Cambridge Healthtech Institute’s Tenth Annual

BIOMARKERS & DIAGNOSTICS

WORLD CONGRESS 2014

APRIL 30 - MAY 2, 2014 | LOEWS PHILADELPHIA HOTEL | PHILADELPHIA, PA

Featured Speakers:

Marc Ladanyi
Chair, Molecular Oncology
Memorial Sloan-Kettering Cancer Center

Nicholas Dracopoli
Vice President, Janssen R&D
Johnson & Johnson

Darrell R. Borger
Director, Biomarker Laboratory
Harvard Medical School

Charles J. Cox
Head, Genetics
GlaxoSmithKline

Michael Burczynski
Executive Director, Biomarker Technologies
Bristol-Myers Squibb

Eric Lai
Senior Vice President, Pharmacogenomics
Takeda Pharmaceuticals

Cecilia Schott
Head, Personalized Healthcare
AstraZeneca

Andrew Schade
Senior Director, Diagnostics
Eli Lilly and Company

Jens R. Wendland
Head, Neuroscience Genetics
Pfizer Worldwide Re&D

The Leading Annual Meeting Dedicated to Biomarkers and Diagnostics Research and Implementation

Conference Programs:

April 30 - May 1

Track 1: Translational Biomarkers in Drug Development

Track 2: Clinical Biomarker Assay Development

Track 3: Executive Summit: Companion Diagnostics

May 1 - 2

Track 4: Biomarkers for Patient Selection

Track 5: Mutation Analysis for Clinical Biomarkers and Diagnostics

Dinner Courses:

• Exosomes and Microvesicles as Cancer Biomarkers (April 29)
• Fit-for-Purpose Biomarker Assay Development and Validation (April 30)
• Non-Coding RNAs as Biomarkers and Diagnostics (April 30)
• Next-Generation Sequencing as a Clinical Test (May 1)
• Laboratory-Developed Tests (May 1)
<table>
<thead>
<tr>
<th>Tuesday, April 29</th>
<th>Track 1: Translational Biomarkers in Drug Development</th>
<th>Track 2: Clinical Biomarker Assay Development</th>
<th>Track 3: Executive Summit: Companion Diagnostics</th>
</tr>
</thead>
<tbody>
<tr>
<td>5:00-6:00 pm</td>
<td>Conference Pre-Registration</td>
<td></td>
<td>(*Separate registration required)</td>
</tr>
<tr>
<td>6:00-9:00</td>
<td>Dinner Course*</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SC1: Exosomes and Microvesicles as Cancer Biomarkers</strong></td>
<td><strong>Commercialization Strategies for Companion Diagnostics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wednesday, April 30</td>
<td>Conference Registration and Morning Coffee</td>
<td>NGS Assays in the Clinic</td>
<td>Integrating Drug-Diagnostic Co-Development</td>
</tr>
<tr>
<td>7:30-8:30 am</td>
<td>Conference Registration and Morning Coffee</td>
<td>*NGS Assays in the Clinic (cont'd)</td>
<td>Regulatory and Reimbursement Strategies for Companion Diagnostics</td>
</tr>
<tr>
<td>8:00-8:15 am</td>
<td>Welcome Remarks from Conference Director</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8:40-10:00</td>
<td>Translation from Biomarker Assay to Companion Diagnostic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10:00-10:30</td>
<td>Networking Coffee Break</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10:30-12:05</td>
<td>Translation from Biomarker Assay to Companion Diagnostic (cont.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12:05-12:50</td>
<td>Luncheon Presentation Sponsored by Meso Scale Diagnostics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1:25-2:45</td>
<td>Biomarkers in Translational Medicine</td>
<td>Protein Biomarker Assay Development</td>
<td></td>
</tr>
<tr>
<td>2:45-3:45</td>
<td>Refreshment Break in the Exhibit Hall with Poster Viewing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3:45-5:00</td>
<td>Technology Showcase: Biomarkers in Drug Development</td>
<td>Technology Showcase: Molecular Diagnostics</td>
<td></td>
</tr>
<tr>
<td>5:00-6:00</td>
<td>Welcome Reception in the Exhibit Hall with Poster Viewing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6:00-9:00</td>
<td>Dinner Courses*</td>
<td></td>
<td>(*Separate registration required)</td>
</tr>
<tr>
<td><strong>SC2: Fit-for-Purpose Biomarker Assay Development and Validation</strong></td>
<td><strong>SC3: Non-Coding RNAs as Biomarkers and Diagnostics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thursday, May 1</td>
<td>Conference Registration for Tracks 4 and 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7:30-8:15 am</td>
<td>Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8:25-9:45</td>
<td>&quot;Big Data&quot; and Biomarker Development</td>
<td>NGS Assays in the Clinic</td>
<td>Integrating Drug-Diagnostic Co-Development</td>
</tr>
<tr>
<td>9:45-10:45</td>
<td>Coffee Break in the Exhibit Hall with Poster Viewing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10:45-12:25</td>
<td>&quot;Big Data&quot; and Biomarker Development (cont.)</td>
<td>NGS Assays in the Clinic (cont'd)</td>
<td>Regulatory and Reimbursement Strategies for Companion Diagnostics</td>
</tr>
<tr>
<td>12:25-1:55</td>
<td>Enjoy Lunch on Your Own</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Track 4: Biomarkers for Patient Selection</strong></td>
<td><strong>Track 5: Mutation Analysis for Clinical Biomarkers and Diagnostics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1:00-2:00</td>
<td>Conference Registration for Tracks 4 and 5</td>
<td>Clinical Utility of &quot;Actionable&quot; Mutations</td>
<td></td>
</tr>
<tr>
<td>1:55-3:20</td>
<td>Personalized Medicine at Big Pharma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3:20-4:15</td>
<td>Refreshment Break in the Exhibit Hall with Poster Viewing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4:15-5:55</td>
<td>Personalized Medicine at Big Pharma</td>
<td>Clinical Utility of &quot;Actionable&quot; Mutations (cont.)</td>
<td></td>
</tr>
<tr>
<td>6:00-9:00</td>
<td>Dinner Courses*</td>
<td></td>
<td>(*Separate registration required)</td>
</tr>
<tr>
<td><strong>SC4: Next-Generation Sequencing as a Clinical Test</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Friday, May 2</td>
<td>Conference Registration for Tracks 4 and 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7:30-8:15 am</td>
<td>Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8:25-10:00</td>
<td>NGS and Mutation Analysis for Patient Selection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10:00-10:50</td>
<td>Coffee Break in the Exhibit Hall with Poster Viewing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10:50-12:30</td>
<td>NGS and Mutation Analysis for Patient Selection (cont.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12:30</td>
<td>Close of Conference</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Biomarkers & Diagnostics World Congress 2014
Distinguished Faculty

