Implementing Personalized Medicine

September 22-25, 2009 • Grand Hyatt Washington • Washington, DC

Inaugural
PERSONALIZED MEDICINE
Delivering on the Promise

September 22-24, 2009

Inaugural
TARGETED THERAPY
Towards Individualized Cancer Treatment

September 24-25, 2009

FEATURED SPEAKERS:

J. Carl Barrett
VP, Global Head
Oncology Translational Medicine Novartis

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

Giora Feuerstein
AVP, Head,
Discovery Translational Medicine, Wyeth Research

Stephen H. Friend
President, Sage Bionetworks

Mark J. Ratain
Chairman, Clinical Pharmacology and Pharmacogenomics
Cancer Research Center, Univ. Chicago

Allen D. Roses
Director, Deane Drug Discovery Institute
Duke Univ. School of Medicine

Douglas C. Throckmorton
Deputy Director, CDER, FDA

Frank L. Douglas
Senior Fellow, Kauffman Foundation

LEAD SPONSORING PUBLICATIONS:

BioITWorld eCliniqua Journal of Biological Motion TheScientist

These are just two of the eight meetings being held at this year’s ADAPT Congress 2009. For more information please visit ADAPTcongress.com
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CHI will gladly provide you the opportunity to host a focus group on-site at the ADAPT Congress. This exclusive gathering can be useful to conduct market research, gather feedback on a new product idea and gather marketing intelligence from industry experts on a specific topic.

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Track 1:
Optimizing Clinical Trials

Third Annual
ADAPTIVE CLINICAL TRIAL DESIGNS
Managing Complexity for Successful Implementation
September 22-24, 2009

Third Annual
CLINICAL BIOMARKERS
Optimizing Drug Development
September 24-25, 2009

Track 2:
Implementing Personalized Medicine

Inaugural
PERSONALIZED MEDICINE
Delivering on the Promise
September 22-24, 2009

Inaugural
TARGETED THERAPY
Towards Individualized Cancer Treatment
September 24-25, 2009

Track 3:
Advancing Cancer Therapy

Second Annual
TRANSLATIONAL CANCER MEDICINE
Optimizing Oncology Drug and Diagnostic Development
September 22-24, 2009

Inaugural
CIRCULATING TUMOR CELLS
Shaping the Future of Cancer Care
September 24-25, 2009

Track 4:
Bridging Silos in Biomarker Development

Third Annual
BIOMARKER DATA ANALYSIS
Integrating Biomarker Data and Establishing Biological and Clinical Relevance
September 22-24, 2009

Seventh Annual
PROTEIN BIOMARKERS
Overcoming Translational Challenges
September 24-25, 2009

SPONSORSHIP & EXHIBIT INFORMATION
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Email: reg@healthtech.com Fax: 781-972-5425

These are just two of the eight meetings being held at this year’s ADAPT Congress 2009. For more information please visit: ADAPTcongress.com
7:30-11:30 Registration for Pre-Conference Events

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

**FIT-FOR-PURPOSE BIOMARKER ASSAY DEVELOPMENT AND VALIDATION**

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

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

11:30-2:30 Pre-Conference Short Course* (*Separate Registration Required)

**BIOMARKER QUALIFICATION AND VALIDATION**

Facilitating the Development and Qualification of Biomarkers through a Novel Public-Private Partnership: The Biomarkers Consortium

David Lee, MPA, Deputy Director, The Biomarkers Consortium, Foundation for National Institutes of Health

OMICS: Premises and Promises for Discovery and Validation of Biomarkers

Eugene Kolker, Ph.D., Chief Data Officer, Seattle Children’s Hospital; Head, Bioinformatics & High-Throughput Analysis Laboratory, Seattle Children’s Research Institute

The Identification and Validation of Novel Prostate Cancer Biomarkers

Robert H. Getzenberg, Ph.D., The Donald S. Coffey Professor, Director, Urology Research, Brady Urological Institute, Oncology and Pharmacology and Molecular Sciences, Johns Hopkins Hospital

Network Multi-Marker Panels towards Next-generation Robust and Interpretable Biomarkers

Jake Y. Chen, Ph.D., Assistant Professor of Informatics and Computer Science, Indiana University School of Informatics; Founding Director, Indiana Center for Systems Biology and Personalized Medicine

SPONSORING PUBLICATIONS:

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

**NOVEL CANCER BIOMARKERS**

Population-Based in vivo Biomarker Discovery

Joerg Heyer, Ph.D., Director, Genetic Models, Translational Research, AVEO Pharmaceuticals

From Discovery to the Clinic: The Novel DNA Methylation Biomarker, Septin 9, for the Detection of Colorectal Cancer in Blood

Shannon R. Payne, Ph.D., Senior Scientist, Molecular Biology & Diagnostics, Epigenomics Inc.

