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

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

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<td>7:30-11:30 Registration for Pre-Conference Events</td>
<td>8:00-10:00 Pre-Conference Short Course* (Separate Registration Required)</td>
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<td>8:25-10:30 Designing Adaptive Trials Personalized Medicine at Big Pharma Top 10 Opportunities in Translational Cancer Medicine</td>
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<td>12:30-2:00 Lunch on your own</td>
<td>2:00-3:30 Challenges in Adaptive Clinical Trial Implementation Value Creation Models in Personalized Medicine</td>
<td>Top 10 Opportunities in Translational Cancer Medicine (continued)</td>
<td>3:30-4:30 Networking Refreshment Break with Poster and Exhibit Viewing</td>
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<td>3:30-4:30 Networking Refreshment Break with Poster and Exhibit Viewing</td>
<td>4:30-6:00 Adaptive Clinical Trials for Personalized Medicine Top 10 Opportunities in Translational Cancer Medicine (continued)</td>
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<td>4:00-5:30 Drug/Diagnostic Co-Development CTCs as Markers Protein Biomarkers for Cancer Targeted Therapy</td>
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be used to assess the skin as a means to explore other local or systemic diseases. The technology called EGIR (Epidermal Genetic Information Retrieval) employs use of the genomic-based assays, however, rely on invasive techniques to obtain tissue eligible individuals. Availability of a blood-based test for CRC is expected to improve screening mortality.  Availability of a blood-based test for CRC is expected to improve screening compliance in the general population. Through DNA methylation-sensitive, restriction enzyme-based biomarker discovery we identified a region of the Septin 9 gene that is methylated in over 90% of colorectal cancer tissues with little or no methylation in normal colon tissue and other controls. Using a systematic method of biomarker development, we demonstrated specific detection of CRC DNA using the Septin 9 methylation biomarker (mSEPT9) in multiple studies of plasma from CRC patients and colonoscopy-verified negative controls. A prospective population-based screening trial is now underway to determine the clinical performance of mSEPT9 in CRC screening guideline-eligible individuals.

The Blood-Based Colon Cancer-Associated Biomarkers, CCSA-2 and CCSA-4
Robert H. Gretenberg, Ph.D., The Donald S. Coffey Professor, Director, Oncology Institute, Oncology and Pharmacology and Molecular Sciences, Johns Hopkins Hospital

Identification of Novel Biomarkers Used in Non-invasive Genomic Assays for Disease Detection
William Washman, M.D., Ph.D., Associate Professor; Medicine, Hematology-Oncology, University of California, San Diego School of Medicine

Genomic biomarkers are rapidly being embraced as a breakthrough technology and a highly accurate means of detecting disease. Their identification and subsequent clinical use of the genomic-based assays, however, rely on invasive techniques to obtain tissue and/or blood samples. Now, an entirely non-invasive approach is being developed that uses changes in the gene expression profile of the skin to detect cancer and other diseases. The technology called EGRIR (Epidermal Genetic Information Retrieval) employs a piece of custom adhesive tape to easily and non-invasively collect cells from the stratum corneum and analyze the extracted RNA that enables a multi-gene biomarker. The first assay we are developing is 19-gene biomarker for the detection of melanoma and results to date show 100% sensitivity and 88% specificity. It is also anticipated that EGRIR can be used to assess the skin as a means to explore other local or systemic diseases and physiologic processes for additional applications, including novel diagnostics and theranostics.

miRNA-Based Biomarkers for Colon Cancer
Søren Møller, Ph.D., Vice President, Research and Development, Exiqon A/S

Abnormal expression of microRNAs (miRNAs) in cancer implies that these small ~22-nucleotide molecules play a role in oncogenesis. Therefore, miRNAs may comprise a novel class of diagnostic and prognostic signatures. This talk will focus on examples of using miRNA for classification and prognosis for colon cancer.

A Predictive Diagnostic Test for Drug Treatment Outcomes in Advanced Breast Cancer Extended to Advanced Colon Cancer for Personalized Anticancer Therapy
Paul Tr Tr, Ph.D., Founder Managing Director, O2 Diagnostics, LLC

Comprehensive Cancer Cells Diagnostics, LLC (C3D) has developed the Drug Response Indicator Test (DRIT) to assist physicians in designing personalized treatment regimes for patients fighting cancer. In one test, the DRIT provides a reliable and detailed profile of a patient’s tumor response for up to six (6) FDA-approved anticancer drugs. The DRIT allows physicians to “choose the appropriate effective drug treatments for individual patients” resulting in optimal use of the time window for treatment, reduction of side effects and significant financial savings.

Metabolomics-Derived Biochemical Markers of Prostate Cancer Aggressiveness
Jeffrey R. Shuster, Ph.D., Director, Diagnostic Development, Metabolon, Inc.

The elucidation of the complex molecular and physiological events that characterize the differences between normal cells and cancer cells is under intense investigation both at the research level and in clinical practice. A large number of studies have been reported with DNA, RNA, and protein-based technologies, however, few studies have been performed to characterize cancer at the biochemical level. It is by gaining this type of mechanistic understanding of a disease that researchers will unlock the keys to discovering new diagnostics. This presentation will provide an overview of a study undertaken to better understand and profile the biochemical changes associated with prostate cancer aggressiveness. Using metabolomics, a global biochemical profiling technology, tissue, urine and plasma samples were analyzed enabling researchers to identify a series of biochemicals (including sarcosine) that are key potential predictors of cancer aggressiveness. Attendees will learn about this study as well as how the underlying technology that fueled this discovery is being applied in hundreds of other areas – like diabetes, drug safety research and even consumer products.

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

The cell surface death receptors are promising targets for cancer therapy. Recombinant human TNF-related apoptosis inducing ligand (TRAIL) and its agnostic antibodies are in clinical trials for treating various malignancies. However, their therapeutic potential is limited by occurring resistance in tumor cells. Our research has been to identify biomarker(s) for prediction of tumor sensitivity to these therapies. This presentation will give an overview of cancer therapies targeting the death receptors and our recent findings on tumor resistance.

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BIOMARKER QUALIFICATION AND VALIDATION

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

David Lee, MPH, Deputy Director, The Biomarkers Consortium, Foundation for 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. Among its signature initiatives is The Biomarkers Consortium launched in late 2006, which includes the involvement of government (including NIH, FDA and CMS), the private sector, the biotechnology, medical device, academia, and non-profits and patient advocacy groups toward the goal of developing and qualifying promising biomarkers in order to help accelerate the delivery of successful new technologies, medicines, and therapies for prevention, early detection, diagnosis, and treatment of disease. These stakeholders recognize that the consortium’s goals are beyond the capacity of any one sector, and are leveraging their scientific and financial resources and sharing the risks. Given that harmonization of approaches to standards for biomarker assessment has not yet been achieved, the consortium offers the best hope that its broad goals of supporting the evolution of predictive, preventive, personalized and participatory medicine can be realized. To date, the Consortium has launched six projects and has a number of other efforts underway in a number of therapeutic areas.

OMICS: Promises 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

OMICS and Integrative Systems Biology bring paradigm shift into modern biomedical and clinical research. Traditional hypothesis-based, reductionist and subtractive approaches are being complemented by new discovery-based, synthesis and integrative approaches. These constitute OMICS Promises. In turn, OMICS Promise to widen, accelerate and transform research capabilities. This presentation reviews existing OMICS, their data integration and applications for discovery and validation of biomarkers.

