FEATURED SPEAKERS

Klaus Lindpaintner
Head, Medical Genomics; VP, Research, Roche

Giora Feuerstein
AVP & Head Discovery, Translational Medicine, Wyeth

Nicholas C. Dracopoli
VP, Biomarkers Centocor, Johnson & Johnson

David Wholley,
Director, Biomarkers Consortium, Foundation for the NIH

Lawrence J. Lesko
Director, Clinical Pharmacology CDER, FDA

C. Thomas Caskey
EVP, Molecular Medicine and Genetics, Univ. of Texas Health Science Center

Geert Kolvenbag
Global Product VP, Oncology, AstraZeneca

Robert S. Epstein
SVP & Chief Medical Officer, Medco Health Solutions

Phil Hewitt
Head, Molecular Toxicology, Merck

Cambridge Healthtech Institute
250 First Avenue, Suite 300
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May 27-29, 2009 | Loews Philadelphia Hotel | Philadelphia, Pennsylvania

PRE-CONFERENCE EVENTS:

- Executive ThinkTank: Collaborations, Consortia, and Funding Opportunities in Biomarker Development
- Short Course: Fit-for-Purpose Biomarker Assay Development & Validation
- Workshop: Biomarkers for Cancer Drug Development

COMPREHENSIVE COVERAGE OF BIOMARKERS IN:

- Personalized Medicine
- Clinical Pharmacology
- Translational Medicine
- Molecular Diagnostics
- Safety Assessment
- Clinical Trials
- Assay Development
- Biomarker Qualification
- Oncology Drugs & Diagnostics

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Michael E. Burczynski, Ph.D., Associate Director, Biomarker Lab, Clinical Translational Medicine, Wyeth Pharmaceuticals

Marci Copeland, Research Scientist, Monarch LifeSciences

Maryellen de Mars, Ph.D., Director, Clinical Biomarkers, The Critical Path Institute

Viswanath Devanarayan, Ph.D., Director, Statistics, Biomarker Research, Abbott Laboratories

Nicholas C. Dracopoli, Ph.D., Vice President, Biomarkers, Centocor Research & Development, Johnson & Johnson

Robert E. Epstein, M.D., M.S., Senior Vice President, Medical & Analytical Affairs; Chief Medical Officer, Medco Health Solutions, Inc.

Giora Feuerstein, M.D., Assistant Vice President & Head, Discovery Translational Medicine, Wyeth Research

Paul J. Fielder, Ph.D., Senior Director & Senior Scientist, Early Development Pharmacokinetics, Pharmacodynamic and Bioanalytical Sciences, Genentech, Inc.

Mark Fidock, Ph.D., Head, Biochemical and Molecular BioMarkers, Experimental Biological Sciences, Pfizer Limited

Dorothee Foernzler, Ph.D., Biomarker-Experimental Medicine Leader, F. Hoffmann-La Roche AG

Alberto Gutierrez, Ph.D., Deputy Director, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), U.S. Food and Drug Administration

Yiwu He, Ph.D., Senior Program Officer, Global Health Discovery, Bill & Melinda Gates Foundation

Phil Hewitt, Ph.D., Head, Molecular Toxicology, Institute of Toxicology, Merck KGaA

Darren Hodgson, Ph.D., Biomics Advisor, Oncology Therapy Area, AstraZeneca

Arthur L. Holden, Ph.D., Chairman and Chief Executive Officer, International Serious Adverse Event Consortium, Ltd. (SAEC)

Martina Kaufmann, Ph.D., Biomarker Project Leader, Head OBI Basel, Oncology Biomarker & Clinical Imaging, Novartis Pharma AG

Geert Kolvenbag, M.D., Ph.D., Global Product Vice President, Oncology, AstraZeneca Pharmaceuticals, Inc.

Kwan R. Lee, Ph.D., Senior Director, Biomarkers and Predictive Analytics, Drug Development Science, GlaxoSmithKline Pharmaceuticals R&D

Lawrence J. Lesko, Ph.D., F.C.P., Director, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Klaus Lindpaintner, M.D., M.P.H., Head, Medical Genomics & Vice President, Research, F. Hoffmann-La Roche AG

Helen M. Moore, Ph.D., Director, Biospecimen Research Network, National Cancer Institute, National Institutes of Health

Scott D. Patterson, Ph.D., Executive Director, Medical Sciences, Amgen, Inc.

Wendy Sanhai, Ph.D., Senior Scientific Advisor, Office of the Commissioner, U.S. Food and Drug Administration

Yaping Shou, M.D., Ph.D., Director, Oncology Biomarkers and Imaging, Novartis Pharmaceuticals

Brian B. Spear, Ph.D., Director, Scientific Affairs, Global Pharmaceutical Research and Development, Abbott Labs

Craig Stovold, Ph.D., Senior Analytical Project Manager, Bioanalytical Sciences, Quotient Bioresearch

Linda C. Surh, M.D., Ph.D., FRCPC, Director, CEDD Global Regulatory Affairs, Neurosciences and Pharmacogenetics, GlaxoSmithKline, UK

Christine Tavano, Ph.D., Field Application Scientist, Ingenuity Systems

Shikha Varma-O'Brien, Ph.D., Associate Director, Life Sciences, Accelrys

Ole Vesterqvist, Ph.D., Senior Director, Biomarker Lab & Outsourcing, Clinical Translational Medicine, Wyeth Research

Xinkang Wang, Ph.D., Head, Imaging Biomarker Group, Discovery Translational Medicine, Wyeth Research

Jeffrey Waring, Ph.D., Associate Research Fellow & Group Leader, Cellular & Molecular Toxicology, Abbott Labs

David Wholley, Director, Biomarkers Consortium, Foundation for the National Institutes of Health

Hans Winkler, Ph.D., Senior Director & Global Head, Oncology Biomarkers, Pharmaceutical Research & Development, Johnson & Johnson

CONFERENCE-AT-A-GLANCE

Wednesday, May 27		
7:30 -12:00	Registration for Pre-Conference Events	
8:00-11:00	Pre-Conference Workshop *(Separate Registration Required)* **Biomarkers for Cancer Drug Development**	
12:00-3:00	Pre-Conference Short Course *(Separate Registration Required)* **Fit-For-Purpose Biomarker Assay Development and Validation**	
12:00-3:00	Executive ThinkTank *(Premium Package Registration Required)* **Collaborations, Consortia, and Funding Opportunities in Biomarker Development**	
3:00-4:00	Conference Registration	
4:00-5:15	Plenary Keynotes	
5:15-6:30	Opening Reception in the Exhibit Hall *Sponsored by* RBM	
Thursday, May 28		
7:00	Registration Open	
7:30-8:15	Breakfast Presentation *Sponsored by* Expression Pathology	
8:25-9:30	**Delivering on the Promise of Personalized Medicine**	
9:30-10:30	Networking Coffee Break with Poster and Exhibit Viewing	
10:30-12:00	TECHNOLOGY SHOWCASE I: **Biomarkers in Early Drug Development**	TECHNOLOGY SHOWCASE II: **Biomarkers in Clinical Development and Diagnostics**
12:00-1:00	Lunch on your own	
1:00-2:30	**Implementing Personalized Medicine**	**Biomarker Adoption in Clinical Trials**
2:30-3:30	Networking Refreshment Break with Poster and Exhibit Viewing	
3:30-5:30	**Molecular Diagnostics for Personalized Medicine**	**Clinical Pharmacology**
Friday, May 29		
7:00	Registration Open	
7:30-8:25	Breakfast Presentation *(Opportunity Available)*	
8:25-9:30	**Biomarkers in Translational Medicine**	
9:30-10:30	2:30-3:30 Networking Refreshment Break with Poster and Exhibit Viewing *Sponsored by* Quest Diagnostics	
10:30-12:30	**Toxicity Biomarkers**	**Biomarker Assay Development**
12:30-2:00	**Luncheon Presentation** *Sponsored by* Caprion Proteomics	**Luncheon Presentation** *Sponsored by* Monarch Life Sciences
2:00-4:00	**Biomarker Qualification: Biological and Analytical Validation**	
4:00	Close of Conference	

