Cambridge Healthtech Institute's Eighth Annual

BIOMARKER WORLD CONGRESS 2012

MAY 21 - 23, 2012 | LOEWS PHILADELPHIA HOTEL | PHILADELPHIA, PA

Pre-Conference Events:

Short Course: Fit-for-Purpose Biomarker Assay Development and Validation

New Company Showcase and Partnering Forum: Next-Generation Biomarkers and Diagnostics

Executive ThinkTank: Partnering Strategies in Drug-Diagnostic Co-Development

The Leading Annual Meeting Dedicated to Biomarker Research and Implementation

Conference Programs

Track 1:
Biomarkers in Drug Development

Track 2:
Molecular Diagnostics

Track 3:
Biomarker Assay Development

Track 4: Executive Summit:
Drug-Diagnostic Co-Development

Featured Speakers

Felix W. Frueh
President
Medco Research Institute

Geert Kolvenbag
Global Product Vice President
AstraZeneca

Nicholas C. Dracopoli
Head, Oncology Biomarkers
Janssen R&D

Walter H. Koch
Head, Global Research
Roche Molecular Diagnostics

Michael C. Little
Global Head, Diagnostics Development
Novartis Molecular Diagnostics

Duncan McHale
VP, Global Exploratory Development
UCB Pharma

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Conference-at-a-Glance

MONDAY, MAY 21				
8:00-9:00 am	Registration for Pre-Conference Events			
9:00 am-12:00 pm	Pre-Conference Short Course: Fit-for-Purpose Biomarker Assay Development and Validation*			
1:00-2:00	Main Conference Registration			
2:00-4:15	Biomarkers as Decision-Making Tools			
4:15-5:15	Welcome Reception in the Exhibit Hall with Poster Viewing			
TUESDAY, MAY 22				
	Track 1: Biomarkers in Drug Development	Track 2: Molecular Diagnostics	Track 3: Biomarker Assay Development	Track 4 Executive Summit: Drug-Diagnostic Co-Development
7:30-8:15 am	Breakfast Presentation MYRIAD RBM			
8:25-9:30	Case Studies in Rx/Dx Co-Development			
9:30-10:30	Coffee Break in the Exhibit Hall with Poster Viewing			
10:30-12:30	TECHNOLOGY SHOWCASE: Biomarkers in Drug Development	TECHNOLOGY SHOWCASE: Biomarkers in Molecular Diagnostics	TECHNOLOGY SHOWCASE: Biomarkers in Molecular Diagnostics	Developing Rx and Dx under One Roof
12:30-2:00	Luncheon Presentation BIOSCALE	Enjoy Lunch on Your Own	Enjoy Lunch on Your Own	LUNCHEON TECHNOLOGY SHOWCASE: Drug-Diagnostic Co-Development
2:00-4:00	Biomarkers to Predict Clinical Outcome	Strategies for Companion Diagnostic Development	The Future of Laboratory-Developed Tests	Strategies for Companion Diagnostic Development
4:00-5:00	Refreshment Break in the Exhibit Hall with Poster Viewing			
5:00-6:00	Use of Biomarkers in Proof-of-Concept	Clinical Genomics: Adoption of Next-Generation Sequencing	Biomarker Assay Development for Diagnostics	Regulatory Strategies for Rx-Dx Co-Development
WEDNESDAY, MAY 23				
7:30-8:15 am	Breakfast Presentation (Sponsorship Opportunity Available)			
8:25-10:00	Biomarker Assays to Support Drug Development	Liquid Biopsy: Using Circulating Biomarkers to Develop Non-Invasive Diagnostics	Biomarker Assays to Support Drug Development	Partnering Strategies for Rx-Dx Co-Development
10:00-11:00	Coffee Break in the Exhibit Hall with Poster Viewing			
11:00-12:00	Biomarker Assays to Support Drug Development (continued)	Liquid Biopsy: Using Circulating Biomarkers to Develop Non-Invasive Diagnostics (continued)	Biomarker Assays to Support Drug Development (continued)	Panel Discussion
12:00-1:30	Enjoy Lunch on Your Own	Luncheon Presentation Singulex	Enjoy Lunch on Your Own	Enjoy Lunch on Your Own
1:30-3:00	Pharmacogenomic Biomarkers to Predict Benefit from Therapy			
3:00	Close of Conference			

*Separate registration required

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Garret Hampton, Ph.D., Senior Director, Oncology Biomarker Development, Development Sciences, Genentech

Bonnie J. Howell, Ph.D., Head, Molecular Biomarkers, Merck West Point

J. Milburn Jessup, M.D., Chief, Diagnostics Evaluation Branch, Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health

Walter H. Koch, Ph.D., Vice President and Head of Global Research, Roche Molecular Diagnostics

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

Michael C. Little, Ph.D., Global Head, Diagnostics Development, Novartis Molecular Diagnostics

Sabah Malek, Senior Regulatory Scientist, IVD/ Medical Devices, Voisin Consulting Life Sciences

Marielena Mata, Ph.D., Principal Research Scientist, Oncology Biomarkers, CNTUS, Janssen Research & Development

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K. Stephen Suh, Ph.D., Director, Genomics and Biomarkers Program, Cancer Center, Hackensack University Medical Center

Mya Thomae, CEO, Myraqa, Inc.

Jennifer E. Van Eyk, Ph.D., Professor, Medicine, Biomedical Engineering, and Biological Chemistry; Director, Biomarker Development Group, Johns Hopkins University School of Medicine

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Pre-Conference Events May 21

8:00-9:00 am Registration for Pre-Conference Events

9:00 am-12:00 pm Pre-Conference Short Course*

Fit-for-Purpose Biomarker Assay Development and Validation

Instructors:

John L. Allinson, FIBMS, Vice President, Biomarker Laboratory Services, ICON Development Solutions

Viswanath Devanarayan, Ph.D., Director, Exploratory Statistics, Abbott Laboratories

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. Pre-analytical 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

Main Conference May 21

1:00-2:00 Main Conference Registration

2:00-2:10 Welcoming Remarks from Conference Director

Julia Boguslavsky, Executive Director, Conferences, Cambridge Healthtech Institute

Biomarkers as Decision-Making Tools

2:10-2:15 Chairperson's Opening Remarks

2:15-2:45 Turning an Active Compound into a Personalized Medicine: Do Biomarkers Help or Hinder?

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

The co-development of drug and biomarker has several inherent risks and challenges. In addition, the expectations and demands of the oncology community have increased over the last years. These challenges will be illustrated by a case study of a very active compound destined for a fast development program as a personalized medicine, but running into scientific, diagnostic and development challenges. This experience creates questions for the development of drugs and diagnostics today and in the future.

2:45-3:15 Evaluation of Biomarker Performance in the Real World: Comparative and Cost-Effectiveness Considerations

Felix W. Frueh, Ph.D., President, Medco Research Institute, Medco Health Solutions, Inc.

The difference between the potential to achieve an outcome and actually achieving it for a biomarker-guided intervention can be measured as the performance of a biomarker under controlled (optimized) conditions and its actual performance in the real-world. Similar to post-approval safety and efficacy evaluations of drug therapies that differ from data found in pre-market assessments, the impact on clinical outcomes using biomarker-guided interventions are often not fully understood until these interventions are performed and analyzed in the heterogeneous environment of real-world clinical practice. Following the two most critical factors, clinical outcomes and cost associated with reaching these outcomes, the Medco Research Institute has been conducting a series of real-world assessments of the performance of biomarkers to determine whether or not they should be integrated into everyday clinical practice.

3:15-3:45 Biomarkers: Finding the Balance between Driving Decision Making and Value or Distraction from Developing Drugs

Ian White, Ph.D., Associate Director, Global Exploratory Development, UCB Pharma

The past 5 years have seen an increasing focus on the identification and qualification of biomarkers. We now have tools which can generate proteomic or nucleotide data on hundreds of thousands of markers in single experiments and whole departments whose aim is to identify and qualify biomarkers. There are now 2 ICH guidances (E15 and E16) on genomic biomarkers and new regulatory processes developed specifically for qualifying biomarkers for use in regulatory decision making. This talk provides examples of where real value has been obtained using biomarkers as well as other areas where it has not. It will ask whether we have the balance right and how much should we invest in biomarkers and when.