John L. Allinson, FIBMS, Head, Biomarker Strategy, Drug Development Services, LGC Group
Jiri Aubrecht, Pharm.D., Ph.D., Senior Director and Safety Biomarker Group Lead, Drug Safety Research & Development, Pfizer
Michael Berger, Ph.D., Assistant Professor, Pathology, Memorial Sloan-Kettering Cancer Center
Mark S. Boguski, M.D., Ph.D., Associate Professor, Pathology, Center for Biomedical Informatics, Harvard Medical School
Darrell R. Borger, Ph.D., Co-Director, Translational Research Laboratory; Director, Biomarker Laboratory, Massachusetts General Hospital and Harvard Medical School
Michael Burcynski, Ph.D., Executive Director, Biomarker Technologies, Discovery Medicine and Clinical Pharmacology, Bristol-Myers Squibb
Tracy Bush, Ph.D., Director, Companion Diagnostics Regulatory Affairs, Roche Diagnostics
Derek Chiang, Ph.D., Research Investigator, Novartis Institutes for Biomedical Research
Charles J. Cox, Ph.D., Head, Genetics Experiment Design and Delivery, GlaxoSmithKline
Seth Crosby, M.D., Director, Partnerships & Alliances, Washington University School of Medicine
Mark E. Curran, Ph.D., Vice President, Immunology, Systems Pharmacology & Biomarkers, Janssen Research & Development
Viswanath Devanarayan, Ph.D., Global Head, Exploratory Statistics, AbbVie, Inc.
Emmanuelle Di Tomaso, Ph.D., Global Correlative Science Lead, Novartis Institutes for BioMedical Research
Marisa Delled-Filhart, Ph.D., Associate Director, Pathology and Companion Diagnostics, Merck
Michael J. Donovan, M.D., Ph.D., Director, Experimental Pathology and Institutional Biorepository, Icahn School of Medicine at Mt. Sinai
Nicholas C. Drapakó, Ph.D., Vice President, Janssen R&D, Johnson & Johnson
Daniel Edelman, Ph.D., Core Manager, Clinical Molecular Profiling Core, National Cancer Institute, NIH
Andrea Ferreira-Gonzalez, Ph.D., Professor and Chair, Division of Molecular Diagnostics; Director, Molecular Diagnostics Laboratory, Department of Pathology, Virginia Commonwealth University
Helen Fernandes, Ph.D., Associate Professor, Pathology and Laboratory Medicine, Weill Cornell Medical College
Andrew Fish, Executive Director, AdvaMedDx
Felix W. Frueh, Ph.D., Executive Partner, Opus Three, LLC
Iris Grossman, Ph.D., Global Head, Personalized Medicine and Pharmacogenomics, Global R&D, Teva Pharmaceutical Industries
Steven Gutman, M.D., Strategic Advisor, Myra’s
Michael Hale, Ph.D., Executive Director, Medical Sciences Biostatistics, Amgen
Sam Hanash, M.D., Ph.D., Director, McCombs Institute for Cancer Early Detection and Treatment, MD Anderson Cancer Center
Xiaolan Hu, Ph.D., Head, Clinical Genetics, Bristol Myers Squibb
Bing-Hua Jiang, Ph.D., Professor, Pathology, Anatomy and Cell Biology, Thomas Jefferson University
Peter M. Kazon, General Counsel, American Clinical Laboratory Association
Iya Khaili, Ph.D., Executive Vice President and Co-Founder, GNS Healthcare
Marc Ladanyi, M.D., William Ruane Chair in Molecular Oncology; Molecular Diagnostics Service and Human Oncology & Pathogenesis Program, Memorial Sloan-Kettering Cancer Center
Eric Lai, Ph.D., Senior Vice President and Head, Pharmacogenomics, Takeda Pharmaceuticals International
Eunice Lee, Ph.D., Regulatory Scientist, Office of In Vitro Diagnostics and Radiological Health, CDRH, FDA
Laurent Lessard, Ph.D., Assistant Professor, Molecular Oncology, John Wayne Cancer Institute
Tovia Libermann, Ph.D., Associate Professor, Medicine, Beth Israel Deaconess Medical Center and Harvard Medical School; Director, BIDMC Genomics, Proteomics, Bioinformatics, and Systems Biology Center and DF/HCC Cancer Proteomics Core
Walter Lukiw, Ph.D., Professor, Neuroscience, Louisiana State University
Rajyalakshmi Luthra, Ph.D., Professor, Hematopathology; Director, Molecular Genetic Pathology Fellowship Program; Director, Molecular Diagnostic Laboratory, MD Anderson Cancer Center
Ron Mazumder, Ph.D., MBA, Global Head, R&D and Operations, Janssen Diagnostics, Janssen Pharmaceutical Companies of Johnson & Johnson
Donna L. Mendrick, Ph.D., Director, Systems Biology, NCTR, FDA
Christopher-Paul Milne, DVM, MPH, J.D., Assistant Research Professor, Director, Research, Center for the Study of Drug Development, Tufts University Medical School
Nirmala Nanguneri, Ph.D., Director and Head, Biomarker Analysis and Informatics, Novartis Institutes for Biomedical Research
Jonathan Pan, Director, Oncology Companion Diagnostic & Disease Strategy, GlaxoSmithKline
Saunya Pant, Ph.D., Research Fellow, Merck
Abhijit Patel, M.D., Ph.D., Assistant Professor, Therapeutic Radiology, Yale University School of Medicine
Rajesh Patel, Ph.D., Scientific Manager, Oncology Biomarker Development, Genentech
Scott D. Patterson, Ph.D., Executive Director, Medical Sciences, Amgen
Suso Piatero, Ph.D., Director, Oncology Biomarkers, Janssen Pharmaceuticals
Victor Prieto, M.D., Ph.D., Professor, Pathology and Dermatology, MD Anderson Cancer Center
Mitch Raponi, Ph.D., Senior Director, Molecular Diagnostics, Clovis Onology
Tarek Sahmoud, M.D., Ph.D., Corporate Vice President, Clinical Research and Development, Celgene Corporation
Avni Santani, Ph.D., Assistant Professor, Clinical Pathology, University of Pennsylvania School of Medicine
Andrew Schade, M.D., Ph.D., Senior Director, Diagnostics and Experimental Pathology, Tailored Therapeutics, Eli Lilly and Company
Cecilia Schott, Pharm.D., MBA, Head, Personalized Healthcare, Corporate Business Development, AstraZeneca
Andreas Schuppert, Ph.D., Vice President, Technology Development, Bayer Technology Services GmbH; Professor, AICES, RWTH Aachen University
Corinne Solier, Ph.D., Pharmaceutical Sciences Head, Extramural Research, F. Hoffmann-La Roche
Kari Stefánsson, M.D., CEO, deCODE Genetics
Douglas D. Taylor, Ph.D., CSO, Exosome Sciences
Liling Warren, Ph.D., Senior Scientific Investigator, GlaxoSmithKline
Bo Wei, MS, Associate Principal Scientist, Molecular Biomarker and Diagnostics, Merck
Russell S. Weiner, Ph.D., Executive Director and Head, Molecular Biomarkers and Diagnostics, Merck
Jens R. Wendland, M.D., Director and Head, Neuroscience Genetics, Pfizer Worldwide R&D
P. Mickey Williams, Ph.D., Director, Molecular Characterization Laboratory, Frederick National Laboratory for Cancer Research
Huiqing Wu, M.D., Assistant Professor, Pathology, City of Hope National Medical Center and Beckman Research Institute
Hang Hubert Yin, Ph.D., Associate Professor, Chemistry and Biochemistry, University of Colorado Boulder
Jenny Zhang, Ph.D., Manager, Biomarker Assay Specialist, Clinical Assay Group, Global Innovative Pharmacology
Short Courses*

**TUESDAY, APRIL 29, 6:00-9:00 PM**

(SC1) Dinner Course: Exosomes and Microvesicles as Cancer Biomarkers

*Exosomes as Non-Invasive Molecular Tools for Genomic Medicine*

Michael J. Donovan, M.D., Ph.D., Director, Experimental Pathology and Institutional Biorepository, Icahn School of Medicine at Mt. Sinai

**Talk Title to be Announced**

Saumya Pant, Ph.D., Research Fellow, Merck

**Development of Exosomal Biomarkers for Clinical Management**

Douglas D. Taylor, Ph.D., CSO, Exosome Sciences

**Developing Non-Invasive Cancer Biomarkers that Detect Exosomes and Microvesicles**

Hang Hubert Yin, Ph.D., Associate Professor, Chemistry and Biochemistry, University of Colorado Boulder

**WEDNESDAY, APRIL 30, 6:00-9:00 PM**

(SC2) Dinner Course: Fit-for-Purpose Biomarker Assay Development and Validation

*Instructors:

John L. Allinson, FIBMS, Head, Biomarker Strategy, Drug Development Services, LGC Group

Viswanath Devanarayan, Ph.D., Global Head, Exploratory Statistics, AbbVie, Inc.

This tutorial will provide recommendations on the “fit-for-purpose” best practices in the development and validation of biomarker assays for exploratory or advanced biomarker applications. Strategies for different applications at various phases of biomarker development will be described. Key elements in the method of development and validation will be illustrated with examples, including reference to standard material, sample stability and collection integrity, validation and QC samples, validity of reference standards, calibration curve fitting methods, method optimization and feasibility studies. Special challenges in protein biomarker assays will be discussed, including strategies for moving from biomarker panels in the exploratory phase to the few markers chosen to support clinical trials, cross-validation of biomarker assays, etc.

**Outline:**

1. Introduction: Nomenclature, types of biomarker methods/assays, method development and validation road-map, fundamental validity, similarity and differences from PK assays and diagnostic applications
2. Preanalytical and bioanalytical elements: Target range, standards, validation and QC samples, stability, matrix effect, specificity and relative selectivity
3. Calibration curve model selection, evaluation and weighting
4. Method feasibility and optimization with precision profiles
5. Evaluation of some pre-study validation characteristics such as precision, bias, sensitivity and quantification limits
6. Use of sample controls for in-study performance monitoring and conformance testing among laboratories
7. Special considerations for multiplex assays, cross-validation of assays, etc.
8. Method comparisons

**WEDNESDAY, APRIL 30, 6:00-9:00 PM**

(SC3) Dinner Course: Non-Coding RNAs as Biomarkers and Diagnostics

*Non-Coding RNA and DNA Utility as Biomarkers in Tissue and Blood*

Laurent Lessard, Ph.D., Assistant Professor, Molecular Oncology, John Wayne Cancer Institute

**Roles and Mechanisms of microRNA Suppression in Cancer Development and Drug Resistance**

Bing-Hua Jiang, Ph.D., Professor, Pathology, Anatomy and Cell Biology, Thomas Jefferson University

**MicroRNA Complexity in the Extracellular Fluid and Cerebrospinal Fluid of Alzheimer’s Disease and Related Neurodegenerative Disorders**

Walter Lukiy, Ph.D., Professor, Neuroscience, Louisiana State University

**Development and Validation of miRNA Signature to Predict Clear Cell Renal Cell Carcinoma Metastasis and Prognosis**

Huiqing Wu, M.D., Assistant Professor, Pathology, City of Hope National Medical Center and Beckman Research Institute

**THURSDAY, MAY 1, 6:00-9:00 PM**

(SC4) Dinner Course: Next-Generation Sequencing as a Clinical Test

*Instructors:

Seth Crosby, M.D., Director, Partnerships & Alliances, Washington University School of Medicine

Avni Santani, Ph.D., Assistant Professor, Clinical Pathology, University of Pennsylvania School of Medicine

Next-Generation Sequencing (NGS) is used widely in clinical research for the discovery of disease-associated genes and the clinical community is beginning to embrace this technology for diagnostic testing. The rapid evolution of NGS technologies presents significant opportunities and challenges for researchers and clinicians for improving health outcomes, particularly with respect to an increased emphasis on personalized and preventive medicine. Adoption of NGS in the clinical laboratory setting requires the adoption of many processes and procedures, such as the analytic and clinical validation of the test, CLIA certification/CAP accreditation, standards for reference materials, availability for proficiency testing, and questions regarding reimbursement and informed consent. The success of NGS as a viable diagnostic modality depends on many branches of the health care community working together. This session will be informative and practical for the researcher and laboratorians who are considering launching NGS as a clinical test.