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For more information, please contact:

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Wednesday, May 27

7:30-12:00 **Registration for Pre-Conference Events**

8:00-11:00 **Pre-Conference Workshop*** *(*Separate Registration Required)*

Biomarkers for Cancer Drug Development

8:00 **Chairperson's Opening Remarks**

Nicholas C. Dracopoli, Ph.D., Vice President, Biomarkers, Centocor Research & Development, Johnson & Johnson

8:00-8:30 **Measuring the Impact of Biomarkers in Cancer Drug Development**

Nicholas C. Dracopoli, Ph.D., Vice President, Biomarkers, Centocor Research & Development, Johnson & Johnson

A recent survey of oncology drugs entering clinical development showed that the attrition rate of molecularly targeted therapies is approximately one third of the rate for all oncology drugs. These data support the idea that greater scientific understanding of a drug target and its biological pathway will lead to lower attrition rates in drug development. This presentation will review the recent impact of biomarkers in confirming mechanism of action in preclinical models, exploring PK/PD interactions and defining Phase II dose, and in developing companion diagnostics to predict drug efficacy for novel oncology therapies. The presentation will also discuss why more companion diagnostics have not been developed, and argue that molecular pathological techniques to provide direct readouts of the functional status of drug targets and downstream pathways remain essential for the development of companion diagnostics for new targeted oncology therapies.

8:30-9:00 **Biomarkers for Anti-Angiogenic Drugs – A Long Way to Go?**

Dorothee Foernzler, Ph.D., Biomarker-Experimental Medicine Leader, F. Hoffmann-La Roche AG

This presentation will examine the relevance of biomarkers for anti-angiogenic therapies in oncology, and discuss status of biomarkers in angiogenesis and evaluation of personalized health care opportunities. I will also discuss biomarker strategy - asking the right questions and using the appropriate technologies to develop biomarkers for anti-angiogenic therapies in oncology, and implementation of the biomarker strategy. This is where the hard work starts: challenges and experiences.

9:00-9:30 **Imaging Biomarkers in Oncology in Drug Discovery and Development**

Xinkang Wang, Ph.D., Head, Imaging Biomarker Group, Discovery Translational Medicine, Wyeth Research

Abstract unavailable at the time of printing.

9:30-10:00 **Networking Coffee Break**

10:00-10:30 **Oncology Drug Development: Letting Biomarkers Lead the Way**

Martina Kaufmann, Ph.D., Biomarker Project Leader, Head OBI Basel, Oncology Biomarker & Clinical Imaging, Novartis Pharma AG

Oncology is leading the way in exploiting molecular biological and genetic information to develop personalized medicine. Biomarkers are pivotal for optimization of dose and schedule, prediction of patients that will respond, rapid detection of tumor response in proof-of-concept trials, use of surrogate endpoints for disease monitoring, assuring safety of drug therapy and development of rational-based combination therapies. A general strategy for use of biomarkers to accelerate oncology drug development will be presented.

10:30-11:00 **Title to be Announced**

Kurtis E. Bachman, Ph.D., Director; Head, Translational Medicine, Cancer Metabolism, Cancer Research, Oncology R&D, GlaxoSmithKline

Abstract unavailable at the time of printing.

11:00 **Close of Pre-Conference Short Course**

12:00-3:00 **Pre-Conference Short Course*** *(*Separate Registration Required)*

Fit-For-Purpose Biomarker Assay Development and Validation

John Allinson, FIBMS, Laboratory Director, Veeda Clinical Research

This tutorial will provide recommendations on the "fit-for-purpose" best practices in the development and validation of biomarker assays for the intended 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. The 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.

Viswanath Devanarayan, Ph.D., Director, Statistics, Biomarker Research, Abbott Laboratories

This tutorial will provide recommendations on the "fit-for-purpose" best practices in the development and validation of biomarker assays for the intended exploratory or advanced biomarker applications. Strategies for different applications at various phases of biomarker development will be described. Key elements in method 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 method feasibility studies. The 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.

Outline:

1. Introduction - Nomenclature, types of biomarker methods/assays, biomarker method development & validation road map, fundamental validity, similarity and differences from PK assays & diagnostic application.
2. Pre-analytical and Bioanalytical elements: Target range, standards, validation & 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.

Please visit www.BiomarkerWorldCongress.com for course outline.

12:00-3:00 **Executive ThinkTank*** *(*Premium Package Registration Required)*

Collaborations, Consortia, and Funding Opportunities in Biomarker Development

12:00 **Chairperson's Opening Remarks**

Phillips Kuhl, President, Cambridge Healthtech Institute

12:00-12:30 **Participant Introductions**

12:30-12:50 **The Role of Public-Private Partnerships in Driving Biomarker Development: The Biomarkers Consortium**

David Wholley, Director, Biomarkers Consortium, Foundation for the National Institutes of Health

Launched in November 2006, the Biomarkers Consortium has experienced both substantial progress and substantial change over the last 12 months. Mr. Wholley, who has served as director of the Consortium since March 2008, will describe how public-private partnerships generally, and the Consortium in particular, are playing a key role in the development and qualification of biomarkers with particular relevance for more efficient and effective development of therapeutics and personalized medicine.

12:50-1:10 **The Serious Adverse Event Consortium, Ltd. (SAEC): Formation and Current Status of an International Effort to Understand the Genetic Basis of Drug Related Serious Adverse Events**

Arthur L. Holden, Ph.D., Chairman and Chief Executive Officer, International Serious Adverse Event Consortium, Ltd. (SAEC)

The Serious Adverse Event Consortium (SAEC) has been formed to identify and validate DNA-variants useful in predicting the risk of drug induced serious adverse events [SAEs]. It is a nonprofit organization comprised of leading international pharmaceutical companies, and academic institutions with scientific and strategic input from the U.S. Food and Drug Administration (FDA). This presentation will summarize the origins and current status of this novel research initiative, its current research methods, results to date and potential new solutions for more efficient and effective SAE research. The SAEC's initial studies will focus on identifying genetic markers associated with drug-related liver toxicity [DILI] and serious skin rash [SSR]. The SAEC will collect SAE samples and data from the participating pharmaceutical companies and academic institutions. These well-characterized cases will be compared with control cases to identify genetic variants that may be associated with these SAEs. The identification of these genetic variations is believed to be essential to develop safer drugs while also identifying patient populations at risk. The SAEC is exploring partnerships with international private and government institutions to better conduct their research.

