotech**  
Biotechnology Portal & B2B Marketplace

**genomeweb**

**selectscience.net**

## HOTEL & TRAVEL INFORMATION

### Conference Hotel:

Sheraton Philadelphia City Center  
17th and Race Streets  
Philadelphia, PA 19103  
www.Sheraton.com  
Phone: 215-448-2000

Discounted Room Rate: **\$159 s/d**

Discounted Cut-off Date: **May 9, 2011**

Please visit our website (worldpharmacongress.com) or call the hotel directly to reserve your sleeping accommodations. Identify yourself as a Cambridge Healthtech Institute conference attendee to receive the discounted room rate. Reservations made after the cut-off date or after the group room block has been filled (whichever comes first) will be accepted on a space- and rate-availability basis. Rooms are limited, so please book early.

### Flight Discounts:

To receive a 5% or greater discount on all American Airline flights please use one of the following methods:

- Call 1-800-433-1790 use Conference code **1361AV**
- Go to [www.aa.com](http://www.aa.com) enter Conference code **1361AV** in promotion discount box
- Contact Wendy Levine, Great International Travel 1-800-336-5248 ext. 137

### Car Rental Discounts:

Special discount rentals have been established with Hertz for this conference.

- Call Hertz directly at 800-654-3131 and reference **Discount Number 04KL0002**



## Maximize your experience on-site at World Pharma Congress 2011!

CHI's  
**INTRONET**  
Networking at its Best

The Intro-Net offers you the opportunity to set up meetings with selected attendees before, during and after this conference, allowing you to connect to the key people you want to meet.

This online system was designed with your privacy in mind and is available only to registered session attendees of this event.

Registered conference attendees will receive more information on accessing the Intro-Net in the weeks leading up to the event!

## Present a poster and save \$50!

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure a poster board and inclusion in the conference materials, your abstract must be submitted, approved and your registration paid in full by April 22, 2011. *Please see page 16 for details.*

Reasons you should present your research poster at this conference:

- Your poster will be exposed to our international delegation
- Receive \$50 off your registration
- Your poster abstract will be published in our conference materials
- Your research will be seen by leaders from top pharmaceutical, biotech, academic and government institutes

Register by April 29 and **Save up to \$200!**

## Pricing and Registration Information

### SHORT COURSE PRICING

#### Choose 1 Short Course

Commercial _____	\$695
Academic, Gov't, Hospital Affiliated _____	\$395

#### Choose 2 Short Courses

Commercial _____	\$995
Academic, Gov't, Hospital Affiliated _____	\$695

#### Monday, June 6<sup>th</sup> (Morning)

Animal Models of Pain: Progress and Challenges  
Use of Stem Cells for Safety Screening  
Advanced Topics in Drug Metabolism

#### Monday, June 6<sup>th</sup> (Afternoon)

Translating Safety Biomarkers from the Lab to the Clinic  
Addressing Safety Concerns for Biological Drugs

#### Wednesday, June 8<sup>th</sup> (Evening)

Molecular Imaging in Drug Discovery and Development: Back to Basics  
Mechanistic Insights into Hepatotoxicity

## CONFERENCE PRICING

### STANDARD PACKAGE

Multiple Conference Pricing (Includes access to 2 conferences, excludes short courses)

	Commercial	Academic, Government, Hospital-Affiliated
Advance Registration Discount until April 29	\$2450	\$1025
Registrations After April 29, and on-site	\$2595	\$1095

### BASIC PACKAGE

Single Conference Pricing (Includes access to 1 conference, excludes short courses)

	Commercial	Academic, Government, Hospital-Affiliated
Advance Registration Discount until April 29	\$1545	\$775
Registrations After April 29, and on-site	\$1745	\$875

**Program Selection** When registering please indicate the program(s) you will attend:

#### SAFETY SUMMIT

June 7 - 8

Cardiotoxicity  
Nephrotoxicity

June 8 - 9

Hepatotoxicity  
ADME/DMPK Predictions

#### DISCOVERY SUMMIT

June 7 - 8

Pain  
Alzheimer's Disease

June 8 - 9

Parkinson's Disease  
*In Vivo* Molecular Imaging

#### SCREENING SUMMIT

June 7 - 8

Tools and Technologies for HTS

June 8 - 9

Cell-Based Screening

## How to Register [WorldPharmaCongress.com](http://WorldPharmaCongress.com)

P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode **WPC F** when registering

Cambridge Healthtech Institute's *10th Annual*

June 7 - 9, 2011



World Pharma Congress

Sheraton Philadelphia City Center, Philadelphia, PA

Please refer to the Registration Code below:

### CONFERENCE DISCOUNTS

Poster Discount (\$50 Off)

#### Poster Submission

Poster abstracts are due by April 22, 2011. 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](mailto: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.

**GROUP DISCOUNTS AVAILABLE!** Special rates are available for multiple attendees from the same organization. For more information on group discounts contact David Cunningham at +1-781-972-5472, [cunningham@healthtech.com](mailto:cunningham@healthtech.com)

I cannot attend but would like to purchase the [World Pharma Congress](#) conference CD for \$750 (plus shipping) 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 <http://www.healthtech.com/regdetails>**

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