3:45-4:15 Predicting Benefit to Therapy: Biomarkers and Molecular Profiles in Oncology Drug Development

Nicholas C. Dracopoli, Ph.D., Head, Oncology Biomarkers, Janssen Research & Development

The main goals of biomarker research in the pharmaceutical industry are to increase efficiency of the drug development process by improving understanding of the mechanism of action, deeper exploration of PK-PD interactions and predicting response to novel therapies in clinical development. However, predictive biomarkers are still only included in the labels of a minority of the oncology drugs approved in the U.S. since Herceptin in 1998. The development of novel biomarkers has enormous potential to impact drug development and improve patient outcomes. However, no complex molecular or protein profiles have been approved by the FDA to drive therapeutic use of any drug. This presentation will show how the small numbers of patients enrolled in clinical trials and the lack of long-term outcome data have limited the discovery of complex molecular profiles with strong predictive values (both negative and positive), and show how simple biomarkers measuring the status of the drug target or pathway (BRAF mutation, ALK-EML4 translocation, etc.) have been much more successful in the identification of highly predictive biomarkers which have been developed as companion diagnostics to drive therapeutic use of novel oncology drugs.

4:15-5:15 Welcome Reception in the Exhibit Hall with Poster Viewing

**Separate Registration Required*

TUESDAY, MAY 22

7:30-8:15 am Breakfast Presentation
Identification of Fluid Biomarkers of Treatment Response in Schizophrenia CSF and Plasma Samples

Sponsored by MYRIAD RBM

Eric Schaeffer, Ph.D., Director, Neuroscience Clinical Biomarkers, Bristol-Myers Squibb

Schizophrenia is a heterogeneous disease of complex and poorly understood etiology. Patients are often prescribed one of several approved medications based on their symptoms, but there is a high rate of switching among medications during a period of trial and error, while physicians seek to identify a drug(s) which will result in stabilization of symptoms. Given the variability in treatment response, there would be considerable value in the identification of a biomarker(s) which could provide an indication of whether a patient is responding to a particular medication early in the treatment regimen. This talk will discuss a biomarker identification and validation strategy focusing on highly multiplexed immunoassay panels offered by Myriad RBM.

Case Studies in Rx/Dx Co-Development

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

8:30-9:00 Zelboraf
The Co-Development of Zelboraf and Its Companion Diagnostic

Walter H. Koch, Ph.D., Vice President and Head of Global Research, Roche Molecular Diagnostics

Cancers can be categorized based on their molecular etiology, including oncogenic driver mutations that are present. The development of targeted therapies alongside companion diagnostics that will identify patients most likely to receive benefit provides the opportunity to increase the success rate for oncology drugs and to decrease development time and associated costs. This presentation will detail the co-development of Zelboraf and the cobas 4800 BRAF V600 mutation test from the diagnostics perspective. This integrated process resulted in approval of the first personalized medicine for the treatment of metastatic melanoma within 6 years of the drug's discovery, a remarkably short time.

9:00-9:30 Crizotinib
The Xalkori, ALK CDx Partnership

Karen S. Long, Vice President, Medical, Regulatory and Clinical Affairs, Abbott Molecular

Pharmaceutical companies are increasingly engaging diagnostic companies to develop companion diagnostics to help select patients for their therapeutics. There are a number of factors that guide the pharmaceutical company's choice of diagnostic partner including IP considerations, diagnostic platform requirements and commercialization capabilities. However, in view of the relative size and importance of the U.S. market, the ability of the diagnostic company to navigate through the sometimes ambiguous regulatory process in the U.S. becomes a critical consideration, as this is vital to achieve product launch timing objectives and overall success of the therapeutic. There have been some recent examples of rapid co-development and approval of therapeutic/diagnostic product combinations in the U.S. including the recent Xalkori/ALK CDx approval. This session explores the factors that were most important in the successful co-development effort, approval and subsequent commercialization of the diagnostic.

9:30-10:30 Coffee Break in the Exhibit Hall with Poster Viewing

TECHNOLOGY SHOWCASE: Biomarkers in Drug Development

10:30-11:00 Successful Mass Spectrometry Strategies for Biomarker Discovery and Verification

Sponsored by CAPRION

Daniel Chelsky, Ph.D., CSO, Caprion Proteomics

Two mass spectrometry methods have been applied for the rapid discovery of biomarker and diagnostic candidates. In the first approach, a non-hypothesis driven strategy was applied to compare multiple disease cohorts in TB. Hundreds of proteins were identified, of which 90 were found to be differentially expressed, based on relative peptide signal intensity. The candidate proteins were then specifically targeted with a multiplexed "MRM" mass spectrometry assay and analyzed in different populations, resulting in verification of many of the disease markers. In a second discovery approach, the non-hypothesis based strategy was bypassed in favor of focusing on the known biology. Hundreds of proteins associated with immune response were specifically targeted in an MRM assay to identify a subset associated with vaccine efficacy.

11:00-11:30 Translational Biomarkers in Drug Development

Sponsored by Huntingdon Life Sciences

Mark Fidock, Ph.D., Global Head, Biomarkers & Translational Sciences, Huntingdon Life Sciences

The Pharmaceutical Industry faces many challenges in the development of new medicines. As part of risk management, the strategic development and use of Biomarkers will ensure that the projects hypothesis is confidently tested in the clinic. To exemplify these principles, a case study form the area of inflammation will describe how Biomarker data was employed for key decision making during the TLR7 drug development programme.

12:30-2:00 Luncheon Presentation
Activity State Quantification of Kinase Pathways Using AMMP Single Plate Technology

Sponsored by BIOSCALE

W. Matthew Dickerson, Ph.D., Senior Scientist, Assay Development, BioScale, Inc.

Gathering data on the activation-state of MAP and PI3 kinases from tumor samples could accelerate drug development. Non-optical, AMMP technology is used to quantitate the activity state of multiple kinases including EGFR, MEK/ERK dimer, AKT, p38 and JNK. Unstimulated tumor lysates were compared with those stimulated by ligands to well-known surface receptors for changes in their phosphorylation states. The data show AMMP assays can monitor the MAP/K pathway activation from EGF stimulation through ERK phosphorylation.

Biomarkers to Predict Clinical Outcome

2:00-2:30 Applying Pharmacogenomics Effectively in Psychiatry and How to Overcome the Hurdles

Nadine Cohen, Ph.D., Senior Director, Head of Pharmacogenomics and Biomarker Execution Leader, Neuroscience Biomarkers, Janssen Pharmaceuticals Companies of Johnson & Johnson

An overview of pharmacogenomics applications at Janssen Neurosciences in Psychiatry will be discussed. Learn about using genomics to redefine mental disorders, managing complexity in psychiatric diseases with heterogeneity in disease biology and treatment response, and identifying genetic markers of clinical utility associated with treatment response for psychiatric drugs.

2:30-3:00 Case Study: Identifying a Predictive Biomarker of Response to Imetelstat, a Telomerase Inhibitor

Katia Bassett, Ph.D., Scientist II, Translational Oncology, Geron Corporation

Imetelstat is a specific inhibitor of telomerase, currently in Phase II clinical trials. Differential sensitivity to Imetelstat has been observed *in vitro*. Diseases with short telomeres are highly susceptible to Imetelstat *in vitro*. Telomere length is a candidate predictive biomarker for Imetelstat responsiveness, being developed to increase probability of success of Imetelstat in the clinic.