The Blood-Based Colon Cancer-Associated Biomarkers, CCSA-2 and CCSA-4

Robert H. Getzenberg, Ph.D., The Donald S. Coffey Professor, Director, Urology Research, Brady Urological Institute, Oncology and Pharmacology and Molecular Sciences, Johns Hopkins Hospital

Identification of Novel Biomarkers Used in Non-invasive Genomic Assays for Disease Detection

William Wachsman, M.D., Ph.D., Associate Professor, Medicine, Hematology-Oncology, University of California, San Diego School of Medicine

miRNA-Based Biomarkers for Colon Cancer

Soren Møller, Ph.D., Vice President, Research and Development, Exiqon A/S

A Predictive Diagnostic Test for Drug Treatment Outcomes in Advanced Breast Cancer Extended to Advanced Colon Cancer for Personalized Anticancer Therapy

Paul Ts’o, Ph.D., Founder, Managing Director, CCC Diagnostics, LLC

Metabolomics-Derived Biochemical Markers of Prostate Cancer Aggressiveness

Jeffrey R. Shuster, Ph.D., Director, Diagnostic Development, Metabolon, Inc.

Predicting Tumor Resistance to the Death Receptor-Targeted Therapies

BaoLin Zhang, Ph.D., Principal Investigator & Quality Reviewer, Division of Therapeutic Proteins, Office of Biotechnology Products, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

11:30-2:30 Pre-Conference Short Course* (*Separate Registration Required)

**CIRCULATING TUMOR CELLS: COMMERCIAL ADVANCES**

Gene Expression Profiling of Circulating Tumor Cells in Breast Cancer Patients

Katarina Kolostova, Ph.D., Department of Tumor Biology, Third Faculty of Medicine, Charles University Prague, Czech Republic TATAA Molecular Diagnostics, Bioinova Prague Czech Republic

Isolation of Circulating Tumor and Endothelial Progenitor Cells from Blood for Cellular and Molecular Analyses on Epithelial Cancers

Wen-Tien Chen, Ph.D., Chief Scientific Officer, Vitatex Inc.

Multiplexed Profiling of Individual Circulating Tumor Cells using a Hyperspectral Imaging System

Harold Garner, Ph.D., Scientific Advisor, Xanaphat LLC; Professor, Internal Medicine and Biochemistry, University of Texas, Southwestern Medical Center

Enumeration and Sequential Molecular Analysis of CTCs using a Microfluidic (CEE) Platform: Assay Optimization for Clinical Validation

Farideh Bischoff, Ph.D., Director, Translational Research and Development, Biocapt, Inc.

Title to be Announced

Alexander Weis, Ph.D., Chief Executive Officer, AdnaGen AG
The FDA’s Role in Improving Drug Development

3:15-3:45

Douglas C. Throckmorton, M.D., Deputy Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

There are many pressures on the medical products endeavor, including the need for more timely and efficient development to support their marketing, and then assessment after marketing to support their best uses. There are many stakeholders with important responsibilities in the healthcare system. As regulators, the FDA has a clear role in responding to these pressures, one that includes both providing a clear path to efficient development as well as a critical role in supporting innovation and collaboration.

Oncology Clinical Trial Design: Opportunities for Rational (and Irrational) Incorporation of Biomarkers to Achieve the Goal of Individualized Therapy

3:45-4:15

Mark J. Ratain, M.D., Leon O. Jacobson Professor of Medicine; Chairman, Committee on Clinical Pharmacology and Pharmacogenomics; Associate Director, Clinical Sciences, Cancer Research Center, The University of Chicago

Biomarkers are often hailed as a panacea to reduce attrition rates of oncology drug development, thereby decreasing drug development costs. To date, the incorporation of predictive biomarkers has had mixed results, including important successes (e.g., HER2 testing for trastuzumab) and failures (e.g., EGFR testing for cetuximab). Pharmacodynamic biomarkers are similarly of theoretical value to accelerate decision-making, but in practice have had limited utility due to lack of technical validation and misconceptions of the value of a biomarker of unknown clinical importance. Novel trial designs incorporating predictive and pharmacodynamic biomarkers will be discussed.

