

19th International  
**Molecular Med**  
**TRI-CON 2012**

Moscone North Convention Center  
San Francisco, CA

February 19-23

 **get  
inspired**

Register by  
January 20<sup>th</sup>, 2012  
and **SAVE!**

## Cancer Channel

### Core Programs

#### Cancer Biologics

Conjugates, Multi-Specifics, Translational Studies  
and Novel Approaches

#### Cancer Molecular Markers

Improving Patient Outcomes

#### Circulating Tumor Cells

Expediting Clinical Use

#### Oncology Clinical Trials

Advancing Cancer Drug Development by Improving  
Trial Methodology

#### Bioinformatics & Cancerinformatics

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Knowledge

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**Luminex** **SomaLogic**

### Keynote Presentations



#### Antibody-Drug Conjugates: An Emerging Modality for the Targeted Therapy of Liquid and Solid Tumors

*Puja Sapra, Ph.D., Director, Bioconjugates,*

*Oncology Research Unit, Pfizer  
Biotherapeutics*



#### The Use of Different Biotherapeutics Platforms for Cancer Drug Development

*Robert Hollingsworth, Ph.D., Director, Cancer  
Biology, MedImmune LLC*



#### PD-1/PD-L1 Blockade

*Alan Korman, Ph.D., Vice President,*

*Discovery Research, Bristol-Myers Squibb*

### Reasons to Attend

1. **NETWORK** with the leading companies in cancer biologics
2. **DISCOVER** research ranging from target discovery and drug optimization to pre-clinical and clinical
3. **HEAR** the latest developments in therapeutic programs for Oncology
4. **LEARN** more about clinical development of personalized cancer therapy and understand the main features of biomarker driven clinical trials
5. **ENJOY** the detailed case studies of clinical trials for recently approved cancer therapies including Xalcori and Zelboraf

# Sponsorship Opportunities

## Podium Presentations –

### Program Agenda

Present your solution for 15 or 30 minutes in the session room during lunch or as part of the main conference program. You will be able to target your audience by selecting a specific program for your talk.

## Plenary Keynote Presentation

Receive optimum visibility by participating in a panel discussion during the Wednesday afternoon Plenary Keynote Session at MMTC. You will have the opportunity to join the discussion and present for up to ten minutes before an audience of over 1,000 delegates.

## Invitation-Only VIP Dinner/ Hospitality Suite

Sponsor will select invitees from the conference pre-registration list for an evening of networking at the hotel or a top local venue. CHI will extend invitations, conduct follow-up and monitor responses. Reminder cards will be placed in the badges of those delegates who will be attending.

## Exclusive Cocktail Receptions

(Program-specific)

CHI will invite all delegates from a specific conference program, of your choice, to your private reception at the host hotel. Cocktails and hors d'oeuvres will be served in a setting conducive to networking. These receptions are available on a first-come, first-served basis.

## Other Promotional Opportunities:

- Conference Tote Bags
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- Focus Groups

### Companies A-K

Jon Stroup, Manager,  
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781-972-5483  
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### Companies L-Z

Joseph Vacca  
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# TRI-CON2012 Sponsors

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## Sponsoring Organization:



February 19-20

## NEW-Symposia

InterContinental San Francisco Hotel 

- Targeting Cancer Stem Cells in Oncology
- Cloud Computing
- Phage and Yeast Display of Difficult Targets
- Point-of-Care Diagnostics
- Next-Generation Pathology



## Pharma-Bio Partnering Forums

InterContinental San Francisco Hotel 

- Emerging Targeted Oncology
- Early Stage Molecular Diagnostics

February 20

## Event Short Courses

The Moscone North Convention Center

February 21-23

## Core Programs

The Moscone North Convention Center

 Diagnostics Channel

- Molecular Diagnostics
- Personalized Diagnostics
- Cancer Molecular Markers
- Circulating Tumor Cells

**NEW** - Genomic Screening and Diagnosis

 Drug Discovery & Development Channel

- Mastering Medicinal Chemistry Summit
- Translational Science

**NEW** - De-Risking Drug Discovery  
Oncology Clinical Trials

 Informatics Channel

- Integrated R&D Informatics for Knowledge Management
- NEW** - Bioinformatics & Cancerinformatics

 Cancer Channel

- Cancer Biologics
- Cancer Molecular Markers
- Circulating Tumor Cells
- Oncology Clinical Trials

**NEW** - Bioinformatics & Cancerinformatics

# Plenary Keynotes

Tuesday, February 21



8:00-9:40am

### Positive Exposure: Celebrating the Beauty of Genetic Diversity

Rick Guidotti, Director, Positive Exposure

Rick, an award-winning fashion photographer, is the founder and director of Positive Exposure, an innovative arts, education and advocacy organization working with individuals living with a genetic difference. Positive Exposure utilizes the visual arts to significantly impact the fields of genetics, mental health and human rights. Rick's photo and video presentation explores the social and psychological experiences of people living with genetic, physical and behavioral conditions of all ages and ethno-cultural heritages. His presentation provides new opportunities to see individuals living with a genetic difference first and foremost as a human being with his/her own challenges rather than as a specific diagnosis/disease entity.

Wednesday, February 22



10:10-11:00am

### Overcoming Adversity When Life Throws Curve Balls

Dave Dravecky, former Pitcher, San Francisco Giants and Cancer Survivor

Dave Dravecky was an outstanding major league baseball pitcher for the San Francisco Giants when life threw him a curve ball. At the height of his pitching career, he was diagnosed with cancer, a desmoid tumor, in the deltoid muscle of his pitching arm. In 1989, Dave recovered and briefly returned to Major League ball. Soon after, cancer claimed his pitching arm and shoulder. Both were amputated. His presentation shares the struggles he and his wife Jan experienced as they dealt with cancer, years of surgery and radiation, and how the power of cancer reshaped their lives.

2:30-3:50pm

### Plenary Keynote Panel: Emerging Technologies & Industry Perspectives

As a change-up to our usual keynote program, we're offering a session that will feature a series of presentations on emerging and hot technologies in diagnostics, drug discovery & development, informatics, and oncology. Interactive Q&A discussion with the audience will be included.

Harry Glorikian, Founder & Managing Partner, Scientia Advisors LLC

Jeremy Bridge-Cook, Senior Vice President, Assay Research and Development, Luminex Corporation

Gary Kennedy, Chairman & CEO, Remedy Informatics

Richard Lawn, Ph.D., Executive Director of Translational Medicine, SomaLogic

Jeffrey T. Yap, Ph.D., Assistant Professor of Radiology, Harvard Medical School, Senior Diagnostic Physicist, Dana-Farber Cancer Institute

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## New This Year!



## TRI-CON ALL ACCESS PACKAGE

### Get the best 5-day value!

Our All Access Package is a convenient, cost-effective way to attend each aspect of Molecular Med TRI-CON 2012. Package includes access to 1 Symposium OR Partnering Forum, 2 Short Courses, 1 Core Program, Plenary Keynotes, and the Exhibit Hall.

*Example of a Suggested ALL ACCESS Package:*

Symposium	Event Short Course	Event Dinner Short Course	Core Program
Targeting Cancer Stem Cells in Oncology	Identification, Characterization and Targeting of Cancer Stem Cells	Digital PCR Applications and Advances	Cancer Biologics

The Symposia and Partnering Forums are taking place at the InterContinental San Francisco Hotel 



# Cancer Biologics

Conjugates, Multi-Specifics, Translational Studies and Novel Approaches

February 21-23

## TUESDAY, FEBRUARY 21

7:00 am Registration

### PLENARY KEYNOTE SESSION

8:00 Plenary Keynote Presentations (See Page 2 for Details)

9:40 Grand Opening Refreshment Break in the Exhibit Hall with Poster Viewing

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**HOLOGIC**  
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### DEVELOPMENTS WITH ANTIBODY-DRUG CONJUGATES

11:00 Chairperson's Opening Remarks

*Ho Sung Cho, Ph.D., CTO, Ambrx, Inc.***11:10 Antibody-Drug Conjugates: An Emerging Modality for the Targeted Therapy of Liquid and Solid Tumors***Puja Sapra, Ph.D., Director, Bioconjugates, Oncology Research Unit, Pfizer Biotherapeutics*

This presentation will provide an update of Pfizer's ADC programs. Phase II/III data of CMC-544, an anti-CD22 calicheamicin conjugate will be discussed. Additionally, pre-clinical data of an ADC targeting the oncofetal antigen 5T4, expressed on tumor initiating cells in solid tumors, will be described.