3:00-3:30 Hodgkin's Lymphoma Biomarkers to Predict Clinical Outcome

K. Stephen Suh, Ph.D., Director, Genomics and Biomarkers Program, Cancer Center, Hackensack University Medical Center

Hodgkin's lymphoma (HL) represents 12% of all lymphoma cases and up to 16% of HL patients are either refractory or undergo multiple relapses. To investigate whether circulating HL cells are associated with poor clinical outcome, PBL of HL patient samples were analyzed for the presence of CD30+/CD15+ cells in the PBL buffy coat. Our data showed that circulating HL cells were only found in the bad outcome group and these cells overexpress SDC1 and FGF2. A subpopulation of HL tissues tested include CD30+ HL cells that co-overexpress SDC1, FGF2 and metastatic markers TGF-beta and MMP9. Together, these data suggest that aggressive HL cells may shed from the tumor microenvironment to enter systemic circulation and metastasize to distant organs.

3:30-4:00 Biomarkers in Discovery and in Clinical Trials

Suso Platero, Ph.D., Director, Oncology Biomarkers, Janssen Research & Development

Biomarkers are the tools that can bring personalized therapy to fruition. They have the ability to become companion diagnostics if there is a good correlation between the readout of the biomarker and response to a specific therapy, such as the recent case of ALK translocation and Crizotinib. Early studies in development of compounds are required if one expects to have biomarkers ready at the same time the drug is approved. The discovery of several predictive and pharmacodynamic biomarkers will be described using both *in vitro* and *in vivo* methods together with their applications in clinical trials.

4:00-5:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Use of Biomarkers in Proof-of-Concept

5:00-5:30 Presentation to be Announced

5:30-6:00 Using Predictive Diagnostics to Enable Therapeutic Proof-of-Concept in Cancer Subpopulations

Garret Hampton, Ph.D., Senior Director, Oncology Biomarker Development, Development Sciences, Genentech

Clinical development of new medicines in cancers has typically taken an all-comers approach, assessing drugs on the basis of anatomic origin. This approach has led to generally high clinical failure rates, increasing the overall cost of bringing new drugs to patients, and creating an unsustainable development paradigm. Here, we discuss how reasonably formulated diagnostic hypotheses, coupled with appropriate clinical trial design and clinical operations, enable therapeutic proof-of-concept in cancer sub-populations. We discuss how these studies further our understanding of disease and enable the co-development of companion diagnostics to make informed treatment decisions.

WEDNESDAY, MAY 23

7:30-8:15 am Breakfast Presentation *(Opportunity Available. Contact Ilana Quigley at iquigley@healthtech.com or 781-972-5457)*

Biomarker Assays to Support Drug Development

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

8:30-9:00 Automated Platforms in Biomarker Analysis Past, Present and Future: Case Studies, Comparisons and Review of Assay Validation Data

John L. Allinson, FIBMS, Vice President, Biomarker Laboratory Services, ICON Development Solutions

Presentation will cover a variety of analytical platforms used to measure biomarkers in support of drug development. It will look at the evolution and development of the platforms, and give case-study data generated on some of them. It will also give a personal insight into possible developments in the future as the use of biomarkers for patient stratification and companion diagnostics increases; and discuss the challenges in developing and transferring methods for new biomarkers on to these platforms—including point-of-care-type equipment.

9:00-9:30 Analytical-Grade Multiplexed Assays—Requirements from the Biomarker Community

Sponsored by MSD Meso Scale Discovery

Robert Umek, Ph.D., Director, External Scientific Affairs, Meso Scale Discovery

Scientists and clinicians appreciate the importance of protein biomarkers in drug development and therapeutic management. We will explore the challenges associated with an increasing demand for reliable, meaningful biomarker panels and how these demands can be met using MSD's multiplexed quantitative immunoassays. This talk focuses on protein biomarkers from a practical perspective, exploring the complex roles played by corporations, regulatory agencies, and independent researchers, and the challenges they face meeting the demand for biomarker panels that support their research and clinical objectives.

9:30-10:00 Leveraging Enabling Technologies for Biomarker Discovery and Validation

Bonnie J. Howell, Ph.D., Head, Molecular Biomarkers, Merck West Point

10:00-11:00 Coffee Break in the Exhibit Hall with Poster Viewing

11:00-11:30 Bioanalytical Challenges to Quantify Soluble "Free" Target Biomarkers in Antibody Therapeutics

Jenny Wang, Ph.D., Principal Scientist, Pharmacokinetics, Dynamics, and Metabolism, Pfizer

Many therapeutic antibodies act through neutralization of soluble targets in circulation. The free target concentration is an important biomarker for understanding the dynamic relationship of the drug and the target for determining therapeutic efficacy and assisting the model-based determination of optimal dose selection and regimen. The association and dissociation of the immune complexes, dynamic ratios of the drug and the target over time after dosing, and multiple sources of disturbance of the drug/target equilibrium during bioanalysis and sample handling pose a tremendous challenge for accurate quantification of free target concentrations in biological samples. In this presentation, a therapeutic antibody against a soluble peptide is used as a case study to illustrate major factors that affect the accuracy of free target measurement. Immune complex separation techniques and critical reagent selection will be discussed.

11:30-12:00 Integrating Proteomics and Genomics into Next-Gen Systems Pathology

Michael H. A. Roehrl, M.D., Ph.D., Assistant Professor and Director of BioBanking, Department of Pathology and Laboratory Medicine, Boston Medical Center

We will discuss proteomic and metabolomic cancer biomarker discovery, cancer exome sequencing, and joint computational data interpretation of next-gen sequencing with proteomics. We will discuss specific applications from our institution of comprehensive omic profiling of solid tumors from patients and the application of cutting-edge technology development in mass spectrometry and next-gen sequencing to drive and innovate personalized molecular medicine. We will demonstrate that ultra-rapid tissue biobanking is critically important for faithful physiome preservation to enable biomarker discovery and next-gen molecular diagnostics.

12:00-1:30 Enjoy Lunch on Your Own

Pharmacogenomic Biomarkers to Predict Benefit from Therapy

1:30-2:00 Discovery of Pharmacogenomic Biomarkers in Cardiovascular and CNS Disorders through Expression Genomics

Wolfgang Sadee, Dr.rer.nat., Professor and Chair, Pharmacology; Director, Program in Pharmacogenomics, The Ohio State University

Genetic biomarkers have potential clinical utility for predicting disease risk and outcomes, including response to therapy. Pharmacogenomic biomarkers are rapidly gaining acceptance in drug discovery, development and therapy; however, a substantial portion of the responsible genetic factors is still uncertain ("missing heritability"). Available evidence suggests that genetic variants affecting expression regulation and RNA processing/translation may account for a large portion of genetically-determined phenotypic variability. We have developed comprehensive assays to detect regulatory variants, recently including the use of second-generation sequencing. Results have revealed the existence of frequent genetic variants with strong influence on clinical phenotypes, including drug response, even in important pharmaco-genes that had been under intense study for some time (e.g., CYP3A4, DRD2, DAT, HTR2A, CETP, ACE, NAT1). Several of these variants have promise as biomarkers for drug therapy, possibly as companion diagnostics in specific cases.

2:00-2:30 Improving Efficacy and Reliability for Personalized Medicine: The Role of Companion Diagnostics in Drug Development

Amelia Warner, Ph.D., Director, Clinical Pharmacogenomics, Merck

Identification of subpopulations of patients who either have subclinical response or toxicity to a drug in clinical development is a challenge. Historically, identification of patients who have less than optimal response to drugs has occurred late in large global clinical trial review. However, the pharmaceutical industry is working to optimize preclinical models, known genetic variation across populations, and earlier inclusion of surrogate biomarkers in early development programs to allow for early identification of populations that will benefit from alternate dosing or alternate therapies. Adapting development strategies to include companion diagnostics remains a challenge, but pharmaceutical companies are developing clear working models to enable development of personalized therapies.

2:30-3:00 Utilization of Biomarkers in Development of Treatments for Heterogeneous Immunologic Diseases

Carrie Brodmerkel, Ph.D., Director, Immunology Biomarkers, Centocor R&D

Ulcerative colitis (UC) and Crohn's disease (CD) are heterogeneous diseases that impact the gastrointestinal system. While anti-TNF therapy is effective in both diseases, there remains a significant population that does not derive benefit. Understanding the molecular signature of response to anti-TNF treatment can identify the core pathway modulation required to achieve clinical response while understanding the non-response signature can aid in identifying novel pathways which may be driving disease in anti-TNF non-responders. Here we present molecular cross-comparison of UC and CD as well as the effects of biologic therapies on the dysregulated pathways. These results offer insight into the patient subpopulations most likely to benefit from therapy.