Personalized Medicine Depends on Drug Pipeline-Efficacy Pharmacogenomics to Create New Targeted Therapies

4:15-4:45

Allen D. Ross, M.D., Professor of Neuroanatomy and Neurology; Director, Deane Drug Discovery Institute; Senior Scholar, Fuguo School of Business; Member, Duke Institute for Genome Sciences & Policy, Duke University School of Medicine

“Personalized medicine” has become a “hot topic,” discussed by many but practiced by few who are accountable for discovering and developing new medicines. I will present the viewpoint that targeted medicines that are reimbursable will drive the incentives of personalized medicine commercially. Currently academic and external investigators have the opportunity to test medicines independent of the sponsors only after they appear on the market. This creates a negative influence on drug developers in that new adverse events and focused efficacy occurs post-marketing, after a price has been set. Each reduces the potential market. Payers understand this and are willing to reimburse safe and effective medicines of value. The time to create that scenario is during drug development, especially with respect to pipeline efficacy. A medicine increases value when the “right” patients can be identified – except, when these data appear in the post-marketing period, the price never goes up with the value. Great strides in pharmaceutical development will be fueled by the prospective and integrated use of pipeline pharmacogenomics and encouragement of informational conversations with regulatory authorities, including but not limited to Voluntary Exploratory Data Submissions (VXDS).

Disease Biology as a Precompetitive Space: Emerging Opportunities for Distributed Contributors to Jointly Evolve Disease Models

4:45-5:15

Stephen H. Friend, M.D., Ph.D., President, Sage Bionetworks

Significant advances in generating probabilistic casual models as pioneered by Eric Schadt and colleagues at Rosetta Inpharmatics over the last five years have afforded an opportunity to share data not as linear files but as they reflect onto predictive models of disease. Examples will be shown that highlight the power of such models in metabolic and oncologic diseases. Experience will be placed on how classical target and pathway representations of disease miss capturing the essential biology needed to generate biomarkers and to develop drugs. Also to be discussed are the new organizational structures being built at the private/public interface that will allow investigators to modify and evolve each other’s models of biology. We posit that when biological data can be reflected onto evolving disease models that clinicians and scientists in academia and industry will be able to enter into connected projects that can evolve the resolving power of disease models in ways natural to chemists but alien to most biologists.

Use of Biomarkers and Translational Science to Accelerate and Improve Oncology Drug Development: Opportunities and Roadblocks

2:00-2:30

J. Carl Barrett, Ph.D., Vice President and Global Head, Oncology Biomarkers and Imaging, Oncology Translational Medicine, Novartis Institutes of BioMedical Sciences, Inc.

The steps in oncology drug development in patients include: optimizing dose-schedule, predicting patients that will respond, detecting tumor responses rapidly for proof-of-concept trials, using surrogate endpoints for disease monitoring, assuring safety of drug therapy, and developing rational-based combination therapies. Biomarkers are pivotal in meeting each of these challenges. A general strategy for using biomarkers in oncology drug development will be presented and includes: having a systematic biomarker plan for each new agent that is consistent, science-based and focused using common standards for assays and data; building a biomarker tool kit with analytically and clinically validated biomarker assays; building on clinical experience (positive and negative) and execution excellence involving a team effort (physicians, clinical staff, biomarker experts and data management) and building a strong partnership between Novartis and its clinical investigators.

Enabling Personalized Medicine through Application of Biomarkers in Clinical Development

2:30-3:00

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

The observer effect describes the changes that the act of observation will make on the phenomenon being observed and has many applications in the physical and experimental sciences. In drug development, if we consider biomarkers as the observer and the clinical trial as the phenomenon, we can ask how the process of analyzing biomarkers impacts the clinical trial process. It is clear that the simple act of collecting biopsies, let alone completing complex bioanalytical studies of these samples, impacts the ability to run clinical trials quickly and economically. Consequently, it is necessary to demonstrate that the value derived from the observation exceeds the cost to the phenomenon. This presentation will discuss how different types of biomarkers can be used during the drug development process to increase probability of success in the successive stages of drug discovery and development, and support decisions for further investment in subsequent development phases. Several examples of biomarker applications to confirm mechanism of action, explore PK/PD interactions and to derive predictive markers in ongoing drug development programs will be described.