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-Vectorizer 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

Panel biomarkers have been shown as superior to single biomarkers in the diagnostic and prognostic management of complex diseases such as cancer and neurodegenerative diseases. However, many panel biomarkers developed today are based on serendipitous associations between measured molecules and disease clinical outcomes on limited populations. Many panel biomarkers developed as such have poor overlaps and arbitrary constituents. In this presentation, I describe the use of sensitivity, specificity, and robustness to improve the analysis of biomarker data and development of biomarker panel with high performance that can be repeated. I will show our latest development that use Terrain visualizations to help develop and validate biomarker data analysis results.

Development of a Biomarker Qualification Regulatory Process at the FDA

Frederico Goodnatt, PhD, Associate Director for Operations in Genomics, Office of Clinical Pharmacology, Office of Translational Science, CDER, U.S. Food and Drug Administration

The path from biomarker discovery to successful applications in drug development is lengthened by uncertainty, not only about the scientific, clinical and technical challenges in the development of tests for these biomarkers, but also about the regulatory interpretation of biomarker data reported in INDs, NDAs and BLAs. We have developed a biomarker qualification process at the FDA to capture consensus on the context of use and supporting data for these biomarkers. We have qualified biomarkers of nephrotoxicity for nonclinical context of use. Experience with these and other biomarkers has strengthened this process and shown how qualification for incremental contexts of use can lead to biomarker qualification pipelines.

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 Kolistova, Ph.D., Department of Tumor Biology, Third Faculty of Medicine, Charles University Prague, Czech Republic

The presence of circulating tumor cells (CTC) in peripheral blood of breast cancer patients is a prognostic factor indicating increased risk of metastasis. We present methodology and results from ongoing prospective study of CTCs in peripheral blood of patients with diagnosed breast cancer (stages I to III) and metastatic disease. 107 patients were enrolled into the study and so far 152 tests have been performed. CTC’s were enriched from 5 mL whole blood using immunomagnetic Adna Test Breast Cancer Select. cDNA from CTC-positive samples was further characterized by real-time quantitative PCR (qPCR) for 35 cancer related genes and 12 reference genes using the high throughput microfluidic BIOMARK qPCR platform. The gene expression profiles of the CTCs are compared to expression profiles measured on samples (FFPE) collected from the primary tumor. The data were processed and analyzed with multivariate methods using GenEx software.

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

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

Recent research advances show that tumor cell intravasation (entry into the circulation), angiogenesis and metastasis occur very early in cancer progression. Clinical studies also illustrate the potential importance of detection of circulating tumor cells (CTCs), circulating endothelial cells and circulating stem or progenitor cells in outcomes of patients with epithelial cancers. Since these cells are extremely rare, comprising as few as one cell per 108 red and white blood cells of cancer patients, current major approaches involve the use of specific cell surface markers to enrich or sort a particular population of rare cells from the peripheral blood. This lecture will focus on a novel functional cell enrichment method, called cell adhesion matrix (CAM) assay, for the isolation and detection of multiple types of rare cells in blood. The CAM-coated device provides a rare cell enrichment platform that enables: (1) high sensitivity detection of CTCs in patients with metastatic diseases and early stages, (2) automated immuno-phenotyping of CAM-isolated cells using multiplex flow cytometry that is useful for serial monitoring of patients during treatment, (3) CAM-isolated cells from cancer patients can be propagated in culture and may allow applications in personalized medicine, and (4) CAM-isolated cells from cancer patients contain stem cell populations (tumor and endothelial progenitor cells) that may be developed into blood tests for non-invasive serial monitoring of patients for drug resistance.

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

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

A new hyperspectral microscope imaging system, named the Intelligent Single Cell Optical Profiling Engine (“I-SCOPE”), is capable of analyzing tumor marker expression levels in individual, intact cells. The system quantifies multiplexed cocktails of engineered fluorophores conjugated to up to 13 markers. Results from analyses of tumor cells in a variety of specimen types will be reviewed.

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

Fardeh Bischoff, Ph.D., Director, Translational Research and Development, Biocept, Inc.

The Biocept CEE (Cell Capture and Extraction) micro-fluidic device is designed to create a randomized flow pattern for maximal cell contact along the channel surface of the fluid path. The micro-channel selectively captures and enriches target circulating tumor cells (CTCs) from blood and other physiological fluids. Because the Biocopt CE device is attached to the surface of a glass slide, the system is particularly suited for direct and immediate single CTC morphologic assessment, in addition to immunohemochromatographic and gene analysis. The processing of blood samples from advanced stage cancer patients, including breast, prostate and lung, has been optimized for CTC capture, enumeration and post capture analysis of protein levels (IHC) and chromosomal/DNA content.

Title to be Announced

Alexander Weiss, Ph.D., Chief Executive Officer, AdnaGene AG

Additional Speakers to be announced. Please visit www.ADAPTcongress.com for additional speakers, schedule details, and other information.
3:15-3:45  Disease Biology as a Precompetitive Space: Emerging Evolving Disease Models That Clinicians and Scientists in Academia and Industry Will Be

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 use. 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.

3:45-4:15  Oncology Clinical Trial Design: Opportunities for Rational (and Irrational) Incorporation of Biomarkers to Achieve the Goal of Individualized Therapy

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.

4:15-4:45  Personalized Medicine Depends on Drug Pipeline-Efficacy Pharmagenetics to Create New Targeted Therapies

Allen D. Roses, M.D., Jefferson-Pilot Professor of Neurobiology and Neurology; Director, Deane Drug Discovery Institute; Senior Scholar, Fuqua 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 occur 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 occur in the post-marketing period, the price never goes up with the value. Great strides in pharmacological development will be fueled by the prospective and integrated use of pipeline pharmagenetics and encouragement of informational conversations with regulatory authorities, including but not limited to Voluntary Exploratory Data Submissions (VXDS).

4:45-5:15  Disease Biology as a Precompetitive Space: Emerging Opportunities for Distributed Contributors to Jointly Evolve Disease Models

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

Significant advances in generating probabilistic causal 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. Emphasis will be placed on how classical target and pathway representations will be shown that highlight the power of such models in metabolic and oncologic diseases. Emphasis will be placed on how classical target and pathway representations will be shown that highlight the power of such models in metabolic and oncologic diseases.

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

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.

2:30-3:00  Enabling Personalized Medicine through Application of Biomarkers in Clinical Development

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 biopases, 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.
**Track 1**

**DESKTOP KEYNOTES**

3:15-5:15  Plenary Session, See Page 6 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.

**DEVELOPMENT OF CLINICAL TRIALS**

8:25-8:30  Chairperson’s Opening Remarks
8:30-9:00  Designing, Simulating, and Executing an Adaptive Trial
Vladimir Dragalin, Ph.D., Assistant Vice President and Research Fellow, Head, Statistical Research and Applications, Wyeth Research

The process of implementing an adaptive design in a dose-ranging study will be reviewed with the emphasis on three major steps: planning, simulating, and executing. The first step involves the review of the clinical plan, identification of the protocol design requirements, and the review of potential designs that can best address these requirements. The simulating step consists of comparing the different design options on simulated data for a set of scenarios, reviewing their operating characteristics, and fine-tuning design parameters. As a result, the most appropriate design is selected for implementation. The execution step comprises the finalization of the protocol, Statistical Analysis Plan (SAP), Data Monitoring Committee (DMC) charter, and then conduct of the interim analyses with the pre-planned adaptations.

9:00-9:30  Design and Implementation of a Comprehensive Data Flow for a Seamless Adaptive Phase 2/3 Trial
Marcia Brackman, CCDM, Data Scientist, Data Management, Eli Lilly and Company

The need for near real-time integrated data for the interim analyses for an adaptive Phase 2/3 seamless trial necessitates functional database(s) prior to trial execution, timely data entry and query resolution, timely integration of key data from multiple sources, and a well-executed data flow. By leading a cross-functional team of both internal and external resources, a comprehensive data flow was designed, tested and implemented prior to actual adaptive randomization updates, ensuring that all parties’ data needs were met. As part of the dataflow design, other supporting documents and processes were also established with regard to data flow risk mitigation, roles and responsibilities, and a communication plan.