*Separate registration required*
**Track 1: Translational Biomarkers in Drug Development**

**TUESDAY, APRIL 29**

5:00-6:00 pm Conference Pre-Registration

6:00-9:00 Dinner Course®

**Exosomes and Microvesicles as Cancer Biomarkers**

(*Separate registration required)

**WEDNESDAY, APRIL 30**

7:30-8:30 am Conference Registration and Morning Coffee

8:30-8:40 Welcome Remarks from Conference Director

Julia Boguslavsky, Executive Director, Conferences, Cambridge Healthtech Institute

8:40-8:45 Chairperson’s Opening Remarks

Michael Burczynski, Ph.D., Executive Director, Biomarker Technologies, Discovery Medicine and Clinical Pharmacology, Bristol-Myers Squibb

8:45-9:10 Transforming a Research Assay to a Companion Diagnostic

Ron Mazumder, Ph.D., MBA, Global Head, R&D and Operations, Janssen Diagnostics, Janssen Pharmaceutical Companies of Johnson & Johnson

Developing a predictive biomarker on a diagnostic platform often involves converting an assay which uses research-grade reagents and a research platform onto a diagnostic instrument which can be commercialized globally with GMP-manufactured and validated reagents. Furthermore, design verification under Quality Systems Regulations, clinical validation and clinical reproducibility must be completed during the drug development process. I will highlight considerations from case studies to explore each of these topics.

9:10-9:35 Tracking Value Creation across Diverse Biomarker Studies and Platforms in Pharmaceutical Development

Michael Burczynski, Ph.D., Executive Director, Biomarker Technologies, Discovery Medicine and Clinical Pharmacology, Bristol-Myers Squibb

An ever-growing list of biomarkers (and diagnostic assays) is frequently analyzed across many stages of drug development. One of the more vexing challenges facing pharmaceutical companies today is determining how to ensure that biomarkers are both judiciously implemented, yet also maximally utilized, to answer questions in translational research. For various reasons (cost, limited resources, shortened cycle times) it is no longer possible or acceptable to simply run multiple biomarker assays in clinical studies for exploratory purposes or to inform future therapeutic strategies. Biomarker assays (irrespective of platform) need to answer the treatment of patients suffering from diseases for which individualized targeted therapy is available. The FDA has approved 19 laboratory tests (as of December 2013) to aid in this improved treatment of patients. Yet, their impact on public health could depend on how personal they have to get. Also, laboratory-developed tests may provide a greater benefit in some circumstances. In this talk I will compare and contrast these and other relevant issues.

9:35-10:00 Successful Implementation of Global Biomarker Strategies Requires Laser Focus on Preanalytical Processes

*Marisa Dolled-Filhart, Ph.D., Associate Director, Pathology and Companion Diagnostics, Merck*

Generation of quality biomarker data begins with the development of an accurate and precise method. However, this is simply not sufficient. Studies show that the activities preceding sample analysis, the preanalytical activities, are as important, if not more important than method performance. Many reports cite significant assay variability being attributed to what happens prior to the sample arriving at the bioanalytical lab. Paying close attention to how the sample is collected, processed and shipped will ultimately determine your success.

10:00-10:30 Networking Coffee Break

10:30-10:55 Talk Title to be Announced

Andrew Schade, M.D., Ph.D., Senior Director, Diagnostics and Experimental Pathology, Tailored Therapeutics, Eli Lilly and Company

10:55-11:20 Companion Diagnostics: How Personal Does It Have to Get?

Daniel Edelman, Ph.D., Core Manager, Clinical Molecular Profiling Core, National Cancer Institute, NIH

Companion diagnostics are becoming an important and critical tool for clinicians in the treatment of patients suffering from diseases for which individualized targeted therapy is available. The FDA has approved 19 laboratory tests (as of December 2013) to aid in this improved treatment of patients. Yet, their impact on public health could depend on how personal they have to get. Also, laboratory-developed tests may provide a greater benefit in some circumstances. In this talk I will compare and contrast these and other relevant issues.

11:20-11:50 BioMarker Development from Discovery to the Clinic

Jeremy Bridge-Cook, Senior Vice President, Research and Development, Luminex Corporation

The development of biomarkers from discovery to clinical implementation as a Companion Diagnostics is a process which is inherently unpredictable; no two development pathways are alike. Given this unpredictability, it is desirable to develop biomarkers using a platform which provides flexibility, but which also reduces complexity as much as possible. The xMAP® platform has been used extensively at all stages of biomarker development. The speaker will highlight some examples of discovery, validation and clinical implementation of biomarkers on xMAP®.

11:50-12:15 pm CyPlex: A Transformational Immunoassay Technology

*Sponsored by CyVek Inc.*

Rajiv Pande, Ph.D., Vice President, Scientific Affairs, CyVek Inc.

CyPlex Systems is a novel quantitative immunoassay platform that integrates a disposable microfluidic cartridge with a fully automated desktop analyzer. Multiple samples can be loaded onto a single CyPlex cartridge, and multiple analytes per sample can be quantified simultaneously, within an hour. CyPlex cartridges combine a unique solid phase approach (glass nanoreactors) with microfluidics to provide high quality multi-analyte results without the typical multiplexing compromises. CyPlex assays show excellent robustness and are extremely easy to perform.
Inconsistencies between biomarker studies can be attributed to variability between assay kit lots. Even CE-marked kits may lack reproducibility because the CE mark is self-regulated. With the use of well-characterized, purified reagents and highly optimized assays, MSD’s V-PLEX™ product portfolio demonstrates consistent and robust immunoassays. MSD has developed a 30-plex human biomarker assay that is analytically validated and shows excellent lot-to-lot reproducibility and superior sensitivity, precision, and accuracy. Biomarkers in Translational Medicine

1:25-1:30 Chairperson’s Opening Remarks
Suso Platero, Ph.D., Director, Oncology Biomarkers, Janssen Pharmaceuticals

1:30-1:55 Biomarkers in Translational Medicine: From Bench to the Clinic and Back
Suso Platero, Ph.D., Director, Oncology Biomarkers, Janssen Pharmaceuticals

Translational medicine could be defined as the application of biomarkers from preclinical models to clinical trials. But also, once we start dosing patients, the generation of hypothesis using clinical samples is a key feature of translational medicine for our understanding of the interaction of the drug with the specific disease. By looking at patients’ samples and correlating their status to drug responses we can identify biomarkers that are important for mechanism of action of the drug and sensitivity of the patient’s disease to the drug. Uniting both approaches will yield better biomarkers that can later on be used in subsequent phases of drug development.

1:55-2:20 Translation of Emerging Biomarkers from Preclinical Species to Human Populations
Jiri Aubrecht, Pharm.D., Ph.D., Senior Director and Safety Biomarker Group Lead, Drug Safety Research & Development, Pfizer

Biomarkers provide essential tools for refining of therapeutic index in drug development, monitoring disease progression and/or examining effects of environmental exposure to chemicals. Despite the success of routine markers used in preclinical and clinical settings a new cohort of safety biomarkers with better sensitivity and specificity is being evaluated. This includes tissue-specific proteins, metabolites and/or circulating miRNAs. Since drug development relies on preclinical evaluation of lead compounds, the biomarker translation across animal species to humans is essential. To study the performance of emerging biomarkers we employ a variety of approaches including animal models and clinical studies. The presentation will introduce recent progress in applying state-of-the-art technologies such as next-generation sequencing in biomarker development as well as several case studies documenting advances in cross species translation for biomarkers of hepatotoxicity and nephrotoxicity.

2:20-2:45 Translational Biomarkers: Need, Progress and Challenges
Donna L. Mendrick, Ph.D., Director, Systems Biology, NCTR, FDA

Biomarkers used in animal testing and in the clinic to identify adverse drug events are inadequate to identify population-based safety risks and individual susceptibilities. System biological approaches offer new discovery modalities to improve the identification and mechanistic understanding of new biomarkers. Published literature is filled with reports of potentially novel and useful biomarkers; however, academic labs do not receive funding to work toward regulatory qualification of such biomarkers so they tend to remain the subject of single publications. To effect change, new biomarkers need to be accepted by the community at large.

2:45-3:45 Refreshment Break in the Exhibit Hall with Poster Viewing

Technology Showcase: Biomarkers in Drug Development

3:45-4:15 Molecular Characterization of Circulating Tumor Cells: Opportunities and Challenges
Denis Smirnov, Ph.D., Associate Scientific Director, US Biomarker Oncology, Janssen R&D US

Molecular characterization of circulating tumor cells (CTCa) offers a unique opportunity to dynamically monitor metastatic process so optimal therapy regimens can be developed and applied in clinic. Potential and challenges of molecular characterization of CTCs will be discussed.

4:15-4:30 A Simple Blood Test to Assess Insulin Resistance (IR) in Clinical Trials: Quantose IR™
Nelson Rhodes, Ph.D., Associate Study Director, Metabolon, Inc.

Identify insulin resistance status and track improvements of subjects in any clinical trial populations. The new, clinically-validated Quantose IR™ blood test is an opportunity to dynamically monitor metabolic process so optimal therapy regimens can be developed and applied in clinic. The new, clinically-validated Quantose IR™ blood test is an accurate and effective tool for determining drug treatment effects in CV/MD/other trial populations.

4:30-5:00 Validation of Patient Selection Biomarkers using Patient Derived Xenograft (PDX) Models in Preclinical Trials of Oncology Therapeutics
Thomas B. Broudy, Ph.D., CSO, Molecular Response LLC

We have established a broad platform of genomically-defined patient derived xenograft (PDX) models enabling preclinical trials to validate patient selection biomarkers in targeted cancer populations. We will share how these clinically relevant models have been used to identify and validate KIT and RAS selection markers for targeted oncology therapeutics. By approximating clinical trials in the preclinical setting, we help our partners establish more confident clinical development strategies—responsive populations, effective combinations, predictive tests, and resistance strategies.