HOTEL & TRAVEL INFORMATION

Conference Venue and Hotel:

Grand Hyatt Washington

1000 H Street NW

Washington, DC 20001

Tel: 202-582-1234   Fax: 202-637-4781

Discounted Room Rate: $279 s/d

Discounted Room Rate Cut-off Date: August 14th, 2009

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Delivering on the Promise
September 22-24, 2009

TUESDAY, SEPTEMBER 22

2:00-3:00 pm Conference Registration
3:00-3:15 Welcoming Remarks from Conference Director
Julia Boguslavsky, Cambridge Healthtech Institute

PLENARY KEYNOTES

3:15-5:15 Plenary Session, See Page 4 for Details
5:15-6:15 Grand Opening Reception in the Exhibit Hall

WEDNESDAY, SEPTEMBER 23

7:00 am Conference Registration Open
7:30-8:15 Breakfast Presentations (Opportunities Available)
Contact Ilana Quigley, Manager, Business Development, at 781-972-5457 or iquigley@healthtech.com.

PERSONALIZED MEDICINE AT BIG PHARMA

8:25-8:30 Chairperson’s Opening Remarks
8:30-9:00 Is the Pharmaceutical Industry Ready for Personalized Medicine?
Frank Douglas, Ph.D., M.D., Senior Fellow, Kauffman Foundation; and Senior Partner, PureTech Ventures
As the debate for personalized medicine ensues, there remains an ever growing need for a response from major players within the pharmaceutical industry. Once regarded as the fastest growing sector of the economy, the pharmaceutical industry has recently been marked by declines in revenues and productivity. Despite the recent trends, many pharmaceutical companies still exhibit entrepreneurial and innovative characteristics. These characteristics hold significant promise that could foster the next generation of scientific breakthroughs and pave the way for personalized medicine. But are these characteristics enough? How strong are they? Is the pharmaceutical industry ready for personalized medicine?

9:00-9:30 Delivering on the Promise of Personalized Healthcare:
Examples from AstraZeneca
Ruth March, Ph.D., Lead, Personalized Healthcare Team, AstraZeneca Pharmaceuticals
This presentation will cover discovering biomarkers in preclinical models, and qualifying biomarkers in clinical trials, as well as commercializing biomarkers for launch.

9:30-10:00 Industry Perspective on Companion Diagnostics and Drug Labels
Nadine Cohen, Ph.D., Head, Pharmacogenomics, Pharmaceutical Research & Development, Johnson & Johnson
An industry perspective on how companion diagnostics are being brought to the market will be presented. This will also include an overview of the current examples of drugs with Pharmacogenomics information in the label and how the analyses were conducted, as well as an example of application at J&J.

10:00-10:30 Practical Aspects of Successfully Applying Translational Biomarkers
Sandra L. Close Kirkwood, Ph.D., Research Advisor, Research Technology, Eli Lilly and Co.
The overall goal of personalized medicine is improving the benefit:risk ratio for patients by improving diagnosis, prognosis, or delivery of the right drug at the right dose at the right time. The application of biomarkers including pharmacogenomics to personalized medicine involves not only identifying but applying markers correlated with drug response, efficacy, or adverse events to make critical drug discovery and development decisions, clinical trial design and ultimately to clinical medicine. This discussion will present an overview of strategies, available tools and technology platforms, and the development and validation of biomarkers. The discussion will utilize examples to discuss hurdles to general application of biomarkers, and the criterion critical for success.

10:30-11:30 Networking Coffee Break with Poster and Exhibit Viewing

TECHNOLOGY SHOWCASE: PERSONALIZED MEDICINE

11:30-12:00 Title to be Announced
Pankaj Oberoi, Ph.D., Director, Scientific Services, Mesa Scale Discovery

12:00-12:15 Metabolite Profiling: Opportunities for Identification and Validation of Novel Biomarkers
Hajo Schiewe, Ph.D., Manager Business Development, Metanomics Health
Metabolite profiling is the parallel measurement of a broad range of endogenous and xenobiotic metabolites in a given biological sample. The metabolome reflects internal or external influences on an organism including drug treatment and disease status. Metanomics Health uses mass spectroscopy based metabolite profiling to identify and validate novel metabolite biomarkers for a range of applications in preclinical and clinical drug development, disease diagnostics and progression. The analysis and interpretation of metabolite changes can increase the mechanistic understanding of diseases, drugs and other influences on an organism.