**11:40 Experiences with Finding a Good Target for ADC Drug Development***Andy Simmons, Ph.D., Principal Scientist, Preclinical Research, Takeda San Francisco, Inc.*

Recent data will be highlighted that expands our understanding of the antigen, antibody, and ADC properties required for potent *in vitro* and *in vivo* cytotoxicity.

**12:10 pm Proteomics for the Discovery of Novel Oncology Antigen Targets and the Subsequent Development of Antibody-Drug Conjugates***Jon Terrett, Ph.D., CSO, Oxford Biotherapeutics, Inc.*

Clinical trials of ADCs are finally producing proof-of-concept with some spectacular results in Oncology. Proteomics is perfectly poised to deliver novel targets for ADC development as detection of cancer specific membrane proteins leads directly to ADC targetable antigens.

**12:40 Luncheon Presentations (Sponsorship Opportunities Available) or Lunch on Your Own**

1:45 Dessert in the Exhibit Hall with Poster Viewing

### DEVELOPMENTS WITH ANTIBODY-DRUG CONJUGATES

2:15 Chairperson's Remarks

*Jon Terrett, Ph.D., CSO, Oxford Biotherapeutics, Inc.***2:20 Optimizing the Performance of Antibody Drug Conjugates with an Expanded Genetic Code***Ho Sung Cho, Ph.D., CTO, Ambrx, Inc.*

The site of conjugation has a significant impact on the plasma stability of cathepsin-cleavable linkers. Site-specific conjugation preserves target binding and minimizes off-target binding. Ambrx ADCs have PK similar to the naked wt-mAb resulting in improved efficacy and Therapeutic Index.

**2:50 Advancements in ADC Technologies Using Potent Auristatin Conjugates***Svetlana Doronina, Ph.D., Senior Principal Scientist, Chemistry, Seattle Genetics, Inc.*

We have developed antibody-drug conjugates of antitumor mAbs attached to highly potent auristatin antimetabolic agents. These contain optimized drugs and linkers and preserve mAb activity. These have been applied to several tumor targets and used in advanced clinical trials.

### LIGAND-RECEPTOR INTERACTIONS

**3:20 Engineered Receptor Tyrosine Kinase Domains for Treatment of Metastatic Cancers***Jennifer Cochran, Ph.D., Assistant Professor, Bioengineering, Stanford University*

We used a soluble receptor as a decoy to inhibit the biological activity of a ligand involved in ovarian cancer metastasis. Yeast surface display was used to engineer variants that bound ligand with 20-fold higher affinity over wild-type receptor. The engineered receptor exhibited a remarkable ability to inhibit ovarian cancer metastasis in several pre-clinical

models in contrast to the wild-type receptor which was only marginally effective.

**3:50 The Serine Protease-like Domain of HGF is an Allosteric Switch that Binds and Activates the Met Receptor***Kyle E. Landgraf, Ph.D., Postdoctoral Research Fellow, Early Discovery Biochemistry, Genentech, Inc.*

4:20 Reception in the Exhibit Hall (Sponsorship Available)

5:20 Breakout Discussions in the Exhibit Hall (see website for details)

6:20 Close of Day

## WEDNESDAY, FEBRUARY 22

### TRANSLATIONAL STUDIES FOR PROGRESSION TO CLINICAL

7:55 am Chairperson's Remarks

*Ezio Bonvini, M.D., Senior Vice President, Research, MacroGenics, Inc.***8:00 Translational Research Strategies Used to Guide the Development of Elotuzumab, an Anti-CS1 Monoclonal Antibody, for the Treatment of Multiple Myeloma***Gary Starling, Ph.D., Director, GPRD Discovery, Oncology Biologics, Abbott Biotherapeutics Corp.*

The enhanced activity of a combination of elotuzumab with lenalidomide in pre-clinical studies as compared to either agent alone has translated to promising clinical activity in Multiple Myeloma.

**8:30 Translational Studies for Progression of ADCs from Discovery to Clinical***Robert Lutz, Ph.D., Vice President, Translational Research & Development, ImmunoGen, Inc.*

Our growing pre-clinical and clinical experience with antibody-maytansinoid conjugates is leading to an enhanced understanding of how to develop new ADCs for the treatment of cancer with respect to improving efficacy and safety.

**9:00 Good Translations: Making the Most of Non-Clinical Data for Clinical Decision-Making***Jay Tibbitts, D.V.M., Ph.D., Senior Scientist, Group Leader, Pharmacokinetics and Pharmacodynamics, Genentech, Inc.*

Optimizing the design and use of non-clinical studies can reduce the uncertainty and increase the success of clinical trials. This talk will explore the use of relevant models, biomarkers, and PKPD to improve translations and, ultimately, allow better decision-making.

9:30 Sponsored Presentations (Opportunities Available)

10:00 Transition to Plenary Keynote

### PLENARY KEYNOTE

10:10 Plenary Keynote Presentation (See Page 2 for Details)

11:00 Refreshment Break in the Exhibit Hall with Poster Viewing

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**HOLOGIC**  
MOLECULAR DIAGNOSTICS

### MATCHING THE TECHNOLOGY TO THE TARGET & BIOMARKERS FOR PATIENT SELECTION

11:55 Chairperson's Remarks

*Gary Starling, Ph.D., Director, GPRD Discovery, Oncology Biologics, Abbott Biotherapeutics Corp.***12:00 pm The Use of Different Antibody Platforms for Cancer Drug Development***Robert Hollingsworth, Ph.D., Director, Cancer Biology, MedImmune, LLC*

Various antibody-based therapeutic technologies are now available. A key to successful development of such drugs is using the right technology for specific targets. MedImmune's experience using different technologies to develop novel cancer antibody therapeutics will be described.

**12:30 Mechanisms of Trastuzumab Resistance and Development of Biomarkers***Wen Jin Wu, M.D., Ph.D., Principal Investigator, Division of Monoclonal Antibodies, FDA*

Despite initial successes and encouraging results, development of monoclonal antibody-

based therapies face several challenges. Among them are the selection of patients most likely to benefit from clinical trials and lack of understanding of mechanisms of resistance to monoclonal antibody-based therapies.

**1:00 Luncheon Presentations** (*Sponsorship Opportunities Available*) or **Lunch on Your Own**

**2:00 Ice Cream Refreshment Break in the Exhibit Hall with Poster Viewing**

## PLENARY KEYNOTE PANEL

**2:30 Plenary Keynote Panel** (*See Page 2 for Details*)

**3:50 Refreshment Break & Poster Awards in the Exhibit Hall**

## ENHANCED EFFECTOR FUNCTION AND PKPD

**4:25 Chairperson's Remarks**

*Norman J. Maitland, Ph.D., Director, Yorkshire Cancer Research Unit and Department of Biology, University of York, UK*

**4:30 New Generation of Targeted Therapeutics: Empowering Therapeutic Monoclonal Antibodies with Cytokine Payloads for Cancers**

*Iqbal S. Grewal, Ph.D., D.Sc., FRCPath, CSO, ImmunGene, Inc.*

We use a novel technology to empower therapeutic antibodies with a biologic payload by recombinantly fusing them with cytotoxic cytokines. This results in highly potent therapeutic antibodies to selectively target tumor cells while reducing the systemic toxicity of the cytokines.

**5:00 Non-Clinical Development of Fc-Domain Optimized Monoclonal Antibodies with Increased Effector Functions**

*Ezio Bonvini, M.D., Senior Vice President, Research, MacroGenics, Inc.*  
Cancer immunotherapeutic mAbs can be enhanced via Fc domain engineering for increased Fc receptor-mediated function. Challenges and solutions in the assessment of Fc-engineered mAbs in animal efficacy models, pharmacology and toxicology will be presented and discussed.

**5:30 Pre-Clinical Developments with a Novel Peptide/Antibody Scaffold with Enhanced PKPD**

*Gary Woodnutt, Ph.D., Executive Director, Biology, CovX Research, LLC*  
Peptides have potential advantages as therapeutics but size and metabolism have reduced their impact for clinical usage. Scaffold approaches reduce these issues. This talk describes hurdles that have been overcome in the development of these agents for oncology indications.

**6:00 Anti-Angiogenic Activity of ALM201, a Targeted Non-Toxic Microtubule Disrupting Agent**

*Iain James, Ph.D., Vice President, Biology, Almac Discovery Ltd.*  
ALM201 is a 23 residue peptide that is not cytotoxic and is internalized by endothelial cells through interaction with CD44. Once inside, it binds to tubulin, causing disruption of microtubules, leading to inhibition of migration and prevention of angiogenesis.