3:00 Close of Conference

TUESDAY, MAY 22

7:30-8:15 am Breakfast Presentation

Sponsored by MYRIAD RBM

Identification of Fluid Biomarkers of Treatment Response in Schizophrenia CSF and Plasma Samples

Eric Schaeffer, Ph.D., Director, Neuroscience Clinical Biomarkers, Bristol-Myers Squibb

Schizophrenia is a heterogeneous disease of complex and poorly understood etiology. Patients are often prescribed one of several approved medications based on their symptoms, but there is a high rate of switching among medications during a period of trial and error, while physicians seek to identify a drug(s) which will result in stabilization of symptoms. Given the variability in treatment response, there would be considerable value in the identification of a biomarker(s) which could provide an indication of whether a patient is responding to a particular medication early in the treatment regimen. This talk will discuss a biomarker identification and validation strategy focusing on highly multiplexed immunoassay panels offered by Myriad RBM.

Case Studies in Rx/Dx Co-Development

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

8:30-9:00 Zelboraf

The Co-Development of Zelboraf and Its Companion Diagnostic

Walter H. Koch, Ph.D., Vice President and Head of Global Research, Roche Molecular Diagnostics

Cancers can be categorized based on their molecular etiology, including oncogenic driver mutations that are present. The development of targeted therapies alongside companion diagnostics that will identify patients most likely to receive benefit provides the opportunity to increase the success rate for oncology drugs and to decrease development time and associated costs. This presentation will detail the co-development of Zelboraf and the cobas 4800 BRAF V600 mutation test from the diagnostics perspective. This integrated process resulted in approval of the first personalized medicine for the treatment of metastatic melanoma within 6 years of the drug's discovery, a remarkably short time.

9:00-9:30 Crizotinib

The Xalkori, ALK CDx Partnership

Karen S. Long, Vice President, Medical, Regulatory and Clinical Affairs, Abbott Molecular

Pharmaceutical companies are increasingly engaging diagnostic companies to develop companion diagnostics to help select patients for their therapeutics. There are a number of factors that guide the pharmaceutical company's choice of diagnostic partner including IP considerations, diagnostic platform requirements and commercialization capabilities. However, in view of the relative size and importance of the U.S. market, the ability of the diagnostic company to navigate through the sometimes ambiguous regulatory process in the U.S. becomes a critical consideration, as this is vital to achieve product launch timing objectives and overall success of the therapeutic. There have been some recent examples of rapid co-development and approval of therapeutic/diagnostic product combinations in the U.S. including the recent Xalkori/ALK CDx approval. This session explores the factors that were most important in the successful co-development effort, approval and subsequent commercialization of the diagnostic.

9:30-10:30 Coffee Break in the Exhibit Hall with Poster Viewing

TECHNOLOGY SHOWCASE: Biomarkers in Molecular Diagnostics

10:30-10:45 Advanced Molecular Diagnostics Based on Ultrasensitive RNA *in situ* Hybridization

Sponsored by ACD

Yuling Luo, Ph.D., Founder, President & CEO, Advanced Cell Diagnostics, Inc.

RNA biomarkers are traditionally analyzed by "grind-and-bind" assays such as RT-PCR, which loses critical cellular context for clinical interpretation. Recent advances in *in situ* RNA analysis capable of detecting single RNA molecules in routine clinical specimens may finally enable more advanced RNA-based diagnostics.

10:45-11:00 Lot Bridging Considerations for Single and Multiplex Immunoassay Kits in Biomarker Studies

Sponsored by BioAgilytix Labs™

Afshin Safavi, Ph.D., Founder & Vice President, BioAnalytical Operations, BioAgilytix Labs

Biomarker analysis has become a common practice by many pharmaceutical and biotechnology companies to help PK/PD modeling. The reliability of outcomes is heavily influenced by the quality of the kits used to support the studies. The goal of this presentation is to increase awareness of the bioanalytical considerations that are involved in bridging immunoassay assay kit lots.

11:00-12:00 Sponsored Presentations *(Opportunities Available)*

Contact Ilana Quigley at iquigley@healthtech.com or 781-972-5457

12:00-12:30 Utilization of One Platform from Discovery to the Clinic: A Multiplex Approach

Sponsored by Luminex

Jeremy Bridge-Cook, Ph.D., Senior Vice President, Assay Group, Luminex Corporation

When formulating a biomarker strategy from discovery to commercialization, one ideally would utilize a flexible assay platform that could be applied to a broad array of biomarker types, could cover one or many biomarkers simultaneously, could be transitioned directly into clinical trials, regulatory submissions, and the clinic, and that is widely adopted in the diagnostics marketplace. A platform which meets all these criteria will be presented, with examples from discovery to diagnostics.

12:30-2:00 Enjoy Lunch on Your Own

Strategies for Companion Diagnostic Development

2:00-2:30 Lessons Learned in the Development of Companion Diagnostics

Theo McCormick, Director, RxDx Services, Management Science Associates, Inc.

Navigating the scientific, medical, regulatory, contractual and political interactions and dynamics between healthcare professionals, the clinical laboratory, drug manufacturers, IVD diagnostic kit manufacturers and health plans are essential for optimal uptake of drug-diagnostic companion products. Those early decisions in the development cycle have complex downstream impact. This session will map out the trouble spots and potential effects of those decisions.

2:30-3:00 Strategies for Companion Diagnostic Development and Commercialization: Perspectives from a Global IVD Company

John F. Beeler, Ph.D., Director, Theranostics and Business Development, bioMerieux

The drug development process is witnessing a paradigm shift in which new therapies need to be tailored to well-defined patient subgroups via a companion diagnostic assay. With several theranostics partnerships in place at bioMerieux, the speaker will address the challenges of co-development programs and discuss strategies to achieve successful commercialization of these IVD products.

3:00-3:30 The Drug/Diagnostic Development Continuum: Does the Ideal Co-Development Scenario Really Exist?

Rosanne Welcher, Ph.D., M.B.A., Vice President, pharmDx Research and Development, Dako North America

The ideal scenario for co-development of a diagnostic and targeted therapeutic is for both parties to engage at an early stage of drug development. The accepted framework for the development cycle is to align IUO assays to phases of the drug clinical program. Despite best efforts, there are numerous examples of diagnostic assays utilized in pivotal clinical trials that have not yet been fully validated or validated on the target indication. What are the strategies employed to "cut in" or post-validate a diagnostic? This presentation will focus on various scenarios that deviate from the ideal, focusing on the risks and benefits to pharma and the diagnostic partner.

3:30-4:00 Combined CLIA and IVD Strategy Accelerates Timing and Mitigates Risk for Companion Diagnostics

Andrew Grupe, Ph.D., Senior Director, Pharmacogenomics, Celera/ Quest Diagnostics

Personalized medicines are heralded as the future of drug development. Bringing a targeted medicine to market requires the concerted efforts of a drug developer and a diagnostics partner. There is no one-size-fits-all approach for these partnerships, and often a tailored relationship is forged between the two partners either before or during a pivotal Phase III trial. Late stage partnerships increase the drug candidate's risk profile when it is deemed to need a predictive biomarker for a pivotal Phase III trial. This presentation will provide specific examples that illustrate the benefits of working with a diagnostics organization with both experienced IVD manufacturing and an extensive CLIA laboratory infrastructure. The tangible benefits that mitigate the drug development risk and may be attractive to both partners if the relationship starts before Phase II will be described.

4:00-5:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Clinical Genomics: Adoption of Next-Generation Sequencing

5:00-5:30 Pathologists, Participatory Medicine and the Third Wave of Medical Genomics

Mark S. Boguski, M.D., Ph.D., Associate Professor, Center for Biomedical Informatics, Harvard Medical School; Founder, Genome Health Solutions, Inc.