5:00-6:00 Welcome Reception in the Exhibit Hall with Poster Viewing

6:00-9:00 Dinner Courses*
• Fit-for-Purpose Biomarker Assay Development and Validation
• Non-Coding RNAs as Biomarkers and Diagnostics
(*Separate registration required)
“Big Data” and Biomarker Development

8:25-8:30 Chairperson’s Opening Remarks
Nicholas C. Dracopoli, Ph.D., Vice President, Janssen R&D, Johnson & Johnson

8:30-8:55 Big Data and Small Trials: Translating Biological Data into Clinical Biomarkers
Nicholas C. Dracopoli, Ph.D., Vice President, Janssen R&D, Johnson & Johnson

All of the companion diagnostic tests approved by the FDA for use in oncology are for “driver mutations” in genes involved in signal transduction pathways. These tests are for single analytes predicting the functional status of the drug target or pathway. There are no approved companion diagnostics for drugs that work through alternative mechanisms such as chemotherapy or immunomodulation. This presentation will discuss why so few biomarkers have been developed, and why we have mostly failed to develop molecular profiles that predict drug response.

8:55-9:20 Talk Title to be Announced
Emmanuelle Di Tomaso, Ph.D., Global Correlative Science Lead, Novartis Institutes for BioMedical Research

9:20-9:45 Clinical Trial Biomarkers in a World of Big Data and Predictive Analytics
Michael Hale, Ph.D., Executive Director, Medical Sciences Biostatistics, Amgen

9:45-10:45 Coffee Break in the Exhibit Hall with Poster Viewing

10:45-11:00 IBM Watson and the Valley of Death
Mark S. Boguski, M.D., Ph.D., Associate Professor, Pathology, Center for Biomedical Informatics, Harvard Medical School

There is a large and widening gap created by our ability to generate data much faster than we can ever ascribe meaning to it via traditional approaches. This gap has been evident in biomedicine since the late 1990s and has now become a “Valley of Death” in the application of new technologies for biomarker discovery and clinical diagnostics. These technologies produce more data than we can ever hope to interpret by consulting the literature, for two reasons. First, there is no literature pertaining to most of the findings and perhaps never will be because the traditional model for follow-up and validation does not scale. Second, even when literature is available, much of it may represent non-reproducible results. For example, it has been estimated that the majority of “breakthrough” research in oncology, women’s health and cardiovascular disease cannot be replicated or confirmed. Systems like IBM Watson that heavily leverage a literature corpus to find connections and make inferences suffer from obvious limitations in this context. There is a way out of the Valley of Death but it will require both researchers and technology developers to approach the problem differently.

11:10-11:35 pm Big Data and Reliability of Biomarker Identification
Andreas Schuppert, Ph.D., Vice President, Technology Development, Bayer Technology Services GmbH; Professor, AICES, RWTH Aachen University

“Big Data” offers great promise both to industry and clinics. Systematic analysis of very large, multivariate data sets is expected to be a powerful technology to improve the overall efficiency in the pharma pipeline as well as to enable the expected benefits of personalized medicine. However, the reality suffers from an apparent lack of reproducibility of the data resulting in a lack of reliability in the biomarkers for complex diseases. We demonstrate on a heterogeneous set of gene expression data from cancer studies that a systematic utilization of the intrinsic correlations in highly multivariate data can be used to extract scores enabling the quantitative characterization of tumor status with a high degree of stability.

11:35-12:00 Talk Title to be Announced
Iya Khalil, Ph.D., Executive Vice President and Co-Founder, GNS Healthcare

12:00-12:30 Panel Discussion
Moderator: Nicholas C. Dracopoli, Ph.D., Vice President, Janssen R&D, Johnson & Johnson

12:30-1:00 Luncheon Presentation: An Acoustic Assay Platform for Developing and Perfoming Biomarker Analysis
Sponsored by
Martin Latterich, CSO, BioScale, Inc.

Biomarkers play a pivotal role in translational research. BioScale has developed an Acoustic Assay technology that enables the user to rapidly and cost-effectively develop novel, reproducible biomarker assays for both circulating biomarkers and intracellular markers. Acoustic assays enable exceptional precision, consume <10% Ab vs ELISA and are hands-free – allowing a sensitive automated immunoassay.

We showcase several collaborative studies from key opinion leaders in the cancer community that demonstrate the benefits of Acoustic Assays.

1:00-1:15 panel discussion

THURSDAY, MAY 1
The present talk will focus on these principles and describe a general approach to 1) studies generated sufficient value to the program or therapeutic area in question.

Biomarker assays (irrespective of platform) need to answer extremely well defined questions in drug development, and should employ associated metrics that can be objectively evaluated after study conclusion to determine whether the biomarker generates sufficient value to the program or therapeutic area in question. The present talk will focus on these principles and describe a general approach to 1) defining the potential value of biomarker assays prior to clinical study execution; 2) tracking biomarker assays and programs in clinical trials at a large pharma company via a specifically designed database strategy; and 3) objectively assessing the impact of biomarker assays following clinical study conclusion.

Translation from Biomarker Assay to Companion Diagnostic

8:40-8:45 Chairperson’s Opening Remarks
Michael Burczynski, Ph.D., Executive Director, Biomarker Technologies, Discovery Medicine and Clinical Pharmacology, Bristol-Myers Squibb

8:45-9:10 Transforming a Research Assay to a Companion Diagnostic
Ron Mazumder, Ph.D., MBA, Global Head, R&D and Operations, Janssen Diagnostics, Janssen Pharmaceutical Companies of Johnson & Johnson

Developing a predictive biomarker on a diagnostic platform often involves converting an assay which uses research-grade reagents and a research platform onto a diagnostic instrument which can be commercialized globally with GMP-manufactured and validated reagents. Furthermore, design verification under Quality Systems Regulations, clinical validation and clinical reproducibility must be completed during the drug development process. I will highlight considerations from case studies to explore each of these topics.

9:10-9:35 Tracking Value Creation across Diverse Biomarker Studies and Platforms in Pharmaceutical Development
Michael Burczynski, Ph.D., Executive Director, Biomarker Technologies, Discovery Medicine and Clinical Pharmacology, Bristol-Myers Squibb

An ever-growing list of biomarkers (and diagnostic assays) is frequently analyzed across many stages of drug development. One of the more vexing challenges facing pharmaceutical companies today is determining how to ensure that biomarkers are both judiciously implemented, yet also maximally utilized, to answer questions in translational research. For various reasons (cost, limited resources, shortened cycle times) it is no longer possible or acceptable to simply run multiple biomarker assays in clinical studies for exploratory purposes or to inform future therapeutic strategies. Biomarker assays (irrespective of platform) need to answer extremely well defined questions in drug development, and should employ associated metrics that can be objectively evaluated after study conclusion to determine whether the biomarker studies generated sufficient value to the program or therapeutic area in question. The present talk will focus on these principles and describe a general approach to 1) defining the potential value of biomarker assays prior to clinical study execution; 2) tracking biomarker assays and programs in clinical trials at a large pharma company via a specifically designed database strategy; and 3) objectively assessing the impact of biomarker assays following clinical study conclusion.

11:20-11:50 BioMarker Development from Discovery to the Clinic
Jeremy Bridge-Cook, Senior Vice President, Research and Development, Luminex Corporation

The development of biomarkers from discovery to clinical implementation as a Companion Diagnostics is a process which is inherently unpredictable; no two development pathways are alike. Given this unpredictability, it is desirable to develop biomarkers using a platform which provides flexibility, but which also reduces complexity as much as possible. The xMAP® platform has been used extensively at all stages of biomarker development. The speaker will highlight some examples of discovery, validation and clinical implementation of biomarkers on xMAP®.

11:50-12:15 pm CyPlex: A Transformational Immunoassay Technology
Rajiv Pande, Ph.D., Vice President, Scientific Affairs, CyVek Inc.

CyPlex Systems is a novel quantitative immunoassay platform that integrates a disposable microfluidic cartridge with a fully automated desktop analyzer. Multiple samples can be loaded onto a single CyPlex cartridge, and multiple analytes per sample can be quantified simultaneously, within an hour. CyPlex cartridges combine a unique solid phase approach (glass nanoreactors) with microfluidics to provide high quality multi-analyte results without the typical multiplexing compromises. CyPlex assays show excellent robustness and are extremely easy to perform.
Track 2: Clinical Biomarker Assay Development

12:15-12:50 Luncheon Presentation

Validated Multiplexed Cytokine Assays: A New Standard for Immunoassays
Pankaj Oberoi, Ph.D., Vice President, Commercial Assays, Meso Scale Discovery

Inconsistencies between biomarker studies can be attributed to variability between assay kit lots. Even CE-marked kits may lack reproducibility because the CE mark is self-regulated. With the use of well-characterized, purified reagents and highly optimized assays, MSD’s V-PLEX™ product portfolio demonstrates consistent and robust immunoassays. MSD has developed a 30-plex human biomarker assay that is analytically validated and shows excellent lot-to-lot reproducibility and superior sensitivity, precision, and accuracy.

Protein Biomarker Assay Development

1:25-1:30 Chairperson’s Opening Remarks
Corinne Soiler, Ph.D., Vice Director, Pharmaceutical Sciences Head of Extramural Research, F. Hoffmann-La Roche

1:30-1:55 The Dawn of a New Era for Lung Cancer Early Detection: CT Screening in Combination with Molecular Diagnostics
Pierie Fioriano, Ph.D., Scientific Manager, McCombs Institute for the Early Detection and Treatment of Cancer, MD Anderson Cancer Center

Findings from the National Lung Cancer Screening Trial have confirmed the benefits of CT screening for lung cancer detection. Moreover, numerous studies have reported biomarker sets that have utility for lung cancer early detection. It has become timely to launch a trial to determine the merits of combining CT-based screening with biomarkers for improved performance compared to CT alone and eventually determine the need for CT based on initial biomarker-based screening.