**6:30 Close of Day**

## THURSDAY, FEBRUARY 23

## ADVANCES WITH MULTI-SPECIFIC PRODUCTS

**8:30 am Chairperson's Remarks**

**8:35 Treatment of Relapsed/Refractory ALL with Bispecific BiTE Antibody Blinatumomab**

*Patrick A. Baeuerle, Ph.D., CSO, Senior Vice President, Research & Development, Micromet, Inc.*

CD19/CD3-bispecific antibody blinatumomab has shown outstanding single-agent activity in treating patients with relapsed or refractory NHL or ALL. BiTE antibodies in pivotal and early stage development emerge as biologicals that can optimally engage T-cells for redirected lysis of cancer cells.

**9:05 Technological Background and Proof-of-Concept Studies of DuoBody™, Novel Bispecific Antibody Platform**

*Janine Schuurman, Ph.D., Director, Strategic Research, Genmab B.V.*  
The DuoBody™ platform generates highly efficient bispecific antibodies by a controlled Fab-arm exchange process. These bispecific antibodies retain the biochemical structure of regular human IgG, have Fc-mediated effector functions and regular IgG1 pharmacokinetics.

**9:35 IMCgp100: a Bi-Specific TCR Anti-CD3 Fusion for the Treatment of Malignant Melanoma**

*Bent Jakobsen, Ph.D., CSO, Immunocore Ltd.*  
ImmTACs are soluble, high affinity T-cell receptors fused to an anti-CD3 scFv domain for re-directed T-cell killing of tumors with the ability to target HLA presented epitopes. A melanoma specific ImmTAC, IMCgp100, is undergoing clinical testing in the UK and the US.

**10:05 Sponsored Presentation** (*Opportunity Available*)

**10:20 Coffee Break**

## COMBINATION THERAPIES

**11:00 Elotuzumab, a Humanized Antibody to CS1 for the Treatment of Relapsed/Refractory Multiple Myeloma: Phase 2 Study Results**

*Anil Singhal, Ph.D., Site Clinical Development Head, Global Pharmaceutical Research & Development, Abbott Biotherapeutics Corp.*

While there is significant recent progress in the treatment of multiple myeloma, additional therapies are needed for this incurable disease. Elotuzumab in combination with lenalidomide/dexamethasone shows very high response in the relapse/refractory disease.

**11:30 Advantages of Sym004: A Synergistic Antibody Mixture Targeting EGFR**

*Michael Kragh, Ph.D., Director, Antibody Pharmacology, Symphogen A/S*  
This presentation will highlight the advantages of recombinant antibody mixtures compared to monoclonal antibody therapy. Sym004, Symphogen's most advanced anti-cancer project, will be used as an example to describe the process from initial idea to clinical trials in patients.

**12:00 pm Anti-HGF Antibody Ficluzumab: Translational Oncology from Target Selection to Phase 2**

*Murray Robinson, Ph.D., Senior Vice President, Translational Medicine, AVEO Pharmaceuticals, Inc.*

We developed and utilized a unique tumor model platform to discover and develop ficluzumab, a potent inhibitor of HGF/Met signaling. Ficluzumab exhibits complex interacting effects with the EGFR pathway which led to a phase 2 combination with gefitinib in NSCLC.

**12:30 Luncheon Presentation** (*Sponsorship Opportunity Available*) or **Lunch on Your Own**

## IMMUNOTHERAPY AND ADOPTIVE T-CELL THERAPY

**1:45 Chairperson's Remarks**

*Iqbal S. Grewal, Ph.D., D.Sc., FRCPath, CSO, ImmunGene, Inc.*

**1:50 Affinity Enhanced T-Cell Receptors for Adoptive T-Cell Therapy**

*Gwendolyn Binder-Scholl, Ph.D., Vice President, US Operations, Adaptimmune, LLC*

Autologous T-cells genetically engineered with affinity-enhanced TCRs overcome the limitation of poor tumor recognition and elimination, and are undergoing evaluation in clinical trials for Mage-A3- and NY-ESO-1-expressing cancers.

**2:20 PD-1/PD-L1 Blockade**

*Alan Korman, Ph.D., Vice President, Discovery Research, Bristol-Myers Squibb*  
We have developed human antibodies targeting Programmed Death-1 (PD-1) and its ligand PD-L1, a negative regulatory pathway that controls T-cell function. The activity of this pathway in murine models, non-human primates, and in-human clinical trials will be described.

**2:50 Vaccination with Patient-Specific Tumor-Derived Antigen in First Remission Improves Disease-Free Survival in Follicular Lymphoma**

*Carlos F. Santos, Ph.D., Senior Vice President, Clinical Development & Regulatory Affairs, Cancer Biologics, Biovest International, Inc.*  
Vaccination with patient-specific hybridoma-derived idotype vaccine after chemotherapy-induced CR/ CRu may prolong disease-free survival in patients with follicular lymphoma. Vaccine isotype may affect clinical outcome and explain differing results between this and other controlled Id-vaccine trials.

**3:20 Close of Conference**

## Alumni Discount

**Receive 20% Off Your Registration!**

Cambridge Healthtech Institute (CHI) appreciates your past participation at the Molecular Med TRI-CON. Through loyalty like yours, CHI has been able to build this event into a must attend for senior level decision-makers. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate. Just check off the box marked Alumni Discount on the registration form to receive the discount! Please note: Our records must indicate you were an attendee of the Tri-Conference event in the past in order to qualify.

CHI's  
**INTRONET**  
Networking at its Best

*Maximize Your Experience onsite at the Molecular Med Tri-Con!*

The Intro-Net offers you the opportunity to set up meetings with selected attendees before, during and after this conference, allowing you to connect to the key people that you want to meet. This online system was designed with your privacy in mind and is only available to registered session attendees of this event.



# Cancer Molecular Markers

Improving Patient Outcomes

February 21-23

## TUESDAY, FEBRUARY 21

7:00 am Registration

### PLENARY KEYNOTE SESSION

8:00 Plenary Keynote Presentations (See Page 2 for Details)

9:40 Grand Opening Refreshment Break in the Exhibit Hall with Poster Viewing



### IMPROVING PATIENT OUTCOMES: INTEGRATED GENE MUTATION, EXPRESSION & METHYLATION

11:00 Chairperson's Opening Remarks

Alan Carter, President, MDx Consulting

### KEYNOTE PRESENTATION

11:10 The Science behind Wide-Scale Adoption of Genomic Analysis in the Clinic

Nicholas J. Schork, Ph.D., Director, Biostatistics and Bioinformatics, The Scripps Translational Science Institute; Professor, Molecular and Experimental Medicine, The Scripps Research Institute

This talk will focus on items that have yet to be refined in routine implementation of genomic analysis in clinical care. It will discuss annotating genomic alterations of relevance to patients, matching patient genomic profiles to therapeutic profiles, and monitoring patients objectively.

11:40 DNA Methylation Profiling Defines Clinically Relevant Biological Subsets of Non-Small Cell Lung Cancer

David S. Shames, Ph.D., Scientist, Development Oncology Diagnostics, Genentech, Inc.

This presentation will discuss the discovery and development of DNA methylation biomarkers that are predictive of sensitivity to molecularly targeted agents such as erlotinib. I will also talk about promising new technology platforms that may be useful in the discovery of new biomarkers.

12:10 pm Methylation-Based Biomarkers for Predictive and Prognostic Use

Wim van Criekinge, Vice President, Science & Technology, MDx Health  
MDxHealth's proprietary Methylation-Specific PCR (MSP) platform identifies DNA methylation-based oncology biomarkers for theranostic applications. A comprehensive epigenome-wide profiling pipeline has been established and will be discussed.

12:40 Luncheon Presentation I

Multiplexing FFPE Samples in Your Lab and Achieving Meaningful Results

BJ Kerns, Senior Vice President, HTG Molecular

Learn how qNPA technology produces significant data from FFPE tissue with no extraction. Successfully quantitating multiple genes in a single well from FFPE differentiates qNPA technology from traditional gene expression methods.



1:10 Luncheon Presentation II

Miniaturized Biomarker Assays in Complex Biological Samples for Drug Discovery and Clinical Trials

Haris Jamil, Ph.D., Vice President, Research, NanoInk, Inc.



1:45 Dessert in the Exhibit Hall with Poster Viewing

2:15 Chairperson's Remarks

2:20 Integrated Molecular Testing and the Critical Need to Engage Physicians

William G. Loudon, M.D., Ph.D., Assistant Professor, Neurosurgery, University of California Irvine; Section Chief, Neurosurgery, Children's Hospital of Orange County

2:50 A New Paradigm for Advancing Personalized Medicine: The Contract Diagnostics Organization

Philip D. Cotter, Ph.D., F.A.C.M.G., Co-Founder, ResearchDx, LLC.