1:10-1:30 **Biomarker Discovery in Global Health**

Yiwu He, Ph.D., Senior Program Officer, Global Health Discovery, Bill & Melinda Gates Foundation

There is an unprecedented need for the development of new drugs/vaccines, diagnostics, and prevention strategies to ease the impact of the infectious diseases such as AIDS, TB, and malaria. Biomarkers hold great promise to identify risk for disease, to make a diagnosis, to assess severity of disease and to guide treatment. Biomarkers can also be used in research and clinical studies to assess drug efficacy and safety. The presentation will provide an overview of biomarker discovery needs in global health area and explore potential collaborating opportunities.

1:30-3:00 **Discussion with all Participants**

MAIN CONFERENCE

Wednesday, May 27

3:00-4:00 **Conference Registration**

4:00-4:15 **Welcoming Remarks from Conference Director**

Julia Boguslavsky, Cambridge Healthtech Institute

Plenary Keynotes

4:15-4:45 **Predictive Biomarkers: Using What's Been Learned from Past Regulatory Decisions to Inform Future Development Plans**

Lawrence J. Lesko, Ph.D., F.C.P., Director, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Biomarker discovery and qualification remains a complex issue in the drug development and approval process. There is an intuitive sense that biomarker-driven decisions can have a positive effect on productivity and diagnostic tests can stratify patients into subgroups with different benefit/risk ratios. Thus, looking at past research examples can provide a solid foundation for future biomarker development strategies. One key and very basic question is: what does experience with biomarker development tell us about the differences between their use in efficacy, safety and dosing?

4:45-5:15 **Opening Reception in the Exhibit Hall** *Sponsored by* RBM

Thursday, May 28

7:00 **Registration Open**

7:30-8:15 **Breakfast Presentation: In-Depth Analysis of Protein Biomarkers in FFPE Tissue** **Sponsored by** Expression Pathology

David Krizman, Ph.D., Chief Scientific Officer and Co-founder, Expression Pathology Inc.

The LiquidTissue® protocol makes it possible to analyze proteins in FFPE tissue. The technology can be used to discover and validate differentially expressed protein biomarkers in FFPE tissue. This opens new opportunities in companion diagnostics, prognostic biomarkers, and drug targets. The technology also has potential in drug development, clinical trials and personalized medicine. It can be used to quantify protein expression in standard patient samples and provide diagnostic and prognostic information to guide treatment decisions.

Delivering on the Promise of Personalized Medicine

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

8:30-9:00 **Biomarkers in Personalized Health Care: Opportunities, Challenges, Approaches**

Klaus Lindpaintner, M.D., M.P.H., Head, Medical Genomics & Vice President, Research, F. Hoffmann-La Roche AG

The discussion about the application of biomarkers to more targeted treatment addresses fundamentally the issues of a better understanding of inter-individual differences in drug response that are independent of particular disease states, as well as a molecular rewriting of the textbook of medicine. The latter is aimed at a more differentiated, basic concept of disease mechanisms which may then allow a shift from the current largely empiric and palliative to a causally targeted pharmacopoeia. However, the associated expense to health care systems will need to be justified by demonstration of appropriate clinical utility, in the sense of incremental cost-efficacy ratios. This will require a systematic, staged, and case-specifically adjusted approach for optimal balance of risk-benefit, and ultimate sustainable success of the concept.

9:00-9:30 Personalized Medicine: Turning Promise into Reality

Geert Kolvenbag, M.D., Ph.D., Global Product Vice President, Oncology, AstraZeneca Pharmaceuticals, Inc.

The promise of personalized medicine is emerging from theoretical discussions for practical applications in cancer care. With a few successful examples already in the clinic, the challenges for developing new personalized medicine approaches have not decreased. In contrast, new and higher hurdles for clinical and biomarker development and approval have appeared in the last few years. A case report will be presented on a new approach, currently in phase II clinical development, highlighting these hurdles and potential approaches to address them.

9:30-10:30 **Networking Coffee Break with Poster and Exhibit Viewing**

TECHNOLOGY SHOWCASE I:

Biomarkers in Early Drug Development

10:30-10:45 **Finding Evidence for Drug-Induced Cholestasis Biomarkers, A Knowledge Profile Approac** *Sponsored by* ARIADNE

Ilya A. Mazo, Ph.D., President, Ariadne, Inc.

Using the proprietary high-content linguistics tool MedScan®, a database of knowledge profiles associated with different diseases and small molecule effects has been compiled by extracting biological facts and relationships from scientific literature. Systematic mining of this database, ChemEffect™, for knowledge on existing drugs/drug candidates garnered from published findings can help in hypothesizing a mechanism behind drug-induced cholestasis. This analysis workflow often leads to identifying potential biomarker candidates, backed with supporting scientific evidence from other studies. In this talk, different approaches to develop mechanistic models from the ChemEffect™ knowledgebase and from microarray data will be described.

10:45-11:00 **Identification of Master-Regulators of Adverse Toxic Reactions of the Antibiotic Drug Trovafloxacin (TVX) through Promoter Analysis and Network Modeling** *Sponsored by* BIOBASE BIOLOGICAL DATABASES

Alexander Kel, Ph.D., Senior Vice President Research & Development, BIOBASE GmbH

In this talk, we will present a case study of applying the BIOBASE Knowledge Library™ and the ExPlain™ Analysis Platform for discovery of drug toxicity biomarkers. We analyzed data on the antibiotic drug trovafloxacin (TVX), which was recently removed from the market because of severe idiosyncratic hepatotoxic side effects. The aim of this study was to find molecular mechanisms of adverse drug reactions and identification of potential causal biomarkers for patient stratification. Expression profiles of primary human hepatocytes treated with trovafloxacin were analysed through ExPlain™ performing promoter analysis of differentially expressed genes followed by topological modeling of signal transduction networks. We predicted the following transcription factors, which are involved in coordinated deregulation of genes upon treatment with TVX: HNF1α, HNF4, AhR/ARNT, ELK1 and others. Topological modeling of respective transcription regulatory and signal transduction networks allowed us to identify master-regulators of the toxic reactions in liver cells and propose perspective causal biomarkers of liver toxicity of trovafloxacin.

TECHNOLOGY SHOWCASE II:

Biomarkers in Clinical Development and Diagnostics

10:30-10:45 **Multiplexed Assays for High-Throughput Biomarker Analysis** *Sponsored by* Quotient Bioresearch

Craig Stovold, Ph.D., Senior Analytical Project Manager, Bioanalytical Sciences, Quotient Bioresearch

The increasing importance of biomarkers to support clinical studies and pharmaceutical licensing provides a number of challenges for the analytical laboratory. An extensive panel of biomarkers is desirable to fully characterise a disease state and drug efficacy, often limited by ethical considerations and the requirement for clinical safety testing. Quotient Bioresearch provide a number of multiplexing methods, including LC-MS/MS for small and large molecules, Meso-Scale Discovery, and Gyrolab®, increasing the throughput of biomarker analysis giving determination of a greater number of analytes, from a smaller sample in a reduced time frame.