9:30-10:00  Evaluating Adaptive and Model-Based Approaches for Dose-Ranging Studies: An Update with Recommendations from the PhRMA Working Group
Jose C. Pinheiro, Ph.D., Senior Biometrical Fellow & Biostatistician, Biostatistics, Novartis Pharmaceuticals

Poor dose selection remains one of the key reasons for the high rate of failure currently observed in late stage clinical trials. To evaluate and promote the use of better designs and methods for dose finding, the Pharmaceutical Research and Manufacturers of America (PhRMA) formed a working group on adaptive dose ranging studies (ADRS) and model-based methods. The ADRS WG undertook extensive simulation studies comparing adaptive and non-adaptive dose finding methods, putting forward preliminary conclusions and recommendations on the use of these methods in drug development. This talk will present an overview of the second round of evaluations produced by the WG, focusing on additional adaptive dose-ranging methods, the use of exposure-response models in dose finding, and the impact of dose selection in Phase II on the probability of success of Phase III programs. Updated conclusions and recommendations will be presented and discussed.

10:00-10:30  Missing Data Mechanisms in a Dose Finding Adaptive Trial
Kenneth Liu, Ph.D., Associate Director, Merck & Co.

We applied the three categories of missing data: missing completely at random (MCAR), missing at random (MAR), and not missing at random (NMAR) and introduce the “mixture missing mechanism” (MMM) to an actual novel adaptive study design which applies adaptive dose-finding methodology within the setting of a three-period crossover study which includes an experimental treatment, an active control and placebo. The dose-adaptive procedure was carried out through evaluation of a utility function based on efficacy comparisons with the active control and tolerability comparisons with placebo. Simulations suggest that this dose-finding adaptive procedure inherently introduces some bias. The NMAR and MMM mechanisms compound the bias leading to a substantial loss of power and potentially incorrectly drawn conclusions. These simulation findings will be interpreted in the context of the actual results of this case study.

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

**TECHNOLOGY SHOWCASE: ADAPTIVE CLINICAL TRIALS**

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

12:00-12:30  Sponsored Presentations (Opportunities Available)
Contact Ilana Quigley, Manager, Business Development, at 781-972-5457 or iquigley@healthtech.com

12:30-2:00  Lunch on your own

**CHALLENGES IN ADAPTIVE CLINICAL TRIAL IMPLEMENTATION**

2:00-2:30  Challenges for Interim Data Monitoring and Decision Making in Confirmatory Adaptive Trials
Paul Gallo, Ph.D., Biometrical Fellow, Director, Biostatistics, Novartis Pharmaceuticals

One of the challenges faced in implementing adaptive designs in confirmatory trials involves the process by which interim data is reviewed for the purposes of making adaptations. Current monitoring conventions in non-adaptive trials hold that sponsor personnel should not have access to accruing results in order to maintain trial integrity; thus, this function is typically performed by an independent Data Monitoring Committee. However, sponsor perspective may be relevant for making certain types of adaptation decisions, and sponsors may be uneasy about the prospect of critical decisions being made solely by an external board without sponsor input or ratification. A typical illustrative example involves seamless adaptive phase II/III trials for dose selection, where the decision process can be complex and would typically, in a conventional separate-trial program, have been the responsibility of the sponsor. An additional issue that should be considered is whether the nature of the adaptation itself conveys too much information to observers about the content of the interim results. In this presentation, we discuss different options for operational models, and their trade-offs, governing the review of interim data for the purposes of making and implementing adaptations.

2:30-3:00  The Biotech Challenge: Efficiently Executing Phase 1 to Phase 3 Clinical Development Using Regulatory Strategy-Risk Management
William L. Schary, Ph.D., RAC, Senior Vice President, Regulatory Affairs and Quality Assurance, Trius Therapeutics, Inc.

Small start up biotech companies are faced with the need to efficiently migrate new investigational products through clinical development to registration while balancing the costs and time constraints of such programs. These constraints lead to creative approaches not only in Phase 1 but also in Phases 2 and 3. Effective planning and regulatory strategy/risk management are key components for success, including utilizing FDA meetings and the EMEA Scientific Advice and Protocol Assistance programs. This presentation will provide examples of navigating the clinical development-regulatory environment through to registration.

3:00-3:30  Innovative Adaptive Trial Designs for Oncology Trials
Tom Parke, Head, Clinical Trial Solutions, Tessella
Scott Berry, Ph.D., President and Statistical Scientist, Berry Consultants

Adaptive Designs for clinical trials give us the opportunity to develop clinical trials that are more ethical, deliver better science and are more efficient to run. Few therapeutic areas are more in need of these benefits than Oncology, but the nature of the progression free survival endpoint means it is not obvious how to achieve this. Based on a unique degree of experience of designing and implementing adaptive trials, we will present a range of ideas for adaptive designs that offer efficiencies across the whole Oncology development program.
Adaptive Clinical Trial Designs
Continued

3:30-4:30 Networking Refreshment Break with Poster and Exhibit Viewing

ADAPTIVE CLINICAL TRIALS FOR PERSONALIZED MEDICINE
(Shared Session with Personalized Medicine meeting)

4:30-5:00 Adaptive Design: A Shortcut to Personalized Medicine?
Yu 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.

5:00-5:30 Personalized Medicine: Using Biomarker Signatures to Predict Response to New Therapies
J. Kyle Wathen, 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.

5:30-6:00 Speaker to be Announced
6:00 Close of Day

THURSDAY, SEPTEMBER 24

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.

CASE STUDIES IN ADAPTIVE TRIAL DESIGN

8:25-8:30 Chairperson’s Opening Remarks
8:30-9:00 Case Study: Implementing a Bayesian Outcome-Adaptive Randomization Trial
Kye Gilder, Ph.D., Lead Biostatistician, Biostatistics, Biogen Idec

In clinical trials, patient allocation to treatment groups is generally fixed and determined a priori in order to obtain statistical estimates of treatment differences. With this traditional design, data obtained during the trial do not influence the randomization probabilities. In contrast, outcome-adaptive randomization uses interim data to update the randomization probabilities in favor of the treatment group(s) with comparatively better outcomes. While this randomized strategy is ethically attractive, it has the potential to reduce sample size, shorten drug development time, and save money and resources; it introduces statistical and logistical complexities. This presentation will describe a Bayesian outcome-adaptive randomization design employed in a Phase 2 trial in ovarian cancer at Biogen Idec. The discussion will address the adaptive design, statistical methods, logistical issues, and lessons learned.

9:00-9:30 Title to be Announced
Michael Krams, M.D., Assistant Vice President, Clinical Development, Adaptive Trials, Wyeth Research

9:30-10:00 Case Study: An Adaptive Trial of Personalized Radiotherapy for Intrahepatic Cancer
Daniel Nonnollie, Ph.D., Director, UPMC Biostatistics Facility, University of Pittsburgh Medical Center

Patients with recurrent intrahepatic cancer or primary hepatocellular carcinoma have poor prognoses. Stereotactic body radiation therapy (SBRT) can be effective for the control, if not cure, of even recurrent intrahepatic cancer, but does increase the risk of radiation-induced liver disease, especially if the liver has been heavily pre-treated. The clearance rate of indocyanine green (IG) is a common marker for liver function. The Department of Radiation Oncology at the University of Michigan has opened a Phase II protocol of personalized two-stage SBRT that uses the change in IG after the first stage of treatment to determine the dose in the second stage. The function used to determine the stage two dose is updated as the trial progresses, using a Bayesian paradigm. We will describe the setup of the trial, how its operating characteristics were determined and described, and our experience in justifying the trial design to various regulatory entities.