3:05 Wrap Up/Debate: Is Integration Realistic?

- No clear regulatory trajectory for such tests and considerable uncertainty
- Cost issues associated with a thorough (prospective) validation
- Availability of suitable tumor tissue

3:35 Biochip Array Technology – A Rapid Multiplex Solution for Mutation Profiling, SNP Genotyping and Pathogen Detection



Scott McKeown, Ph.D., R&D Consultant, Radox Laboratories

Biochip Array Technology is a class-leading multiplex platform, which in combination with a proprietary multiplex PCR amplification process is capable of simultaneous detection of up to 22 mutations, SNPs or pathogen biorecognition elements, with applications developed for oncology (KRAS/BRAF/PIK3CA mutation profiling), cardiovascular disease (risk SNP array) pharmacogenomics and infectious diseases (including sexually transmitted infections and respiratory pathogens). Data from clinical validation studies for a number of these arrays will be presented.

3:50 Integrated Biomarker Discovery: Multi-Method Approach to Enable Early Biomarker Success

Sponsored by



Graham Speight, Ph.D., Head of Genomic Biomarkers, Oxford Gene Technology

How high-throughput biomarker discovery can enable rich datasets for rapid proof-of-concept, analysis and validation.

4:20 Reception in the Exhibit Hall (Sponsorship Available)

5:20 Breakout Discussions in the Exhibit Hall (see website for details)

6:20 Close of Day

## WEDNESDAY, FEBRUARY 22

7:55 am Chairperson's Remarks

8:00 PANEL DISCUSSION: How Have Biomarkers Been Applied in Clinical Development?

Moderator: Prakash Purohit, Ph.D., Associate Director, Scientific Affairs, IPSEN Biomeasure, Inc.

Panelists:

Dominic G. Spinella, Ph.D., Head, Translational and Molecular Medicine, Pfizer

James Watters, Ph.D., Head, Applied Genomics, Sanofi Oncology

Suso Platero, Ph.D., Director, Oncology Biomarkers, Centocor, Ortho Biotech Oncology R&D, a unit of J&J PRD, LLC

Panelists will discuss how to much more efficiently turn biomarker assays into diagnostics. What challenges are there? What strategies are best for future use of biomarkers for clinical development? Case examples will be used.

9:30 From Bench to Clinic: Quantitatively Assessing Cancer Targets and Biomarkers for Targeted Therapies



Corinne Ramos, Ph.D., Executive Director, Clinical Research, Theranostics Health

Theranostics Health utilizes Laser Capture Microdissection and highly sensitive, quantitative protein microarrays to accurately measure the presence and phosphoactivation status of the target and its downstream signaling pathway elements in tumor or diseased cells at the site of drug action.

9:45 Sponsored Presentation (Opportunity Available)

10:00 Transition to Plenary Keynote

### PLENARY KEYNOTE

10:10 Plenary Keynote Presentation (See Page 3 for Details)

11:00 Refreshment Break in the Exhibit Hall with Poster Viewing



12:00 pm KEYNOTE PANEL DISCUSSION:

Rapid NGS for Public Health Preparedness & Clinical Microbiology: Bioinformatics, Legal, and Social Issues

Moderator: Dag Harmsen, M.D., Professor & Head, Research, Peridontology, University Münster

Featured Guests:

João André Carriço, Auxiliary Researcher, Microbiology Institute, Faculty of Medicine, University of Lisbon

Matthew W. Gilmour, Ph.D., Director, Bacteriology and Enteric Diseases Division, National Microbiology Laboratory Public Health Agency of Canada, Winnipeg, MB, Canada

Gary Procop, M.D., Chairman, Clinical Pathology, Cleveland Clinic



1:00 pm Luncheon Presentation I:

### Multiplex Protein Biomarkers from Discovery to Personalized Diagnostics

Pankaj Oberoi, Ph.D., Director, Scientific Services and Director, Research and Development, Meso Scale Discovery  
Scientists appreciate the importance of protein biomarkers in drug development and therapeutic management. We will explore the challenges associated with the increasing demand for reliable, meaningful biomarker panels and how these demands can be met using MSD's multiplexed, quantitative immunoassays.



2:00 Ice Cream Refreshment Break in the Exhibit Hall with Poster Viewing

## PLENARY KEYNOTE PANEL

2:30 Plenary Keynote Panel (See Page 3 for Details)

3:50 Refreshment Break & Poster Awards in the Exhibit Hall

## NOVEL TECHNOLOGIES SESSION

4:25 Chairperson's Remarks

Avraham Rasooly, Ph.D., Program Director, Cancer Diagnosis Program, National Cancer Institute

4:30 Nano-Velcro Technology to Improve Capture of Circulating Cancer Cells

Hsian-Rong Tseng, Ph.D., Associate Professor, Department of Molecular and Medical Pharmacology, Crump Institute for Molecular Imaging, Institute for Molecular Medicine, University of California, Los Angeles; California NanoSystems Institute

This presentation will introduce a circulating tumor cell (CTC) enrichment/identification technology that allows isolation of viable (preservative-free) CTCs, enabling their functional and molecular analyses in sequence.

5:00 Laser-Cavitation Based Isolation of Circulating Cancer Cells

John F. Zhong, Ph.D., Assistant Professor, Pathology; Director, Bioinformatics, Gene Therapy Laboratories, University of Southern California School of Medicine

We have developed a laser-cavitation based system to isolate and manipulate single-cells for molecular characterization. With this system, we investigate the expression level of various cancer genes at the single-cell level.

5:30 Detection and Isolation of Circulating Melanoma Cells Using Photoacoustic Flowmetry

John A. Viator, Ph.D., Associate Professor, Biological Engineering and Dermatology, University of Missouri

Photoacoustic flowmetry, similar to flow cytometry, is suited to detect melanoma cells in blood. Using photoacoustics and microfluidic principles, we detect and capture circulating melanoma cells in human blood samples to diagnose metastatic disease.

6:00 Microfluidic Biochips for the Label-Free Detection, Isolation & Retrieval of Circulating Tumor Cells

Chwee Teck Lim, Ph.D., Principal Investigator, Mechanobiology Institute; Faculty Fellow, Singapore-MIT Alliance for Research & Technology (SMART); Professor, Division of Bioengineering & Department of Mechanical Engineering, National University of Singapore

We have devised a separation method in a microfluidic biochip based on knowledge that CTCs are larger and stiffer than blood cells. Physical cell traps placed in the blood flow path block CTCs while deformable blood constituents are removed. Viable unlabeled CTCs are then collected by flow reversal.

6:30 Close of Day

## THURSDAY, FEBRUARY 23

### ENABLING CLINICAL GRADE NGS/WGS

8:30 am Chairperson's Remarks

German Pihan, M.D., Director, Hematopathology Lab, Department of Pathology, Beth Israel Deaconess Medical Center and Harvard Medical School

8:35 Realizing the Promise of Personalized Medicine: Use of High-Throughput Genome Sequencing in Everyday Clinical Laboratory Diagnostics

Jeffrey E. Saffitz, M.D., Mallinckrodt Professor & Head, Department Pathology, Beth Israel Deaconess Medical Center

Advances in next-generation sequencing technology will soon make it practical and affordable to perform whole genome analysis on patients. This talk will briefly describe steps required to bring high-throughput genome sequencing into everyday clinical laboratory diagnostics.

9:05 Are Clinical Genomes Already Becoming Semi-Routine for Patient Care?

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

This presentation will elucidate issues relating to workforce needs and requirements, legal and regulatory aspects of "laboratory developed tests," and insurance reimbursement for "multi-analyte" diagnostics.

9:35 WGA, Efficacy, Accuracy, and Application in Best Practice Care

Peter J. Tonellato, Ph.D., Visiting Professor & Senior Research Scientist Pathology, BIDMC & Center for Biomedical Informatics, Harvard Medical School

This presentation will discuss the approach taken at Harvard Medical School and Beth Israel Deaconess Medical Center to develop a genomic processing and clinical variant annotation pipeline to aid in clinical decision making.

10:05 Sponsored Presentation (Opportunity Available)

10:20 Coffee Break

11:00 Navigating Uncharted Seas: Ethical Issues in Clinical Genomics

Lauren C. Briere, M.S., Licensed Genetic Counselor, Division of Genetics, Department of OB/GYN, Beth Israel Deaconess Medical Center

This talk will cover issues including informed consent, pre- and post-test counseling, result reporting, long-term follow-up, and data rights and explore possible frameworks to address them.