10:45-11:00 **Current Information Trends in Biomarker Research** *Sponsored by* THOMSON REUTERS

Colin Williams, Ph.D., Product Manager, Biology & Bioinformatics, Thomson Reuters

Biomarkers are becoming a key tool in enhancing the productivity of pharmaceutical research & development, both in discovery and the clinic and an essential element for regulatory purposes. It will become increasingly difficult to manage the rapidly increasing information about a biomarker. A new fully indexed biomarker database, BIOMARKERcenter, will help to address this problem. Using BIOMARKERcenter we will show how biomarkers mimic the lifecycle of a drug, from discovery to approval, and show the diversity of roles and techniques currently being employed in biomarker research.

11:00-11:30 **Prioritization of Biomarker Candidates Based on Pathway and Phenotype Associations** *Sponsored by*

Christine Tavano, Ph.D., Field Application Scientist, Ingenuity Systems

As technologies that detect transcripts, microRNA levels, and epigenetic events mature to become common components of biomarker discovery programs, the challenge has shifted to translating large scale datasets into biomarkers that can be used to diagnose disease and predict patient response to treatment. Prioritization of biomarker candidates requires – at a very practical level – an understanding of candidates' expression patterns in bodily fluids and target tissues and – at the mechanistic level – identification of molecular paths between candidate markers and physiological responses, cellular phenotypes, or disease processes of interest. In this session we will present a case study in which the biomarker discovery tool IPA was used to prioritize biomarker candidates and elucidate the molecular mechanisms connecting those markers to disease phenotypes and pathways.

11:30-11:45 **Advances in xMAP Technology: Optimized Multiplex Biomarker Assessment** *Sponsored by*

Sean M. Higgins, Ph.D., Senior Field Marketing Scientist, Luminex Corp.

11:45-12:00 **Unlocking Biomarker Knowledge in Public and Proprietary Experimental Data** *Sponsored by*

James Flynn, Ph.D., Field Application Scientist, NextBio

The development of novel Biomarkers holds great promise to improve upon current clinical attrition rates. In this presentation we will demonstrate how the NextBio platform can be used to unlock the biomarker data within public and proprietary genomic data, semantically link knowledge sources, and stimulate hypotheses generation and validation. The NextBio platform allows you to validate hypotheses in biological terms that every scientist understands and before experiments and clinical trials are run, thereby improving the success of experiments.

11:00-11:30 ***In Situ* Multiparametric Analysis of Biomarkers In Heterogeneous FFPE Tissue Using the Definiens XD™ Image Analysis Platform** *Sponsored by*

Peter A. Duncan, Director, Marketing and Business Development Life Sciences, Definiens Inc.

Although we are now beginning to benefit from the genetic, genomic, and proteomic discoveries over the last decade, the implementation of biomarkers for patient stratification to improve diagnostics, prognostics, and companion assays for oncology targeted therapies is still an extremely challenging endeavor with limited success. This is due to many factors including the lack of implementation of true systems-based approaches to achieve in situ multiplexed, multiparametric, phenotypic profiling of protein biomarkers. This talk will illustrate how this challenge is currently being met utilizing the Definiens XD image analysis platform, citing specific examples including: The automation of the Dako Herceptest, and the development of a multivariate model for overall survival of non-small cell lung cancer patients treated with Iressa®. Applications of the Definiens XD image analysis platform to xenograft detection and 3D in vivo imaging will also be presented.

11:30-11:45 **The Use of Biomarkers in Global Clinical Trials** *Sponsored by*

Maribeth Raines, Ph.D., Director, Scientific Affairs, Quest Diagnostics

As biomarkers become more critical in drug development studies, their prevalence in global clinical trials has increased. The challenges of supporting biomarker testing for global clinical studies will be discussed in the context of how it influences biomarker development and validation as well as strategies for deploying and standardizing biomarker testing worldwide.

12:00-1:00 **Lunch on your own**

Implementing Personalized Medicine

1:00 **Chairperson's Opening Remarks**

Chairperson to be Announced

1:00-1:30 **Promulgating use of Pharmacogenomics Tests on a National Level: The Medco Experience**

Robert E. Epstein, M.D., M.S., Senior Vice President, Medical & Analytical Affairs; Chief Medical Officer, Medco Health Solutions, Inc.

This session will cover experience to date of a pharmacy benefit manager 'rolling out' programs that promulgate the use of pharmacogenomic tests. From data gleaned from actual experience with programs that address both Tamoxifen and Warfarin pharmacogenomics, payer concerns, results of actual physician and member adoption, ability of test values to change treatment decisions, and other practical issues will be shared. Opportunities for improvement to the healthcare system to facilitate greater adoption will be suggested.

1:30-2:00 **A Business Context for Personalized Medicine Research & Development**

Brian B. Spear, Ph.D., Director, Scientific Affairs, Global Pharmaceutical Research and Development, Abbott Labs

Targeting new medicines to specific patients is an attractive concept commercially as well as medically. However, not all new drugs will be suited to this approach. Whether a personalized medicine strategy is appropriate for any specific drug will depend on, among other things, the nature of the disease, variability in patient response, the competitive environment, and the availability of biomarkers for patient categorization. The presentation will describe criteria useful in assessing the likelihood of success in the development and commercialization of a targeted or personalized medicine.

2:00-2:30 **Biostatistics Challenges in Personalized Medicine**

Kwan R. Lee, Ph.D., Senior Director, Biomarkers and Predictive Analytics, Drug Development Science, GlaxoSmithKline Pharmaceuticals R&D

Personalized medicine is the delivery of the right drug, at the right dose, for the right patient, at the right time. In theory, personalized medicine is the management of a patient's disease or disease predisposition, by using molecular analysis to achieve the optimal medical outcomes for that individual — thereby improving the quality of life and health, and potentially reducing overall healthcare costs. In practice, personalized medicine is a comprehensive approach utilizing molecular analysis of both patients and healthy individuals to guide decisions throughout all stages of the discovery and development of pharmaceuticals and diagnostics. It involves application of this knowledge in clinical practice for a more efficient delivery of accurate and quality healthcare through improved prevention, diagnosis, treatment, and monitoring methods. Pharmacogenomics is the science that allows us to predict a response to drugs based on an individual's genetic makeup (genome and expression of genes) and it is the major contributor to the theory and practice of personalized medicine. In this talk we will briefly review the important biostatistics component of Pharmacogenomics. Topics will include design and analysis of 'omics data and reliable diagnostic algorithm development. We will also discuss biomarker based targeted clinical trials, and early biomarker development in oncology drug discovery and how pharmacogenomics allows us to project the information to clinical development.

Biomarker Adoption in Clinical Trials

1:00 **Chairperson's Opening Remarks**

Hans Winkler, Ph.D., Senior Director & Global Head, Oncology Biomarkers, Pharmaceutical Research & Development, Johnson & Johnson

1:00-1:30 **Considerations on the Level of Evidence for Biomarker Adoption**

Scott D. Patterson, Ph.D., Executive Director, Medical Sciences, Amgen, Inc.

