Cambridge Healthtech Institute's *Seventh Annual*

BIOMARKER WORLD CONGRESS 2011

MAY 2 - 4, 2011 • LOEWS PHILADELPHIA HOTEL • PHILADELPHIA, PA

The leading annual meeting dedicated to biomarker research and implementation

Featured Speakers

Nicholas Dracopoli
Vice President, Centocor
Johnson & Johnson

Felix Frueh
President, Medco Research Institute, Medco

Philip Hewitt, Ph.D.
Head, Molecular and Cellular Toxicology, Merck Seono Research

Hakan Sakul
Global Head, Diagnostics
Pfizer

Stefan Scherer
Global Biomarker Head
Genentech

Michael Nohaile
Global Head
Novartis Molecular Diagnostics

Track 1: Biomarkers in Drug Development

- Biomarkers for drug safety assessment
- Translational biomarkers
- Personalized medicine

Track 2: Biomarkers in Molecular Diagnostics

- Biomarker assay development and translation
- Circulating tumor cells
- PGx biomarkers for patient selection

Track 3: Executive Summit: Drug-Diagnostic Co-Development

- Drug-diagnostic co-development challenges and case studies
- Partnering strategies
- Regulatory requirements for companion diagnostics

Pre-Conference Short Course:

Fit-for-Purpose Biomarker Assay Development and Validation

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Conference-at-a-Glance

Monday, May 2			
8:00-9:00am	Registration for Pre-Conference Short Course (Millennium Foyer)		
9:00am -1:00pm	Pre-Conference Short Course* *(*Separate Registration Required)* **Fit-for-Purpose Biomarker Assay Development and Validation** (Congress AB)		
	Track 1: BIOMARKERS IN DRUG DEVELOPMENT	Track 2: BIOMARKERS IN MOLECULAR DIAGNOSTICS	Track 3: EXECUTIVE SUMMIT: DRUG-DIAGNOSTIC CO-DEVELOPMENT
1:00-2:00	Main Conference Registration (Millennium Foyer)		
2:00-2:10	Welcoming Remarks from Conference Director (Commonwealth A-D)		
2:10-4:15	**Plenary Keynotes: Biomarkers as Decision-Making Tools**		
4:15-5:15	Opening Reception in the Exhibit Hall with Exhibit & Poster Viewing (Millennium Hall)		
Tuesday, May 3			
7:30-8:15am	Breakfast Presentation *Sponsored by* RBM (Commonwealth D)		
8:25-9:30	**Plenary Keynotes: Implementing Personalized Medicine** (Commonwealth A-C)		
9:30-10:30	Networking Coffee Break in the Exhibit Hall with Exhibit & Poster Viewing (Millennium Hall)		
10:30am -11:45pm	**Technology Showcase I** (Commonwealth BC)	**Technology Showcase II** (Commonwealth D)	**Drug-Diagnostic Co-Development: Pharma Perspective** (Commonwealth A)
11:45-12:30	**PANEL DISCUSSION (Commonwealth BC)** **Impact of Next Generation Sequencing on Companion Diagnostics** *Co-Sponsored by* GenomeQuest NGS Leaders		12:00 Luncheon Technology Showcase *Sponsored by* 20/20 biodesix Quest Diagnostics
12:30-2:00	Enjoy Lunch On Your Own		
2:00-3:30	**Translational Biomarkers** (Commonwealth BC)	**Biomarker Assay Development and Translation** (Commonwealth D)	**Drug Diagnostic Co-Development: Dx Perspective** (Commonwealth A)
3:30-4:30	Networking Refreshment Break in the Exhibit Hall with Exhibit & Poster Viewing (Millennium Hall)		
4:30-5:30	**Translational Biomarkers** (Commonwealth BC)	**Biomarker Assay Development and Translation** (Commonwealth D)	**Partnering Strategies for Drug-Diagnostic Co-Development** (Commonwealth A)
5:30	Close of Day		
Wednesday, May 4			
7:30-8:15am	Breakfast Presentation *Sponsored by* CAPRION (Commonwealth D)		
8:25-10:30	**Toxicity Biomarkers** (Commonwealth BC)	**Circulating Tumor Cells** (Commonwealth D)	**Case Studies in Drug-Diagnostic Co-Development** (Commonwealth A)
10:30-11:30	Networking Coffee Break in the Exhibit Hall with Exhibit & Poster Viewing *(last chance to view exhibits)* (Millennium Hall)		
11:30am -12:30pm	**Biomarker Development and Qualification**	**Translating Genome Sequencing to Diagnostics**	**Panel Discussion: Strategies for Drug-Diagnostic Co-Development**
12:30-2:00	Luncheon Presentation *Sponsored by* Waters THE SCIENCE OF WHAT'S POSSIBLE.™ (Congress Room)		
2:00-3:30	**PGx Biomarkers and Patient Selection** (Commonwealth B-D)		
3:30-4:00	Networking Refreshment Break (Commonwealth Foyer)		
4:00-5:00	**PGx Biomarkers and Patient Selection** (Commonwealth B-D)		
5:00	Close of Conference		

Distinguished Faculty Includes:

- **John L. Allinson,** *FIBMS, Vice President, Biomarker Laboratory Services, ICON Development Solutions*
- **Michael Amos, Ph.D.,** *Scientific Advisor, Material Measurement Laboratory, National Institute of Standards and Technology Measurement; ex-officio member, Secretary's Advisory Committee on Genetics Health and Society, Department of Health and Human Services*
- **Haifeng Bao, Ph.D.,** *Senior Scientist, R&D, Translational Sciences, MedImmune*
- **Mark S. Boguski, M.D., Ph.D.,** *Associate Professor, Center for Biomedical Informatics, Harvard Medical School*
- **Carrie M. Brodmerkel, Ph.D.,** *Director, Immunology Biomarkers, Centocor*
- **Miu Chau, Ph.D.,** *Senior Project Manager, Companion Diagnostics, Genentech*
- **Varsha Desai, Ph.D.,** *Research Biologist, Center for Functional Genomics, Division of Systems Biology, National Center for Toxicological Research, Department of Health and Human Services, U.S. Food and Drug Administration*
- **Viswanath Devanarayan, Ph.D.,** *Director, Exploratory Statistics, Abbott Laboratories*
- **Nicholas C. Dracopoli, Ph.D.,** *Vice President, Centocor R&D, Johnson & Johnson*
- **Andrew N. Freedman, Ph.D.,** *Chief, Clinical and Translational Epidemiology Branch, Division of Cancer Control and Population Sciences, National Cancer Institute*
- **Felix W. Frueh, Ph.D.,** *President, Medco Research Institute, Medco Health Solutions, Inc.*
- **Cynthia Gawron-Burke, Ph.D.,** *External Scientific Affairs – Oncology Licensing, Merck Research Laboratories, Merck, Sharpe, & Dohme Corp.*
- **Andrew Grupe, Ph.D.,** *Senior Director, Pharmacogenomics, Celera*
- **Abdel Halim, Pharm.D., Ph.D.,** *DABCC, FACB, Director, Clinical Biomarkers, Daiichi Sankyo Pharma Development*
- **Garret Hampton, Ph.D.,** *Senior Director, Oncology Biomarker Development, Development Sciences, Genentech*
- **Philip Hewitt, Ph.D.,** *Head, Molecular and Cellular Toxicology, Merck Serono Research*
- **Darren R. Hodgson, Ph.D.,** *Biomics Advisor, AstraZeneca*
- **Pravin Jadhav, Ph.D.,** *FCP, Team Leader, Division of Pharmacometrics, Center for Drug Evaluation and Research, U.S. Food and Drug Administration*
- **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*
- **Hanlee P. Ji, M.D.,** *Assistant Professor, Oncology, Stanford University School of Medicine; Senior Associate Director, Stanford Genome Technology Center*
- **Michael Kalos, Ph.D.,** *Adjunct Associate Professor; Director, Translational and Correlative Studies Laboratory, Abramson Family Cancer Center and Department of Pathology and Laboratory Medicine, University of Pennsylvania*
- **Andrea H. Lauber, Ph.D.,** *Head, Transactions for Clinical Biomarkers and Pharmacodiagnostics, Strategic Transactions Group, Bristol-Myers Squibb*
- **Michael S. Lebowitz, Ph.D.,** *Director, R&D, 20/20 GeneSystems, Inc.*
- **Jinhe Li, Ph.D.,** *Research Investigator, AT Translational Sciences, Global Pharmaceutical R&D, Abbott Laboratories*
- **Minetta C. Liu, M.D.,** *Associate Professor of Medicine and Oncology, Lombardi Comprehensive Cancer Center, Georgetown University Hospital*
- **George Maliekal, M.B.A.,** *Senior Director, Business Development and Licensing, Abbott Molecular*
- **Ruth E. March, Ph.D.,** *Personalized Healthcare Leader, AstraZeneca*
- **Iain D. Miller, Ph.D.,** *Executive Director, Theranostics Strategy and Business Development, bioMerieux*
- **Vijay Modur, M.D., Ph.D.,** *Head, Diagnostic Discovery, Novartis Molecular Diagnostics*
- **Madhu S. Mondal, Ph.D.,** *DABT, Head of Protein and Analytical Toxicology Laboratory, Investigative Toxicology, Preclinical Safety, Translational Sciences, Novartis Institute of Biomedical Research, Inc.*
- **Aaron L. Nelson, M.D., Ph.D.,** *Senior Investigator, Translational Sciences, Novartis*
- **Michael Nohaile, Ph.D.,** *Global Head, Novartis Molecular Diagnostics*
- **Timothy J. O'Leary, M.D., Ph.D.,** *Deputy Chief Research and Development Officer, Veterans Health Administration*
- **Suso Platero, Ph.D.,** *Director, Oncology Biomarkers, Centocor, Johnson & Johnson Pharmaceutical R&D*
- **Paul W. Rhyne, Ph.D.,** *Associate Director, Bioanalytical Sciences, Bristol-Myers Squibb*
- **Donna Roscoe, Ph.D.,** *Senior Scientific Reviewer, U.S. Food and Drug Administration, Center for Devices and Radiological Health, Office of in vitro Diagnostic Device Evaluation, Division of Immunology and Hematology Devices*
- **Mollie Roth, J.D.,** *COO, Diaceutics*
- **Hakan Sakul, Ph.D.,** *Senior Director, Translational Oncology Group, Oncology Business Unit, Pfizer*
- **Stefan Scherer, M.D., Ph.D.,** *Global Biomarker Head, Product Development Oncology, Genentech*
- **Judy Siuciak, Ph.D.,** *Scientific Program Manager, Biomarkers Consortium, Foundation for the National Institutes of Health*
- **Sandra C. Souza, Ph.D.,** *Team Head, Exploratory and Translational Sciences, Molecular Biomarkers, D&O, Merck Research Laboratories*
- **Dominic Spinella, Ph.D.,** *Executive Director, Translational Medicine, Pfizer*
- **Alan H. B. Wu, Ph.D.,** *Professor, Laboratory Medicine; Chief, Clinical Chemistry, Toxicology and Pharmacogenomics Laboratories, University of California, San Francisco*
- **Helen Y. Wu, Ph.D.,** *Director, Genomics and Oncology, Roche Molecular Systems*
- **Wei Zhou, M.D., Ph.D.,** *Director, Molecular Epidemiology Research, Pfizer*

Hotel & Travel Information

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

Discounted Room Rate: $199 s/d
Discounted Cut-off Date: April 13, 2011

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For more information please contact: **Ilana Quigley**
Manager, Business Development
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MONDAY, MAY 2

PRE-CONFERENCE SHORT COURSE

8:00-9:00 am Registration for Pre-Conference Short Course

9:00 am-1:00 pm Pre-Conference Short Course

FIT-FOR-PURPOSE BIOMARKER ASSAY DEVELOPMENT AND VALIDATION*

*(*Separate Registration Required)*

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.

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 Can Biomarkers Explain Why Drugs Fail? The Impact of Measuring Target Engagement, Downstream Effects and Preselecting Patients on Meeting Clinical Endpoints

Nicholas C. Dracopoli, Ph.D., Vice President, Centocor R&D, Johnson & Johnson

2:45-3:15 Talk Title to be Announced

Pravin Jadhav, Ph.D., FCP, Team Leader, Division of Pharmacometrics, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

3:15-3:45 Applied Biomarkers: Where We Need More Research and Where We Don't

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

3:45-4:15 Personalized Medicine: Use of Biomarkers for Clinical Decision Making

Dominic Spinella, Ph.D., Executive Director, Translational Medicine, Pfizer

Biomarkers are widely used in the clinical development of drugs, as pharmacodynamic endpoints to prove drug/target interaction and help select dose and schedule, as decision making surrogates for clinical benefit, and as tools for identifying patients who should or should not receive specific drugs. This talk will describe actual and hypothetical case studies to illustrate some practical aspects and points to consider when incorporating biomarkers into drug development programs, from the initial process of biomarker qualification and validation, to discrimination between predictive and prognostic biomarkers, to aspects of biomarker assays as they relate to patient selection and clinical decision-making.

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

TUESDAY, MAY 3

7:30-8:15 am Breakfast Presentation
Increasing the Information Content of Studies with Transcriptional and Protein Biomarkers
Timothy C. Burn, Ph.D., Applied Technology Group, Incyte

Sponsored by RBM

IMPLEMENTING PERSONALIZED MEDICINE

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

8:30-9:00 From Nicety to Necessity – Realizing the Promise of Personalized Medicine
Michael Nohaile, Ph.D., Global Head, Novartis Molecular Diagnostics
While not yet on the endangered species list, the traditional "blockbuster model" is clearly facing threats to its existence. In addition, pressures on healthcare costs continue to mount on virtually every front. As a result, old notions of personalized medicine as a "nice to have" are rapidly evolving into a profound new appreciation for the potential patient benefits and business opportunities stemming from targeted therapies. In this session, ways that pharma can work with key stakeholders to jointly realize the promise of personalized medicine will be discussed. Also covered will be some of the innovative ways that Novartis is integrating molecular diagnostics across its pharmaceutical research, development and commercialization activities to help shape the future of personalized medicine.

9:00-9:30 The Yin and Yang of Biomarkers
Stefan Scherer, M.D., Ph.D., Global Biomarker Head, Product Development Oncology, Genentech
Personalized healthcare (PHC) is built on the premise that laboratory tests can accurately predict the response of individual patients to a particular treatment. The recent stakeholder behaviors, from regulators to payers and patients, physicians and pharmaceutical and diagnostic industry, suggest that the pursuit of therapeutic stratification will become a standard in oncology drug development. Among the growing number of examples for individualization of cancer therapy, Avastin and Herceptin will be presented as case studies for translation of results from pre-clinical research into a successful targeted therapy in a selected patient population and to demonstrate the associated challenges.

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

TECHNOLOGY SHOWCASE

10:30-10:45 How Integration of Biomarker Information can Accelerate Drug Research
Alan Livingston, Director, Product Marketing, Science Solutions, Thomson Reuters

Sponsored by THOMSON REUTERS

As the pharmaceutical industry is faced with higher drug development costs and lower drug discovery success rates companies are looking to include Biomarker data as an element of their research strategies in their discovery programs. This presentation explores how, when used appropriately, Biomarker information can enhance drug research.

10:45-11:00 Personalized Medicines for Oncology: Building a Platform for Collaborative Research
Matt Gianni, Senior Consultant, Translational Medicine, IDBS

Sponsored by idbs

The convergence of life science research and medicine is leading to more personalised healthcare. This means organisations need to implement advanced clinical research information systems (ACRIS) that are able to bring together clinical, molecular and imaging data to support translational research. ACRIS architectures typically have a research data repository (RDR) that is separate from medical record systems and is designed to answer scientific questions and assess patient outcomes. Collaborative Web based access to RDR's enable clinical data to be browsed and patient cohorts to be easily created by clinicians and researchers. Critically, sample, molecular and research results also stored in the RDR can be used to stratify the patient cohorts. This presentation will detail key lessons learned in designing and developing ACRIS-type systems for oncology, cardiovascular and neuroscience disease areas; it will also look at technical challenges of clinical data ETL and terminology mapping, pseudonymisation, coping with large data sets such as Next Gen Sequencing (NGS) and cloud based deployment.