11:30 Clinically Actionable Genomic Information Database: Bridging the Gap between Genomics and the Clinic

Dennis P. Wall, Director & Assistant Professor, Computational Biology Initiative, Harvard Medical School

This talk describes our efforts to formalize the definition of clinical actionability through the construction of infrastructure and procedures for the annotation of whole-genomic data. It describes how this is being used to generate medical impact reports for decision support in cancer prognosis and treatment.

12:00 pm From Data to Information to Knowledge: Whole Genome MUD GUI for Clinicians

German Pihan, M.D., Director, Hematopathology Lab, Department of Pathology, Beth Israel Deaconess Medical Center and Harvard Medical School

This presentation will offer a blueprint for the curation, analysis, mining, interpretation and visualization of complex digital WGS data to generate readily available clinically actionable information, effectively enabling the looming revolution in personalized medicine.

12:30 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

## MOLECULAR ANALYSIS IN THE REAL WORLD – Overcoming Challenges with Clinical Samples

1:45 Chairperson's Remarks

David Neil Hayes, M.D., M.P.H., Associate Professor, Clinical Research, Hematology/Oncology, University of North Carolina, Chapel Hill

1:50 QA of Tumor Tissue Samples for Molecular Analyses

David Eberhard, Research Associate Professor, Comprehensive Cancer Center and Research Associate Professor, Pathology & Lab Medicine, University of North Carolina, Chapel Hill

High-quality clinical practice and high-quality research depend on rigorous sample QA. Sample parameters that must be considered include Diagnosis, Description, Composition, Quantity and Quality.

2:20 Providing Comprehensive, Clinical-Grade Molecular Profiles for FFPE Tumor Samples

Maureen Cronin, Ph.D., Senior Vice President, Research and Product Development, Foundation Medicine, Inc.

Massively parallel sequencing technologies enable a new class of molecular diagnostic for oncology patients. Performing high sensitivity, high specificity sequencing on small amounts of FFPE tumor allows comprehensive assessment of clinically useful genomic markers, fully informing therapeutic treatment planning.

2:50 Presentation to be Announced

3:20 Close of Conference

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# Circulating Tumor Cells

Expediting Clinical Use

February 21-23

## TUESDAY, FEBRUARY 21

7:00 am Registration

### PLENARY KEYNOTE SESSION

8:00 Plenary Keynote Presentations (See Page 3 for Details)

9:40 Grand Opening Refreshment Break in the Exhibit Hall with Poster Viewing

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MOLECULAR DIAGNOSTICS

### CTCs IN THE CLINIC

11:00 Chairperson's Opening Remarks

Massimo Cristofanilli, M.D., F.A.C.P., Professor and Chairman

### KEYNOTE PRESENTATIONS

11:10 The Prognostic and Predictive Value of Enumeration and Molecular Characterization

Massimo Cristofanilli, M.D., F.A.C.P., Professor and Chairman, Department of Medical Oncology, G. Morris Dorrance Jr. Endowed Chair in Medical Oncology, Fox Chase Cancer Center

This presentation will review the clinical value of enumeration, introduce the most recent advancements in defining the molecular phenotype of CTCs, integrate this information for the prognosis and monitoring of response to therapy, and introduce their utility in pharmacodynamic monitoring.

11:40 Circulating Tumor Cells as Potential Biomarker for Metastatic Prostate Cancer Clinical Trials for Predicting Benefit and Monitoring Patients

Howard Scher, M.D., Chief, Genitourinary Oncology Service, Memorial Sloan-Kettering Cancer Center

12:10 pm Clinical Significance of Circulating Tumor Cells in Breast Cancer

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

Prospective clinical trials demonstrate that the enumeration of circulating tumor cells (CTCs) has clinical utility when used in conjunction with radiographic imaging and clinical evaluations in the setting of metastatic breast cancer.

12:40 Molecular Analysis of Circulating Tumor Cells Using the IsoFlux System

Carolyn Conant, Ph.D., Senior Scientist, Fluxion Biosciences

We discuss required attributes of CTC samples for downstream molecular diagnostics. The IsoFlux System is a novel platform that provides access to CTCs with high recovery, high purity, and low liquid volume. Clinical and analytical data will be shown that identifies sensitivity limits for genetic analyses using PCR and FISH approaches.

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12:55 A Microfluidic System for the Selection of Circulating Tumor Cells that Utilizes both Affinity and Size Capture Technologies

Denis A. Smirnov, Director, On-Q-ity Inc.

Detection of rare circulating tumor cells (CTC) from blood promises to be valuable for diagnosis, prognosis and treatment of cancer patients. Current techniques, based solely on antibody affinity capture, are compromised by low capture efficiencies, presumably due to limited cell surface antigen expression. We will describe a novel CTC platform combining affinity capture with size filtration capture (C5 CTC chip). Utility of this system for enumeration and characterization of circulating cells will also be described.

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1:10 Luncheon Presentation (Sponsorship Opp Avail) or Lunch on Own

1:45 Dessert in the Exhibit Hall with Poster Viewing

### NOVEL APPROACHES FOR CTC ANALYSIS

2:15 Chairperson's Remarks

Steven A. Soper, Ph.D., University of North Carolina, Chapel Hill

2:20 Collection, Manipulation and Molecular Profiling of Circulating Tumor Cells (CTCs) Using Microfluidics

Steven A. Soper, Ph.D., William H. Pryor Emeritus Professor, Biomedical Engineering and Chemistry; Director, Center for Biomolecular System, University of North Carolina, Chapel Hill; and WCU Scholar, UNIST, S. Korea

This presentation will discuss a polymer-based modular microfluidic system that can recover CTCs from whole blood, release the CTCs and then manipulate the CTCs into a containment reservoir using electrokinetics which can then be imaged for enumeration and genotyped at the single-cell level.

2:50 Isolation and Genotyping of Circulating Tumor Cells in a Miniaturized System

Chengxun Liu, Ph.D., Senior Researcher, Functional Nanosystems Group, imec This system integrates immunomagnetic isolation and genotyping for CTCs. The cell isolation module counts cells using a microelectronic sensor. Twenty specific genetic markers were reversely transcribed, amplified by multiplex ligation probe amplification and electrochemically detected in an automated miniaturized system.

3:20 Multi-Orifice Flow Fractionation (MOFF) for the Isolation and Characterization of Circulating Tumor Cells

Hyo-Il Jung, Ph.D. (Cantab), Associate Professor, School of Mechanical Engineering, Yonsei University

This talk will present a new microfluidic method for isolating circulating tumor cells (CTCs) through the combined use of inertial lift forces and turbulent secondary flows generated in a topographically patterned microchannel (MOFF, multi-orifice flow fractionation).

3:50 A Workflow for Single-Cell Resolution, Automated, Image-Based Sorting of Pure Circulating Tumor Cells and Their Comprehensive Molecular Characterization

Nicolò Manaresi, Ph.D., CTO, Silicon Biosystems S.p.A.

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ADVANCED CELL DIAGNOSTICS, INC.4:05 CTCscope: A Novel Platform for Detection and Characterization of CTCs Using Multiplex RNA *in situ* Hybridization

Yuling Luo, Ph.D., Advanced Cell Diagnostics, Inc.

4:20 Reception in the Exhibit Hall (Sponsorship Available)

5:20 - 6:20 Breakout Discussions in the Exhibit Hall (see website)

## WEDNESDAY, FEBRUARY 22

### CLINICAL USE OF CTCs

7:55 am Chairperson's Remarks

Richard Cote, M.D., FRCPath, Professor and Chairman

### KEYNOTE PRESENTATION

8:00 Circulating and Disseminating Tumor Cells in Cancer Care

Stefanie Jeffrey, M.D., Chief, Surgical Oncology Research, Stanford University Applications for CTCs and DTCs in cancer management will be discussed, including different analytic approaches and strategies for personalized therapy.

8:30 CTC in the Neoadjuvant Setting: Why Do We Need More Information than Tumor PCR?

Jean-Yves Pierga, M.D., Medical Oncology, Institute Curie, Paris

Few studies have shown no correlation between pCR and CTC detection. CTC detection could be a valuable tool to predict relapse even in complete responders. Monitoring CTCs after tumor removal could be a surrogate marker for evaluating adjuvant treatment efficacy.

9:00 Novel Nanotechnology Approaches to Circulating Tumor Cell Capture and Characterization

Richard Cote, M.D., FRCPath, Professor and Chair, Department of Pathology; Director, University of Miami Biomedical Nanoscience Institute, University of Miami Miller School of Medicine

We have precision-engineered a novel parylene-microfilter-based, antigen expression-agnostic, open platform that allows capture, enumeration and characterization of CTCs. This platform enables longitudinal assessment of CTC as 'liquid biopsy' and can serve as a companion diagnostic through study of CTCs in pre-clinical models.