Patient stratification biomarkers would ideally be implemented prior to randomization of pivotal trials, but this may not always occur due to a sufficient understanding of the mechanisms of resistance to therapy being elucidated later in the clinical trial process rather than early. The various factors one needs to consider will be presented through example in this presentation.

1:30-2:00 **Biomarkers in Drug Development Compared to Medical Practice: Overlaps, Gaps, and Flaps**

Linda C. Surh, M.D., Ph.D., FRCPC, Director, CEDD Global Regulatory Affairs, Neurosciences and Pharmacogenetics, GlaxoSmithKline, UK

The context in which emerging biomarkers are used is critical, so that appropriate decision-making can be made in the face of limited resources whether in industry, government or medicine. This presentation will attempt to take an emerging biomarker beyond the 'what is the technology and why do it' to 'what is the clinical relevance and where to do it.' Using pharmacogenomics (PGx) as an example of an emerging biomarker, it is evident that with assay capabilities more widely understood, it is now important to address the challenges of clinical interpretations in different situations. Thus, depending on the pipeline phase, how do innovative biomarkers integrate so as to aid in the progression of new medicines which are timely, effective, and safe.

2:00-2:30 **Use of a Surrogate Biomarker as an Efficacy Endpoint in Clinical Trials and a Monitoring Tool in Routine Patient Management**

Yaping Shou, M.D., Ph.D., Director, Oncology Biomarkers and Imaging, Novartis Pharmaceuticals

The presentation will discuss the definition and qualification criteria of surrogate endpoints and as a case study, describe the development of blood BCR-ABL transcripts as a surrogate endpoint in CML. The technical challenges and regulatory considerations will be discussed in the implementation of this surrogate endpoint in clinical drug development and routine clinical practice.

2:30-3:30 **Networking Refreshment Break with Poster and Exhibit Viewing** **Sponsored by**

Molecular Diagnostics for Personalized Medicine	Clinical Pharmacology
3:30-4:00 Predictive Biomarkers in Clinical Development *Darren Hodgson, Ph.D., Biomics Advisor, Oncology Therapy Area, AstraZeneca* When, how and why can one develop a new predictive biomarker in parallel to a candidate drug? In this talk we will discuss the requirements of assays, human samples, data and trials needed in order to develop diagnostic pre-cursors and the decision making data required to justify investing in a co-development program.	**3:30-4:00 Application of Pharmacodynamic Markers for Proof of Principle** *Hans Winkler, Ph.D., Senior Director & Global Head, Oncology Biomarkers, Pharmaceutical Research & Development, Johnson & Johnson* Novel targeted therapeutics are expected to improve the treatment of cancer. However, they are expected to be effective in only a subpopulation of any tumor type. It is therefore of prime importance to identify these tumors up front and select patients for treatment based on predictive markers. Before major investments in such a strategy are warranted, the value of a compound needs to be assessed thoroughly. Demonstration in the clinic of adequate target modulation (Proof of Principle) is critical for progressing compounds to efficacy analyses. Examples of clinical pharmacodynamic results, opportunities and pitfalls will be discussed.
4:00-4:30 Strategies for Companion Diagnostic Development in a Pharmaceutical Research & Development Setting *John C. Bloom, V.M.D., Ph.D., Executive Director, Diagnostic & Experimental Medicine, Eli Lilly & Co.* The development and commercialization of novel diagnostics that enhance the value of drugs to patients, payers and prescribers is increasingly critical to "personalizing" medicines and differentiating new drugs in the marketplace. Strategies for building the capability to address such anticipated and unforeseen opportunities entail understanding the regulatory process and options for approval; and ensuring access to the appropriate specimens required for development, intellectual property rights and mutually profitable business partnerships. This presentation will review the challenges that building the required virtual technical and process diagnostic development expertise entail in today's rapidly changing Research & Development environment.	**4:00-4:30 Translational Pharmacology: Using PD-Biomarkers and PK/PD Modeling to Bridge Preclinical and Clinical Pharmacology** *Paul J. Fielder, Ph.D., Senior Director & Senior Scientist, Early Development Pharmacokinetics, Pharmacodynamic and Bioanalytical Sciences, Genentech, Inc.* The development of novel biological therapies is a complex and dynamic process, which involves the interplay between the pharmacology and biology of both the disease target and the biology of the therapeutic. These unique complexities can impact molecule selection, preclinical testing strategies, development of clinical plans, and help inform second generation molecules. Translational pharmacology is an approach which combines data from preclinical efficacy studies and knowledge about the clinical target and uses PD-biomarkers and PK/PD modeling to help inform the development path. A major focus will be on how to use these novel approaches to inform key decision points during the development process and to inform second generation molecules.
4:30-5:00 Regulatory Perspective of the Role of *In Vitro* Diagnostics in Personalized Medicine *Alberto Gutierrez, Ph.D., Deputy Director, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), U.S. Food and Drug Administration* *In Vitro* Diagnostics are medical devices. FDA regulation is science-based and involves an overlapping series of well-defined but flexible pre-market and post-market controls. Personalized medicine has placed the diagnostic in center stage, since the safety and effectiveness of therapeutic decisions are dependent on a single diagnostic. The regulatory challenges presented by this prominent role will be discussed.	**4:30-5:00 Developing Biomarkers for Proof-of-Pharmacology** *Mark Fidock, Ph.D., Head, Biochemical and Molecular BioMarkers, Experimental Biological Sciences, Pfizer Limited* The presentation will describe the utilization of biomarkers in early clinical drug development. This will focus on developing techniques to successfully identify molecules or processes that have changed in response to therapeutic treatment to deliver accurate decision making data. It will include a case study of assays for immune modulation in pre-clinical species and in man.
5:00 Close of Day	

Friday, May 29

7:00 **Registration Open**

7:30-8:25 **Breakfast Presentation** *(Opportunity Available. Contact Ilana Schwartz at 781-972-5457 or ischwartz@healthtech.com.)*

Biomarkers in Translational Medicine

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

8:30-9:00 **Translational Medicine in the Pharmaceutical Industry: Addressing Multiple Challenges in the New Environment**

Giora Feuerstein, M.D., Assistant Vice President & Head, Discovery Translational Medicine, Wyeth Research

The pharmaceutical industry is facing tremendous new challenges in innovative drug discovery and development. These include translation and validation of large genetic/genomic databases into disease relevant targets, unprecedented pharmacovigilance in safety and tolerability, personalized medicine needs, regulatory policy makers, and patient advocacy group and payers' needs. Translational medicine in the pharmaceutical industry is a new entity within research & development that aligns and integrates discovery, pre-clinical development and clinical development to optimize success in meeting the new environment challenges. Specific illustrations on how translational medicine solves problems will be discussed.

9:00-9:30 **Biomarkers in Translational Medicine: Importance of Technological and Operational Innovation**

Michael E. Burczynski, Ph.D., Head, Biomarker Lab, Clinical Translational Medicine, Wyeth Pharmaceuticals

The primary role of translational medicine in drug development is to support decision-making through the use of biomarkers and experimental studies in humans. This presentation will discuss the importance of both technological and operational innovations in translational medicine. It will provide some concrete examples of innovative technologies such as the Singulex Erenna™ technology, mass spectrometry and multiplexed assay platforms. The presentation will also discuss the importance of operational innovation and how it can significantly impact the use of biomarkers in the development process.