11:00-11:15 Assessing the Reliability of Pancreastatin Measurement as a Biomarker for Monitoring Tumor Progression in Patients with Neuroendocrine Carcinoid Tumors
John J. Reddington, Ph.D., DVM, COO, Cambridge Biomedical Inc.

Sponsored by Cambridge Biomedical

Increasing prevalence of Gastroenteropancreatic Neuroendocrine/ Carcinoid tumors are igniting efforts for identifying biomarkers to treat these cancers. Existing markers Chromogranin-A and Serotonin are unreliable for monitoring tumor progression during treatment. Our validated Radioimmunassay for measuring Pancreastatin levels in these patients demonstrates that Pancreastatin is a more reliable and robust biomarker.

11:15-11:30 PhosphoSignatures – Novel Protein Activity Based Biomarkers for Responder Prediction
Andreas Jenne, Ph.D., Senior Vice President, Biomarker Discovery, Evotec AG

Sponsored by evotec

Global quantitative phosphoproteome analyses in vivo based on state-of-the-art mass spectrometry methods provide detailed insights into the cellular mode of action of targeted drugs. A case study will be presented to illustrate how differentially regulated protein phosphorylations may be used as stratification biomarkers to predict the response of drug treatment in patients.

11:30-11:45 Using IPA to Select and Characterize Biomarker Candidates
Stuart Tugendreich, Ph.D., Director, Product Management, Ingenuity Systems, Inc.

Sponsored by INGENUITY SYSTEMS

IPA® is used to select and characterize potential biomarkers based on a number of characteristics, including their expression in body fluids and tissues plus their relationship to other genes, proteins, RNAs, diseases and known biomarkers, by leveraging the Ingenuity® Knowledge Base which stores biological and chemical relationships extracted from the scientific literature.

11:45 am-12:30 pm PANEL DISCUSSION
Impact of Next Generation Sequencing on Companion Diagnostics

Co-Sponsored by GenomeQuest and NGS Leaders

Topics to be discussed include:

- Will Next Generation Sequencing (NGS) be a practical and high-ROI area for genomics and, if so, why?
- What practical steps and investments should pharma be making in NGS?
- How will NGS affect the design and operation of clinical trials?
- Can NGS be transformational in drug rescue and, if so, how so?
- Do massive probing of analytes present new opportunities in personalized medicine?

Panelists to be Announced

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

TRANSLATIONAL BIOMARKERS

2:00-2:30 Biomarkers: From Pre-Clinical Models to Clinical Trials

Suso Platero, Ph.D., Director, Oncology Biomarkers, Centocor, Johnson & Johnson Pharmaceutical R&D

Nowadays, the use of biomarkers is even a requirement in some clinical trials. Perhaps the first question is, how does one find biomarkers? I will explore the use of pre-clinical models, both *in vitro* and *in vivo,* to look for biomarkers. Finding them is not enough: they need to be converted into assays that are ready during clinical trials; those trials need to be run with the biomarker endpoint in them. Specific examples will be used to illustrate the discovery and implementation of biomarkers for clinical trials.

2:30-3:00 Biomarkers: Case Studies in Translation

Sponsored by COVANCE

Rachel Y. Reams, DVM, Ph.D., Director, Biomarker Center of Excellence, Molecular & Anatomical Imaging, Covance, Discovery & Translational Services

3:00-3:30 Development of Mutiplexed Immunoassays for Personalized Medicine

Sponsored by MSD Meso Scale Discovery

Robert Umek Ph.D., Director of Research and Critical Reagents, Meso Scale Discovery

Meso Scale Discovery offers a high throughput, sensitive platform allowing for the quantification of biomarkers that can vary over a wide range of concentrations in single or multiplexed format. Early stages of biomarker screening require examination of a broad panel of markers. A focused subset of markers (typically 2-10) emerges from the screen and the immunoassays used to measure them require a greater degree of analyticity and longevity. In this presentation, case studies involving the development and qualification of multiplexed protein biomarker assays for different stages of personalized medicine biomarker applications using Meso Scale Discovery's plate based electrochemiluminescent platform will be presented.

3:30-4:30 Networking Refreshment Break in the Exhibit Hall with Poster Viewing

4:30-5:00 Incorporating Biomarker Strategies in Late Development and Beyond: Ustekinumab and Psoriasis

Carrie M. Brodmerkel, Ph.D., Director, Immunology Biomarkers, Centocor

Biomarkers can serve an important role in late development even for projects which do not require prediction of response. The late stage psoriasis program for ustekinumab, an anti-il12p40 monoclonal antibody, was designed to incorporate biomarkers to assess mechanism of action. Data from the ACCEPT trial, a Phase III study comparing ustekinumab versus etanercept in moderate to severe psoriasis will be presented as well as the strategy for use of this data in response to health authorities and the general dermatology community. In addition, how the biomarker data has been used to impact the early discovery pipeline will also be discussed.

5:00-5:30 An Integrated "Omics" Approach to Discover and Validate Target Engagement Biomarkers

Sandra C. Souza, Ph.D., Team Head, Exploratory and Translational Sciences, Molecular Biomarkers, D&O, Merck Research Laboratories

Fibroblast growth factor 21(FGF21) is currently a drug candidate for the treatment of type 2 diabetes with a critical need for target engagement (TE) biomarker(s). We performed phosphoproteomic studies in adipocytes, and RNA profiling of mouse models after FGF21 treatment to define phosphoproteins, transcript-based and serum protein biomarkers. This "omics" approach defined a robust TE biomarker package for FGF21 in pre-clinical species and also for human clinical studies.

5:30 Close of Day

WEDNESDAY, MAY 4

7:30-8:15 am BREAKFAST PRESENTATION Transforming Highly Multiplexed Protein Assays through MRM Technology, with Applications to Biomarkers, Diagnostics and Toxicology

Sponsored by CAPRION

Daniel Chelsky, Ph.D., CSO, Caprion

Multiplexed MRM assays are a fast and cost-effective alternative to immunoassays for tracking large panels of protein biomarkers simultaneously and capable of unparalleled specificity, sensitivity and robustness. MRM panels can also be easily adapted to various species providing a seamless shift from pre-clinical to clinical samples supporting the entire drug development process. Learn how Caprion deploys MRM protein assays using a variety of sample types and applications including, toxicology panels and disease-specific panels.

TOXICITY BIOMARKERS

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

8:30-9:00 State-of-the-Art Detection of Nephrotoxicity by Urinary Protein Biomarkers

Philip Hewitt, Ph.D., Head, Molecular and Cellular Toxicology, Merck Serono Research

In-house pre-validation of FDA/EMA qualified acute rodent nephrotoxicity markers in sub-acute rodent studies. Three nephrotoxic compounds have been tested, and global gene expression has been included to help understand the mechanisms of action. In addition, a platform comparison: Luminex (protein) vs. MesoScale (protein) vs. gene expression markers has been conducted. To become more cost efficient and to account for the 3R-principle it is the next logical step to develop and validate *in vitro* screening systems for the early identification of compounds with the potential to injure renal cells. Therefore, new cell systems and biomarkers are being assessed, including human cell lines and human specific biomarkers.

9:00-9:30 Enabling Decisions with Translational Safety Biomarkers

Aaron L. Nelson, M.D., Ph.D., Senior Investigator, Translational Sciences, Novartis

Pre-clinical toxicity and clinical safety remain major challenges in development of novel therapeutics, with development risk further confounded by novel targets and therapeutic modalities. While biomarkers are increasingly employed in early drug development to empower decisions around pharmacodynamic or therapeutic questions, they are only rarely employed to enable decisions around safety concerns. Development and implementation of safety biomarkers can be compared and contrasted with efforts to establish other kinds of markers. Finally, case studies will be presented on the use of safety biomarkers to enable project decisions.

9:30-10:00 Alanine Aminotransferase Isozymes as Investigative Biomarkers of Drug-Induced Liver Damage: Development of Methods and Their Applications

Madhu S. Mondal, Ph.D., DABT, Head of Protein and Analytical Toxicology Laboratory, Investigative Toxicology, Pre-Clinical Safety, Translational Sciences, Novartis Institute of Biomedical Research, Inc.