The first two waves of medical genomics focused on therapeutics and pre-symptomatic testing for disease risk assessment. These waves were largely within the purview of the pharmaceutical industry and primary care and public health communities, respectively. The Third Wave focuses on post-symptomatic, precision diagnostics for individualized and optimized disease management. The Third Wave is rising around laboratory physicians and empowered patients working together in a cooperative model of healthcare and outcomes research. Genomics for precision medicine and social networking tools for health communication are key technology enablers of the Third Wave.

5:30-6:00 Use of Next-Generation Sequencing in Clinical Development: The Future Is Here

Premal Shah, Ph.D., Director, Business Development, Genomic Health, Inc.

The use of next-generation sequencing promises to change the drug development paradigm—particularly in oncology. As prices for sequencing drop faster than a Moore's law effect, the real challenge will be to process all the data, ask the right questions, and share information throughout the organization. Just last year it seemed the use of NGS in the clinic seemed 3-5 years away. Not so. The power of NGS combined with falling prices provides an opportunity for biopharma companies to quickly move into this space, gaining a competitive advantage and most importantly, developing targeted therapeutics that will help patients.

WEDNESDAY, MAY 23

7:30-8:15 am Breakfast Presentation *(Opportunity Available. Contact Ilana Quigley at iquigley@healthtech.com or 781-972-5457)*

Liquid Biopsy: Using Circulating Biomarkers to Develop Non-Invasive Diagnostics

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

8:30-9:00 Clinical Microfluidics: Bioengineering and Clinical Applications of the Circulating Tumor Cell Chip (CTC-Chip)

Shannon Stott, Ph.D., Research Fellow, Surgery, Massachusetts General Hospital, Harvard Medical School

This presentation will describe the engineering design and clinical validation of a high-throughput microfluidic mixing device, the "CTC-chip," that allows the isolation and characterization of CTCs from the peripheral blood of cancer patients. The chip design was centered on the concept of passive mixing of blood through the generation of microvortices, ultimately improving the capture of rare cells by dramatically increasing the number of interactions between the target CTCs and the antibody-coated substrate. Multiparameter characterization was conducted on CTCs to help better understand their origin and metastatic potential.

Sponsored by

VERIDEX LLC
a Johnson & Johnson company

9:00-9:30 CellSearch®: Prelude to an Information Rich Future

Mark C. Connelly, Ph.D., Scientific Director, Cellular Research, Janssen Oncology Biomarkers & Site Director, Veridex

- Technology development for rare cell capture and isolation
- Prognostic applications for drug and diagnostic development
- Clinical relevance in breast, prostate and colorectal cancer

9:30-10:00 CTCs: Beyond the Enumeration of EpCam Positive Cells

Marielena Mata, Ph.D., Principal Research Scientist, Oncology Biomarkers, CNTUS, Janssen Research & Development

10:00-11:00 Coffee Break in the Exhibit Hall with Poster Viewing

11:00-11:30 Personalization of Ischemic Disease: Brain and Heart

Jennifer E. Van Eyk, Ph.D., Professor, Medicine, Biomedical Engineering, and Biological Chemistry; Director, Biomarker Development Group, Johns Hopkins University School of Medicine

There is a need to develop circulating biomarkers for assessing an individual's physiological and pathological status. Our initial focus was on the assessment of brain and myocardial ischemia and injury in adult and pediatric clinical settings. This required development of proteomic-based strategies for the robust identification of circulating biomarkers and the large-scale accurate quantification of proteins and/or their disease-induced modified forms using ELISA or targeted multiplex mass spectrometry assays to tease out the individualized response to injury in a large number of clinical settings. This comprehensive approach personalizes the application of biomarkers, enhancing their usability in specific clinical situations.

11:30-12:00 Presentation to be Announced

12:00-1:30 Enjoy Lunch on Your Own

Pharmacogenomic Biomarkers to Predict Benefit from Therapy

1:30-2:00 Discovery of Pharmacogenomic Biomarkers in Cardiovascular and CNS Disorders through Expression Genomics

Wolfgang Sadee, Dr.rer.nat., Professor and Chair, Pharmacology; Director, Program in Pharmacogenomics, The Ohio State University

Genetic biomarkers have potential clinical utility for predicting disease risk and outcomes, including response to therapy. Pharmacogenomic biomarkers are rapidly gaining acceptance in drug discovery, development and therapy; however, a substantial portion of the responsible genetic factors is still uncertain ("missing heritability"). Available evidence suggests that genetic variants affecting expression regulation and RNA processing/translation may account for a large portion of genetically-determined phenotypic variability. We have developed comprehensive assays to detect regulatory variants, recently including the use of second-generation sequencing. Results have revealed the existence of frequent genetic variants with strong influence on clinical phenotypes, including drug response, even in important pharmaco-genes that had been under intense study for some time (e.g., CYP3A4, DRD2, DAT, HTR2A, CETP, ACE, NAT1). Several of these variants have promise as biomarkers for drug therapy, possibly as companion diagnostics in specific cases.

2:00-2:30 Improving Efficacy and Reliability for Personalized Medicine: The Role of Companion Diagnostics in Drug Development

Amelia Warner, Ph.D., Director, Clinical Pharmacogenomics, Merck

Identification of subpopulations of patients who either have subclinical response or toxicity to a drug in clinical development is a challenge. Historically, identification of patients who have less than optimal response to drugs has occurred late in large global clinical trial review. However, the pharmaceutical industry is working to optimize preclinical models, known genetic variation across populations, and earlier inclusion of surrogate biomarkers in early development programs to allow for early identification of populations that will benefit from alternate dosing or alternate therapies. Adapting development strategies to include companion diagnostics remains a challenge, but pharmaceutical companies are developing clear working models to enable development of personalized therapies.

2:30-3:00 Utilization of Biomarkers in Development of Treatments for Heterogeneous Immunologic Diseases

Carrie Brodmerkel, Ph.D., Director, Immunology Biomarkers, Centocor Research & Development

Ulcerative colitis (UC) and Crohn's disease (CD) are heterogeneous diseases that impact the gastrointestinal system. While anti-TNF therapy is effective in both diseases, there remains a significant population that does not derive benefit. Understanding the molecular signature of response to anti-TNF treatment can identify the core pathway modulation required to achieve clinical response while understanding the non-response signature can aid in identifying novel pathways which may be driving disease in anti-TNF non-responders. Here we present molecular cross-comparison of UC and CD as well as the effects of biologic therapies on the dysregulated pathways. These results offer insight into the patient subpopulations most likely to benefit from therapy.

3:00 Close of Conference

TUESDAY, MAY 22

7:30-8:15 am Breakfast Presentation

Sponsored by MYRIAD RBM

Identification of Fluid Biomarkers of Treatment Response in Schizophrenia CSF and Plasma Samples

Eric Schaeffer, Ph.D., Director, Neuroscience Clinical Biomarkers, Bristol-Myers Squibb

Schizophrenia is a heterogeneous disease of complex and poorly understood etiology. Patients are often prescribed one of several approved medications based on their symptoms, but there is a high rate of switching among medications during a period of trial and error, while physicians seek to identify a drug(s) which will result in stabilization of symptoms. Given the variability in treatment response, there would be considerable value in the identification of a biomarker(s) which could provide an indication of whether a patient is responding to a particular medication early in the treatment regimen. This talk will discuss a biomarker identification and validation strategy focusing on highly multiplexed immunoassay panels offered by Myriad RBM.

Case Studies in Rx/Dx Co-Development

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

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Cancers can be categorized based on their molecular etiology, including oncogenic driver mutations that are present. The development of targeted therapies alongside companion diagnostics that will identify patients most likely to receive benefit provides the opportunity to increase the success rate for oncology drugs and to decrease development time and associated costs. This presentation will detail the co-development of Zelboraf and the cobas 4800 BRAF V600 mutation test from the diagnostics perspective. This integrated process resulted in approval of the first personalized medicine for the treatment of metastatic melanoma within 6 years of the drug's discovery, a remarkably short time.