9:30-10:30 **Networking Coffee Break with Poster and Exhibit Viewing**

Toxicity Biomarkers

10:30 **Chairperson's Opening Remarks**

Jeffrey Waring, Ph.D., Associate Research Fellow & Group Leader, Cellular & Molecular Toxicology, Abbott Labs

10:30-11:00 **Predictive Safety Biomarkers in Non-Clinical Development**

Phil Hewitt, Ph.D., Head, Molecular Toxicology, Institute of Toxicology, Merck KGaA

This presentation will examine the benefits of safety biomarkers as decision making tools, current predictive safety biomarkers, and assessing the impact of toxicogenomics. It will consider the question: Can we predict hepatotoxicity using gene expression changes in primary hepatocytes? And, finally, will discuss combining 'omics technologies with traditional toxicology endpoints: a unique strategy for toxicity prediction and mechanistic elucidation.

11:00-11:30 **Identification of Proteasome Gene Regulation in a Rat Model for Hyperlipidemia using Microarray Analysis**

Jeffrey Waring, Ph.D., Associate Research Fellow & Group Leader, Cellular & Molecular Toxicology, Abbott Labs

Elevations in serum triglycerides and cholesterol can be an adverse effect associated with some classes of new drug candidates. Identifying candidates in these drug classes that are not associated with dyslipidemia has been hindered by the lack of mechanistic information and the unavailability of relevant animal models. The present study evaluated the potential use of gene expression changes in rat liver in the development of an exploratory hyperlipidemia model.

11:30-12:00 **Finding Biomarkers that Predict Rare Adverse Events: Assessing the Risk for Acute Idiosyncratic Hepatocellular Injury (AIHI)**

John C. Bloom, V.M.D., Ph.D., Executive Director, Diagnostic & Experimental Medicine, Eli Lilly & Co.

Finding biomarkers that predict rare idiosyncratic adverse events has been problematic for many reasons. This has been particularly true for hepatotoxicity, or Acute Idiosyncratic Hepatocellular Injury (AIHI), which is the adverse event that most frequently leads to regulatory action on drugs, including failure to approve, post-marketing warnings added to the label and withdrawal from the market. Additional biomarkers are needed to enable more effective risk assessment and management of AIHI, including markers for identifying candidate drugs with this toxic potential and patients at risk or predisposed to AIHI, and for early detection and management of patients affected in clinical trials and practice. Approaches to the discovery and validation of such markers were reviewed in a recent meeting jointly sponsored by the Food and Drug Administration, the Pharmaceutical Research and Manufacturers of America, and the American Association for the Study of Liver Diseases; and in a recent Institute of Medicine Forum on Assessing and Accelerating the Development of Biomarkers for Drug Safety. This presentation will review the options that were identified for finding clinical biomarkers that predict AIHI, based on our current understanding of the mechanisms of this toxicity and the clinical populations at risk, and the research proposals that emerged from these discussions.

Biomarker Assay Development

10:30 **Chairperson's Opening Remarks**

Michael E. Burczynski, Ph.D., Head, Biomarker Lab, Clinical Translational Medicine, Wyeth Research

10:30-11:00 **The Critical Role of Characterizing Emerging Technologies Prior to Biomarker Development**

Cynthia S. Spittle, Ph.D., Senior Research Scientist & Head, Pharmacogenomics, Biomarker Lab, Clinical Translational Medicine, Wyeth Research

Novel technologies enabling more specific and highly sensitive assays for detection and/or quantitation of biomarkers are constantly emerging. While the benefits of such instrumentation advances are clearly evident, a thorough understanding of the molecular principles (and limitations) by which these biomarker detection technologies work is required. Careful characterization and analytical validation of these platforms is a critical first step prior to generating data that will assist in biomarker-driven decision making in clinical development.

11:00-11:30 **Discovery of Serum/Plasma Biomarkers for the Early Detection of Ovarian Cancer: Issues and Approaches**

Sponsored by GYROS

Patrick M. Sluss, Ph.D., Director, Special Chemistry Core Laboratories, Massachusetts General Hospital, Associate Professor, Harvard Medical School

11:30-12:00 **Fit-for-Purpose Assay Validation in the Protein Biomarker Pipeline**

Sponsored by nextgen sciences

Richard C. Jones, Ph.D., Head, Mass Spectrometry, NextGen Sciences, Inc.

The ability to generate putative protein biomarkers increases every year with improved discovery platforms in multiple disciplines. However, a major bottleneck has been the ability to develop assays in an acceptable timeframe in order to begin to validate putative biomarkers and move the viable biomarker candidates forward. Multiplexed mass spectrometry based assays are of considerable interest as they offer a potential solution to the biomarker validation problem. Using a multiplexed mass spectrometry platform it is possible to significantly shorten assay development time relative to other more conventional platforms such as immuno-affinity based methods. This allows resources to be focused on the utility of the putative biomarker and not on the development of the assay. Depending on the application, the level of bioanalytical assay validation may be tailored such that it is fit for a given purpose. In early biomarker discovery stages, minimal validation is required but as the usefulness of a single biomarker or a panel of multiple biomarkers is more clearly defined, the level of assay validation increases. Here, we will discuss several example assays and outline the level of validation deemed fit-for-purpose in their application.

12:00-12:30 Speaker to be Announced

12:00-12:30 Meso Scale Discovery's Multiplexed Assays for Safety and Toxicology Assays

Sponsored by MSD Meso Scale Discovery

Pankaj Oberoi, Ph.D., Director, Qualified Kit Development, Meso Scale Discovery

Traditional clinical markers for organ toxicity are not always sensitive enough to detect subtle damage and histopathology is not amenable to high enough throughput for preclinical studies. Meso Scale Discovery (MSD) has an electrochemiluminescence platform that is fast (1-3 minutes per plate independent of plate density), robust (non-fluidics instrument), radioactive free, sensitive (detection limits near 10 attomoles) and has a wide dynamic range (5 logs) with multiplexing capabilities. MSD has developed several multiplex panels for traditional and emerging safety biomarkers for kidney, cardiac, muscle, vascular, and liver damage. This talk will discuss assay development challenges (critical reagent characterization, specificity, abundance of biomarkers, and matrix interaction) encountered during development of Qualified kits used in preclinical and clinical studies.

12:30-2:00 Luncheon Presentation *Sponsored by* CAPRION PROTEOMICS

Biomarker Discovery, Validation and Implementation for Drug Development and Commercialization

Daniel Chelsky, Ph.D., Chief Scientific Officer, Caprion Proteomics

Caprion Proteomics and Covance have teamed up to provide a full biomarker service, including pre-clinical and clinical studies, biomarker discovery and validation, as well as assay development and implementation.