10:00-10:30 Variations on a Theme, the First 20 Years of a “Virtual Clinical Trial” to Find a Cure for Multiple Myeloma
Clyde Bailey, B.S., Director, Bioinformatics, Myeloma Institute for Research and Therapy, University of Arkansas for Medical Sciences

Since its inception in 1989, the Myeloma Institute for Research and Treatment has run over 100 investigator initiated clinical trials, many of them quite similar, many of them modified several times, and all frequently analyzed together as if they were one, 6000+ subjects, 20 year long clinical trial. To accomplish this, we have developed a single-database model for tracking clinical trial related information. I’ll discuss some of the challenges of developing this system, some of the “Translational” opportunities we have taken advantage of, and give some pointers as to how the next group who tries this can avoid some of the pitfalls and do it better.

10:30-11:30 Networking Coffee Break with Poster and Exhibit Viewing
11:30 Close of Adaptive Clinical Trial Designs meeting

Track 1

CLINICAL BIOMARKERS
Optimizing Drug Development
September 24-25, 2009

THURSDAY, SEPTEMBER 24

TECHNOLOGY SHOWCASE: CLINICAL BIOMARKERS

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 ties 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 speedy clinical validation of drugmarker 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
The discovery, assay development and testing of synovial fluid samples of bio-

paradigms, creating enormous increases in capabilities and capacity that will

validation, and engages normally passive “bystanders” to be active participants.

which research can be conducted, slashes the time and cost of discovery and

A new paradigm for research will be described which expands the areas in

Carol J. McCall, FSA, MAAA, Vice President, Research and Development, Humana, Inc.

8:30-9:00 From Science to Solutions: new Paradigms in Biomarker

Continued

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 Targeted Therapy 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 and Personalized Medicine, 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 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 Caney, 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.

3:00 Networking Coffee Break

Biomarkers for Patient Selection

(Shared Session with Targeted Therapy meeting)

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, UMCCC; 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.

12:00 Close of Congress
PERSONALIZED MEDICINE AT BIG PHARMA

9:00-9:30  Chairperson’s Opening Remarks
Frank Douglas, Ph.D., M.D., Senior Fellow, Kauffman Foundation; and Senior Partner, PureTech Ventures

9:30-10:00  Delivering on the Promise of Personalized Healthcare: Examples from AstraZeneca
Ruth E. March, Ph.D., Lead, Personalized Healthcare Team, AstraZeneca Pharmaceuticals

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.

PERSONALIZED MEDICINE

8:25-8:30  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 E. 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:risks 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
PERSONALIZED MEDICINE

Continued

5:00-5:30 Personalized Medicine: Using Biomarker Signatures to Predict Response to New Therapies
J. Kyle Washen, 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.

5:30-6:00 Speaker to be Announced
6:00 Close of Day

THURSDAY, SEPTEMBER 24

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

IMPLEMENTING PERSONALIZED MEDICINE: CHALLENGES AND OPPORTUNITIES

8:25-8:30 Chairperson’s Opening Remarks
8:55-9:00 Chairperson’s Opening Remarks
9:00-9:30 Personalized Medicine: The Changing Landscape of Healthcare
Edward Abrahams, Ph.D., Executive Director, Personalized Medicine Coalition

This presentation will explore the case for, the status of, and the barriers to the development and implementation of personalized medicine from discovery to delivery.

10:00-10:30 The Future of Personalized Medicine and How Standards Can Play a Role in Innovation of New Technologies
Michael D. Ames, 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 (SACGHS); 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.

12:30-2:00 lunch on your own

2:00-3:00 Plenary Session, See Page 6 for Details
3:00-4:00 Networking Refreshment Break with Poster and Exhibit Viewing

PLEINARY KEYNOTES

4:00-4:40 The Potential Impact of Recently Approved and Emerging Molecular Diagnostics in Drug-Diagnostics Co-Development
Francis Kalush, Ph.D., Network Leader, Diagnostics and Personalized Medicine, 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 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.
Implementing Personalized Medicine

challenges that face multiplex diagnostics in the marketplace. For example, the troponin test saves lives by diagnosing heart attacks, but the market prices of laboratory tests are very small compared to their clinical value. For less of the size of their clinical value to the public. The problem is, historically, otherwise the tests will have a negative total value for the test developer regarding-substantial market price may be fully commensurate with the test’s clinical worth, a based market price may be fully commensurate with the test's clinical value. However, the tests are similar to pharmaceuticals in that the cost of goods sold may be small in proportion to the development 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.
Adapting Cancer Therapy

Optimizing Oncology Drug and Diagnostic Development

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 6 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 Presentation
Sponsored by Discovering and Measuring Protein Biomarkers in FFPE Tissue
David Kriyan, Ph.D., Chief Scientific Officer and Scientific Co-founder, Expression Pathology Inc.
Expression Pathology is a leader in tissue proteomics. Focusing on the gold standard in clinical tissue preservation, formalin-fixed paraffin-embedded tissue, we are developing proprietary new Liquid Tissue® MRM cancer tests for tissue protein biomarkers. Our technology has great potential in drug development, clinical trials and personalized medicine. Measuring protein expression in standard formalin-fixed tissue samples can provide diagnostic and prognostic information to guide treatment decisions.

Combining Liquid Tissue® sample preparation with Multiple Reaction Monitoring mass spectrometry enables precise, multiplex protein quantitation.

TOP 10 OPPORTUNITIES IN TRANSLATIONAL CANCER MEDICINE

8:25-8:30 Chairperson’s Opening Remarks
1. Combination Therapies
2:00-3:00 The Use of Genetically Engineered Mice for Preclinical Testing of Novel Cancer Therapeutics
Kwok-kin Wong, M.D., Ph.D., Associate Professor, Lowe Center for Thoracic Oncology, Dana Farber Cancer Institute, Harvard Medical School
Lung cancer is the leading cause of cancer related mortality for both men and women in the United States, accounting for over 28% of all cancer deaths in 2007. Worldwide, lung cancer accounts for over one million deaths per year. Adenocarcinoma, the most common type of non-small cell lung cancer (NSCLC), now accounts for more than 40% of all lung cancer cases. Despite advances in cytotoxic drug development, radiotherapy, and patient management, the cure rate for advanced NSCLC cancer remains dismal. Recent intense efforts to define the genome of human lung adenocarcinomas have identified and validated over 50% of the oncogenic drivers in lung adenocarcinomas. In the U.S., KRAS (25%) and EGFR (10 to 15%) comprise over 40% of all activating oncogenic mutations of lung adenocarcinomas, with activating genetic alterations in HER2 (2 to 5%), BRAF (2 to 5%), PIK3CA (2 to 5%), ALK (3 to 5%) and ROS1 (1 to 3%) comprising the rest of the known oncogenic mutations. Unlike other cancer types, the oncogenic mutations in lung adenocarcinomas are thought to be mutually exclusive, as known activating oncogenic mutations rarely co-occur within the same cancer. Using the bitsransgenic mouse modeling platform, we have generated inducible mouse lung cancer models that are driven by each of these oncogenic mutations. These mouse models have given valuable insights into the molecular mechanisms of lung tumorigenesis. Equally importantly, these models serve as unique platforms for testing of novel therapeutics that specifically target each of these oncogenic mutations and their associated downstream pathways.

3. Molecular Diagnostics
9:30-10:00 Enabling Personalized Medicine from FFPE Tissue
Austin Tanney, Ph.D., Scientific Liaison Manager, Almac Group
Molecular profiling and molecular diagnostics are the key to development of the prognostic and predictive tests which will usher in the era of personalized medicine. The development of such tests is often hampered by the lack of suitable tissue samples. Profiling of DNA and RNA from routinely stored formalin fixed and paraffin embedded (FFPE) tissue samples has proved to be hugely challenging. This talk provides an overview of some of the issues surrounding working with FFPE tissue and how these can now be addressed. Examples will be given showing the application of RNA profiling in biomarker discovery from FFPE tissue.