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12:00-12:30 Utilization of One Platform from Discovery to the Clinic: A Multiplex Approach

Sponsored by Luminex

Jeremy Bridge-Cook, Ph.D., Senior Vice President, Assay Group, Luminex Corporation

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12:30-2:00 Enjoy Lunch on Your Own

The Future of Laboratory-Developed Tests

2:00-2:30 LDTs in the Context of CLIA: An NCI Experience

Daniel Edelman, Ph.D., Facility Head, Clinical Molecular Profiling Core, NIH/NCI/CCR/Genetics Branch

The mission of the Clinical Molecular Profiling Core (CMPC) of the National Cancer Institute (NCI) is to provide state-of-the-art genomic testing for specimens obtained from NCI clinical trials. The greatest impact is affected where test results have immediate clinical application for personalized cancer therapy for individual patients enrolled in these trials. To that end, the CMPC is CLIA compliant and provides a growing set of clinical test modalities. In this talk we'll present and discuss the challenges of meeting CLIA regulations for high-complexity tests that did not exist as diagnostic tests when the federal guidelines were written.

2:30-3:00 Laboratory-Developed Tests: Regulatory Requirements in the U.S.

Franklin R. Cockerill, III, M.D., Ann and Leo Markin Professor and Chair, Laboratory Medicine and Pathology, Mayo Clinic College of Medicine; President and CEO, Mayo Medical Laboratories

Testing performed in clinical laboratories in the United States is regulated by CLIA and FDA. Additionally, testing for New York State patients has additional requirements. Laboratory-Developed Tests (LDTs) are those tests developed and performed in laboratories which have not been approved or cleared by the FDA. Validation of clinical testing includes both analytical and clinical components. CLIA has traditionally regulated analytical validation and FDA/New York State, clinical validation. Recently, validation of LDTs has come under increasing scrutiny by the FDA with an announcement that a guidance document is forthcoming. This lecture will review specific requirements by these agencies, identify redundancies, and provide potential solutions towards a consolidated approach for efficient value-driven regulation of clinical laboratory testing.

3:00-3:30 Talk Title to be Announced

Andrea Ferreira-Gonzalez, Ph.D., Professor and Chair, Division of Molecular Diagnostics; Director, Molecular Diagnostics Laboratory, Department of Pathology, Virginia Commonwealth University

3:30-4:00 Regulatory Considerations for Using a Laboratory-Developed Test (LDT) During a Pivotal Clinical Trial

Mya Thomae, CEO, Myraqa, Inc.

LDTs offer many advantages in the clinical trial setting including rapid development and service-oriented delivery. If an LDT will be used as a companion diagnostic, these benefits need to be carefully weighed against other considerations, including availability of appropriate documentation, level of regulatory sophistication and geographic limitations of the test itself. The presentation will explore best practices for risk mitigation to ensure that an LDT-based diagnostic does not hold up drug approval.

4:00-5:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Biomarker Assay Development for Diagnostics

5:00-5:30 Early Results of the NCI Clinical Assay Development Program

J. Milburn Jessup, M.D., Chief, Diagnostics Evaluation Branch, Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health

Academic investigators and small companies find it increasingly difficult to develop clinically useful diagnostics that are integral markers and essential for performance of clinical trials. The NCI initiated the Clinical Assay Development Program (CADP) to aid such development. CADP has a network of 8 CLIA-certified laboratories (3 commercial and 5 academic laboratories) that develop assays selected after competitive review and give them back to the investigator for performance in a clinical trial. To date 16 applications have been reviewed in 3 rounds of funding

with 3 projects under development that include assays to detect somatic mutations, 2-HG and validation of a gene expression assay. CADP offers advice for those assays that are not selected for development.

5:30-6:00 Building the Cancer Diagnostics Pipeline One Biomarker at a Time

John T. McDevitt, Ph.D., Brown-Wiess Professor, Bioengineering & Chemistry, Rice University

This presentation features creation of programmable nano-bio-chip sensors that are capable of sophisticated measurements of strategic biomarkers from bio-fluid samples like blood, urine and saliva. This universal detection modality is now on a fast track to FDA approval through the simultaneous completion of 6 clinical trials in the area of HIV immune function (number one global humanitarian issue), cardiac heart disease (largest killer globally) and three types of cancers (oral, ovarian, prostate).

WEDNESDAY, MAY 23

7:30-8:15 am Breakfast Presentation *(Opportunity Available. Contact Ilana Quigley at iquigley@healthtech.com or 781-972-5457)*

Biomarker Assays to Support Drug Development

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

8:30-9:00 Automated Platforms in Biomarker Analysis Past, Present and Future: Case Studies, Comparisons and Review of Assay Validation Data

John L. Allinson, FIBMS, Vice President, Biomarker Laboratory Services, ICON Development Solutions

Presentation will cover a variety of analytical platforms used to measure biomarkers in support of drug development. It will look at the evolution and development of the platforms, and give case-study data generated on some of them. It will also give a personal insight into possible developments in the future as the use of biomarkers for patient stratification and companion diagnostics increases; and discuss the challenges in developing and transferring methods for new biomarkers on to these platforms—including point-of-care-type equipment.

Sponsored by MSD Meso Scale Discovery

9:00-9:30 Analytical-Grade Multiplexed Assays—Requirements from the Biomarker Community

Robert Umek, Ph.D., Director, External Scientific Affairs, Meso Scale Discovery

Scientists and clinicians appreciate the importance of protein biomarkers in drug development and therapeutic management. We will explore the challenges associated with an increasing demand for reliable, meaningful biomarker panels and how these demands can be met using MSD's multiplexed quantitative immunoassays. This talk focuses on protein biomarkers from a practical perspective, exploring the complex roles played by corporations, regulatory agencies, and independent researchers, and the challenges they face meeting the demand for biomarker panels that support their research and clinical objectives.

9:30-10:00 Leveraging Enabling Technologies for Biomarker Discovery and Validation

Bonnie J. Howell, Ph.D., Head, Molecular Biomarkers, Merck West Point

10:00-11:00 Coffee Break in the Exhibit Hall with Poster Viewing

11:00-11:30 Bioanalytical Challenges to Quantify Soluble "Free" Target Biomarkers in Antibody Therapeutics

Jenny Wang, Ph.D., Principal Scientist, Pharmacokinetics, Dynamics, and Metabolism, Pfizer

Many therapeutic antibodies act through neutralization of soluble targets in circulation. The free target concentration is an important biomarker for understanding the dynamic relationship of the drug and the target for determining therapeutic efficacy and assisting the model-based determination of optimal dose selection and regimen. The association and dissociation of the immune complexes, dynamic ratios of the drug and the target over time after dosing, and multiple sources of disturbance of the drug/target equilibrium during bioanalysis and sample handling pose a tremendous challenge for accurate quantification of free target concentrations in biological samples. In this presentation, a therapeutic antibody against a soluble peptide is used as a case study to illustrate major factors that affect the accuracy of free target measurement. Immune complex separation techniques and critical reagent selection will be discussed.

11:30-12:00 Integrating Proteomics and Genomics into Next-Gen Systems Pathology

Michael H. A. Roehrl, M.D., Ph.D., Assistant Professor and Director of BioBanking, Department of Pathology and Laboratory Medicine, Boston Medical Center

We will discuss proteomic and metabolomic cancer biomarker discovery, cancer exome sequencing, and joint computational data interpretation of next-gen sequencing with proteomics. We will discuss specific applications from our institution of comprehensive omic profiling of solid tumors from patients and the application of cutting-edge technology development in mass spectrometry and next-gen sequencing to drive and innovate personalized molecular medicine. We will demonstrate that ultra-rapid tissue biobanking is critically important for faithful physiome preservation to enable biomarker discovery and next-gen molecular diagnostics.

Sponsored by Singulex

12:00-1:30 Luncheon Presentation
Advanced Single Molecule Detection: Accelerating Biomarker Development through Ultrasensitive Immunoassay Technology

Lynn Zieske, Ph.D., Vice President, Commercial Solutions, Singulex, Inc.