12:15-12:30 Sponsored Presentation (Opportunity Available)
Contact Ilana Quigley, Manager, Business Development, at 781-972-5457 or iquigley@healthtech.com.

12:30-2:00 Lunch on your own

VALUE CREATION MODELS IN PERSONALIZED MEDICINE

2:00-2:30 Where is the ROI for Targeted Therapies?
Understanding the Barriers to and Benefits of Adopting Personalized Medicine
Asif Dhar, M.D., M.B.A., Senior Fellow, Deloitte Center for Health Solutions; Senior Manager, Deloitte Consulting LLP
During this discussion we will examine whether or not personalized medicine has a quantifiable ROI, and if an economic framework can be derived from case studies that will demonstrate differences in ROI across stakeholders. We will also discuss who stands to benefit most from personalized medicine, as well as what barriers stand in the way of achieving the promise of personalized medicine.

2:30-3:00 Defining the Value of Personalized Medicine: Will Health Reform be a Catalyst or a Challenge?
Kathryn A. Phillips, Ph.D., Professor, Health Economics & Health Services Research, School of Pharmacy, Institute for Health Policy Studies and UCSF Comprehensive Cancer Center, University of California, San Francisco
The urgency to find approaches to increase the value of health care has intensified because of looming health reform efforts. As HHS Secretary Sebelius noted in testimony during the Senate confirmation hearings, personalized medicine represents a “key strategy of healthcare reform.” Will health reform serve as a catalyst to the adoption of personalized medicine or conversely, will health reform be a challenge to adoption? This talk will examine the potential contribution of personalized medicine to health reform, focusing particularly on defining its contribution to improving the value of health care.

3:00-3:30 Panel Discussion: Benefits and Challenges in Personalized Medicine
3:30-4:30 Networking Refreshment Break with Poster and Exhibit Viewing

ADAPTIVE CLINICAL TRIALS FOR PERSONALIZED MEDICINE

4:30-5:00 Adaptive Design: A Shortcut to Personalized Medicine?
Yi Shyr, Ph.D., Ingram Professor of Cancer Research; Chief & Director, Cancer Biostatistics Center, Vanderbilt University School of Medicine
Adaptive clinical trial designs offer promise for the development of personalized treatment regimens for diseases such as cancer, heart disease, and diabetes. This presentation will discuss the pros and cons of biomarker endpoints, surrogate endpoints, and clinical endpoints in adaptive trials. We also will look at the difference between prognostic biomarkers and predictive biomarkers. Finally, we will review recent developments in biomarker-adaptive trial design, as well as the limitations of such designs.
Inaugural

**TARGETED THERAPY**

Towards Individualized Cancer Treatment

**September 24-25, 2009**

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**THURSDAY, SEPTEMBER 24**

**TECHNOLOGY SHOWCASE: TARGETED THERAPY**

**11:30-12:00 Safety and Efficacy Considerations for Biomarkers in Retrospective Analysis of Completed Clinical Trials**

Robert L. Becker, Jr., M.D., Ph.D., Chief Medical Officer, Office of In Vitro Diagnostic Device Evaluation and Safety, Center for Devices and Radiological Health, U.S. Food and Drug Administration

*Personalized medicine* is safe and efficacious use of drugs to performance of diagnostic tests. For biomarkers recognized late in drug development, re-examining cases and samples collected in completed trials is attractive for speeding clinical validation of drug/marker combinations. This approach presents risks for bias that need to be controlled. The level of evidence needed for safety considerations may vary from the level needed for efficacy claims. In any event, reliable performance characteristics for the diagnostic test are essential, and best assured with thorough regulatory review of the test.

**12:00-12:30 Translational Medicine Strategies in Musculoskeletal Diseases: On a Quest to Improve Predictability**

Salvatore Alesci, M.D., Ph.D., Director, Discovery Translational Medicine, Wyeth Research

The development of innovative drugs that address unmet medical needs in Musculoskeletal Disorders is often halted by the heterogeneity of the patient populations, and in particular lack of biomarkers predictive of disease progression and likelihood of response/resistance to treatment. This presentation will provide an overview of translational medicine strategies and research implemented to address these issues and advance drug development in this area.