4. Companion Diagnostics
10:00-10:30 Personalized Healthcare Strategies and Challenges in Oncology
Lin W. Ph.D., Director, Genomics & Oncology, Riche Molecular Systems, Inc.
10:30-11:30 Networking Coffee Break with Poster and Exhibit Viewing

TECHNOLOGY SHOWCASE: TRANSLATIONAL CANCER MEDICINE

11:30-12:00 Current Information Trends in Biomarker Research
Jorge Marriñque, Senior BioDiscovery Consultant, Thomson Reuters
Biomarkers are becoming a key tool in enhancing the productivity of pharmaceutical research & development, both in discovery and the clinic and an essential element for regulatory purposes. It will become increasingly difficult to analyze and manage the rapidly increasing information about biomarkers across all of their utilities. A new fully indexed biomarker database, BIOMARKER Center, will help to address this problem. Using BIOMARKERcenter we will show how biomarkers mimic the lifecycle of a drug, from discovery to approval, and show the diversity of roles and techniques currently being employed in biomarker research.

11:45-12:30 Sponsored Presentations
Sponsored by Contact Ilana Quigley, Manager, Business Development, at 781-972-6457 oriquigley@healthtech.com.

12:30-2:00 Lunch on your own

5. Better Cancer Models
10:00-10:30 Personalized Healthcare Strategies and Challenges in Oncology
Nicholas C. Dracopoli, Ph.D., Vice President, Biomarkers, Centocor Research & Development, Johnson & Johnson
Circulating tumor cell (CTC) enumeration has been established as a useful prognostic tool for the evaluation of patients with metastatic breast, prostate and colorectal cancer and as a predictive tool for therapeutic effectiveness in these indications. Comprehensive characterization of CTCs offers a new opportunity to obtain extensive biomarker data from tumor derived material that is otherwise unavailable using standard invasive procedures. New technologies using minimal amounts of biological templates derived from increasingly pure isolates of CTCs will, for the first time, allow individualized therapy for each patient based on the molecular pathologies detected in their CTCs.
7. Targeting The Tumor Microenvironment

3:00-3:30  Targeting Tumor Microenvironment
Suresh Mohla, Ph.D., Associate Director and Chief, Tumor Biology and Metastasis Research; Program Director, Tumor Microenvironment Network, Division of Cancer Biology, NCI

3:30-4:30  Networking Refreshment Break with Poster and Exhibit Viewing

8. Cancer Biologics

4:30-5:00  Translational Sciences in Oncology Drug Development: A Risk Mitigation Strategy
Theresa LaVallee, Ph.D., Director, Translational Sciences Oncology, MedImmune

9. Phase 0 Clinical Trials

5:00-5:30  Risk-based Compliance for Production of Agents for Phase 0 Studies
John A. Gilly, Ph.D., Deputy Director, Biopharmaceutical Development Program, SAIC-Frederick/NIA Frederick

5:30-6:00  Development of a Large-Scale Multicenter Clinical Trial Network to Facilitate the Use of Imaging Biomarkers in Clinical Trials
Michael M. Graham, M.D., Ph.D., Professor of Radiology and Director, Nuclear Medicine, Department of Radiology, University of Iowa

Developers of investigational drugs have expressed a need to use investigational PET imaging biomarkers in clinical trials for the early assessment of efficacy, and also to enrich populations in subsequent large-scale trials. The SNM has obtained FDA approval for a multicenter IND for one such novel imaging biomarker, and this IND is being used for cross-reference by investigational therapeutics developers. Another major issue for sponsors attempting to complete adequate, well-controlled trials using PET imaging agents is the lack of standardization of protocols and equipment. We have developed and are using phantoms at sites registered with us (over 200 world-wide currently) to ensure and maintain imaging standardization at the clinical imaging sites. I plan to discuss the highlights of these two important developments that should facilitate multicenter trials of imaging biomarkers.

6:00  Close of Day

THURSDAY, SEPTEMBER 24

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.

IMPLEMENTING PERSONALIZED MEDICINE: CHALLENGES AND OPPORTUNITIES
(Shared Session with Personalized Medicine meeting)

8:55-9:00  Chairperson’s Opening Remarks

9:00-9:30  Personalized Medicine: The Changing Landscape of Healthcare
Edward Abrahams, Ph.D., Executive Director, Personalized Medicine Coalition

This presentation will explore the case for, the status of, and the barriers to the development and implementation of personalized medicine from discovery to delivery.

9:30-10:00  How Pharmacy Benefit Management Enables the Translation of Personalized Medicine Approaches into Clinical Practice
Felix W. Fuhr, Ph.D., Vice President, Research & Development, Personalized Medicine, Medco Health Solutions, Inc.

The translation of personalized medicine into clinical practice requires access to patients at the time of clinical therapeutic decision making. Physicians and pharmacists are ideally positioned to implement this translation, while pharmacy benefit managers (PBMs) are a “hub” for broadly and consistently providing pertinent information to physicians and pharmacists, as well to patients themselves. Medco, the nation’s largest PBM, has created several commercial and research programs in personalized medicine that already today provide access to genetic testing for warfarin and tamoxifen for more than 6 million lives and investigate the clinical effectiveness of a variety of new markers for optimizing drug therapy, respectively.

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 (SACGHS), 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, NDA, IVD-MIA products are reaching market and the nuclear acid-based signatures they

Contact Ilana Quigley, Manager, Business Development, at 781-972-5457 or iquigley@healthtech.com.
potential opportunities for further analysis and molecular characterization of these cells, evaluation of treatment response and use in disease staging. Isolation of CTC also offers predictive of survival in breast, colorectal, and prostate metastatic disease. It is likely that can serve as an independent prognostic marker for clinically managing patients with disease aggressiveness and response to therapy are, therefore, extremely useful aides in their clinical behavior. Prognostic indicators that are of proven value in predicting metastatic cancers, even when of the same tissue type, show considerable variability among millions of normal cells. These preclinical studies, after further development, may provide a new form of medical diagnostic testing of the lymphatics that could be supplementary to blood cancer testing.

12:00-12:30 In Vivo Detection of Circulating Tumor Cells in Lymphatics as an Earliest Marker of Metastasis
Ekaterina Galashina, Ph.D., Assistant Professor, University of Arkansas for Medical Sciences Compared to blood cancer tests, the assessment of circulating (disseminated) tumor cells (CTCs) in lymphatics is not well established. We introduce a novel, ultra-sensitive method using a flow cytometry schematic for in vivo, non-invasive photoacoustic lymph testing for cancer cells directly in lymph flow. This assay is based either on label-free counting of CTCs with pre-expressed intrinsic biomarkers or on using functionalized gold nanoparticles as high contrast photoacoustic molecular multicolor agents. The study on tumor-bearing mouse models demonstrated quantification of CTCs within lymphatics in vivo with a threshold sensitivity of one metastatic cell among millions of normal cells. These preclinical studies, after further development, may provide a new form of medical diagnostic testing of the lymphatics that could be supplementary to blood cancer testing.