1:55-2:20 Antibody-Based Proteomics and Biomarker Research: Current Status and Limitations
Corinne Soiler, Ph.D., Vice Director, Pharmaceutical Sciences Head of Extramural Research, F. Hoffmann-La Roche

Antibody-based proteomics plays a very important role in biomarker discovery and validation. Mass spectrometry is a method of choice for hypothesis-free, high-throughput evaluation of candidate markers; however, antibody-based technologies remain the main solution to achieve optimal sensitivity in complex samples. This presentation will review the benefits and limitations of antibody-based proteomics in biomarker research for discovery and validation in body fluids and tissue. The combination of antibodies and mass spectrometry utilizing the best of both worlds opens new avenues in biomarker research.

2:20-2:45 Clinical Biomarker Method Development and Fit-for-Purpose Validation in Support of Biotherapeutics Drug Development: Challenges, Learning and Opportunities
Jenny Zhang, Ph.D., Manager, Biomarker Assay Specialist, Clinical Assay Group, Global Innovative Pharmacology

For a clinical study to support biotherapeutics drug development, it is important to apply a bioanalytical method that is capable of generating precise and accurate biomarker PD data for critical decision making, PK/PD modeling, and dose selection. When multiple platforms (such as ELISA and LC/MS/MS assays) are available, a suitable bioanalytical method must be identified. The presentation will focus on the strategy of method selection, fit-for-purpose method validation, and data impact on the clinical trials. Three unique case studies will be discussed.

2:45-3:45 Refreshment Break in the Exhibit Hall with Poster Viewing

Technology Showcase: Molecular Diagnostics

3:45-4:15 Proteomics-Assisted Discovery of a Host Response Plasma Biomarker Panel to Accurately Diagnose Persistent Coughers with Active TB Disease
Rushdy Ahmad, Ph.D., Research Scientist, The Broad Institute of Harvard and MIT

A simple to use, robust and accurate blood-based rapid diagnostic test is needed for tuberculosis control and prevention. Each year approximately 9 million people are infected with TB. The lack of a rapid TB diagnostic test contributes to nearly 1.5 million deaths every year. TB is one of the top killers of women worldwide, resulting in half a million deaths annually. At the Broad Institute of MIT and Harvard, the Proteomics group has utilized high quality plasma samples from TB and control patients in conjunction with Myriad-RBM's Human Inflammation MAP to develop a specific and sensitive host response biomarker panel to diagnose adult persistent coughers with active TB disease. We will present results from this 5-year long prospective study and chart next steps to translate these promising results into a field deployable rapid TB diagnostic test. Such a test has the potential to be a game changer, saving many hundreds of thousands of lives every year.

4:15-4:45 Assay and Kit Lot Bridging Considerations for Single and Multiplex Biomarker Analysis in Support of Clinical Studies
Afshin Safavi, Ph.D., Founder and CSO, BioAgilytix Labs

Biomarker analysis has become a common practice by many pharmaceutical companies to help PK/PD modeling. The reliability of outcomes is heavily influenced by the quality of the reagents. One of the challenges that bioanalytical labs face when running biomarker studies is the control of lot-to-lot variability of critical reagents and commercial immunoassay kits. Case studies will be presented to highlight the key bioanalytical considerations involved in running successful biomarker analyses in support of clinical studies.

4:45-5:00 Quantitative Low-Abundance Biomarker Measurement and Its Impact on Disease Management
Joe Barco, Ph.D., Senior Product Manager, Life Sciences, Singulex, Inc.

Several considerations must be taken into account to establish a clinical biomarker, including the ability to measure normal states. Singulex's proprietary single molecule counting technology helps overcome challenges in biomarker translation from discovery to clinic. This presentation reviews applications of quantitative and sensitive detection technology in ‘real life’ applications.

5:00-6:00 Welcome Reception in the Exhibit Hall with Poster Viewing

6:00-9:00 Dinner Courses*
• Fit-for-Purpose Biomarker Assay Development and Validation
• Non-Coding RNAs as Biomarkers and Diagnostics
(*Separate registration required)
**Track 2: Clinical Biomarker Assay Development**

**THURSDAY, MAY 1**

7:30-8:15 am **Breakfast Presentation** (Sponsorship Opportunity Available) or Morning Coffee

**NGS Assays in the Clinic**

8:25-8:30 **Chairperson's Opening Remarks**

Seth Crosby, M.D., Director, Partnerships & Alliances, Washington University School of Medicine

8:30-8:55 **Does NGS Make Sense for Prospective Trials?**

Seth Crosby, M.D., Director, Partnerships & Alliances, Washington University School of Medicine

NGS data that informs patient stratification decisions must be generated in a clinically certified lab. The challenges and expense of validating and reporting a clinical NGS panel are quite distinct from that of translational research. What is involved in this process? With the falling prices and changing regulatory environment of NGS, has the time come to pre-profile prospective trial participants? If so, should NGS be done internally or should you outsource?

8:55-9:20 **Developing a Next-Generation Sequencing Test for Lung Cancer Mutations**

Derek Chiang, Ph.D., Research Investigator, Novartis Institutes for Biomedical Research

9:20-9:50 **Next-Generation Cancer Diagnostics at Illumina**

Sponsored by Illumina

Frank S. Ong, M.D., Associate Director, Medical Affairs, Illumina, Inc.

Illumina provides a comprehensive line of products that address the scale and breadth of functional analysis required to achieve the goals of molecular medicine. From biomarker discovery to the development of MDx assays, our offering includes leading-edge solutions for NGS, genotyping, CNVs, GEx profiling, and DNA methylation. In this session we will provide an update on our clinical oncology strategy and discuss the work we are doing to position ourselves as a leading partner for the development of next-gen cancer diagnostics.

9:50-10:45 **Coffee Break in the Exhibit Hall with Poster Viewing**

10:45-11:10 **Practical Applications of NGS-Based Assays in a Clinical Molecular Oncology Laboratory**

Helen Fernandes, Ph.D., Associate Professor, Pathology and Laboratory Medicine, Weill Cornell Medical College

The utility of targeted next-generation sequencing-based assays for identification of genomic variants continues to revolutionize the field of molecular diagnostics. Several organizations are working on new guidelines to standardize indications for testing and reporting of NGS-based assays. This presentation will focus on validation of analytic performance characteristics of assays for the identification of mutations and genomic variants in solid tumors. The issues involved for optimal performance, implementation in a routine clinical laboratory and reporting of results will be discussed.

11:10-11:35 **A High-Throughput Microfluidics-Based Mutation and Copy Number Variation (CNV) Detection Panel for Analysis of Clinical Samples**

Rajesh Patel, Ph.D., Scientific Manager, Oncology Biomarker Development, Genentech

Molecular profiling of tumor DNA has taken center stage for determining treatment options for patients and for enrolling patients in clinical trials for testing targeted therapies. Detecting somatic mutations in targeted genes – for example, BRAF in melanoma, EGFR for lung cancer and KRAS for colorectal cancer – has become an integral part of personalized medicine. We have developed a high-throughput microfluidics-based mutation detection (MUT/MAP) panel for detecting over 120 hotspots across 13 genes using 2-100 ng of extracted DNA from fresh frozen and formalin-fixed paraffin-embedded tissue samples. Additionally, the same chip integrates CNV analysis of 24 genes.

11:35-12:00 pm **Next-Generation Sequencing of Hematologic Malignancies in the CLIA Environment**

Rajyalakshmi Luthra, Ph.D., Professor, Hematopathology; Director, Molecular Genetic Pathology Fellowship Program; Director, Molecular Diagnostic Laboratory, MD Anderson Cancer Center

Clinical NGS-based testing for simultaneous detection of somatic mutations in multiple genes provides insights into prognosis and therapeutic choices for clinical management of patients with leukemia. However, the constantly changing NGS landscape presents challenges in terms of clinical validation and implementation. This presentation will discuss clinical validation, data processing, interpretation and reporting of NGS-based targeted sequencing in the CLIA environment.

12:00-12:25 **Circulating Tumor DNA as a Biomarker of Response and Resistance to Treatment**

Abhijit Patel, M.D., Ph.D., Assistant Professor, Therapeutic Radiology, Yale University School of Medicine

Our group has developed an ultrasensitive, multi-target assay that can identify and quantify mutant ctDNA using error-suppressed next-generation sequencing. Broad coverage of mutation hotspots and warm-spots allows detection of ctDNA without prior knowledge of the tumor’s mutation profile. Clinical examples will be presented in which this approach is used to non-invasively monitor changes in ctDNA levels in response to treatment and to track the emergence of mutations that confer resistance to targeted therapies.

12:25-1:55 **Enjoy Lunch on Your Own**
Translation from Biomarker Assay to Companion Diagnostic

Michael Burczynski, Ph.D., Executive Director, Biomarker Technologies, Discovery Medicine and Clinical Pharmacology, Bristol-Myers Squibb

An ever-growing list of biomarkers (and diagnostic assays) is frequently analyzed across many stages of drug development. One of the more vexing challenges facing pharmaceutical companies today is determining how to ensure that biomarkers are both judiciously implemented, yet also maximally utilized, to answer questions in translational research. For various reasons (cost, limited resources, shortened cycle times) it is no longer possible or acceptable to simply run multiple biomarker assays in clinical studies for exploratory purposes or to inform future therapeutic strategies. Biomarker assays (irrespective of platform) need to answer complex questions in drug development, and should employ associated metrics that can be objectively evaluated after study conclusion to determine whether the biomarker studies generated sufficient value to the program or therapeutic area in question. The present talk will focus on these principles and describe a general approach to 1) defining the potential value of biomarker assays prior to clinical study execution; 2) tracking biomarker assays and programs in clinical trials at a large pharma company via a specifically designed database strategy; and 3) objectively assessing the impact of biomarker assays following clinical study conclusion.