Biomarker verification and validation programs are in need of sensitive detection technologies to provide precise biomarker measurements in clinically relevant samples. To address this critical need, the patented Erenna® Immunoassay system from Singulex offers sub-picogram per mL resolution at an improvement of 1-3 fold over standard ELISAs. Here we present case studies demonstrating how the use of the Erenna Immunoassay System has provided critical insights toward improving the clinical utility of biomarkers.

Pharmacogenomic Biomarkers to Predict Benefit from Therapy

1:30-2:00 Discovery of Pharmacogenomic Biomarkers in Cardiovascular and CNS Disorders through Expression Genomics

Wolfgang Sadee, Dr.rer.nat., Professor and Chair, Pharmacology; Director, Program in Pharmacogenomics, The Ohio State University

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2:00-2:30 Improving Efficacy and Reliability for Personalized Medicine: The Role of Companion Diagnostics in Drug Development

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2:30-3:00 Utilization of Biomarkers in Development of Treatments for Heterogeneous Immunologic Diseases

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3:00 Close of Conference

TUESDAY, MAY 22

7:30-8:15 am Breakfast Presentation

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Identification of Fluid Biomarkers of Treatment Response in Schizophrenia CSF and Plasma Samples

Eric Schaeffer, Ph.D., Director, Neuroscience Clinical Biomarkers, Bristol-Myers Squibb

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Case Studies in Rx/Dx Co-Development

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The Co-Development of Zelboraf and Its Companion Diagnostic

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9:00-9:30 Crizotinib
The Xalkori, ALK CDx Partnership

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9:30-10:30 Coffee Break in the Exhibit Hall with Poster Viewing

Developing Rx and Dx under One Roof

10:30-11:00 Personalized Medicine and Companion Diagnostics at Novartis

Michael C. Little, Ph.D., Global Head, Diagnostics Development, Novartis Molecular Diagnostics

Personalized medicine is here and now, after many years of promise and anticipation. Although early in the evolution of the impending revolution, the changes will bring positive impacts to healthcare. Nonetheless, the path to this future state is not a straightforward one, given the multiple elements such as development costs, clinical impacts, test performance, and regulatory constraints that must be aligned. Dr. Little will discuss how Novartis is approaching this space to ensure it provides the best solution for our patients, physicians, and payors.

11:00-11:30 Overcoming Challenges in Developing Companion Diagnostics

Ron Mazumder, Ph.D., M.B.A., Product Development Leader, Companion Diagnostics Center of Excellence, Johnson & Johnson

The development of companion diagnostics alongside targeted therapies presents a number of scientific, regulatory, organizational, and commercial challenges. This talk will highlight how the Companion Diagnostics Center of Excellence has addressed these issues in the context of Johnson & Johnson's drug development programs. Lessons learned from case studies will also be presented.

11:30-12:00 Drug and Diagnostic Co-Development: Under One Roof

Monica Reinholz, Ph.D., Senior Manager, Biomarker Strategy; Director, Clinical Studies, Translational Diagnostics, Ventana Medical Systems

In oncology where there is a growing trend toward developing drugs targeting selected patient populations that are most likely to benefit, it is particularly helpful for pharmaceutical teams to involve diagnostics experts as early as possible in clinical development. This increases the efficiency and speed of discovering and developing patient selection markers that could have an actual impact in the clinic, and make an important difference to patients' lives. In order to do this at a high frequency for drug candidates across multiple indications it is highly advantageous to have a dedicated in-house diagnostics effort. Examples of co-development of drug candidate and companion diagnostic will be discussed.

12:00-12:30 Illuminating the Path for Co-Developing Drugs and Diagnostics: A Bayer Case Study

Carol Peña, Ph.D., Associate Director, Oncology Biomarkers, Bayer

This talk will present considerations impacting drug-diagnostic co-development, along with a Bayer case study. Dr. Peña will discuss the relevant regulatory guidance and precedents available. She will also address factors that need to be considered in designing a biomarker/CDx-based clinical development program, such as the prognostic value of the biomarker, and the challenge of defining biomarker "positive" vs. biomarker "negative." Lastly, Dr. Peña will present a Bayer case study in oncology, including pre-clinical/non-clinical data supporting a CDx-based project, and the design of trials supporting clinical validation of both drug and companion diagnostic.

LUNCHEON TECHNOLOGY SHOWCASE: Drug-Diagnostic Co-Development

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Strategies for Companion Diagnostic Development

2:00-2:30 Lessons Learned in the Development of Companion Diagnostics

Theo McCormick, Director, RxDx Services, Management Science Associates, Inc.

Navigating the scientific, medical, regulatory, contractual and political interactions and dynamics between healthcare professionals, the clinical laboratory, drug manufacturers, IVD diagnostic kit manufacturers and health plans are essential for optimal uptake of drug-diagnostic companion products. Those early decisions in the development cycle have complex downstream impact. This session will map out the trouble spots and potential effects of those decisions.

2:30-3:00 Strategies for Companion Diagnostic Development and Commercialization: Perspectives from a Global IVD Company

John F. Beeler, Ph.D., Director, Theranostics and Business Development, bioMerieux

The drug development process is witnessing a paradigm shift in which new therapies need to be tailored to well-defined patient subgroups via a companion diagnostic assay. With several theranostics partnerships in place at bioMerieux, the speaker will address the challenges of co-development programs and discuss strategies to achieve successful commercialization of these IVD products.

3:00-3:30 The Drug/Diagnostic Development Continuum: Does the Ideal Co-Development Scenario Really Exist?

Rosanne Welcher, Ph.D., M.B.A., Vice President, pharmDx Research and Development, Dako North America

The ideal scenario for co-development of a diagnostic and targeted therapeutic is for both parties to engage at an early stage of drug development. The accepted framework for the development cycle is to align IUO assays to phases of the drug clinical program. Despite best efforts, there are numerous examples of diagnostic assays utilized in pivotal clinical trials that have not yet been fully validated or validated on the target indication. What are the strategies employed to "cut in" or post-validate a diagnostic? This presentation will focus on various scenarios that deviate from the ideal, focusing on the risks and benefits to pharma and the diagnostic partner.

3:30-4:00 Combined CLIA and IVD Strategy Accelerates Timing and Mitigates Risk for Companion Diagnostics

Andrew Grupe, Ph.D., Senior Director, Pharmacogenomics, Celera/Quest Diagnostics

Personalized medicines are heralded as the future of drug development. Bringing a targeted medicine to market requires the concerted efforts of a drug developer and a diagnostics partner. There is no one-size-fits-all approach for these partnerships, and often a tailored relationship is forged between the two partners either before or during a pivotal Phase III trial. Late stage partnerships increase the drug candidate's risk profile when it is deemed to need a predictive biomarker for a pivotal Phase III trial. This presentation will provide specific examples that illustrate the benefits of working with a diagnostics organization with both experienced IVD manufacturing and an extensive CLIA laboratory infrastructure. The tangible benefits that mitigate the drug development risk and may be attractive to both partners if the relationship starts before Phase II will be described.

4:00-5:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Regulatory Strategies for Rx-Dx Co-Development

5:00-5:30 Zelboraf: Lessons Learned and Future Regulatory Implications for Drug/Diagnostic Contemporaneous Development

Linda Burdette, Ph.D., Director, Drug Regulatory Affairs, F. Hoffmann-La Roche

The recent approval of Roche/Genentech's BRAF-targeted therapy, Zelboraf™, with its companion diagnostic exemplifies the regulatory contemporaneous co-development process encouraged in FDA's 2011 *In Vitro* Companion Diagnostic Devices draft guidance. As a case study, "Zelboraf Lessons Learned" also highlights next steps for CDER/CDRH guidance development, including the regulatory pathway when the companion diagnostic is identified late in clinical development, when clinical utility data in attribute-negative population is needed, what level of evidence is required for approval of a new indication for an approved diagnostic, and conditions whereby a diagnostic may be granted approval for a class of drugs.