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

CTCs AS MARKERS

4:00-4:30 Multicenter Phase III Clinical Trial Validation of Circulating Tumor Cells in Blood as Prognostic Biomarkers in Melanoma Patients Receiving Immunotherapy
Dave S.B. Hoon, Ph.D., Department of Molecular Oncology, John Wayne Cancer Institute, Saint John’s Health Center
Melanoma is often an aggressive disease with poor prognosis when metastasis occurs, although some patients have better outcome than others in treatment responses. Identification of these patients will help improve overall survival. Development of new therapeutic and monitoring patients during treatment requires critical assessment of patients with efficient blood biomarkers to identify those patients with good and poor prognosis. Circulating tumor cells (CTC) are a form of blood biomarkers that can potentially identify prognosis in patients. In a recently completed Phase III international multicenter clinical immunotherapy trial we validated mRNA CTC biomarkers in correlation with disease outcome. CTC biomarkers before treatment as well as during treatment were significantly prognostic of disease-free and overall survival in AJCC stage IV melanoma patients. This presentation will discuss an international study that demonstrated the utility of CTC blood biomarkers.

4:30-5:00 The Clinical Utility of Circulating Tumor Cell Analysis: What Have We Learned So Far?
Beverly C. Handy, Ph.D., Assistant Professor, Clinical Chemistry, Department of Laboratory Medicine, The University of Texas, M.D. Anderson Cancer Center
Metastatic cancers, even when of the same tissue type, show considerable variability in their clinical behavior. Prognostic indicators that are of proven value in predicting disease aggressiveness and response to therapy are, therefore, extremely useful aids for optimizing individual treatment planning. Among these, a growing body of literature indicates that the enumeration of circulating tumor cells (CTC) from peripheral blood can serve as an independent prognostic marker for clinically managing patients with some types of metastatic cancers. In particular, the level of CTC has been shown to be predictive of survival in breast, colorectal, and prostate metastatic disease. It is likely that it will be useful in tumors of other organs as well. Additional potential applications include evaluation of treatment response and use in disease staging. Isolation of CTC also offers potential opportunities for further analysis and molecular characterization of these cells, which may allow further optimization of treatment.
CTC DETECTION TECHNOLOGIES

10:30-11:00 Detection of Circulating Tumor Cells in the Blood of Cancer Patients using a Process which Only Depletes Normal Cells

Jeffrey J. Chalmers, Ph.D., Department of Chemical and Biomolecular Engineering; Director, University Cell Analysis and Sorting Core, The Ohio State University

We have developed a rare cell enrichment technology which can enrich for circulating tumor cells by only targeting normal cells. In one study of 47 blood samples from patients with Head and Neck cancer, 53 percent contained CTCs and the number of CTCs identified per ml of blood collected ranged from 0 to 2,632. The final purity ranged from 1 CTC in 9 total cells to 1 CTC in 20,000 total cells, the final purity being both a function of the number of CTC’s and the performance of the specific enrichment. Since only normal cells were targeted, a number of different tumor cell markers can be used. In addition to being positive for cytokeratin markers, CTCs can also be positive for vimentin and potential cancer stem cell markers such as CD44. Initial patient outcome correlations will be presented.

11:00-11:30 Non-Invasive Detection and Elimination of Circulating Tumor Cells using in vivo Photoacoustic Blood Cancer Test

Vladimir Zharov, Ph.D., D.Sc., Professor, Director, Laser Research, Phillips Classic Laser and Nanomedicine Laboratories, University of Arkansas for Medical Sciences

The clinical utility of circulating tumor cells (CTC) for prevention of metastasis remains unclear, since incurable metastases may already be present at the time of the initial diagnosis. We introduce a novel ultra-sensitive method using a flow cytometry schematic for in vivo, non-invasive photoacoustic blood cancer testing directly in the bloodstream. This assay is based either on label-free counting of CTCs with over-expressed intrinsic biomarkers or on using functionalized gold nanoparticles as high-contrast photoacoustic multicolor molecular agents. The study on tumor-bearing mouse models and spiked human blood samples demonstrated detection of rare melanoma and breast CTCs prior to the development of metastases. If oncoming pilot clinical trials are successful, this technology can provide breakthroughs in early CTC detection and metastasis prevention.

11:30-12:00 Genome-Subtractive Cancer-Specific Blood Assay

Amin Kassis, Ph.D., Director, Radiobiology and Experimental Radionuclide Therapy, Harvard Medical School

Many Circulating Tumor Cells (CTCs) undergo apoptosis and die. We postulated that the clearance of such cells (and subcellular fragments thereof) from circulation by phagocytic WBC leads to the acquisition of tumor-specific signatures specifically by these cells and the absence of these signatures in nonphagocytic WBC. Preliminary studies in tumor-bearing mice and cancer patients have shown that (i) oncogenes and tumor-specific genomic signatures are selectively expressed within phagocytic WBC, (ii) these genes are not expressed or are underexpressed in nonphagocytic cells; and (iii) the assay can differentiate between tumor-bearing animals/patients and nontumor bearing mice and healthy blood donors with 100% accuracy.

12:00 Close of Congress

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Third Annual

BIOMARKER DATA ANALYSIS
Integrating Biomarker Data and Establishing Biological and Clinical Relevance
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 6 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 iqquigley@healthtech.com.

SYSTEMS BIOLOGY APPROACH TO BIOMARKER DISCOVERY

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

8:30-9:00 Systems Approach to Biomarker Identification
Gordon B. Mills, Ph.D., Chair & Professor of Systems Biology, University of Texas, M.D. Anderson Cancer Center

Many different approaches are available to characterize DNA and RNA. However, there is a major need for a high-throughput functional proteomics approach. We have analyzed over 300 cell lines and 3000 patient samples with reverse phase protein arrays (RPPA) encompassing over 150 antibodies of relevance to cancer. These data have identified a number of important signaling processes in different cancer lineages and their relationships to underlying genomic aberrations. Further, we have identified a series of protein markers able to classify tumors and predict outcomes. Validation of these markers could result in marked improvements in patient outcomes.

9:00-9:30 Systems Level Derived Biomarkers in Personalized Medicine
Stephen Naylor, Ph.D., Chief Executive Officer and Chairman, Predictive Physiology & Medicine, Inc.

The complexity of individual human physiology is often overlooked in the search for specific and sensitive biomarkers of health, wellness and disease. The use of a systems-level approach to determine the molecular bioprofile of an individual’s cardiovascular health will be described and compared with individual and panels of similar biomarkers currently used in cardiovascular disease.

9:30-10:00 Practical Applications of Mechanistic Modeling
Keith Elliston, Ph.D., President and Chief Executive Officer, Genstruck, Inc.

The field of systems biology has grown to encompass both large-scale, multi-Omics mechanistic modeling approaches, as well as dynamic and quantitative modeling of biological systems. Large-scale mechanistic modeling has been applied to the discovery of new biological mechanisms, and has lead to the identification of mechanistic biomarkers. The identification of a molecular mechanism can directly lead to the discovery of relevant biomarkers, and can define activity states of systems which effectively obviate biomarkers. An approach to mechanistic modeling powered by multi-Omic datasets will be presented, along with two relevant case studies in cancer and metabolic disease.

10:00-10:30 Modeling and Simulation for Biomarker Identification and Personalized Medicine
Alex L. Bangs, Ph.D., Chief Technology Officer & Co-Founder, Entelos, Inc.

Disease physiology models offer a novel approach to biomarker identification. “Virtual patients” representing real-world patient diversity can be simulated under many experimental protocols, providing a rich data set for identifying biomarker candidates. Specific case studies will be presented highlighting this approach for biomarkers of efficacy, safety, and prognosis. An extension of this approach, using biomarkers and simulation for personalized medicine, will also be highlighted.