Generation of quality biomarker data begins with the development of an accurate and precise method. However, this is simply not sufficient. Studies show that the activities preceding sample analysis, the preanalytical activities, are as important, if not more important than method performance. Many reports cite significant assay variability being attributed to what happens prior to the sample arriving at the bioanalytical lab. Paying close attention to how the sample is collected, processed and shipped will ultimately determine your success.

10:00-10:30 Networking Coffee Break

10:30-10:55 Talk Title to be Announced
Andrew Schade, M.D., Ph.D., Senior Director, Diagnostics and Experimental Pathology, Tailored Therapeutics, Eli Lilly and Company

10:55-11:20 Companion Diagnostics: How Personal Does It Have to Get?
Daniel Edelman, Ph.D., Facility Head, Clinical Molecular Profiling Core, National Cancer Institute, NIH

Companion diagnostics are becoming an important and critical tool for clinicians in the treatment of patients suffering from diseases for which individualized targeted therapy is available. The FDA has approved 19 laboratory tests (as of December 2013) to aid in this improved treatment of patients. Yet, their impact on public health could depend on how personal they have to get. Also, laboratory-developed tests may provide a greater benefit in some circumstances. In this talk I will compare and contrast these and other relevant issues.

11:20-11:50 BioMarker Development from Discovery to the Clinic
Jeremy Bridge-Cook, Senior Vice President, Research and Development, Luminex Corporation

The development of biomarkers from discovery to clinical implementation as a Companion Diagnostics is a process which is inherently unpredictable; no two development pathways are alike. Given this unpredictability, it is desirable to develop biomarkers using a platform which provides flexibility, but which also reduces complexity as much as possible. The xMAP® platform has been used extensively at all stages of biomarker development. The speaker will highlight some examples of discovery, validation and clinical implementation of biomarkers on xMAP®.

11:50-12:15 pm CyPlex: A Transformational Immunoassay Technology
Rajiv Pande, Ph.D., Vice President, Scientific Affairs, CyVek Inc.

CyPlex Systems is a novel quantitative immunoassay platform that integrates a disposable microfluidic cartridge with a fully automated desktop analyzer. Multiple samples can be loaded onto a single CyPlex cartridge, and multiple analytes per sample can be quantified simultaneously, within an hour. CyPlex cartridges combine a unique solid phase approach (glass nanoreactors) with microfluidics to provide high quality multi-analyte results without the typical multiplexing compromises. CyPlex assays show excellent robustness and are extremely easy to perform.
Commercialization Strategies for Companion Diagnostics

1:25-1:30 Chairperson’s Opening Remarks
Cecilia Schott, Pharm.D., MBA, Head, Personalized Healthcare, Corporate Business Development, AstraZeneca

1:30-1:55 Commercializing Companion Diagnostics: The Long Road Ahead
Jeffrey Emch, Director, Global Diagnostics Marketing, Immunotherapeutics, GlaxoSmithKline
Commercialization of a companion diagnostic is an oxymoron with a business model that does not easily meld with the pharmaceutical business model. In this case, many sales channels and established processes available to a pharmaceutical company are not there in the commercialization of a diagnostic. Hence, be prepared to pay for some or all of the efforts to promote access to the test. In this talk, we will discuss some of the key considerations in defining the commercialization path.

1:55-2:20 Talk Title to be Announced
Cecilia Schott, Pharm.D., MBA, Head, Personalized Healthcare, Corporate Business Development, AstraZeneca

2:20-2:45 Companion versus Complementary Diagnostics: Economic, Regulatory, and Strategic Considerations
Christopher-Paul Milne, DVM, MPH, JD, Assistant Research Professor, Director, Research, Center for the Study of Drug Development, Tufts University Medical School
Companion diagnostics, as defined by FDA, are devices that provide information for the safe and effective use of a corresponding therapeutic product, typically linked to a specific drug within its approved labeling. Complementary diagnostics are tests that can improve disease management, early diagnosis, patient risk stratification, and drug monitoring related to associated therapeutics. These tests are not intended to be used in conjunction with specific drugs and are not regulated by the FDA. Regulatory considerations and potential economic impacts are discussed in this presentation.

2:45-3:45 Refreshment Break in the Exhibit Hall with Poster Viewing

Technology Showcase: Molecular Diagnostics

3:45-4:15 Proteomics-Assisted Discovery of a Host Response Plasma Biomarker Panel to Accurately Diagnose Persistent Coughers with Active TB Disease
Rushdy Ahmad, Ph.D., Research Scientist, The Broad Institute of Harvard and MIT
A simple to use, robust and accurate blood-based rapid diagnostic test is needed for tuberculosis control and prevention. Each year approximately 9 million people are infected with TB. The lack of a rapid TB diagnostic test contributes to nearly 1.5 million deaths every year. TB is one of the top killers of women worldwide, resulting in half a million deaths annually. At the Broad Institute of MIT and Harvard, the Proteomics group has utilized high quality plasma samples from TB and control patients in conjunction with Myriad-RBM’s Human Inflammation MAP to develop a specific and sensitive host response biomarker panel to diagnose adult persistent coughers with active TB disease. We will present results from this 5-year long prospective study and chart next steps to translate these promising results into a field deployable rapid TB diagnostic test. Such a test has the potential to be a game changer, saving many hundreds of thousands of lives every year.

4:15-4:45 Assay and Kit Lot Bridging Considerations for Single and Multiplex Biomarker Analysis in Support of Clinical Studies
Afshin Safavi, Ph.D., Founder and CSO, BioAgilytix Labs
Biomarker analysis has become a common practice by many pharmaceutical companies to help PK/PD modeling. The reliability of outcomes is heavily influenced by the quality of the reagents. One of the challenges that bioanalytical labs face when running biomarker studies is the control of lot-to-lot variability of critical reagents and commercial immunoassay kits. Case studies will be presented to highlight the key bioanalytical considerations involved in running successful biomarker analyses in support of clinical studies.

4:45-5:00 Sponsored Presentation (Opportunity available)

5:00-6:00 Welcome Reception in the Exhibit Hall with Poster Viewing

6:00-9:00 Dinner Courses*
• Fit-for-Purpose Biomarker Assay Development and Validation
• Non-Coding RNAs as Biomarkers and Diagnostics

(*Separate registration required)
THURSDAY, MAY 1

7:30-8:15 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee

Integrating Drug-Diagnostic Co-Development

8:25-8:30 Chairperson's Opening Remarks
Kenneth Emancipator, M.D., Director, Companion Diagnostics, Merck Research Labs

8:30-8:55 Clinical Development of a Drug with a Companion Diagnostic: It's Not Just about the Drug!
Kenneth Emancipator, M.D., Director, Companion Diagnostics, Merck Research Labs
When a companion diagnostic is co-developed with a therapeutic (drug or biologic), the clinical development program must support the registration requirements for both products. This presentation discusses the regulatory concepts, the key elements for planning successful clinical trials, various options for clinical trial design, and, most importantly, the common pitfalls encountered during the course of co-development programs.

8:55-9:20 Strategies for a Successful Integration of Diagnostics into Drug Development
Felix W. Frueh, Ph.D., Executive Partner, Opus Three, LLC

9:20-9:45 Regulatory Considerations for Companion Diagnostics
Eunice Lee, Ph.D., Regulatory Scientist, Office of In Vitro Diagnostics and Radiological Health, CDRH, FDA

9:45-10:45 Coffee Break in the Exhibit Hall with Poster Viewing

Regulatory and Reimbursement Strategies for Companion Diagnostics

Chairperson's Opening Remarks
Tracy Bush, Ph.D., Director, Companion Diagnostics Regulatory Affairs, Roche Diagnostics

10:45-11:10 Policy Implications of Next-Generation Sequencing
Andrew Fish, Executive Director, AdvaMedDx
The Food and Drug Administration recently issued its first clearance of a next-generation sequencing platform to validate sequencing of any part of a patient's genome. In a concurrent statement, FDA noted that the platform would allow labs to develop tests for clinical use with greater confidence. This presentation will address ongoing questions about how FDA will regulate molecular and companion diagnostics, particularly with regard to next-generation and whole genome sequencing. The presentation also will address key issues related to diagnostic reimbursement challenges.

11:10-11:35 Global Regulation of Companion Diagnostic Products: Current Status and Future Trends
Tracy Bush, Ph.D., Director, Companion Diagnostics Regulatory Affairs, Roche Diagnostics

Globally, the regulatory frameworks for CDx and targeted drugs are still being established. This presentation will provide an introduction to current companion diagnostics regulatory definitions and basic registration pathway, both in the US and globally. Submission requirements and labeling expectations will be summarized and compared, and we will learn what changes to expect as the CDx regulatory paradigm continues to evolve.

11:35-12:00 pm Legal Developments Affecting Molecular Testing
Peter M. Kazon, General Counsel, American Clinical Laboratory Association

The regulation of molecular testing continues to be increasingly complex. The FDA has not explicitly regulated molecular testing performed as laboratory-developed tests, but it has taken a variety of actions that could have an impact in that area, including the issuance of its Guidance on Research Use Only/Investigational Use Only Products. Similarly, the Medicare Program has developed new processes for dealing with molecular testing, most importantly, the MolDx Program, which is overseen by Palmetto Government Services, one of its payment contractors. Finally, the payment for this testing is also in great flux, as CMS has just completed a year-long “gap filling” exercise that resulted in new pricing for most of this testing. This program will examine these various developments and attempt to predict what other initiatives lay ahead.