9:30 Capture and Detection of CK+ and CK- CTCs for Subsequent Molecular Analysis Using the OncoCEE™ Platform

Farideh Bischoff, Ph.D., Vice President, Translational R&amp;D, Biocept

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10:00 Transition to Plenary Keynote

### PLENARY KEYNOTE

10:10 Plenary Keynote Presentation (See Page 3 for Details)

**11:00 Refreshment Break in the Exhibit Hall with Poster Viewing**

**12:00 pm Circulating Tumor Cells (CTCs) with EMT Phenotype for Predicting Breast Cancer Progression**

*Sendurai A. Mani, Ph.D., Assistant Professor, Molecular Pathology, MD Anderson Cancer Center*

CTCs detected using the expression of EpCAM are proven prognostic markers in cancer patients. Evidence demonstrates that EMT plays a critical role in promoting metastasis and that carcinoma cells lose expression of EpCAM during EMT. Clinical association of CTCs with and without EMT property will be discussed.

**12:30 Molecular Characterization of CTCs: Expression of EMT Markers in CTCs of Breast Cancer Patients**

*Evi Lianidou, Ph.D., Associate Professor, Chemistry, University of Athens*  
It has been shown that subsets of CTCs have a putative breast cancer stem-cell phenotype, and express EMT markers. Research on the molecular characterization of CTCs offers an approach to understand the biology of metastasis and resistance to established therapies.

**1:00 Luncheon Presentation**

**A Mini-Device for Rapid Isolation by Size and Extensive Characterization of Rare Circulating Tumor Cells**

*Yvon E. Cayre, M.D., D.Sci., Professor, Pierre and Marie Curie University; CSO, ScreenCell*

The ScreenCell® is a mini device to isolate circulating tumor cells (CTCs). It was developed, including a removable filter, to provide links allowing full access to a complete menu of analytic tools: cellular studies, cell culture and molecular biology tests.

**1:30 Clinical Impact of ISET, A Highly Sensitive Diagnostic Method for Isolation and Immuno-Molecular Characterization of CTC**

*Patrizia Paterlini Brechot, M.D., Ph.D., Professor of Cell Biology/Oncology, University Paris Descartes, Director of INSERM, Unit 807 and CSO, Rarecells*  
ISET allows the diagnostic identification of CTC and their specific mutation analysis (KRAS, EGFR, HER2, BRAF etc). Its clinical impact has been demonstrated in patients with non metastatic cancers, showing its value in Personalized Medicine and Predictive Oncology.

**2:00 Ice Cream Refreshment Break in the Exhibit Hall, Poster Viewing**

## PLENARY KEYNOTE PANEL

**2:30 Plenary Keynote Panel (See Page 3 for Details)**

**3:50 Refreshment Break & Poster Awards in the Exhibit Hall**

## NOVEL TECHNOLOGIES SESSION

**4:25 Chairperson's Remarks**

*Avraham Rasooly, Ph.D., Program Director, Cancer Diagnosis Program, National Cancer Institute*

**4:30 Nano-Velcro Technology to Improve Capture of Circulating Cancer Cells**  
*Hsian-Rong Tseng, Ph.D., Associate Professor, Department of Molecular and Medical Pharmacology, Crump Institute for Molecular Imaging, Institute for Molecular Medicine, University of California, Los Angeles; California NanoSystems Institute*

This presentation will introduce a circulating tumor cell (CTC) enrichment/identification technology that allows isolation of viable (preservative-free) CTCs, enabling their functional and molecular analyses in sequence.

**5:00 Laser-Cavitation Based Isolation of Circulating Cancer Cells**

*John F. Zhong, Ph.D., Assistant Professor, Pathology; Director, Bioinformatics, Gene Therapy Laboratories, University of Southern California School of Medicine*  
We have developed a laser-cavitation based system to isolate and manipulate single-cells for molecular characterization. With this system, we investigate the expression level of various cancer genes at the single-cell level.

**5:30 Detection and Isolation of Circulating Melanoma Cells Using Photoacoustic Flowmetry**

*John A. Viator, Ph.D., Associate Professor, Biological Engineering and Dermatology, University of Missouri*

Photoacoustic flowmetry, similar to flow cytometry, is suited to detect melanoma cells in blood. Using photoacoustics and microfluidic principles, we detect and capture circulating melanoma cells in human blood samples to diagnose metastatic disease.

**6:00 Microfluidic Biochips for the Label-Free Detection, Isolation & Retrieval of Circulating Tumor Cells**

*Chwee Teck Lim, Ph.D., Principal Investigator, Mechanobiology Institute; Faculty Fellow, Singapore-MIT Alliance for Research & Technology (SMART); Professor, Division of Bioengineering & Department of Mechanical Engineering, National University of Singapore*

We have devised a separation method in a microfluidic biochip based on knowledge

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that CTCs are larger and stiffer than blood cells. Physical cell traps placed in the blood flow path block CTCs while deformable blood constituents are removed. Viable unlabeled CTCs are then collected by flow reversal.

**6:30 Close of Day**

## THURSDAY, FEBRUARY 23

### CLINICAL USE OF CIRCULATING TUMOR CELLS

**8:30 am Chairperson's Remarks**

*Michail Ignatiadis, M.D., Ph.D., Department of Medical Oncology, Jules Bordet Institute, Brussels, Belgium*

**8:35 Bioengineering and Clinical Applications of Microfluidic Circulating Tumor Cell Chip**

*Shyamala Maheswaran, Ph.D., Associate Professor, Surgery & Molecular Biology, Harvard Medical School*

This presentation will describe the engineering design and clinical validation of the microfluidic CTC-chip.

**9:05 Detection of Viable Circulating Tumor Cells (CTC) in Solid Tumors Using the EPISPOT Assay**

*Catherine Alix-Panabières, Ph.D., Professor Assistant, Laboratory of Rare Human Circulating Cells, Institute of Research in Biotherapy, University Medical Center of Montpellier*

The EPISPOT assay is combined to a depletion of CD45+ hematopoietic cells, avoiding positive enrichment based on EpCAM expression. We detected viable CTC with specific phenotypes and applied it to various cancers. Due to the heterogeneity, several sub-populations may release different proteins.

**9:35 HER2 Expression on CTCs/DTCs in Breast Cancer: Is there Any Role in Clinical Practice?**

*Michail Ignatiadis, M.D., Ph.D., Department of Medical Oncology, Jules Bordet Institute, Brussels, Belgium*

Results from an international ring study to interrogate inter-reader variability in CTC and HER2-positive CTC detection using the CellSearch technology in early breast cancer will be presented. And update on ongoing trials testing the clinical utility of HER2 expression on CTCs will also be provided.

**10:05 The Development of a Circulating Melanoma Cell Assay**

*M. Craig Miller, Manager, Clinical Sciences, Veridex, LLC*

- Provide an overview of the development and validation of this new Research Use Only assay which utilizes the CellSearch® system for the isolation, enumeration, and characterization of circulating melanoma cells.
- Present a few examples of how this new standardized assay for CMCs may help you in your research and drug development programs for metastatic melanoma.

**10:20 Coffee Break**

### NOVEL TECHNOLOGIES SESSION

**10:55 Chairperson's Remarks**

*Shyamala Maheswaran, Ph.D., Associate Professor, Surgery & Molecular Biology, Harvard Medical School*

**11:00 Technology "Show 'N Tell" Demonstration in the Foyer**

*Presenters to be Announced - see website for details*

**12:30 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own**

### FUNDING AND REGULATION OF CTCs

**1:45 Chairperson's Remarks**

**1:50 Grants Available through SBIR**

*Xing-Jian Lou, Ph.D., Program Director, SBIR Development Center, National Cancer Institute*

**2:10 NCI/NIH Funding Opportunities**

*Avraham Rasooly, Ph.D., Program Director, Cancer Diagnosis Program, National Cancer Institute*

### FUTURE TRENDS IN CTC DIAGNOSTICS

**2:25 Chairperson's Remarks**

*Steven A. Soper, University of North Carolina; and Dave Hoon, John Wayne Cancer Institute*

**2:30 Future Trends in Clinical Development**

*Dave Hoon, M.Sc., Ph.D., Director, Molecular Oncology, John Wayne Cancer Institute*

**3:00 Future Trends in Technology Development**

*Steven A. Soper, Ph.D., William H. Pryor Emeritus Professor, Department of Biomedical Engineering and Chemistry; Director, Center for Biomolecular System, University of North Carolina, Chapel Hill; and WCU Scholar, UNIST, S. Korea*

**3:30 Close of Conference**



# Oncology Clinical Trials

Bringing Targeted & Tailored Cancer Therapy to Patient

February 21-23

## TUESDAY, FEBRUARY 21

7:00 am Registration

### PLENARY KEYNOTE SESSION

8:00 Plenary Keynote Presentations (See Page 3 for Details)

9:40 Grand Opening Refreshment Break in the Exhibit Hall with Poster Viewing

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## CANCER CLINICAL TRIALS IN THE ERA OF PERSONALIZED MEDICINE

11:00 Chairperson's Opening Remarks

11:10 Cancer Clinical Trials in the Era of Personalized Medicine: A Sponsor's Perspective

Hal Barron, M.D., Executive Vice President, CMO, Global Product Development, Roche Holding AG

11:40 Cancer Clinical Trials in the Era of Personalized Medicine: An Investigator's Perspective

Margaret A. Tempero, M.D., Doris and Donald Fisher Distinguished Professorship, Clinical Cancer Research; Professor, Medicine, Division of Hematology and Oncology; Director, Research Programs; Deputy Director, UCSF Helen Diller Family Comprehensive Cancer Center

Recent breakthroughs in clinical science suggest there is more diversity in malignant disease than we previously appreciated. Identifying clinically actionable biomarkers demands a paradigm shift in clinical trial design and a focus on small subsets.