In drug discovery, the total serum alanine aminotransferase (ALT) activity serves as a routine surrogate marker for liver injury, although the levels of this activity may not correlate with the extent of liver injury or histopathology findings. In drug development, this can create false negative or false positive predictions for liver injury, thus undermining the diagnostic value of the total serum ALT activity measurement. To improve upon these uncertainties, we have conducted an investigation of the two isozymes — ALT1 and ALT2 — that are expressed

differentially in various tissues and serum. Using large-scale two dimensional gel electrophoresis (2DGE), westerns/mass spectrometry methodologies, and functional activity measurements in various tissues, we have established specific methods to detect and identify ALT1 and ALT2 isozymes. Additionally, in this presentation, we discuss how ALT1 and ALT2 levels and their activities could be used as a possible specific signature for liver damage.

10:00-10:30 Development of Mitochondrial Toxicity Biomarkers

Varsha Desai, Ph.D., Research Biologist, Center for Functional Genomics, Division of Systems Biology, National Center for Toxicological Research, Department of Health and Human Services, U.S. Food and Drug Administration

A growing body of evidence indicates mitochondrial dysfunction as one of the major factors associated with a number of degenerative diseases, metabolic disorders, and drug- and chemical-induced toxicities. However, a precise role of mitochondria in these diseases and toxicities is still not well defined. We have developed a mitochondria-specific mouse gene array to obtain better insights into the complex interactions between various metabolic processes and pathways within mitochondria. This approach may allow identification of predictive biomarkers of early events of degenerative diseases or drug-induced toxicities associated with mitochondrial dysfunction.

10:30-11:30 Networking Coffee Break in the Exhibit Hall with Poster Viewing

BIOMARKER DEVELOPMENT AND QUALIFICATION

11:30am-12:00pm Novel Public-Private Partnerships Facilitating the Development and Qualification of Biomarkers in Alzheimer's Disease

Judy Siuciak, Ph.D., Scientific Program Manager, Biomarkers Consortium, Foundation for the National Institutes of Health

The Foundation for the National Institutes of Health (FNIH) is the sole entity authorized by the U.S. Congress to raise private funds in support of NIH's mission of improving health through scientific discovery and translational research. Since 1996, FNIH has raised over $500 million towards over 100 projects, including the Alzheimer's Disease Neuroimaging Initiative (ADNI) and The Biomarkers Consortium (BC). The mission of the BC is to strengthen the evidence for using new and existing biomarkers to improve diagnosis, measure disease progression, guide treatment, accelerate drug development and target therapies to individuals in several therapeutic areas, including neuroscience. This pre-competitive public-private collaboration is designed to break the traditional barriers of biomedical/pharmaceutical research with all results made available to the public. The BC includes broad participation from government, industry, academia and patient advocacy and other non-profit private sector organizations.

12:00-12:30 Grand Challenges in Proteomics: Technologies, Resource Development and Applications

Michael Amos, Ph.D., Scientific Advisor, Material Measurement Laboratory, National Institute of Standards and Technology Measurement; ex-officio member, Secretary's Advisory Committee on Genetics Health and Society, Department of Health and Human Services

Researchers need new technologies to better understand how complex biological systems function and malfunction. To accomplish this and to extend the lessons learned from genomics, major technical and non-technical barriers must be overcome in order to both improve existing and create new technologies required for performing simultaneous and accurate measurements of thousands of proteins. In addition, improved computing capacity will be necessary for scientists to visualize the results of such massively complex experiments. The presentation will describe the findings from a recent workshop to develop a white paper for submission to the National Science and Technology Committee, Biotechnology Subcommittee to the Office of Science and Technology Policy (OSTP) in the Executive Office of the President of the United States.

Sponsored by Waters THE SCIENCE OF WHAT'S POSSIBLE.™

12:30-1:15 A Comprehensive UPLC-MSE Biomarker Analysis Workflow Incorporating Advanced Statistical Methods and Chemical Intelligence

Stephen McDonald, Manager, Business Development, Waters Corporation

Mass spectrometry coupled with Liquid Chromatography is one of the most powerful techniques for biomarker discovery due to the attributes that these tools exhibit over other methods. Of these, perhaps the most important is the facile manner in which compounds can be isolated and structural information can be determined. Evidence of this can be seen in the substantial adoption of these technologies for both metabolomic and lipidomic analysis In this presentation we will discuss the Waters Metabolic Profiling workflow; a simple rapid approach for the detection and analysis of biomarkers. This system solution redefines the quantity and quality of information which is freely available to the scientist.

PGx BIOMARKERS AND PATIENT SELECTION

2:00-2:30 Personalized Healthcare – When, How and Why is It Different to Good Clinical Development Practice?

Darren R. Hodgson, Ph.D., Biomics Advisor, AstraZeneca

This talk will cover what we should look for when contemplating driving co-dependent changes in diagnostic and treatment practice, what data drive the investment decisions from a commercial, scientific and clinical perspective, and how to build all external stakeholders into the process.

2:30-3:00 Clinical Diagnostic Strategies to Predict Patient Benefit in Early Development

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

Targeted therapeutics have shown significant promise in cancers driven by well defined genetic alterations, but clinical development of these agents still tends to follow an all-comers approach, leading to high clinical failure rates. 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.

3:00-3:30 Biomarkers for Patient Selection: Issues and Lessons Learned

Wei Zhou, M.D., Ph.D., Director, Molecular Epidemiology Research, Pfizer

Biomarkers used for patient selection may be based on 1) better response observed among the biomarker positive group in pre-clinical or early phase trials, or 2) retrospective analysis of existing clinical trial data. For the first category, common issues may include results extrapolation from pre-clinical data, using convenient, small sample size and non-representative patient samples, or questionable/incomplete clinical information. For the second category, common issues may include retrospective analysis without a priori hypothesis, and "false positive" results from multiple comparisons. Using real examples, I will discuss these issues and lessons learned from recent clinical development.

3:30-4:00 Networking Refreshment Break

4:00-4:30 Clinical Pharmacogenomic Testing for Clopidogrel and Treatment for Hepatitis C

Alan H. B. Wu, Ph.D., Professor, Laboratory Medicine; Chief, Clinical Chemistry, Toxicology and Pharmacogenomics Laboratories, University of California, San Francisco

In March 2010, the FDA announced a black box warning for clopidogrel recommending pharmacogenomic testing. Unfortunately, the warning did not describe how therapy should be altered for variants. In November 2010, the GRAVITAS study showed that doubling the plavix dose had no effect on outcomes, therefore alternate drugs should be considered. In 2009, investigators demonstrated that for chronic hepatitis C, IL28B SNPs predicted treatment outcomes for pegylated interferon alfa and ribavirin. Non-responders should not be treated, or be given novel protease inhibitor therapies in addition to the traditional dual therapy.

4:30-5:00 Prognosis and Core Processes in Metastatic Breast Cancer: Correlation of a Composite Metastasis Score (cMS) and Oncotype Dx® Recurrence Score

Andrew Grupe, Ph.D., Senior Director, Pharmacogenomics, Celera

Different gene expression sets have been reported to reproducibly assess the metastatic potential of early stage operable breast tumors. An explanation for this apparent counter-intuitive observation is that the disparate genes of different signatures query common pathways or core biological processes. The most rigorous comparative analysis of expression signatures requires profiling of the same tumor samples. The irreplaceable nature of archived samples with long-term follow-up discourages duplicate testing for what are expected to be similar signatures, so we chose to carry out a statistical concordance study. Specifically, we sought to compare a composite metastasis score (cMS) consisting of a previously reported metastasis score (MS), a proliferation index, plus progesterone receptor with the Oncotype Dx® Recurrence Score (RS) and component constituents of these scores using a contemporary sample set. We further examined the correlation of estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) results with the Oncotype DX® assay.

5:00-5:30 Integrating Discoveries in Basic, Clinical and Population Sciences to Advance Predictive Cancer Care

Andrew N. Freedman, Ph.D., Chief, Clinical and Translational Epidemiology Branch, Division of Cancer Control and Population Sciences, National Cancer Institute

To fully realize the potential of personalized cancer treatment, it will be essential to connect and integrate basic discoveries in drug development and pharmacogenomic variability, outcome and genomic data from randomized clinical trials, and data on the effects of drugs and their interactions with genomic variants in large heterogeneous patient populations. In this talk we will present recent research findings that illustrate how pharmacogenomic marker discoveries from clinical trials and observational studies can lead to both clinical utility and novel insights into the underlying biology of drug response phenotypes.