12:00-12:25 A Roadmap for Companion Diagnostics – Lessons Learned from Successful FDA Submissions
Steven Gutman, M.D., Strategic Advisor, Myraqa

Over the past ten years companion diagnostics have become viewed as a critical component in drug development. It is now common practice to use molecular targeting in early phases of drug study and selection and to consider clinical testing to reduce heterogeneity in treatment effect. Although FDA guidance mandates review of companion diagnostics, to date few have received formal approval or clearance by FDA. Review information is publically available for these and provides a useful roadmap of secrets to success.

12:25 Enjoy Lunch on Your Own
THURSDAY, MAY 1

1:00-2:00 Conference Registration

Personalized Medicine at Big Pharma

1:55-2:00 Chairperson’s Opening Remarks

Jens R. Wendland, M.D., Director and Head, Neuroscience Genetics, Pfizer Worldwide R&D

2:00-3:00 Fifteen Years of Personalized Medicine: Looking Back and into the Future

Eric Lai, Ph.D., Senior Vice President and Head, Pharmacogenomics, Takeda Pharmaceuticals International

The completion of the Human Genome Project, the International HapMap Project and the development and application of new molecular technologies, especially high-throughput DNA sequencing, have provided critical knowledge for understanding human diseases and have promised to greatly improve healthcare. Despite these advances, the clinical application of personalized medicine is still limited. This presentation will discuss other potential ways of applying pharmacogenomics to drug development and the use of big research datasets to address unmet medical needs and patient stratification strategies for personalized medicine.

3:00-3:30 Challenges and Opportunities

Jens R. Wendland, M.D., Director and Head, Neuroscience Genetics, Pfizer Worldwide R&D

Many pharma clinical trials in neuroscience target subpopulations of patients based on, for example, incomplete overall response to standard of care (treatment-resistant depression) or categorical non-response of specific psychopathological phenomena (negative symptoms in schizophrenia). Biomarkers that robustly enable stratification would therefore be highly valuable, yet they remain scarce – and therefore, most efforts are focused on exploratory biomarker analyses. We will present challenges and opportunities of using state of the art human genetics for exploratory neuroscience biomarker analyses in clinical trials.

3:00-3:15 Who to Treat: A Multi-Response Approach for Subgroup Identification

Scott Marshall, Ph.D., Head, Bioanalytics, BioStat Solutions, Inc.

We have developed a novel approach for treatment-specific subgroup identification that has the ability to aggregate data across assay platforms and estimate patient-specific multi-marker molecular signatures, which then serve as a surrogate marker for membership in the unobserved underlying treatment-specific subgroup or disease subtype.

3:20-4:15 Refreshment Break in the Exhibit Hall with Poster Viewing

4:15-4:40 Making Decisions about Conducting Efficacy Pharmacogenetic Studies

Liling Warren, Ph.D., Senior Scientific Investigator, GlaxoSmithKline

Efficacy pharmacogenetic (PGx) studies conducted during clinical development have the potential to identify predictive markers that may have translational impact to aid medical development and subsequently to inform clinical decisions. When the overall trial fails to demonstrate efficacy, there is often particular interest to investigate whether PGx can identify a subset of patients who may benefit from the medicine. Through theoretical and simulation work, we quantify chances of success for efficacy PGx studies during clinical development. Our work suggests that it is generally unlikely that PGx can “rescue” a trial that fails for efficacy. When a trial demonstrates overall efficacy, opportunities for well-powered PGx efficacy studies will increase. Nevertheless, for nearly all studies there will be some range of marker frequencies and effects, however small, that are well powered even at a genome-wide scale. As the cost of genotyping continues to decline and the recognition of the potential value a predictive marker may bring to medicine development and ultimately patient outcome, a strategy to routinely screen for predictive PGx markers in clinical trials may eventually be justified.

4:40-5:05 Biomarkers and Patient Selection: The Theory and the Practice

Tarek Sahmoud, M.D., Ph.D., Corporate Vice President, Clinical Research and Development, Celgene Corporation

Development of targeted therapy in oncology is one of the most promising avenues for future therapies. Such development raises specific questions in terms of methodological and regulatory aspects associated with the validation of the target being most challenging. We will first discuss the methodology of such trials, realistic estimation of the magnitude of the expected effect, proportion of sensitive patients, selection of the appropriate patient population, choice of the primary endpoint, sample size calculations, and whether stratification is needed. We will also discuss the use of pharmacokinetics and pharmacodynamics as an integral component of development of targeted agents.

5:05-5:30 Personalized Medicine and Pharmacogenomics — Biomarker Strategies to Optimize Drug R&D

Iris Grossman, Ph.D., Global Head, Personalized Medicine and Pharmacogenomics, Global R&D, Teva Pharmaceutical Industries

Shifting away from the traditional “trial-and-error” approach to clinical practice requires a tailored approach early on in drug R&D. Teva’s Personalized Medicine and Pharmacogenetics (PMP) unit applies state-of-the-art biomarker strategies to optimize the benefit-risk profile of its drugs and ultimately drive global improvement in patient care. PMP activities span the R&D pipeline, from the discovery phase through to late-stage development and patient stratification for marketed drugs. This presentation will review PMP’s global strategy, supported by key examples.

5:30-5:55 Predictive Modeling for the Discovery of Efficacy Markers Towards Patient Selection

Nirmala Nanguneri, Ph.D., Director and Head, Biomarker Analysis and Informatics, Novartis Institutes for Biomedical Research

6:00-9:00 Dinner Courses*

• Next-Generation Sequencing as a Clinical Test
• Laboratory-Developed Tests

(*Separate registration required)
FRIDAY, MAY 2

7:30-8:15 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee

NGS and Mutation Analysis for Patient Selection

8:25-8:30 Chairperson’s Opening Remarks
Scott D. Patterson, Ph.D., Executive Director, Medical Sciences, Amgen

8:30-8:55 Exploring Tumor Somatic Mutations to Further Refine the Responding Patient Population
Scott D. Patterson, Ph.D., Executive Director, Medical Sciences, Amgen

Rigorous hypothesis testing is a key final element in demonstrating the clinical validity of a biomarker. But to get to that stage, a sufficient level of evidence has to be generated to gain the confidence of key stakeholders to test a given biomarker hypothesis. Further, as the implementation of a therapeutic is usually intended to be global in nature, considerations for global diagnostic implementation should be taken into account. Biomarkers of the EGFR pathway will be described in this context.

8:55-9:20 Talk Title to be Announced
Xiaolan Hu, Ph.D., Head, Clinical Genetics, Bristol-Myers Squibb

9:20-9:45 Utilization of Point-of-Care Genotyping Technologies to Actively Recruit into a Genotype-Stratified Three Period Crossover Experimental Medicine Trial
Charles J. Cox, Ph.D., Head, Genetics Experiment Design and Delivery, GlaxoSmithKline

9:45-10:00 Panel Discussion
Moderator: Saumya Pant, Ph.D., Research Fellow, Merck

10:00-10:50 Coffee Break in the Exhibit Hall with Poster Viewing

10:50-11:15 Molecular Diagnostics of Cancer for Precision Medicine: Strategies and Challenges for Improving Clinical Outcome
Towia Libermann, Ph.D., Associate Professor, Medicine, Beth Israel Deaconess Medical Center and Harvard Medical School; Director, BIDMC Genomics, Proteomics, Bioinformatics, and Systems Biology Center and DF/HCC Cancer Proteomics Core

Advances in NGS are unraveling cancer mutations, providing opportunities for developing precision medicine diagnostics. Growing understanding of cancer pathways combined with innovative targeted therapies enable discovery of actionable mutations in individual patients. Strategies to tailor therapy based on each patient’s genetic characteristics are postulated to change the course of cancer. While an attractive concept, tumor heterogeneity and clinical trial complexities are major challenges for improving clinical outcome. Advances and challenges in cancer diagnostics for precision medicine will be discussed.

11:15-11:40 Next-Generation Sequencing Strategies for Selecting Patients Who May Benefit from PARP Inhibitor Therapy
Mitch Raponi, Ph.D., Senior Director, Molecular Diagnostics, Clovis Oncology

The discussion will address the following questions: What biomarkers should we be focusing on to identify appropriate patients who will likely benefit from PARP inhibitors? How can we apply next-generation sequencing technologies to identify all patients who will respond to the PARP inhibitor rucaparib? What regulatory challenges are we faced with for approval of NGS companion diagnostics?