12:10 pm Methodologic Issues in Clinical Trials in the Era of Personalized Therapy

Steven Piantadosi, M.D., Ph.D., Chair & Director, Phase One Foundation, Samuel Oschin Comprehensive Cancer Institute

This talk will discuss issues in the design and analysis of trials that test therapies that rely on "personalized" therapy, such as those tailored to specific genetic or other characteristics of the study subjects.

12:40 Sponsored Presentation To be Announced

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12:40 Keynote Panel Discussion: Clinical Trials as a Way to Improve Abilities to Diagnose, Treat and Prevent Cancer

1:45 Dessert in the Exhibit Hall with Poster Viewing

## INDUSTRY-ACADEMIA COLLABORATION

2:15 Chairperson's Remarks

Ionel Mitrica, Ph.D., Director, Clinical Development, Oncology, GlaxoSmithKline

2:20 SWOG, An International NCI-Funded Cancer Cooperative Group Collaboration on Biomarker Development, Cancer Prevention and Cancer Treatment with Industry

Laurence H. Baker, D.O., Professor of Medicine and Pharmacology, University of Michigan Medical School; Group Chair, Southwest Oncology Group (SWOG) SWOG is engaged in studies designed to improve our abilities to diagnose, treat and prevent cancer. Our clinical trials are performed by 4,000 physicians at over 500 sites. In this presentation we will highlight the methodology of the collaboration as well as describe some obstacles to success.

2:50 Cooperation between Industry and Academic Collaborative Groups in Oncology

Ionel Mitrica, Ph.D., Director, Clinical Development, Oncology, GlaxoSmithKline This presentation discusses how to effectively approach partnerships between pharma and academic cooperative groups, while meeting both sides' needs as well as regulatory requirements, and ultimately also improving the output of oncology R&D.

## NOVEL SURROGATE ENDPOINTS

3:20 Laboratory and Clinical Endpoints in Cancer Immunotherapy

Michael A. Morse, M.D., MHS, Associate Professor, Division of Medical Oncology, GI Oncology, Duke University Medical Center

Cancer immunotherapies such as cellular therapies and immune modulators have been recognized to provide clinical benefit, and have received marketing approval in the

United States. Nonetheless, well accepted clinical surrogates may not provide effective guidance toward the development of other immunotherapies, or extending the use of the currently approved therapies. The laboratory and clinical endpoints recognized as critical to demonstrating effectiveness will be addressed, along with discussion of their role in

informing the development of novel agents. **3:50 CTCs as a Liquid Biopsy** Marielena Mata, Ph.D., Principal Research Scientist, Oncology Biomarkers, Johnson & Johnson

From counting to "seeing" the tumor, CTCs provide access to tumor related information that may significantly impact clinical development decisions. Overview of the use of CTCs in clinical trials as prognostic and predictive markers including practical considerations and logistics.

4:20 Reception in the Exhibit Hall (Sponsorship Available)

5:20 Breakout Discussions in the Exhibit Hall (see website for details)

6:20 Close of Day

## WEDNESDAY, FEBRUARY 22

## CASE STUDIES OF LED-TO-APPROVAL CLINICAL TRIALS

**Xalkori Case Study**

7:55 am Chairperson's Remarks

Keith Wilner, Ph.D., Senior Director, Oncology Clinical Development, Pfizer, Inc.

8:00 Integrating Companion Diagnostics into Clinical Drug Development: Crizotinib Case Study

Hakan Sakul, Ph.D., Executive Director & Head, Diagnostics, Worldwide Research & Development, Clinical Research and Precision Medicine, Pfizer, Inc. Fully integrating a diagnostic test into crizotinib pivotal trials, leading to a simultaneous submission of a drug-diagnostics combination, presented many challenges as well as opportunities in the development of crizotinib for treatment of NSCLC patients.

8:30 Speed of Drug Development by Incorporation of a Companion Test: Crizotinib Case Study

Keith Wilner, Ph.D., Senior Director, Oncology Clinical Development, Pfizer, Inc.

The use of a diagnostic test to appropriately identify a patient population expected to benefit from crizotinib treatment led to smaller clinical trials in NSCLC to meet the primary statistical endpoints as well as a greater chance of successful trials.

9:00 Simultaneous Approval of a Therapeutic & Companion Diagnostic: Crizotinib Case Study

Erling Thor Donnelly, Ph.D., R.A.C., Director, Worldwide Regulatory Strategy, Pfizer, Inc.

The simultaneous submission and approval of Pfizer's crizotinib and Abbott Molecular's anaplastic lymphoma kinase (ALK) break-apart FISH companion diagnostic presented unique clinical and regulatory challenges, requiring novel approaches as well as close collaboration between Pfizer, Abbott, CDER, and CDRH.

9:30 Transforming Clinical Development with Adaptive Trials Oncology – A Case Study of an Oncology Registration Trial

Cryus Mehta, Ph.D., President and Co-Founder, Cytel Inc.

Why are adaptive approaches on the rise in late phase oncology studies?

Over 50% of confirmatory studies end in failure - a distressing reality for cancer treatment developers and the medical community. In response, adaptive design strategies are helping reverse this discouraging trend. Using examples of ongoing adaptive trials - including the ongoing VALOR trial a pivotal study for the treatment of Acute Myeloid Leukemia, you'll learn:

- the adaptations the FDA and EMA allow in both earlier and confirmatory stages
- harnessing Conditional Power to effectively "de-risk" oncology development
- to make the most of interim analysis with the validated
- "Promising Zone" design strategy
- ethical considerations: what do participating patients gain in an adaptive study?

10:00 Transition to Plenary Keynote

### PLENARY KEYNOTE

10:10 Plenary Keynote Presentation (See Page 3 for Details)

11:00 Refreshment Break in the Exhibit Hall with Poster Viewing

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## Adcetris Case Study

### 12:00 pm Clinical Development of Brentuximab Vedotin: Five Remarkable Years from First Patient Treated to Accelerated Approval

*Eric Sievers, M.D., Vice President, Clinical Affairs, Seattle Genetics*

Observation of multiple complete remissions among advanced lymphoma patients treated in a phase one setting led Seattle Genetics to pursue paired, single-arm, registrational trials. We will review the overall strategy that led to marketing registration in 2011.

### 12:30 Accelerated Approval of a Targeted Antibody-Drug Conjugate (ADC): Brentuximab Vedotin Case Study

*Elaine S. Waller, Pharm.D., M.B.A., Senior Vice President, Regulatory Affairs, Seattle Genetics, Inc.*

FDA review of the brentuximab vedotin BLAs was complex due to inclusion of two indications, the ADC technology, and an ODAC environment influenced by recent hearings on accelerated approval of oncology drugs.

### 1:00 Luncheon Presentations (Sponsorship Opportunities Available) or Lunch on Your Own

### 2:00 Ice Cream Refreshment Break in the Exhibit Hall with Poster Viewing

## PLENARY KEYNOTE PANEL

2:30 Plenary Keynote Panel (See Page 3 for Details)

### 3:50 Refreshment Break & Poster Awards in the Exhibit Hall

## Zelboraf Case Study

### 4:25 Chairperson's Remarks

*Elaine S. Waller, Pharm.D., M.B.A., Senior Vice President, Regulatory Affairs, Seattle Genetics, Inc.*

### 4:30 Zelboraf in Metastatic Melanoma: Interim Analysis Considerations in a Phase III Trial

*Chris Bowden, M.D., Vice President, Oncology Clinical Development, Genentech, Inc.*

BRIM-3, a randomized Phase III trial in patients with V600+ metastatic melanoma, compared Zelboraf to dacarbazine treatment. The rationale for changing the primary endpoint from overall survival to the co-primary endpoints of overall survival and progression-free survival will be discussed.