5:30 Close of Conference

TUESDAY, MAY 3

7:30-8:15 am Breakfast Presentation

Sponsored by RBM RULES-BASED MEDICINE

Increasing the Information Content of Studies with Transcriptional and Protein Biomarkers

Timothy C. Burn, Ph.D, Applied Technology Group, Incyte

IMPLEMENTING PERSONALIZED MEDICINE

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

8:30-9:00 From Nicety to Necessity – Realizing the Promise of Personalized Medicine

Michael Nohaile, Ph.D., Global Head, Novartis Molecular Diagnostics

While not yet on the endangered species list, the traditional "blockbuster model" is clearly facing threats to its existence. In addition, pressures on healthcare costs continue to mount on virtually every front. As a result, old notions of personalized medicine as a "nice to have" are rapidly evolving into a profound new appreciation for the potential patient benefits and business opportunities stemming from targeted therapies. In this session, ways that pharma can work with key stakeholders to jointly realize the promise of personalized medicine will be discussed. Also covered will be some of the innovative ways that Novartis is integrating molecular diagnostics across its pharmaceutical research, development and commercialization activities to help shape the future of personalized medicine.

9:00-9:30 The Yin and Yang of Biomarkers

Stefan Scherer, M.D., Ph.D., Global Biomarker Head, Product Development Oncology, Genentech

Personalized healthcare (PHC) is built on the premise that laboratory tests can accurately predict the response of individual patients to a particular treatment. The recent stakeholder behaviors, from regulators to payers and patients, physicians and pharmaceutical and diagnostic industry, suggest that the pursuit of therapeutic stratification will become a standard in oncology drug development. Among the growing number of examples for individualization of cancer therapy, Avastin and Herceptin will be presented as case studies for translation of results from pre-clinical research into a successful targeted therapy in a selected patient population and to demonstrate the associated challenges.

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

TECHNOLOGY SHOWCASE

10:30-10:45 Functional Biomarkers: An Integrative Knowledge-Based Approach to Biomarker Discovery

Sponsored by ALMAC

Nicolas Goffard, Ph.D., Bioinformatics Scientist, Bioinformatics Data Analysis, Almac Diagnostics

The effectiveness of biomarker discovery can be advanced by integrating statistical and knowledge-based approaches. Here we present functional mining as a precursor to biomarker discovery and as an integrative tool to inform signature model selection.

10:45-11:00 Ultra-Sensitive Ligand-Binding Assays Based on Imperacer®: Applications and Clinical Case Studies

Sponsored by chimera biotec

Jan Detmers, Ph.D., Director, Business Development, Chimera Biotec

Approximately 5-7% of clinical ligand-binding assays have to face limitations in assay sensitivity or show limitations in assay performance due to matrix effects. Imperacer® assays (www.imperacer.com) are on an average about 1,000-fold more sensitive than ELISA, and in addition the ultra sensitivity of Imperacer® enables to overcome assay specificity problems. This talk gives an introduction to the principles of ultra-sensitive ligand-binding assays and an overview on clinical as well as pre-clinical applications (e.g. PK/PD, biomarker, study enrollment). Furthermore, clinical case studies from various indications (cancer, replacement therapy, anti-cytokine drugs) are presented and discussed.

11:00-11:30 Genome-Wide Proteomic Tools for Biomarker Discovery with a Goal of Developing Assays for Every Human Protein

Sponsored by ORIGENE

Jim Lazar, Ph.D., Vice President, Assay Development, OriGene Technologies

Biomarker discovery and validation requires high quality proteomic tools such as cDNA clones, proteins and monoclonal antibodies. Until recently, these were only available for a small percentage of the proteins in the human genome. We have embarked on a project to develop critical reagents necessary for the development of assays for every human protein. So far over 12,000 full-length human proteins have been expressed and 5,000 proteins purified. These mammalian-cell produced proteins maintain authentic protein structure and post-translational modification making them ideal for functional screening and antibody development. We will present examples of various assay platforms employing these proteins to detect important biomarkers, including protein arrays, MRM, and Luminex assays.

11:30-11:45 The PROOF Centre Biomarker Journey: From Hype to Hope to Helping Patients

Sponsored by PROOF Centre of Excellence

Bruce McManus, M.D., Ph.D., Director, PROOF Centre of Excellence

A long, challenging pathway must be navigated from determining where a new blood test can change patient care to implementation into healthcare systems. Such a journey requires a multi-dimensional team of experts who share vision and intent. Case studies will be discussed in early success in establishing a pipeline from discovery to implementation.

11:45 am-12:30 pm PANEL DISCUSSION

Co-Sponsored by GenomeQuest NGS Leaders

Impact of Next Generation Sequencing on Companion Diagnostics

Topics to be discussed include:

- Will Next Generation Sequencing (NGS) be a practical and high-ROI area for genomics and, if so, why?
- What practical steps and investments should pharma be making in NGS?
- How will NGS affect the design and operation of clinical trials?
- Can NGS be transformational in drug rescue and, if so, how so?
- Do massive probing of analytes present new opportunities in personalized medicine?

Panelists to be Announced

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

BIOMARKER ASSAY DEVELOPMENT AND TRANSLATION

2:00-2:30 The NCI Clinical Assay Development Program: A Resource to Support Molecular Diagnostic Development for Management of Cancer Patients

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

Molecular prognostic and predictive markers are increasingly critical for assuring that patients receive the right therapy at the right time. These diagnostics require robust analytical performance of their assays within the clinical context of their intended use. The NCI has initiated a Clinical Assay Development Program (CADP) that will convert discovery or research assays into clinically useful assays so that investigators may use them in clinical trials. The CADP is not a grants program but a resource to

benefit both academia and industry in the development of clinically useful assays that can be performed in CLIA-certified laboratories. Access to, scope of and details about this program will be presented.

2:30-3:00 Analysis of Clinical Biomarkers for the Study of Alzheimer's Disease

Paul W. Rhyne, Ph.D., Associate Director, Bioanalytical Sciences, Bristol-Myers Squibb

Many clinical biomarkers are used to assess the effectiveness of new drugs targeted for Alzheimer's disease including Amyloid Beta derived peptides, Tau, phosphorylated Tau, and TFF3. Commercially available assays for these biomarkers are widely used to support clinical trials; however, they often are not suitable for clinical use due to inconsistent lot-to-lot reproducibility, insufficient assay sensitivity, or poor accuracy and precision. This presentation will provide data from analytical validation, clinical validation, and performance characteristics for commercial and in-house derived assays. Discussion will focus on the clinical performance of these assays and methods that may be used to improve their use.

3:00-3:30 An Integrative Paradigm for Biomarker Assay Development: The Relevance of Breadth and Quality

Michael Kalos, Ph.D., Adjunct Associate Professor; Director, Translational and Correlative Studies Laboratory, Abramson Family Cancer Center and Department of Pathology and Laboratory Medicine, University of Pennsylvania

Biomarkers are defined as any biochemical feature that can be used to measure the effects of treatment on patients or on the progress of disease. Accordingly, biomarkers play critical roles in the clinical evaluation and development plan, since they have the potential to both development and approval pathway for novel therapeutics. Nonetheless, despite occasional successes, by and large biomarker studies have largely failed to reveal correlates between treatment and disease outcome. Emerging biomarker-dependent paradigms for clinical research such as the adaptive and two-stage clinical trial design further highlight the need to develop more robust, meaningful and relevant approaches for biomarker assay development. This presentation will focus on critical issues related to the appropriate development of biomarker studies to more effectively support translational and clinical trials, with an emphasis on the need to and approaches for developing comprehensive and quality enabled biomarker studies that can be interpreted and integrated across laboratories.