10:30-11:30 Networking Coffee Break with Poster and Exhibit Viewing
Bridging Silos in Biomarker Development

3:00-3:30 A Comprehensive Combinatorial Biomarker Discovery Strategy
Raymond Ng, Ph.D., Professor, Department of Computer Science, The University of British Columbia

Monitoring cardiac transplant subjects for acute rejection requires the use of endomyocardial biopsy, an invasive and expensive procedure. Over the past four years, the Biomarkers in Transplantation team developed single platform Omic biomarkers for the diagnosis of cardiac allograft rejection. The team establishes a comprehensive analysis pipeline for combining genomic, proteomic, and clinical variables. The combinatorial biomarker panel identified using this analysis pipeline has a superior performance to that of the single platform Omic biomarkers.

3:30-4:30 Networking Refreshment Break with Poster and Exhibit Viewing

4:30-5:00 Molecular Synergy of Driver Genes in Colon Cancer
Mark Chance, Ph.D., Professor and Director, Center for Mass Spectrometry & Proteomics, Case Western Reserve University

Candidate driver genes that are frequently mutated in colorectal cancer (CRC) and other cancers have been discovered by sequencing and genotyping of human colorectal tumor biopsies. These frequently mutated genes lie on well-connected sub-networks of proteins in the human interactome. We show that when considered together, the proteins (crossstalkers) in these sub-networks are more robust discriminators of disease than single genes or gene signatures. Furthermore, studies of established mouse models illustrate driver gene synergy in intestinal epithelial cancers (e.g., p21-/- and APC1638N+/+) single mutant mouse models have modest phenotypes while the double mutant mouse exhibits an aggressive tumorigenic phenotype. With a view to identifying molecular signatures that mediate the cross-talk between these drivers and their interactions, we have developed a bioinformatics pipeline that will integrate various levels of molecular interaction data to identify CRC network signatures.

5:00-5:30 Leveraging Biomarkers: Integrating Genomic and Proteomic Data for Biomarker Discovery
Karin Rodland, Ph.D., Science Lead, Biological Sciences, Pacific Northwest National Laboratory (PNNL)

Efforts to identify biomarkers for early diagnosis or prognosis of cancer and other diseases have often focused on a singular molecular species, with preference given to mRNA, micro RNA, proteins, auto-antibodies or metabolites based on available technologies and model systems. Each one of these measurements provides a snapshot of cell function, but a dynamic understanding of disease processes really requires the integration of all these modalities to the extent possible. Particularly in the context of developing non-invasive assays, it is important to leverage gene expression data with protein abundance data. Doing so not only provides more confidence in the biomarker, but can also provide insight into disease mechanisms.

5:30-6:00 Integration of Omics Data Reveals Multi-Level Regulation of Biological Systems
Jun Zhu, Ph.D., Associate Scientific Director, Genetics, Rosetta Inpharmatics, a wholly owned subsidiary of Merck and Co., Inc.

There are many Omics data sets, such as genomics, transcriptomics, proteomics, metabolomics and more. Each type of data covers different aspects of biological systems. Integration of different Omics data can generate a more comprehensive view and help to better understand biological systems.

6:00 Close of Day

THURSDAY, SEPTEMBER 24

7:00 am Conference Registration Open

7:30-8:15 Breakfast Presentation Sponsored by BioFortis

Advancing the Data Management and Data Exploration Process within Biomarker Discovery and Translational Research
Jian Wang, Ph.D., Chief Executive Officer, BioFortis, Inc.

Typical biomarker discovery pipelines consist of two phases: large scale data exploration followed by statistical analysis. Currently, data exploration is an inefficient process involving multiple individuals and weeks of time. In addition, data sets are not aggregated and scientists are not able to access and query data without technical support. This talk will address these issues and share the experiences of several research teams who have employed the Labmatrix™ environment. We will demonstrate how researchers are using this simple tool to quickly and easily access their data, run hypothesis testing, and gain insights never possible before.

PREDICTIVE VALUE OF OMIC DATA

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

8:30-9:00 An Effective Framework for Omic Data Analysis
Jie J. Cheng, Ph.D., Drug Development Sciences, GlaxoSmithKline

We will present an effective framework for biomarker discovery and predictive modeling from high dimensional Omic data. The framework is based on a novel feature selection technique and robust cross validation procedures. We will demonstrate the utility of the method on six MicroArray Quality Control Phase II (MAQC-II) datasets. We will also present our findings from challenging clinical classification problems including treatment response and prognostic prediction in clinically homogeneous subsets of breast cancers.

9:00-9:30 Prioritization of Biomarker Candidates Sponsoreed by

Candidates Based on Pathway and Phenotype Associations
Deborah Riley, Ph.D., Senior Manager, Application Science, Ingenuity Systems

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

9:30-10:00 Prospective Comparison of Clinical and Genomic Biomarker Predictors of Patients’ Chemotherapeutic Response in Breast Cancer
Jae K. Lee, Ph.D., Associate Professor, Biostatistics and Epidemiology, Department of Public Health Sciences, University of Virginia School of Medicine

Several different multivariate prediction models using routine clinical variables or multi-gene signatures have been proposed to predict pathologic complete response to combination chemotherapy in breast cancer. We prospectively compared the performance of several different previously published predictors in an independent cohort of 100 stage I-III breast cancer patients prior to preoperative paclitaxel, 5-FU, doxorubicin and cyclophosphamide combination chemotherapy. Pathologic response was correlated with prediction results from a clinical nomogram, a human cancer-derived genomic predictor (LDLA31), and an optimized cell line-derived (in vivo-COXEN) predictor. The nomogram and the DLDA31 genomic predictor had similar performances, and the in vivo-COXEN that used informative genes from cell lines but was trained on a separate human data set also showed significant predictive value. These conceptually different predictors performed similarly in this validation study and tended to identify the same patients as responders.

10:00-10:30 Networking Coffee Break with Poster and Exhibit Viewing

11:30 Close of Biomarker Data Analysis meeting
Bridging Silos in Biomarker Development

**September 24-25, 2009**

**THURSDAY, SEPTEMBER 24**

**TECHNOLOGY SHOWCASE: PROTEIN BIOMARKERS**

**11:30-11:45 am Drug-Induced Nephrotoxicity – Multiplex Detection of Key Kidney Damage Biomarkers in Rat Urine**

Speaker to be Announced

In 2008 the Predictive Safety Testing Consortium (PSTC), a public-private consortium led by the Critical Path Institute (C-Path) submitted a list of urinary biomarkers indicative of drug-induced kidney damage to the FDA and EMEA regulatory authorities. The FDA and EMEA have issued new guidelines on the submission of the biomarkers as indicators of kidney damage in pre-clinical studies. Rules Based Medicine worked with the members of the PSTC to develop the assays used in the kidney toxicity study, and made the assays available in the Rat Kidney MAP testing service. EMD and Rules Based Medicine have collaborated to develop these assays as commercially available kits, exclusively for the Luminox® xMAP® Technology platform, to support preclinical rat nephrotoxicity studies. This presentation will describe the assessment of temporal and dose-dependent changes in biomarker levels in response to known kidney damaging agents.

**11:45-12:15 The Speed and Flexibility of Building Protein Biomarker Assays with the Peptide MRM Method**

Michael Pisano, Ph.D., Chief Executive Officer, NextGen Sciences, Inc.

Biomarkers are needed throughout the drug discovery and development pipeline, which means the biomarker assays need to work in different species and sample types. The translation from an animal model to the human situation needs to be available for the start of clinical studies. The Peptide MRM method is designed from the amino acid sequence of a protein. Thus, the translation of an assay from species to species is done computationally. The translation from sample type to sample type (e.g., tumor to plasma) of the same species is done experimentally. Examples of both types of translation will be included in the presentation.

**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**

**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**

**PROTEIN BIOMARKERS FOR CANCER TARGETED THERAPY**

**4:00-4:30 Towards a More Efficient Protein Biomarker Development Process**

Henry Rodriguez, Ph.D., M.B.A., Director, Clinical Proteomic Technologies for Cancer, Center for Strategic Scientific Initiatives, Office of the Director, National Cancer Institute.