11:40-12:05 pm Talk Title to be Announced
Saumya Pant, Ph.D., Research Fellow, Merck

12:05-12:30 The Use of Targeted NGS Assays to Identify Tumor Molecular Defects and Support Treatment Selection in NCI-Sponsored Clinical Trials
Jason Lih, Ph.D., Principal Scientist, Molecular Characterization & Clinical Assay Development Laboratory, Leidos Biomedical Research, Inc., Frederick National Laboratory for Cancer Research

12:30 Close of Conference
Clinical Utility of “Actionable” Mutations

Marc Ladanyi, M.D., William Ruane Chair in Molecular Oncology; Molecular Diagnostics Service and Human Oncology & Pathogenesis Program, Memorial Sloan-Kettering Cancer Center

2:25-2:50 Mining Genomic Data on an Entire Nation
Kári Stefánsson, M.D., CEO, deCODE Genetics

4:15-4:40 Broad-Based Clinical Genotyping in Personalizing Cancer Therapy
Darrell R. Borger, Ph.D., Co-Director, Translational Research Laboratory; Director, Biomarker Laboratory, Massachusetts General Hospital and Harvard Medical School

4:40-5:05 Biomarkers in Cutaneous Melanoma
Victor Prieto, M.D., Ph.D., Professor, Pathology and Dermatology, MD Anderson Cancer Center

5:05-5:30 Genomic Approaches for Discovering and Profiling Biomarkers of Drug Response in Cancer
Michael Berger, Ph.D., Assistant Professor, Pathology, Memorial Sloan-Kettering Cancer Center

5:30-5:55 Validation of NGS Cancer Panels for Clinical Somatic Mutation Profiling — Identification of Source of Variations and Artifacts Using FFPE Tissues
Ken Chang, Ph.D., Senior Principal Scientist, Clinical Biomarkers and Diagnostics, Merck Research Labs

6:00-9:00 Dinner Courses*
• Next-Generation Sequencing as a Clinical Test
• Laboratory-Developed Tests
(*Separate registration required)
Track 5: Mutation Analysis for Clinical Biomarkers and Diagnostics

10:50-11:15 Molecular Diagnostics of Cancer for Precision Medicine: Strategies and Challenges for Improving Clinical Outcome
Towia Libermann, Ph.D., Associate Professor, Medicine, Beth Israel Deaconess Medical Center and Harvard Medical School; Director, BIDMC Genomics, Proteomics, Bioinformatics, and Systems Biology Center and DF/HCC Cancer Proteomics Core
Advances in NGS are unraveling cancer mutations, providing opportunities for developing precision medicine diagnostics. Growing understanding of cancer pathways combined with innovative targeted therapies enable discovery of actionable mutations in individual patients. Strategies to tailor therapy based on each patient's genetic characteristics are postulated to change the course of cancer. While an attractive concept, tumor heterogeneity and clinical trial complexities are major challenges for improving clinical outcome. Advances and challenges in cancer diagnostics for precision medicine will be discussed.

11:15-11:40 Next-Generation Sequencing Strategies for Selecting Patients Who May Benefit from PARP Inhibitor Therapy
Mitch Raponi, Ph.D., Senior Director, Molecular Diagnostics, Clovis Oncology
The discussion will address the following questions: What biomarkers should we be focusing on to identify appropriate patients who will likely benefit from PARP inhibitors? How can we apply next-generation sequencing technologies to identify all patients who will respond to the PARP inhibitor rucaparib? What regulatory challenges are we faced with for approval of NGS companion diagnostics?

11:40-12:05 pm Talk Title to be Announced
Saumya Pant, Ph.D., Research Fellow, Merck

12:05-12:30 The Use of Targeted NGS Assays to Identify Tumor Molecular Defects and Support Treatment Selection in NCI-Sponsored Clinical Trials
Jason Lih, Ph.D., Principal Scientist, Molecular Characterization & Clinical Assay Development Laboratory, Leidos Biomedical Research, Inc., Frederick National Laboratory for Cancer Research

12:30 Close of Conference

Present a Poster
Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions.

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

To secure a poster board and inclusion in the conference materials, your abstract must be submitted, approved and your registration paid in full by March 28, 2014.
CHI offers comprehensive sponsorship packages which include presentation opportunities, exhibit space and branding, as well as the use of the pre and post-show delegate lists. Customizable sponsorship packages allow you to achieve your objectives before, during, and long after the event. Signing on early will allow you to maximize exposure to hard-to-reach decision makers!

**Agenda Presentations - Within the Main Agenda!**
Showcase your solutions to a guaranteed, highly-targeted audience. Package includes a 15- or 30-minute podium presentation within the scientific agenda, exhibit space, on-site branding and access to cooperative marketing efforts by CHI.

**Breakfast & Luncheon Presentations**
Opportunity includes a 30-minute podium presentation. Boxed lunches are delivered into the main session room, which guarantees audience attendance and participation. A limited number of presentations are available for sponsorship and they will sell out quickly. Sign on early to secure your talk!

**Invitation-Only VIP Dinner/Hospitality Suite**
Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations and deliver prospects. 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 high-level conference delegates. Speak face-to-face with prospective clients and showcase your latest product, service, or solution.

*Inquire about additional branding opportunities!

---

Looking for additional ways to drive leads to your sales team?
Cambridge Healthtech Institute can help!

We offer clients numerous options for custom lead generation programs to address their marketing and sales needs, including:

- Live Webinars
- White Papers
- Market Surveys
- Podcasts
- And More!

**Benefits of working with Cambridge Healthtech Institute for your lead generation needs:**
- Your campaign will receive targeted promotion to Cambridge Healthtech Institute’s unparalleled database of over 800,000 individuals, all of which are involved in all sectors of the life sciences – lists can be segmented based on geography, research area, title and industry.
- All custom lead generation programs are promoted through our experienced marketing team that will develop and drive targeted campaigns to drive awareness and leads to your lead generation program.
- For our webinar programs, we offer assistance in procuring speakers for your web symposia through our extensive roster of industry recognized speakers across multiple disciplines within life sciences, as well as provide an experienced moderator and dedicated operations team who will coordinate all efforts.
- If choosing a white paper program, we can offer editorial experience and provide an industry recognized author to write your white paper.

**To customize your participation at this event, please contact:** Ilana Quigley – Business Development Manager
781-972-5457 | iquigley@healthtech.com

---

**Corporate Sponsors**

- BioAgilitytix Labs
- BIOSCALE
- BioStat Solutions
- CyVek
- illumina
- janssen
- Luminex
- MOLECULAR RESPONSE
- MYRIAD RBM
- SINGULEX
- SomaLogic
- ThermoFisher Sientific

---

**Lead Sponsoring Publications**

**Biomarkers in Medicine**

---

**Media Partners**

- BioIT World
- BioSpace.com
- BioVoice
- Nanomedicine
- Pharma
- ProtectMonitor
- Ovid
- TheScientist

---

**Click Here to Register Online!**
BiomarkerWorldCongress.com

REGISTER BY APRIL 4
SAVE UP TO $250
Hotel & Travel Information

Top Reasons to Stay at The Loews Philadelphia

- Minutes from Amtrak 30th Street Station and 20 minutes from Philadelphia Airport
- Complimentary wireless internet in your guest room
- Close to many of Philadelphia’s historical sites, including the Liberty Bell and Independence Hall
- Steps from Reading Terminal Market, which offers an exhilarating selection of baked goods, meats, poultry, seafood, produce, flowers and more
- Pet-friendly accommodations including specialty pet menus, gifts upon arrival and dog-walking services
- Located in the historic PSFS Building: A 20th Century Masterpiece

ConfERENCE HOTEL:

Loews Philadelphia Hotel
1200 Market Street
Philadelphia, PA 19107
Phone: 215-627-1200

Discounted Room Rate: $249 s/d
Discounted Room Rate Cut-off Date: April 7, 2014

Please visit our conference website to make your reservation online or call the hotel directly to reserve your sleeping accommodations. You will need to identify yourself as a Cambridge Healthtech Institute conference attendee to receive the discounted room rate with the host hotel. 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:
Special discount rentals have been established with American Airlines for this conference.
- Call American Airlines 1-800-433-1790 and use Conference code 8353BL.
- Go to www.aa.com/group and enter Conference code 8353BL in promotion discount box.
- Contact our dedicated travel agents at 1-877-559-5549 or chi@protravelinc.com.

Car Rental Discounts:
Special discount rentals have been established with Hertz for this conference.
- Call Hertz 1-800-654-3131 and use our Hertz Convention Number (CV): 04KL0003
- Go to www.hertz.com and use our Hertz Convention Number (CV): 04KL0003
How to Register: BiomarkerWorldCongress.com
reg@healthtech.com • P: 781.972.5400 or Toll-free in the U.S. 888.999.6288
Please use keycode BMC F when registering

DINNER COURSES

<table>
<thead>
<tr>
<th></th>
<th>Commercial</th>
<th>Academic, Government, Hospital-affiliated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Dinner Course Pricing</td>
<td>$595</td>
<td>$295</td>
</tr>
<tr>
<td>Double Dinner Course Pricing</td>
<td>$895</td>
<td>$495</td>
</tr>
<tr>
<td>Triple Dinner Course Pricing</td>
<td>$1199</td>
<td>$799</td>
</tr>
</tbody>
</table>

April 29, 2014                      April 30, 2014                      May 1, 2014

SC1: Exosomes and Microvesicles as Cancer Biomarkers
SC2: Fit-for-Purpose Biomarker Assay Development and Validation
SC3: Non-Coding RNAs as Biomarkers and Diagnostics
SC4: Next-Generation Sequencing as a Clinical Test

CONFERENCE PRICING

ALL ACCESS Executive Pricing: Includes access to entire 3-days of Congress programs, including Executive Summit. (Does not include access to dinner courses.)

Advance Registration by April 4, 2014          $2445          $1145
Late Registration after April 4, 2014          $2695          $1195

BEST VALUE Main Conference Pricing: Includes access to entire 3-days of Congress programs. (Does not include access to Executive Summit or dinner courses.)

Advance Registration by April 4, 2014          $2199          $1099
Late Registration after April 4, 2014          $2399          $1149

Single Conference Pricing: Includes access to 1 program. (Does not include access to Executive Summit or dinner courses.)

Advance Registration by April 4, 2014          $1599          $729
Late Registration after April 4, 2014          $1799          $799

April 30 - May 1, 2014                      May 1 - 2, 2014

Track 1: Translational Biomarkers in Drug Development
Track 2: Clinical Biomarker Assay Development
Track 3: Executive Summit: Companion Diagnostics
Track 4: Biomarkers for Patient Selection
Track 5: Mutation Analysis for Clinical Biomarkers & Diagnostics

CONFERENCE DISCOUNTS

Poster Submission-Discount ($50 Off)
Poster abstracts are due by March 28, 2014. 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.

Additional discounts are available for multiple attendees from the same organization. For more information on group rates contact David Cunningham at +1-781-972-5472

Needham, MA 02494
250 First Avenue, Suite 300,
Cambridge Healthtech Institute,
www.healthtech.com