3:30-4:30 Networking Refreshment Break in the Exhibit Hall with Poster Viewing

4:30-5:00 Biomarker Detection in Paraffin-Embedded Tissue: Challenges and (Partial) Solutions

Timothy J. O'Leary, M.D., Ph.D., Deputy Chief Research and Development Officer, Veterans Health Administration

Archival formalin-fixed, paraffin-embedded tissue is an ideal source for development of tissue-based biomarkers, because it may be accompanied by a wealth of conventional prognostic information, treatment data and clinical follow-up. Indeed, these factors have been extensively exploited in the development of molecular testing strategies, and have led to the development of commercially available tests for providing prognostic information to patients and clinicians. The development of protein biomarkers has been significantly limited by the inaccessibility of formalin-fixed, paraffin-embedded tissue for biomarker discovery, as well as limitations imposed by the use of immunohistochemical techniques in clinical practice. Recently these limitations have been overcome by the development of techniques, including high-pressure protein recovery, that make archival tissue almost as useful as fresh tissue for mass-spectroscopy-based proteomics, together with ultrasensitive protein detection techniques that may be used together with mass spectrometry to provide high-throughput discovery and validation algorithms. In this talk we present the chemical bases for these techniques, together with an algorithm by which they might be combined to facilitate biomarker discovery.

5:00-5:30 Effect of Human Cerebrospinal Fluid Sampling Frequency on Aß Levels In Clinical Trials

Jinhe Li, Ph.D., Research Investigator, AT Translational Sciences, Global Pharmaceutical R&D, Abbott Laboratories

ß-amyloid peptide (Aß) is associated with neurodegeneration in Alzheimer's disease (AD). Emerging evidence indicates that Aß levels in cerebrospinal fluid (CSF) may serve as a biomarker for diagnosing the disease and evaluating potential therapeutic effects in clinical trials. It is critical to understand if intra-subject levels of CSF Aß are consistent between sampling intervals, in order to determine if Aß can be used as a biomarker for drug candidates. Conflicting observations have been reported in the intra-subject stability of CSF Aß levels. The current study examined the Aß levels in CSF collected with various sampling frequencies from three clinical trials conducted in healthy young or elderly subjects at the same investigative site. The results suggest that CSF sampling frequency contributes to intra-subject variability in CSF Aß levels, and that lowering the CSF sampling frequency may help minimize this effect. These results will help guide clinical trial design for AD therapy.

5:30 Close of Day

WEDNESDAY, MAY 4

Sponsored by

CAPRION

7:30-8:15 am BREAKFAST PRESENTATION Transforming Highly Multiplexed Protein Assays through MRM Technology, with Applications to Biomarkers, Diagnostics and Toxicology

Daniel Chelsky, Ph.D., CSO, Caprion

Multiplexed MRM assays are a fast and cost-effective alternative to immunoassays for tracking large panels of protein biomarkers simultaneously and capable of unparalleled specificity, sensitivity and robustness. MRM panels can also be easily adapted to various species providing a seamless shift from pre-clinical to clinical samples supporting the entire drug development process. Learn how Caprion deploys MRM protein assays using a variety of sample types and applications including, toxicology panels and disease-specific panels.

CIRCULATING TUMOR CELLS

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

Robert McCormack, Ph.D., Head, Technology Innovation and Strategy, Veridex

8:30-9:00 Circulating Tumor Cells: Big Demand but Bigger Challenges Need to be Addressed

Abdel Halim, Pharm.D., Ph.D., DABCC, FACB, Director, Clinical Biomarkers, Daiichi Sankyo Pharma Development

CTC enumeration and molecular characterization are very attractive, potentially predictive, prognostic and pharmacodynamic biomarker tools in oncology drug development and, presumably, patient management with hopes to replace tumor biopsies. Proof of utility, however, is still sporadic and not convincing. This presentation provides an unbiased, realistic view of the clinical demand and applicability, as well as biological, clinical, and analytical limitations and challenges, aiming to bridge the gap between technology providers and end users.

9:00-9:30 Evaluating Utility of Rare Cells as Tumor Biomarkers in Pharmaceutical Drug Development

Haifeng Bao, Ph.D., Senior Scientist, R&D, Translational Sciences, MedImmune

A trend in cancer treatment is personalized medicine. The challenge in "personalized" treatment of cancer is how to characterize the complexity of cancer. Rare cells, such as disseminated tumor cells in peripheral blood

and urine and circulating endothelial cells, may offer a minimally invasive means to analyze solid tumors and monitor tumor response to anti-cancer agents. We have attempted to use different technologies to characterize these rare cells and evaluate their utility as potential tumor biomarkers to support pharmaceutical drug development. This talk will share our findings and experience in this research area.

9:30-10:00 The Development of a Circulating Melanoma Cell Assay

Sponsored by VERIDEX LLC a Johnson & Johnson company

M. Craig Miller, B.S., Manager, Clinical Sciences, Veridex, LLC

In the development of more effective therapies for metastatic melanoma patients, the use of a validated assay for the enumeration of circulating melanoma cells may provide insights. We will review the development and validation of a new research use only assay for circulating melanoma cells utilizing the CellTracks Analyzer II® System.

10:00-10:30 Significance and Characterization of Circulating Tumor Cells in Breast Cancer

Minetta C. Liu, M.D., Associate Professor of Medicine and Oncology, Lombardi Comprehensive Cancer Center, Georgetown University Hospital

The enumeration of circulating tumor cells (CTCs) is used to optimize treatment for patients with metastatic breast cancer. Two prospective clinical trials using the CellSearch® technology in this patient population demonstrate clinical utility when used in conjunction with radiographic imaging and clinical evaluations. CTC enumeration may be helpful in resolving discrepancies between imaging results and clinical findings or in guiding the timing of costly imaging studies in asymptomatic patients. Refinements of the current technology — or the development of improved technologies — are needed in order to increase the detection threshold of CTCs and to allow for further phenotypic and genotypic characterization of the collected cells. These advances may translate into use of CTC analysis in earlier stages of breast cancer for diagnosis and/or clinical management.

10:30-11:30 Networking Coffee Break in the Exhibit Hall with Poster Viewing

TRANSLATING GENOME SEQUENCING TO DIAGNOSTICS

11:30 am-12:00 pm Whole Genome Analysis as a Universal Diagnostic

Mark S. Boguski, M.D., Ph.D., Associate Professor, Center for Biomedical Informatics, Harvard Medical School

12:00-12:30 The Personalized Cancer Genome Project - Highlights from the Stanford Experience

Hanlee P. Ji, M.D., Assistant Professor, Oncology, Stanford University School of Medicine; Senior Associate Director, Stanford Genome Technology Center

With the rapid advances in technology on multiple fronts such as DNA sequencing and computational analysis, personalized cancer medicine is fast becoming a reality. We have launched the Personal Cancer Genome Project to provide individuals diagnosed with cancer better options regarding the clinical decisions they face regarding therapy, screening and understanding of recurring risk. This project integrates our efforts in 1) primary sequencing technology development for rapid throughput and cost-effective innovative technologies for cancer genome diagnostic resequencing, 2) genome assessment of inherited genetic risk of cancer and 3) identification of personalized therapeutic options from complete cancer genome sequencing.

12:30-1:15 A Comprehensive UPLC-MSE Biomarker Analysis Workflow Incorporating Advanced Statistical Methods and Chemical Intelligence

Sponsored by Waters THE SCIENCE OF WHAT'S POSSIBLE.™

Stephen McDonald, Manager, Business Development, Waters Corporation

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PGX BIOMARKERS AND PATIENT SELECTION

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3:00-3:30 Biomarkers for Patient Selection: Issues and Lessons Learned

Wei Zhou, M.D., Ph.D., Director, Molecular Epidemiology Research, Pfizer

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Non-responders should not be treated, or be given novel protease inhibitor therapies in addition to the traditional dual therapy.