CPTC’s initiatives are paradigm shifting in that they aim to develop a more refined, efficient, and reliable biomarker discovery process. These pipelines are anticipated to produce better credentialed candidate leads, ultimately accelerating the discovery of new cancer biomarkers for diagnostics and prognostic purposes.

**4:30-5:00 Use of Activated Protein Pathway Biomarkers at the Bedside: Realizing the Promise of Personalized Therapy**

Emanuel F. Petricoin, Ph.D., Co-Director, Center for Applied Proteomics & Molecular Medicine, George Mason University, College of Arts & Sciences.

Recently, whole genome mutational screening analysis of a number of solid tumors has revealed that cancer is a protein pathway disease at the functional level. However, since genomic and transcript profiling likely cannot alone sufficiently predict protein pathway activation in each patient’s tumor, and it is these signaling pathways that represent the targets for new molecular guided therapeutics, it is critical that we begin to define human cancer at a functional pathway activation level. Post-translational modification such as phosphorylation drive and underpin nearly all cell signaling processes that are aberrantly activated in cancer and are epigenetic events, and not necessarily directly predictable using genomic approaches. Thus, the promise of proteomics resides in the study of molecules that are not just predictive or prognostic factors, but extend beyond correlation to causality. We have invented a new type of technology, called reverse phase protein microarrays, to generate a functional map of known cell signaling networks or pathways for an individual patient obtained directly from a biopsy specimen. This patient-specific circuit diagram provides key information that identifies critical nodes or pathways that may serve as drug targets for individualized or combinatorial therapy through the quantification of phosphorylation states of proteins. The identification of activated networks on a patient-by-patient basis can be used as both a diagnostic and a therapeutic guide to patient selection and stratification.

**5:30-6:00 MRM and iMALDI for Protein Biomarker Discovery and Validation**

Christoph H. Borchers, Ph.D., Director, Biochemistry & Microbiology, University of Victoria Genome BC Proteomics Center.

For protein biomarker discovery and validation two mass spectrometry centric approaches – Multi-Reaction Monitoring (MRM) and immuno-MALDI (iMALDI) – have great potential since these approaches are rapid, highly specific and enable absolute and multiplex protein quantitation. The University of Victoria – Genome BC Proteomics Centre has developed a 45 protein MRM-assay for validation of numerous cardio-vascular disease (CVD) biomarkers in human blood plasma and developed iMALDI approaches for the clinic. We applied the MRM-assay in a medium scale project analyzing 60 blood samples in triplicate verifying four proteins that are distinguishable between different CVDs. The combined approach of the immuno-enrichment of peptides followed by MALDI-MS (iMALDI) has been developed into a clinical assay for hypertension. This iMALDI technique will replace the currently used radio-immunoassay in a Vancouver hospital due to its higher specificity, speed, accuracy and sensitivity at lower cost.

**6:00 Close of Day**

**FRIDAY, SEPTEMBER 25**

**7:30-8:15 am Breakfast Presentations (Opportunities Available)**

Contact Ilana Quigley, Manager, Business Development, at 781-972-5457 or iquigley@healthtech.com.

**PROTEIN BIOMARKERS FOR CANCER**

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

**8:30-9:00 Accelerating Biomarker Discovery through an Integrated Organ Specific Approach**

Oliver John Semmes, Ph.D., Professor of Microbiology & Molecular Cell Biology, Eastern Virginia Medical School.

The clinical needs specific to prostate cancer have shifted from early detection of all cancers to a more defined discrimination of significant/insignificant disease. Thus, improved classification of disease with respect to clinical significance at diagnosis is a priority target in prostate cancer. In order to meet this demand we have developed an organ and organ proximal fluid based integrated approach to biomarker discovery. We employ imaging mass spectrometry of prostate tissue, glycan-based analysis of expressed prostatic secretions and analysis of surface proteins in prostate cancer cell lines. Although each of these technologies has independent value, significant overlap surrounding surface glycoproteins is achieved by design. Discussed will be our current findings using this integrated discovery approach.
We have developed an integrated approach to marker identification for gastric cancer for both cancer tissues and patient serum, through combining exon array experiments and associated data analysis for identification of genes with differentially expressed patterns in gastric cancer tissues versus reference tissues from the same patients. Our identification of differentially expressed alternatively spliced isoforms in cancer versus reference tissues, computational prediction of proteins that may get secreted into blood, computational prediction and experimental validation of serum protein markers for gastric cancer. By applying this approach to 80 pairs of gastric cancer and reference tissues, we have identified a number of highly promising gene markers in gastric cancer tissues and protein markers in serum for gastric cancer. Our study integrates computational and experimental approaches and takes full advantage of the information derived from microarray exon expression data to guide our marker identification in serum. Our identification results demonstrate that our overall strategy is highly effective.

We have applied a novel approach to measure proteins in clinical specimens at the nanoscale. In as few as 25 cells, 5 pgs or 200 nl of specimen we can measure and quantify proteins and their phosphorylation state. Our approach enables us to perform detailed proteomic analysis on clinical specimens. In particular, we have been able to examine proteomic changes in response to a targeted therapeutic in vivo in human patients. Our strategy can be applied to the development of many types of new therapeutics.

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# ADAPT 2009

**Accelerating Development & Advancing Personalized Therapy**

**September 22-25, 2009**

**Grand Hyatt Washington**

**Washington, DC**

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**Key Code 974F**

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**HOW TO REGISTER:**

- **Phone:** 781-972-5400 Option 1
- **Fax:** 781-972-5425

- **Email:** reg@healthtech.com

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**Yes! Please register me for ADAPT CONGRESS 2009**

**REGISTRATION INFORMATION**

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

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**How would you prefer to register for ADAPT congress?**

1. Email
2. Fax

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**Registration deadlines:**

- **Advance Registration Deadline** until August 21, 2009
- **Registrations after August 21, 2009 and on-site**

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**REGISTRATION INFORMATION**

- **Yes! Please register me for ADAPT COngress 2009**

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**MAIN CONFERENCE PRICING**

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<th>Pricing Package</th>
<th>Comm.</th>
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<th>Hospital-affiliated</th>
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<td><strong>Premium Registration Package - BEST VALUE!</strong></td>
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<td>(Premium registration package includes access to all tracks and plenary sessions, exhibit halls, and conference proceedings. This package does not include access to any pre-conference short courses.)</td>
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**REQUIRED - Please select the conferences you will attend. Please select ONE from each set of dates**

**September 22-24**

- 1A Adaptive Clinical Trial Designs
- 2A Personalized Medicine
- 3A Translational Cancer Medicine
- 4B Biomarker Data Analysis

**September 24-25**

- 2A Personalized Medicine
- 3B Circulating Tumor Cells
- 4B Protein Biomarkers

**Premium Registration Package - BEST VALUE!**

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- 4B Protein Biomarkers

**Two Short Course Pricing**

- **Single Short Course:** $695
- **Two Short Courses:** $995

**Poster Discount**

- **$50 off**

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**PAYMENT INFORMATION**

- **Cardholder:**
- **Expiration Date:**

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**Posters and Exhibits**

- **Yes, I am interested in presenting a poster at ADAPT Congress 2009. (Select one poster session)**

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**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 abstract submission instructions via email.

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**CHI Insight Pharma Reports**

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

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**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.barnettinternational.com.

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**Additional Registration Details**

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

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**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.

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**Handicapped Equal Access**

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

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**Substitution/Cancellation Policy**

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

- Transfer your registration to a colleague within your organization. Credit your registration to another Cambridge Healthtech Institute program.
- Request a refund minus a $100 processing fee per conference.
- Request a refund minus the cost $750 of ordering the conference proceedings link.

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

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