12:30-2:00 Luncheon Presentation *Sponsored by* Monarch LifeSciences

Use of Mass Spectrometry-Based Protein Assays for Sensitive and Selective Analysis of Biomarkers in Preclinical and Clinical Efficacy and Physiology Models

Marci Copeland, Research Scientist, Monarch LifeSciences

Biomarkers for use in preclinical animal models and clinical applications can be instrumental in studying disease physiology and drug efficacy. Often sensitive and selective antibodies and subsequent immune or radioimmunoassays, are unavailable. Additionally, in cases where isoforms of a protein or modifications of a protein require discrimination, a reagent based assay might be impractical or subject to poor selectivity. In these instances a mass-spectrometry (MS) based assay may be a viable and sensitive alternative. We will discuss the development of several highly sensitive, high-throughput mass spectrometry-based assays for use in preclinical and clinical analysis or biomarkers. One assay for P1NP from rat plasma or serum that does not rely on antibody reagents and a second assay for human Alcohol Dehydrogenase (ADH) which distinguishes the various isoforms in liver tissue will be discussed in detail. Sample preparation considerations, development of sensitive and selective MS-based assays, and absolute quantification methodology will be discussed. P1NP immunoassay data will be compared to MS-based P1NP data to access reproducibility. In addition to absolute selectivity, the MS-based assays provide throughput parallel to that of most antibody-based assays so they can handle a large number of samples that are generated from preclinical animal studies.

Biomarker Qualification: Biological and Analytical Validation

2:00 Chairperson's Opening Remarks

Chairperson to be Announced

2:00-2:30 Biomarker Development and their Clinical Qualification

Wendy Sanhai, Ph.D., Senior Scientific Advisor, Office of the Commissioner, U.S. Food and Drug Administration

A biomarker is a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention. In this regard, the spectrum of uses for biomarkers ranges from diagnostic tools (early identifiers of disease, target identification), patient identification/triage (e.g. Her-2-Nu positive for treatments with Herceptin), tools in assessing response to therapy (mechanistic biomarkers and imaging modalities) and biomarkers that are used for staging disease progression. This presentation will describe some of the biomarker development efforts underway at FDA and in partnership with FDA, and will list some of the benefits obtained to date.

2:30-3:00 Critical Path Institute: Collaboration Towards Biomarker Qualification

Maryellen de Mars, Ph.D., Director, Clinical Biomarkers, The Critical Path Institute

Critical Path Institute creates innovative collaborations in research and education that enable the safe acceleration of the process for developing new medical products. One particular area of focus for C-Path-led efforts is the development of biomarkers and qualification for use in assessing drug safety and drug efficacy. Ongoing projects in cancer (efficacy) and cardiovascular (safety) biomarkers will be highlighted. The aim of these collaborative efforts is to help define and streamline a process for developing qualified biomarkers and to standardize the evaluation and validation of molecular diagnostics.

3:00-3:30 Biospecimen Research to Enable Molecular Medicine

Helen M. Moore, Ph.D., Director, Biospecimen Research Network, National Cancer Institute, National Institutes of Health

Biospecimens, such as tissue, blood or urine, are routinely collected to aid in patient diagnosis and disease research. Notably, biospecimens are vulnerable to environmental and biological stresses introduced by routine collection, processing, storage, and transport procedures prior to analysis. These "pre-analytical" variables may transform the molecular profile of the biospecimen before it ever reaches the clinician or researcher. Without proper understanding of the impact of pre-analytical variables, molecular changes may be misinterpreted as disease-related or even disease-specific findings. New attention to this issue is needed, particularly with the movement toward an era of "Personalized Medicine," where appropriate preservation of biospecimens will be essential for molecular tests that diagnose disease and target therapies based on patient molecular characteristics. The National Cancer Institute has recently established a new research program, "The Biospecimen Research Network," to improve the quality of biospecimen-based research by sponsoring, conducting, and collaborating on research studies to assess the effects of human specimen pre-analytical variables on the outcome of genomic and proteomic studies. These results will support discovery efforts and contribute to the development of evidence-based best practices for the collection, processing, storage, and analysis of biospecimens, building on the "NCI Best Practices for Biospecimen Resources.

3:30-4:00 RNA Readouts as Clinical Biomarkers

Stewart Bates, Ph.D., Director, Stevenage Core Technologies Group, Discovery Technology Group, GlaxoSmithKline

RNA profiling technologies provide an opportunity for unbiased biomarker discovery, and recent years have seen a significant increase in the translation of these RNA-based endpoints in clinically utility. We have used RNA profiling to identify candidate pharmacological and diagnostic biomarkers across a range of applications in preclinical and clinical drug discovery. In particular, coupling the use of RNA profiling to *ex vivo* human cell and tissue models, we have not only been able to identify candidate gene signatures, but also translate these findings into clinically validated biomarkers. I will discuss some examples of both diagnostic and pharmacological biomarkers that we have validated through this translational model.

4:00 Close of Conference

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MAIN CONFERENCE		
Standard Package: The Standard Package includes access to all Plenary Sessions, Exhibit Hall functions, and conference proceedings.		
Early Registration Discount until February 27, 2009	❒ $1495	❒ $595
Advance Registration Discount until April 10, 2009	❒ $1695	❒ $695
Registration after April 10, 2009 and on-site	❒ $1895	❒ $795
Premium Package		
(Qualified Attendance only): The Premium Package includes access to all Plenary Session and Pre-Conference Executive ThinkTank. Access is limited to delegates who are Senior Management-level or above at pharmaceutical, diagnostic or biotechnology companies. Every registration application is subject to approval by conference organizers. For additional information, please contact Julia Boguslavsky at ***juliab@healthtech.com***		
Early Registration Discount until February 27, 2009	❒ $2195	
Advance Registration Discount until April 10, 2009	❒ $2395	
Registration after April 10, 2009 and on-site	❒ $2695	
Poster Discount	❒ - $50	❒ - $50

Biomarker BRIDGE

❒ I am a member of the **Biomarker Bride Community Network**
❒ I would like receive information about the **Biomarker Bridge Community Network**
Click here or contact Bethany Gray at 781-972-5494 - biomarkerbridge@healthtech.com for more informaiton

❒ I cannot attend but would like to purchase the Biomarker World Congress 2009 conference CD's for $500 (plus shipping). Massachusetts delivery will include 5% sales tax.

❒ Please send information on exhibiting and opportunities to present workshops.

PAYMENT INFORMATION

❒ Enclosed is a check or money order payable to Cambridge Healthtech Institute, drawn on a U.S. bank, in U.S. currency.

❒ **Invoice me, but reserve my space with credit card information listed below.**

Invoices unpaid two weeks prior to conference will be billed to credit card at full registration rate. Invoices must be paid in full and checks received by the deadline date to retain registration discount. If you plan to register on site, please check with CHI beforehand for space availability.

❒ Please charge: ❒ AMEX (15 digits) ❒ Visa (13-16 digits) ❒ MasterCard (16 digits)

Card # Exp. Date

Cardholder

Signature

Cardholder's Address (if different from above)

City/State/Postal Code Country

Fax or Mail Registration to:
Cambridge Healthtech Institute
250 First Avenue, Suite 300, Needham, MA 02494
T: 781.972.5400 • Toll-free in the U.S. 888.999.6288
F: 781.972.5425 • www.healthtech.com

Please send information about related CHI conferences:

❒ Personalized Medicine GVR
❒ Biomarker Assay Development BMA
❒ Protein Biomarkers BMK
❒ Clinical Biomarkers BMD

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 CD, your abstract must be submitted, accepted and registration paid in full by **April 15, 2009**. Register online to use the Poster Abstract Submission form or, if you register by phone, fax, or mail, you will receive Poster Abstract Submission guidelines via email. I am interested in presenting a poster at:

❒ BIOMARKER WORLD CONGRESS
and will submit a completed one-page abstract by **April 15, 2009**. (Please Note: Registration must be paid in full to present a poster.)