4:30-5:00 Prognosis and Core Processes in Metastatic Breast Cancer: Correlation of a Composite Metastasis Score (cMS) and Oncotype Dx® Recurrence Score

Andrew Grupe, Ph.D., Senior Director, Pharmacogenomics, Celera

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5:00-5:30 Integrating Discoveries in Basic, Clinical and Population Sciences to Advance Predictive Cancer Care

Andrew N. Freedman, Ph.D., Chief, Clinical and Translational Epidemiology Branch, Division of Cancer Control and Population Sciences, National Cancer Institute

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5:30 Close of Conference

TUESDAY, MAY 3

7:30-8:15 am Breakfast Presentation
Increasing the Information Content of Studies with Transcriptional and Protein Biomarkers

Sponsored by RBM RULES-BASED MEDICINE

Timothy C. Burn, Ph.D, Applied Technology Group, Incyte

IMPLEMENTING PERSONALIZED MEDICINE

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

8:30-9:00 From Nicety to Necessity – Realizing the Promise of Personalized Medicine

Michael Nohaile, Ph.D., Global Head, Novartis Molecular Diagnostics

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9:00-9:30 The Yin and Yang of Biomarkers

Stefan Scherer, M.D., Ph.D., Global Biomarker Head, Product Development Oncology, Genentech

Personalized healthcare (PHC) is built on the premise that laboratory tests can accurately predict the response of individual patients to a particular treatment. The recent stakeholder behaviors, from regulators to payers and patients, physicians and pharmaceutical and diagnostic industry, suggest that the pursuit of therapeutic stratification will become a standard in oncology drug development. Among the growing number of examples for individualization of cancer therapy, Avastin and Herceptin will be presented as case studies for translation of results from pre-clinical research into a successful targeted therapy in a selected patient population and to demonstrate the associated challenges.

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

DRUG-DIAGNOSTIC CO-DEVELOPMENT: PHARMA PERSPECTIVE

10:30-11:00 Top 10 Changes Needed in Drug-Diagnostic Co-Development

Glenn A. Miller, Ph.D., VP and Head, Personalized Healthcare and Biomarker Strategy, Portfolio and Alliances, AstraZeneca Pharmaceuticals LP

Companies have been engaged in drug-diagnostic co-development for over a decade, yet the number of marketed drugs with successful companion diagnostics remains low. What would have to change to transform the efficiency of personalized healthcare? A group of leaders across the industry proposed far-reaching changes: consolidation of communication, creative thinking and innovative collaboration, better tools for early drug development, pragmatic ways to test for biomarkers, higher rates of consent for biomarker testing, patient selection to increase probability of success, increased incentives, openness to value-based pricing and improved economic models. This talk will explore these ideas further and illustrate them with relevant examples.

11:00-11:30 Optimal and Pragmatic Approaches to Drug-Diagnostic Co-Development: Therapeutic Developer's Challenges

Christopher T. Harbison, Ph.D., Senior Research Investigator, Oncology Biomarkers, Bristol-Myers Squibb

This presentation will focus on two examples of drug-diagnostic co-development. The first example will describe companion diagnostic test development for expression of ß-III tubulin (ß3T) using immunohistochemistry, for studies of Ixempra® in non-small cell lung cancer. The second example will focus on companion diagnostic development efforts for K-Ras mutation using a quantitative PCR assay, for patient selection for Erbitux® in metastatic colorectal cancer. This section will cover a) the scientific basis and clinical data demonstrating the role of K-Ras mutations as predictive of Erbitux® efficacy in metastatic colorectal cancer, b) the rapid clinical adoption and impact of K-Ras testing on ongoing clinical investigations in colorectal cancer and drug label change and c) companion drug-diagnostic development challenges and a path forward.

11:30 am-12:00 pm Challenges of Companion Diagnostics Development – A Pharma Perspective

Miu Chau, Ph.D., Senior Project Manager, Companion Diagnostics, Genentech

The ultimate goal of personalized medicine is to deliver the right drug to the right patient, at the right dose, and at the right time. The ability to identify the specific patient subpopulation that shows substantial benefits from the targeted treatment is crucial for success. Much effort has been spent on the identification of biomarkers that will help predict patient response to treatments. Ultimately a commercially available and robust assay for patient selection is required for drug approval. This requires close collaboration of pharma and diagnostic companies to ensure that companion diagnostic assay development is aligned with drug development. The presentation will focus on the challenges involved in companion diagnostics development from partner selection to assay commercialization.

LUNCHEON TECHNOLOGY SHOWCASE

12:00-12:15pm Reducing Risk and Cost in Drug: Diagnostic Co-Development

Sponsored by Quest Diagnostics

Stephanie H. Astrow, Ph.D., MBA, Scientific Director, Oncology, Quest Diagnostics

The regulatory guidelines and co-development strategies between pharma, IVD, and reference labs for companion diagnostics continue to evolve. We will describe one approach to co-development that enables early availability of an assay for clinical development, while controlling risk and cost. An immunohistochemical assay for Notch signaling, a pathway tied to a number of cancers, will be used to illustrate this approach.

12:15-12:30 Bringing Personalized Medicine to Market – A New Vision for the Drug-Diagnostic Value Paradigm

Sponsored by biodesix

Paul Beresford, Ph.D., Vice President, Business Development & Strategic Marketing, Biodesix

The development of high-medical value diagnostic tests that enables personalized medicine accompanies high hurdles for clinical validation, high development costs, and comparatively low reimbursement rates. Overcoming these challenges can only happen if there is recognition of "value-based diagnostics" that improve patient care and reduce

healthcare spend from the drug developers investing in companion diagnostics, and from payers covering the cost of these tests at the appropriate level of reimbursement.

Sponsored by

12:30-12:45 So Many Markers, So Little Tissue: The Layered IHC Solution for Personalized Medicine

Michael S. Lebowitz, Ph.D., Director, R&D, 20/20 GeneSystems, Inc.

Sponsored by

12:45-1:00 Data-Driven Research and Use Cases for Biomarker Discovery

Ilya Kupershmidt, Co-founder & Vice President, Products, NextBio

Little progress has been made since the 8q24 "gene desert" was found in multiple cancer GWAS. We present curated genomic data from NextBio linking a recently mapped nearby gene to cancer progression and possible use as a cancer stem cell biomarker.

1:00-2:00 Sponsored Presentations (Opportunities Available)

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

DRUG-DIAGNOSTIC CO-DEVELOPMENT: DX PERSPECTIVE

2:00-2:30 Strategies for Successful Partnering and Co-Development from an IVD Industry Perspective

Iain D. Miller, Ph.D., Executive Director, Theranostics Strategy and Business Development, bioMerieux

The speaker will discuss bioMerieux's successful theranostic partnering strategy. With two partnerships with GSK and others including Merck and Ipsen, bioMerieux has developed a real-world knowledge of win-win deal terms, co-development strategies and alliance management. The speaker will discuss specific case studies illustrating bioMerieux's approach and will comment on the likely future evolution of partnering in this field.

2:30-3:00 Oncology Biomarkers in the Era of Targeted Therapy and Personalized Medicine

Vijay Modur, M.D., Ph.D., Head, Diagnostic Discovery, Novartis Molecular Diagnostics

The example of imatinib, a drug highly selective for its target (e.g. BCR-ABL) and leads to clear-cut efficacy in CML, a highly selected patient population, has been a paradigm for targeted therapy showing that if a drug can achieve the right exposure in the right patient population, remarkable efficacy may be achieved. However in the vast majority of oncology drug development programs, initial studies are indicative but not confirmatory of drug efficacy. In such instances further biomarker studies can allow optimization of development to ensure that a drug can achieve its full therapeutic potential. Biomarkers can facilitate this by optimizing selection of dose and schedule, selection of the right patient subsets, determination of potential molecular pathways that are impacted in tumor on drug exposure, to plan mechanism-based combinations and monitoring for efficacy by using sensitive read-outs. To ensure biomarker studies result in such planned outcomes, it is important to have a comprehensive strategy that addresses the key translational questions and address future diagnostic needs to make drugs successful.

3:00-3:30 Companion Diagnostics: Avoiding the Pit and the Pendulum

Donna Roscoe, Ph.D., Senior Scientific Reviewer, U.S. Food and Drug Administration, Center for Devices and Radiological Health, Office of in vitro Diagnostic Device Evaluation, Division of Immunology and Hematology Devices

Companion diagnostics (CoDx) require coordination of submissions to centers at the FDA. There are many important considerations and time-sensitive components to the regulatory process for co-development of drugs and devices. This talk is intended to provide a description of current regulatory processes for CoDx submissions to the Office of in vitro Diagnostic Device Evaluation and Safety (OIVD) in the FDA's Center for Devices and Radiological Health (CDRH), and describe the types of information to provide and pitfalls to avoid to promote success.