**12:30-2:00 Lunch on your own**

**PLENARY KEYNOTES**

**2:00-3:00** Plenary Session, See Page 6 for Details

**3:00-4:00** Networking Refreshment Break with Poster and Exhibit Viewing

**DRUG/DIAGNOSTIC CO-DEVELOPMENT**

*(Shared Session with Clinical Biomarkers meeting)*

**4:00-4:30** The Potential Impact of Recently Approved and Emerging Molecular Diagnostics in Drug-Diagnostics Co-Development

Francis Kalush, Ph.D., Network Leader, Diagnostics, Office of the Center Director, Center for Devices and Radiological Health, U.S. Food and Drug Administration

The FDA under its Critical Path Initiative is leading several efforts to streamline regulatory pathways in Personalized Medicine. An overview of the strategies and impact of recently and emerging molecular diagnostic biomarkers in companion drug-diagnostics will be discussed.

**4:30-5:00** Biomarkers - Driven Drug and Diagnostic Co-Development in Oncology: Current Trends and Future Approaches

Miro Venturi, Ph.D., Senior Biomarker & Experimental Medicine Leader, Roche Pharma Development, Roche Diagnostics GmbH

Nowadays a combination of novel and established molecular tools with biomarker analysis embedded on most of the trials in clinical development are offering huge opportunities to embark as early as possible in co-development of the drug and its associated diagnostic test. As the approach evolves and refines, both the private and the public sector build the mission.

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5:00-5:30 Personalized Medicine: Using Biomarker Signatures to Predict Response to New Therapies

J. Kyle Watthen, Ph.D., Research Statistician, University of Texas, M.D. Anderson Cancer Center

The ISPY2 process is a new approach to conducting clinical research that utilizes a patient’s biomarker measurements to predict which treatment is most likely to provide benefit. Patients will be adaptively randomized and the treatment assignment probabilities will be altered to favor the treatment that, on average, appears superior for a given patient’s biomarker characteristics. In contrast to the traditional phase II clinical trial, which has a fixed number of treatments, the ISPY2 process will allow new agents to enter the trial as they become available and will “graduate” treatments based on the likelihood of future success in a subset of the patient population. A simulation study is presented and examples given to demonstrate the adaptive nature of the design.

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10:00-10:30 The Future of Personalized Medicine and How Standards can Play a Role in Innovation of New Technologies

Michael D. Amos, Ph.D., Biosciences Advisor, Director’s Office, Chemical Science and Technology Laboratory, National Institute of Standards & Technology Measurement; Ex-Officio Member, Secretary’s Advisory Committee on Genetics Health and Society (SACCOHS), Department of Health and Human Services

New measurement technologies can play an important role in expanding the current vision of personalized medicine from mostly encompassing pharmacogenomics and electronic health records to one involving early detection and prevention of the chronic diseases (cancer, diabetes, cardiovascular and other diseases) that cause massive pain and suffering and represent more than 80% of U.S. health care spending. New multiplex measurement tools are making it possible to, for the first time, analyze the complex biomolecular network systems and gain a better understanding of the molecular pathology of diseased cells. DNA microarray, IVD-MIA products are reaching market and the nucleic acid-based signatures they can discern appear to possess greater diagnostic and prognostic value than single measurements alone. The same will probably also be true for multiplex proteome analysis. However, because these technologies are considerably more complex, their utility in the clinic will require entirely new and innovative approaches to standards to enable their further development and deployment.

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*For more information please visit: [ADAPTCongress.com](https://chidb.com/register/2009/adapt/reg.asp)*
to cooperate together to make personalized healthcare a reality. We will review some of the modern approaches to develop oncology companion diagnostics, critically shed light into the necessary analytical and clinical steps and provide some thinking for the future geared to improve the lives of cancer patients.

5:00-5:30 Challenges of Integrating Targeted Biomarker Tests into Clinical Practice
Walter Carney, Ph.D., Head, Oncogene Science, Diagnostics, Siemens Healthcare Dx
For HER-2/neu Positive breast cancer patients, the availability of HER-2 targeted therapies is becoming increasingly important. The challenge that exists is to select the patients who will benefit most from these therapies, as well as correctly identify who is eligible and who is not eligible for HER-2/neu targeted therapies. Unfortunately, not all HER-2/neu tests are equivalent, thus leading to uncertainty in the HER-2 status of many patients. Therefore it is critical that the HER-2 status be accurately determined which is not always the case leading to some patients not having access to these valuable new therapies.