5:30-6:00 Bridging the Gap: Co-Development of Targeted Therapeutics and Companion Diagnostics in the U.S. and EU

Sabah Malek, Senior Regulatory Scientist, IVD/Medical Devices, Voisin Consulting Life Sciences

This presentation will focus on the major regulatory issues that concern diagnostic and pharmaceutical partners during co-development of a targeted therapeutic and companion diagnostic, including current development trends related to companion diagnostics, coordination of clinical trials, and the regulatory review of both products in the U.S. and EU. After months of discussions on personalized medicine and the use of companion diagnostics with targeted therapeutics, the much-anticipated draft FDA guidance document on *in vitro* companion diagnostics was finally released by the agency for comments. In contrast, the EU has yet to release any specific guidance on companion diagnostic development and/or finalize changes in the regulatory framework. We will discuss both the impact of the proposed draft guidance issued by the FDA and the expected major changes surrounding companion diagnostic regulation to occur in the EU.

WEDNESDAY, MAY 23

7:30-8:15 am Breakfast Presentation *(Opportunity Available. Contact Ilana Quigley at iquigley@healthtech.com or 781-972-5457)*

Partnering Strategies for Rx-Dx Co-Development

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

8:30-9:00 Partnering Strategies for Companion Diagnostic Development and Commercialization

Cynthia Gawron-Burke, Ph.D., Director, Scientific Liaison, External Scientific Affairs—Oncology Licensing, Merck Research Laboratories, Merck, Sharpe, & Dohme Corp.

Successful partnerships between biopharmaceutical and diagnostic companies are a critical component of realizing the future promise of personalized medicine. Partnering considerations such as collaboration models, challenges in negotiating collaboration agreements, and best practices to ensure successful partnerships will be discussed.

9:00-9:30 Talk Title to be Announced

Cecilia Schott, Ph.D., M.B.A., Business Development Director, Personalized Healthcare, AstraZeneca (tentative)

9:30-10:00 Challenges of Introducing Pharmacodiagnostics to Drug Development Teams

George A. Green, IV, Ph.D., Director, Pharmacodiagnostics, Bristol-Myers Squibb

Therapeutic development strategies that include companion diagnostic products have become common in today's pharmaceutical programs. Incorporating diagnostics into the strategy for delivering a drug program has influence on the development, clinical, regulatory, and commercial strategies, and has overall implications for the program plan and schedule. In addition, many companion diagnostic programs are partnered with external diagnostic development companies, further complicating the strategy. Many drug development organizations do not have extensive experience with the diagnostic product development process, regulatory guidelines, and business models. In this complex and highly matrixed environment, co-development of the companion diagnostic and therapeutic strategies depends on proper education, decision-making, and alliance management to ensure timely and effective delivery of the programs.

10:00-11:00 Coffee Break in the Exhibit Hall with Poster Viewing

11:00-12:00 Panel Discussion

12:00-1:30 Lunch on Your Own

Pharmacogenomic Biomarkers to Predict Benefit from Therapy

1:30-2:00 Discovery of Pharmacogenomic Biomarkers in Cardiovascular and CNS Disorders through Expression Genomics

Wolfgang Sadee, Dr.rer.nat., Professor and Chair, Pharmacology; Director, Program in Pharmacogenomics, The Ohio State University

Genetic biomarkers have potential clinical utility for predicting disease risk and outcomes, including response to therapy. Pharmacogenomic biomarkers are rapidly gaining acceptance in drug discovery, development and therapy; however, a substantial portion of the responsible genetic factors is still uncertain ("missing heritability"). Available evidence suggests that genetic variants affecting expression regulation and RNA processing/translation may account for a large portion of genetically-determined phenotypic variability. We have developed comprehensive assays to detect regulatory variants, recently including the use of second-generation sequencing. Results have revealed the existence of frequent genetic variants with strong influence on clinical phenotypes, including drug response, even in important pharmaco-genes that had been under intense study for some time (e.g., CYP3A4, DRD2, DAT, HTR2A, CETP, ACE, NAT1). Several of these variants have promise as biomarkers for drug therapy, possibly as companion diagnostics in specific cases.

2:00-2:30 Improving Efficacy and Reliability for Personalized Medicine: The Role of Companion Diagnostics in Drug Development

Amelia Warner, Ph.D., Director, Clinical Pharmacogenomics, Merck

Identification of subpopulations of patients who either have subclinical response or toxicity to a drug in clinical development is a challenge. Historically, identification of patients who have less than optimal response to drugs has occurred late in large global clinical trial review. However, the pharmaceutical industry is working to optimize preclinical models, known genetic variation across populations, and earlier inclusion of surrogate biomarkers in early development programs to allow for early identification of populations that will benefit from alternate dosing or alternate therapies. Adapting development strategies to include companion diagnostics remains a challenge, but pharmaceutical companies are developing clear working models to enable development of personalized therapies.

2:30-3:00 Utilization of Biomarkers in Development of Treatments for Heterogeneous Immunologic Diseases

Carrie Brodmerkel, Ph.D., Director, Immunology Biomarkers, Centocor Research & Development

Ulcerative colitis (UC) and Crohn's disease (CD) are heterogeneous diseases that impact the gastrointestinal system. While anti-TNF therapy is effective in both diseases, there remains a significant population that does not derive benefit. Understanding the molecular signature of response to anti-TNF treatment can identify the core pathway modulation required to achieve clinical response while understanding the non-response signature can aid in identifying novel pathways which may be driving disease in anti-TNF non-responders. Here we present molecular cross-comparison of UC and CD as well as the effects of biologic therapies on the dysregulated pathways. These results offer insight into the patient subpopulations most likely to benefit from therapy.

3:00 Close of Conference

Participating Organizations in 2011 Included:

'20 20 GeneSystems

A

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Abbott Labs
Abbott Molecular
Actelion Pharmaceuticals US Inc
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CHI offers comprehensive sponsorship packages which include presentation opportunities, exhibit space, branding as well as the use of the pre and post show delegate list. Sponsorship allows you to achieve your objectives before, during, and long after the event. Any sponsorship can be customized to meet your company's needs and budget. Signing on earlier will allow you to maximize exposure to hard-to-reach decision makers.

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Opportunity includes a 20-minute podium presentation with a 10-minute Q&A session. A limited number of presentations are available for sponsorship and they will sell out quickly. Sign on early to secure your talk!

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

Promotional opportunities include, but are not limited to:

- Branded Tote Bags
- Chair Drop of Company Literature
- Branded Badge Lanyard
- Conference Padfolios
- Tote Bag Inserts of Company Literature
- Exhibit Hall Reception
- And More...

For additional sponsorship and exhibit information, please contact:

Ilana Quigley
Manager, Business Development
781-972-5457 | iquigley@healthtech.com

Hotel & Travel Information

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

Discounted Room Rate: $205 s/d

Discounted Cut-off Date: April 24, 2012

Reservations: biomarkerworldcongress.com

Visit the 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 discounts have been established with American Airlines for this conference.

- Call 1-800-433-1790 and use Conference code 5552AY
- Go to www.aa.com/group and enter Conference code 5552AY in promotion discount box
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- Go to www.hertz.com to make your reservation and reference our Discount Number 04KL0003
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Pricing and Registration Information

PRE-CONFERENCE EVENTS

	Commercial	Academic, Government, Hospital-affiliated
Fit-for-Purpose Biomarker Assay Development and Validation	$595	$295

CONFERENCE PRICING

Main Conference Pricing

Includes access to Tracks 1, 2 & 3, Exhibit Hall functions, and conference proceedings. Does not include access to Track 4 (Executive Summit)

Registrations after April 6, 2012, and on-site	$1945	$945

Executive Package Pricing

Includes access to Track 4 Executive Summit, Tracks 1, 2, & 3, Exhibit Hall functions, and conference proceedings.

Registrations after April 6, 2012, and on-site	$2395	$1195

Conference Tracks:

Track 1: Biomarkers in Drug Development
Track 2: Molecular Diagnostics
Track 3: Biomarker Assay Development
Track 4: **Executive Summit**: Drug-Diagnostic Co-Development

Poster Submission Discount ($50 Off)

Poster abstracts are due by April 6, 2012. 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.

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ADDITIONAL REGISTRATION DETAILS

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

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

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How to Register: **BiomarkerWorldCongress.com**

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Please refer to the Registration Code below:

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