3:30-4:30 Networking Refreshment Break in the Exhibit Hall with Poster Viewing

PARTNERING STRATEGIES FOR DRUG-DIAGNOSTIC CO-DEVELOPMENT

4:30-5:00 Rx/Dx Companion Products: Partnerships that Meet the Challenges

Andrea H. Lauber, Ph.D., Head, Transactions for Clinical Biomarkers and Pharmacodiagnostics, Strategic Transactions Group, Bristol-Myers Squibb

The value of therapeutics (Rx) and companion diagnostics (Dx) is recognized as central to the delivery of personalized medicine. Development of Rx/Dx products often requires that partners from different sectors of our industry align to co-develop separate, eventually interrelated, assets. The discussion will address strategies that support successful partnerships in this emerging space.

5:00-5:30 Optimizing Personalized Medicine Partnerships: Emerging Industry Models

Mollie Roth, J.D., COO, Diaceutics

This panel will consider the current disconnect between the business models in the pharmaceutical and diagnostic industries and will discuss whether new models are required to successfully launch a targeted therapy. Panelists will give their insights into what a truly effective partnership in the PM space might look like and specifically what changes are required to move from the current supplier/buyer paradigm into such a true partnership. An overview of the numerous types of emerging models will be presented, and panelists will discuss the pros and cons of each model.

WEDNESDAY, MAY 4

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7:30-8:15 am Breakfast Presentation Transforming Highly Multiplexed Protein Assays through MRM Technology, with Applications to Biomarkers, Diagnostics and Toxicology

Daniel Chelsky, Ph.D., CSO, Caprion

Multiplexed MRM assays are a fast and cost-effective alternative to immunoassays for tracking large panels of protein biomarkers simultaneously and capable of unparalleled specificity, sensitivity and robustness. MRM panels can also be easily adapted to various species providing a seamless shift from pre-clinical to clinical samples supporting the entire drug development process. Learn how Caprion deploys MRM protein assays using a variety of sample types and applications including, toxicology panels and disease-specific panels.

CASE STUDIES IN DRUG-DIAGNOSTIC CO-DEVELOPMENT

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

8:30-9:30 CASE STUDY: Partnering for Success in Diagnostic/ Therapeutic Co-Development

• George Maliekal, M.B.A., Senior Director, Business Development and Licensing, Abbott Molecular

• Hakan Sakul, Ph.D., Senior Director, Translational Oncology Group, Oncology Business Unit, Pfizer

9:30-10:30 CASE STUDY: Putting the "Companion" in Diagnostics: Considerations for Successful Pharma-Diagnostics Collaborations

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

• Helen Y. Wu, Ph.D., Director, Genomics and Oncology, Roche Molecular Systems

The development and commercialization of companion diagnostics is highly dependent upon successful partnerships between biopharmaceutical and diagnostic companies. Pharmaceutical and diagnostic company partnering considerations will be discussed, such as choosing partners, contractual considerations, as well as best practices to ensure successful partnerships. A case study of a recent Roche Molecular System/Merck companion diagnostic partnership will be presented.

10:30-11:30 Networking Coffee Break in the Exhibit Hall with Poster Viewing

11:30 am-12:30 pm Panel Discussion: Strategies for Drug-Diagnostic Co-Development

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

12:30-1:15 A Comprehensive UPLC-MSE Biomarker Analysis Workflow Incorporating Advanced Statistical Methods and Chemical Intelligence

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Stephen McDonald, Manager, Business Development, Waters Corporation

Mass spectrometry coupled with Liquid Chromatography is one of the most powerful techniques for biomarker discovery due to the attributes that these tools exhibit over other methods. Of these, perhaps the most important is the facile manner in which compounds can be isolated and structural information can be determined. Evidence of this can be seen in the substantial adoption of these technologies for both metabolomic and lipidomic analysis In this presentation we will discuss the Waters Metabolic Profiling workflow; a simple rapid approach for the detection and analysis of biomarkers. This system solution redefines the quantity and quality of information which is freely available to the scientist.

PGX BIOMARKERS AND PATIENT SELECTION

2:00-2:30 Personalized Healthcare – When, How and Why is It Different to Good Clinical Development Practice?

Darren R. Hodgson, Ph.D., Biomics Advisor, AstraZeneca

This talk will cover what we should look for when contemplating driving co-dependent changes in diagnostic and treatment practice, what data drive the investment decisions from a commercial, scientific and clinical perspective, and how to build all external stakeholders into the process.

2:30-3:00 Clinical Diagnostic Strategies to Predict Patient Benefit in Early Development

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

Targeted therapeutics have shown significant promise in cancers driven by well defined genetic alterations, but clinical development of these agents still tends to follow an all-comers approach, leading to high clinical failure rates. 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.

3:00-3:30 Biomarkers for Patient Selection: Issues and Lessons Learned

Wei Zhou, M.D., Ph.D., Director, Molecular Epidemiology Research, Pfizer

Biomarkers used for patient selection may be based on 1) better response observed among the biomarker positive group in pre-clinical or early phase trials, or 2) retrospective analysis of existing clinical trial data. For the first category, common issues may include results extrapolation from pre-clinical data, using convenient, small sample size and non-representative patient samples, or questionable/ incomplete clinical information. For the second category, common issues may include retrospective analysis without a priori hypothesis, and "false positive" results from multiple comparisons. Using real examples, I will discuss these issues and lessons learned from recent clinical development.

3:30-4:00 Networking Refreshment Break

4:00-4:30 Clinical Pharmacogenomic Testing for Clopidogrel and Treatment for Hepatitis C

Alan H. B. Wu, Ph.D., Professor, Laboratory Medicine; Chief, Clinical Chemistry, Toxicology and Pharmacogenomics Laboratories, University of California, San Francisco

In March 2010, the FDA announced a black box warning for clopidogrel recommending pharmacogenomic testing. Unfortunately, the warning did not describe how therapy should be altered for variants. In November 2010, the GRAVITAS study showed that doubling the plavix dose had no effect on outcomes, therefore alternate drugs should be considered. In 2009, investigators demonstrated that for chronic hepatitis C, IL28B SNPs predicted treatment outcomes for pegylated interferon alfa and ribavirin. Non-responders should not be treated, or be given novel protease inhibitor therapies in addition to the traditional dual therapy.

4:30-5:00 Prognosis and Core Processes in Metastatic Breast Cancer: Correlation of a Composite Metastasis Score (cMS) and Oncotype Dx® Recurrence Score

Andrew Grupe, Ph.D., Senior Director, Pharmacogenomics, Celera

Different gene expression sets have been reported to reproducibly assess the metastatic potential of early stage operable breast tumors. An explanation for this apparent counter-intuitive observation is that the disparate genes of different signatures query common pathways or core biological processes. The most rigorous comparative analysis of expression signatures requires profiling of the same tumor samples. The irreplaceable nature of archived samples with long-term follow-up discourages duplicate testing for what are expected to be similar signatures, so we chose to carry out a statistical concordance study. Specifically, we sought to compare a composite metastasis score (cMS) consisting of a previously reported metastasis score (MS), a proliferation index, plus progesterone receptor with the Oncotype Dx® Recurrence Score (RS) and component constituents of these scores using a contemporary sample set. We further examined the correlation of estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) results with the Oncotype DX® assay.

EXECUTIVE SUMMIT: DRUG-DIAGNOSTIC CO-DEVELOPMENT

5:00-5:30 Integrating Discoveries in Basic, Clinical and Population Sciences to Advance Predictive Cancer Care

Andrew N. Freedman, Ph.D., Chief, Clinical and Translational Epidemiology Branch, Division of Cancer Control and Population Sciences, National Cancer Institute

To fully realize the potential of personalized cancer treatment, it will be essential to connect and integrate basic discoveries in drug development and pharmacogenomic variability, outcome and genomic data from randomized clinical trials, and data on the effects of drugs and their interactions with genomic variants in large heterogeneous patient populations. In this talk we will present recent research findings that illustrate how pharmacogenomic marker discoveries from clinical trials and observational studies can lead to both clinical utility and novel insights into the underlying biology of drug response phenotypes.

5:30 Close of Conference

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