5:30 Close of Day

8:25-8:30 Chairperson’s Opening Remarks
8:30-9:00 Biomarkers and Diagnostics in Drug Development: Making Medicines Better
Walter H. Koch, Ph.D., Vice President and Head, Global Research, Roche Molecular Systems, Inc.
Disease heterogeneity is one explanation of why some patients treated with a given therapy do not show adequate responses. Biomarkers afford the opportunity to classify subtypes of disease at a molecular level, and in some cases, to specifically predict the likelihood of therapy response. Knowledge of oncogenic pathway dysregulation is also increasingly helping to guide stratification of patient populations to improve patient response in clinical trials, and routine treatment. Recent examples include selection of targeted therapies based on the presence, activation by mutation, or overexpression of a drug target (e.g. ER, EGFR, HER2), as well as knowledge of downstream signaling activation that renders a particular growth factor receptor inhibition strategy less effective (e.g. KRAS ). Examples of clinical trial strategies using mutational status of relevant cancer genes to guide patient selection, and the associated diagnostics development ramifications will be presented.

9:00-9:30 Personalized Diagnostics: The Struggle for Position
Bruce Quinn, M.D., Ph.D., Senior Health Policy Specialist, Foley Hoag; Former California Medical Director, NHIC
Multiplex and other complex diagnostics apply cutting-edge molecular biology techniques to clinical challenges in patient care. As technology advances, the technology becomes reliable enough for clinical use and the per-patient costs of the technology become practical. However, the tests are similar to pharmaceuticals in that the cost of goods sold may be small in proportion to the development risks and the costs of clinical trials to validate the test. Therefore, while the value-based market price may be fully commensurate with the test’s clinical worth, a substantial market price is also required just to recover the development costs. Otherwise, the tests will have a negative total value for the test developer regardless of the size of their clinical value to the public. The problem is, historically, the prices of laboratory tests are very small compared to their clinical value. For example, the troponin test saves lives by diagnosing heart attacks, but the market price of the test is under $20 dollars. This lecture discusses the opportunities and challenges that face multiplex diagnostics in the marketplace.

9:30-10:00 Panel Discussion: Integrating Biomarkers and Diagnostics into Drug Development

10:00-10:30 Networking Coffee Break

10:30-11:00 Translational Medicine’s Role in Target Validation and Patient Selection in Oncology Drug Development
Giora Feuerstein, M.D., Assistant Vice President and Head, Discovery Translational Medicine, Wyeth Research
The modern era of molecular oncology attempts to deliver anti-cancer drugs that interfere with specific pathways that drive the oncogenic transformation of tumors. Therefore, identifying the specific signaling pathways that underwrite the particular growth and metastasis of each individual tumor in each patient requires meticulous profiling of the tumor tissue for the targeted oncogenic cause. Biomarkers that provide evidence on the presence of mutations and/or activation of such pathways are critical to match the treatment to the particular patient’s tumor. This talk will provide the strategies and case studies on the role of Translational Medicine and biomarkers in modern oncology drug discovery and development.

11:00-11:30 Predictive Markers for Optimizing Selection of Colorectal Cancer Patients for Treatment with ERBITUX® (Cetuximab)
Shrin Khambata-Ford, Ph.D., Director, Oncology Biomarkers, Oncology, Bristol-Myers Squibb Co.
Cetuximab is a chimeric monoclonal antibody directed against the epidermal growth factor receptor (EGFR) with proven clinical efficacy in metastatic colorectal cancer (mCRC) and several other solid tumor types. Several candidate predictive markers of cetuximab efficacy in mCRC have emerged recently from clinical studies, most notably the K-Ras mutation status of the tumor. Retrospective data strongly suggest that the benefit/risk ratio for cetuximab treatment in patients with wild-type K-Ras mCRC tumors is greater than for patients with mutant K-Ras tumors. In addition, a gene expression signature including genes for the EGFR ligands epiregulin and amphiregulin may also identify patients who are likely to benefit from cetuximab. The addition of gene expression information to K-Ras mutation status could further optimize the selection of patients most likely to benefit from cetuximab treatment.