Title

CHI Insight Pharma Reports
A series of reports that evaluate the salient trends in pharmaceutical technology, business, and therapy markets. Keep abreast of the latest advances in pharmaceutical R&D, their potential applications and business impacts, and their current and future position in the marketplace. For a list of reports, visit InsightPharmaReports.com, or contact Rose LaRaia, rlaraia@healthtech.com, 781-972-5444.

Barnett Educational Services
Live and web seminars, customized training, and publications for professionals involved in the drug develpment and clinical trials industry. Visit www.barnettinternational.com.

Additional Registration Details
Each registration includes all conference sessions, posters and exhibits, food functions, and a copy of the conference CD.

Group Discounts
Special rates are available for multiple attendees from the same organization. Contact David Cunningham at 781-972-5472 to discuss your options and take advantage of the savings.

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.

Substitution/Cancellation Policy
In the event that you need to cancel a registration, you may:

- Transfer your registration to a colleague within your organization. Credit your registration to another Cambridge Healthtech Institute program.
- Request a refund minus a $100 processing fee per conference.
- Request a refund minus the cost ($500) of ordering a copy of the CD .

NOTE: Cancellations will only be accepted up to two weeks prior to the conference.
Program and speakers are subject to change.

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

CAMBRIDGE HEALTHTECH INSTITUTE OFFERS AN EXPANSIVE SUITE of information resources specific to Biomarkers and Diagnostics. Follow these links for articles, social networking, research, seminars and conferences all pertaining to Biomarkers and Diagnostics.

Bio·IT World
Technologies Driving Discovery, Development, and Clinical Trials

Insights on Biomarkers and Diagnostics

Bio-IT World magazine – CHI's flagship publication – publishes critical insight, analysis, and opinion on the tools and results of predictive biology, drug discovery, informatics, clinical research, and personalized medicine, in addition to the strategic decisions made by companies in these areas. Please visit **www.bio-itworld.com** to view feature articles, white papers, and podcasts on the life sciences industry and to subscribe to the magazine.

A series of insightful and informative articles focusing on Biomarkers and Diagnostics are below. Please click on each article link to read.

- **Using Molecular Diagnostics**
  By Larry Hand
- **Amgen's Personalized Medicine Story**
  By Kevin Davies, Ph.D.
- **The Biomarker Business**
  By Christopher Huels
- **Merck-Moffitt Partnership Breaks Down Silos**
  By Catherine Varmazis
- **Dutch Drug Development Heats Up**
  By Allison Proffitt

Related Web Site

Introducing **www.eCliniqua.com** – a web site focusing on the clinical trials industry.

CAMBRIDGE HEALTHTECH MEDIA GROUP **STAY INFORMED with free eNewsletters focusing on the life sciences industry from Cambridge Healthtech Media group - www.chimediagroup.com.**

The latest industry news, commentary and highlights from Bio•IT World.

eCliniqua
Innovative management in clinical trials.

Predictive Biomedicine
Informatics tools and strategies driving decisions.

CHI's Biomarker Series: Six Years of Success

CONFERENCES HEALTHTECH.COM

CHI's Biomarker Series features several biomarker related events annually, attracting upwards of 500 participants. Due to an overwhelming response from the scientific community and a consistent track-record of delivering cutting-edge programs and an expert audience, this series has shown a positive growth and has branched out to include coverage in Translational Medicine, Biomarker Assay Development, Personalized Medicine, Oncology, and Clinical Pharmacology to name a few. In order to bring you the solutions and strategies that impact the bottom line, as well as provide a forum to address the most timely opportunities and the most burning issues industry-wide, we spent years researching the issues pertaining to biomarker implementation and staying in close contact with pharmaceutical executives and leading scientists. We believe that the potential value of biomarkers can best be exploited by working together and sharing information. We invite you to join us in this process. The Biomarker Series flag ship event is the Fifth Annual Biomarker World Congress, to be held May 27-29, 2009 in Philadelphia. This event features more than 500 attendees, 30 exhibits, 60 presentations and numerous networking opportunities.

- **The Biomarker World Congress**
- **Biomarker Assay Development**
- **Translational Cancer Medicine**
- **Translational Medicine**
- **Biomarker Discovery Summit**
- **Biomarkers Europe**
- **ADAPT**
- **Protein Biomarkers**

Bio〉marker BRIDGE

What is the Biomarker Bridge?

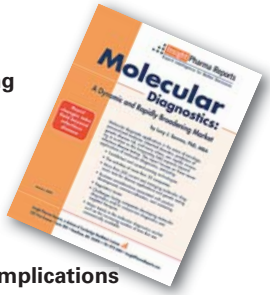
An interactive collaborative network community for pharmaceutical, clinical and IT professionals who are interested in gaining and sharing knowledge about technologies, research, and regulatory issues around life science. ■ **Sign up today!**

Insight Pharma Reports

Insight Pharma Reports Targets Cardiotoxicity and Biomarker SOPs

Insight Pharma Reports is the premier life science information provider. Insight Pharma Reports offer unparalleled coverage of key issues in biomarkers and diagnostics. Our reports are used by leading pharmaceutical, biotech, diagnostic, and other life science companies to keep abreast of the latest developments in pharmaceutical R&D and their potential applications and business impacts. The reports are written by experts in consulting and industry, and are supported by hundreds of hours of primary and secondary research.

- **Molecular Diagnostics: A Dynamic and Rapidly Broadening Market**
- **Cancer Biomarkers: Adoption Is Driving Growth**
- **Disease-Related Biomarkers: Their Potential in Patient Screening, Prognosis, and Stratification**
- **Biomarker SOPs: Getting Optimum Value from Your Biomarker Programs**
- **Biomarkers in Clinical Development: Implications for Personalized Medicine and Streamlining R&D**



BARNETT EDUCATIONAL SERVICES

Barnett Seminars Keep You Informed on the Latest in Biomarkers and Diagnostics Issues

CHI's Barnett International is the premier provider of clinical research training resources. Through its live courses, web-based training, eLearning, and in-house training and consulting services, and publications, Barnett partners with leading sponsors, CROs and clinical research sites to ensure that research teams are trained according to FDA, ICH and global regulatory standards. Featured events and services include:

- **Biomarkers of Drug Efficacy and Safety Training**
- **Clinical Trials for Pharmaceuticals: Design and Development**
- **Adverse Events: Managing and Reporting for Pharmaceuticals**
- **Curriculum Compliance Assessment and Development**

D·S·E·C **The Drug Safety Executive Council (DSEC)** is a peer-to-peer membership of over 1,500 drug safety leaders with the common objective of advancing the development of better and safer medicines.