11:30-12:00 Oncology Biomarkers and Response to Therapy
Jill M. Kolesar, Pharm.D., Director, Analytical Instrumentation Laboratory for Pharmacokinetics, Pharmacodynamics, and Pharmacogenetics, UWCCC, Associate Professor of Pharmacy, School of Pharmacy, University of Wisconsin
Anticancer therapies are nearly universally expensive and toxic, yet efficacy is limited to a small subset of treated patients. A number of predictive biomarkers are emerging as a method to individualize cancer therapy, treating only those likely to benefit and sparing likely non-responders from the toxicity and expense of unnecessary treatment. Recent advances in Kras and C-met mutational analysis for predicting response to EGFR inhibitors will be discussed.

12:30 Close of Congress
**HOW TO REGISTER:**

- **Email:** reg@healthtech.com
- **Phone:** 781-972-5400 Option 1
- **Fax:** 781-972-5425

**Key Code 974F3D**

- Yes! Please register me for ADAPT CONGRESS 2009

**REGISTRATION INFORMATION**

- **Name:**
- **Job Title:**
- **Company:**
- **Address:**
- **City/State/Postal Code:**
- **Country:**
- **Telephone:**
- **Email:**

How would you prefer to receive notices from CHI? Email: Yes No Fax: Yes No

*Email is not a mandatory field. However, by excluding your email you will not receive notification about online access to pre-conference presenter materials, conference updates, networking opportunities and requested eNewsletters.

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<tr>
<th><strong>MAIN CONFERENCE PRICING</strong></th>
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**Standard Registration Package - Two day pricing**

(Standard registration package includes access (September 22-24 OR September 24-25) to all plenary sessions, exhibit hall functions and conference proceedings). This package does not include registration to any pre-conference short courses.

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**September 22 • Short Course Pricing**

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**REGISTER 3 - 4th IS FREE**

Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply. Please reproduce this registration form as needed.

- I cannot attend but would like to purchase the ADAPT 2009 conference CD for $750 (plus shipping). Massachusetts delivery will include sales tax.
- I am interested in presenting a poster at ADAPT Congress 2009 (Select ONE poster session)
- Adaptive Clinical Trial Designs
- Personalized Medicine
- Clinical Biomarkers
- Targeted Therapy
- Translational Cancer Medicine
- Biomarker Data Analysis
- Circulating Tumor Cells
- Protein Biomarkers
- Other

**PAYMENT INFORMATION**

- AMEX (15 digit)
- Visa (13-16 digit)
- MasterCard (16 digits)
- Check
- DJC

**Card #** | **Expiration Date**
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**Weekly Update**

The latest industry news, commentary and highlights from BioIT World

**eCliniqua**

Innovative management in clinical trials

**Predictive Biomedicine**

Informatics tools and strategies driving decisions

**Present a Poster and Save $50!**

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure a poster board and inclusion in the conference proceedings, your abstract must be submitted, approved and your registration paid in full by **August 14, 2009**. Register online, or by phone, fax or mail. Indicate that you would like to present a poster and you will receive exhibition instructions via email.

**Yes! I am interested in presenting a poster at ADAPT Congress 2009 (Select ONE poster session)**

- Adaptive Clinical Trial Designs
- Personalized Medicine
- Clinical Biomarkers
- Targeted Therapy
- Translational Cancer Medicine
- Biomarker Data Analysis
- Circulating Tumor Cells
- Protein Biomarkers
- Other

**CHI Insight Pharma Reports**

A series of diverse reports designed to keep life science professionals informed of the salient trends in pharmaceutical technology, business, clinical development, and therapeutic disease markets. For a detailed list of reports, visit InsightPharmaReports.com, or contact Rose LaFlaa, rlaflaa@chimedialll.com, 781-972-5444.

**Barnett Educational Services**

Barnett is a recognized leader in clinical education, training, and reference guides for life science professionals involved in the drug development process. For more information, visit www.barnettintemational.com.

**Additional Registration Details**

Each registration includes all conference sessions, posters and exhibits, food functions, and a copy of the conference proceedings link.

**Group Discounts**

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

**Handicapped Equal Access**

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

**Substitution/Cancellation Policy**

In the event that you need to cancel a registration, you may:

- Transfer your registration to a colleague within your organization. Credit your registration to another Cambridge Healthtech Institute program.
- Request a refund minus the cost $750 of ordering a copy of the CD.

**NOTE:** Cancellations will only be accepted up to two weeks prior to the conference.

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