### 5:00 Zelboraf/Cobas Lessons Learned: Prospective Co-Development of a Companion Diagnostic in Cancer Medicine

*Jeffrey Lawrence, M.D., Director, Oncology, Roche Molecular Systems, Inc.*

The cobas 4800 BRAF V600 Mutation Test was the companion diagnostic assay used to screen >2,300 melanoma patients for Phase II and Phase III trials of Zelboraf. Clinical validation of the cobas BRAF test vs. Sanger sequencing will be discussed.

### 5:30 Zelboraf Regulatory Perspectives: Lessons Learned and Future Implications

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

Approval of the BRAF-targeted therapy ZELBORAF with the cobas BRAF diagnostic test exemplifies the process encouraged in FDA's 2011 *In Vitro* Diagnostic Companion Guidance. Lessons learned highlight considerations for navigating co-development approvals and next steps for CDER/CDRH guidance.

### 6:00 PANEL DISCUSSION: Lessons Learned from Case Studies

*Moderator: Hakan Sakul, Ph.D., Executive Director & Head, Diagnostics, Worldwide Research & Development, Clinical Research and Precision Medicine, Pfizer, Inc.*

### 6:30 Close of Day

## THURSDAY, FEBRUARY 23

## BIOMARKER-DRIVEN CLINICAL TRIALS

### 8:30 am Chairperson's Remarks

*Hal Mann, Vice President, Clinical Research Services, ResearchDx, LLC*

## KEYNOTE PRESENTATION

### 8:35 The Story of MetMab Discovery and Development

*Stuart Lutzker, M.D., Ph.D., Vice President, BioOncology Exploratory Clinical Development, Genentech*

### 9:05 Translational Genomics in a Phase II Clinical Trial for Patients with Previously Treated Advanced Pancreatic Adenocarcinoma.

*Michael Barrett, Ph.D., Associate Professor, Clinical Translational Research Division, Unit Head, Oncogenomics Laboratory, TGEN.*

We have developed unbiased methods to molecularly profile tumor genomes in highly admixed and complex clinical biopsies in the setting of a clinical trial. The data for each patient are integrated with prior knowledge of tumor signaling pathways in order to advance improved clinical outcomes.

### 9:35 Personalized Medicine in a Phase I Clinical Trials Program: The MD Anderson Cancer Center Initiative

*Apostolia-Maria Tsimberidou, M.D., Ph.D., Associate Professor, Department of Investigational Cancer Therapeutics, University of Texas, MD Anderson Cancer Center*  
Tumor molecular profiling for identification of molecular aberrations and use of matched targeted therapy is associated with superior rates of response, time to treatment failure and survival compared to the standard approach in patients with advanced cancer.

### 10:05 Sponsored Presentation (Opportunity Available)

### 10:20 Coffee Break

### 11:00 Testing the Predictive Value of a Genomic Assay

*William Barlow, Ph.D., Senior Biostatistician, Cancer Research & Biostatistics Research; Professor, Department of Biostatistics, University of Washington*  
Prediction refers to the ability of a marker to choose the best treatment for a patient. We illustrate how to test a continuous marker in a clinical trial and how to design a trial to test a marker's predictive value.

### 11:30 Clinical Trial Strategies for Deploying Modern Immunotherapies as Monotherapy or in Combinations

*Ravi A. Madan, M.D., Assistant Clinical Investigator, Laboratory of Tumor Immunology and Biology & Medical Oncology Branch, National Cancer Institute*  
Modern immunotherapies such as therapeutic cancer vaccines are mechanistically different from standard cytotoxic agents, and thus require special considerations for population selection and clinical trial design. Appropriate trial endpoints for monotherapy may be different from studies which employ immune-based combinations.

### 12:00 pm New Approaches to the Treatment of Breast Cancer: The I-SPY TRIAL

*Laura Jean Esserman, M.D., M.B.A., Director, Carol Franc Buck Breast Care Center Professor of Surgery and Radiology, University of California, San Francisco*

I-SPY 2 is a precompetitive collaboration that employs an adaptive design, streamlined operational infrastructure, and uses pathologic complete response (pCR) as a "surrogate endpoint" in the neoadjuvant breast cancer setting, to speed the evaluation of new drugs and associated biomarkers.

### 12:30 Lunch on your Own

### 1:45 Chairperson's Remarks

### 1:50 Key Dimensions and Difficulties when Identifying Predictive Signatures in the Survival Analysis Setting

*Jared Lunceford, Senior Biometrician, Merck Research Laboratories*  
In the context of microarray gene expression profiling and the modeling of overall survival or progression free survival, the search for a predictive signature is a delicate task and we will review some of the key statistical issues involved when constructing *de novo* models for survival endpoints.

### 2:20 Panel Discussion: Biomarkers in Cancer Clinical Trials: a Tool or a Goal?

*Laura Jean Esserman, M.D., MBA, Director, Carol Franc Buck Breast Care Center Professor of Surgery and Radiology, University of California, San Francisco*

### 3:20 Close of Conference



### TRI-CON ALL ACCESS PACKAGE - BEST VALUE!

Please see the bottom of the Registration page for recommended Symposia, Partnering Forum, and Short Courses.

## Hotel Information

Primary Conference Venue  
**The Moscone North Convention Center**  
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Symposia, Partnering Forums & Host Hotel  
**InterContinental San Francisco Hotel**  
888 Howard Street • San Francisco, CA 94103  
Discounted Group Rate: \$215 s/d • Discounted Room Rate Cut Off Date: January 19, 2012  
(T) 415-616-6500  
\* Room Rate includes complimentary internet access in your guestroom.

Additional Recommended Hotel  
**Marriott San Francisco Hotel**  
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Discounted Group Rate: \$229 s/d • Discounted Room Rate Cut Off Date: January 25, 2012  
Reservations 888-575-8934 (T) 415-896-1600

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# Bioinformatics & Cancerinformatics

Turning the Data Deluge into Meaningful Biological Knowledge

February 21-23

## TUESDAY, FEBRUARY 21

7:00 am Registration

### PLENARY KEYNOTE SESSION

8:00 Plenary Keynote Presentations (See Page 3 for Details)

9:40 Grand Opening Refreshment Break in the Exhibit Hall with Poster Viewing

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## DATA STORAGE, MANAGEMENT AND INTEGRATION STRATEGIES

11:00 Chairperson's Opening Remarks

### KEYNOTE PRESENTATION

#### 11:10 NCI caBIG®: Enabling Collaborative Research

*Ken Buetow, Ph.D., Associate Director, Bioinformatics and Information Technology, National Cancer Institute*

The National Cancer Institute (NCI) through its caBIG® program has prototyped a standards-based interoperable infrastructure to manage, annotate, and analyze biomedical research data. These community-generated and supported open-source capabilities enable collaborative research among all constituents of the biomedical research ecosystem.

#### 11:40 PubChem as a Tool to Facilitate Drug Design

*Jun (Luke) Huan, Ph.D., Associate Professor, Department of Electrical Engineering and Computer Science, University of Kansas*

NIH and a number of universities recently started drug discovery programs. These initiatives create huge volumes of data, which is collected in an open and collaborative environment, primarily stored at Pubchem. We will talk about our experience analyzing Pubchem data.

#### 12:10 pm Oncology Pharmacogenomics Data Integration and Beyond: Right Information and Smart Information

*Lihua Yu, Ph.D., Director of Bioinformatics, H3 Biomedicine, Inc.*

AstraZeneca's cancer pharmacogenomics data integration systems manage multi-dimensional data from compound profiling to cell line and *in vivo* model molecular profiling. Learn the system's key functionalities, its application to drug discovery and translational science projects, and how crowd intelligence is changing its information delivery.

#### 12:40 Luncheon Presentation I Integrated Biobanking - Specimen Management from an Institutional Perspective

*Steve Chen, Director of Marketing, BioFortis, Inc.*

Most biobanks today use stand-alone biobanking software to address the operational aspects of their biospecimen collections. As a result, additional IT resources are needed if researchers want to tie-in data repositories that contain clinical, molecular, and other types of information about those samples. In this presentation, we describe how an "integrated biobanking" approach can better support biospecimen management and drive scientific discovery from an enterprise, multi-group, multi-study perspective.

#### 1:10 Luncheon Presentation II Integrating R&D Data in a Highly Distributed Data Environment

*Todd Jones, Director of Business Development, Spry  
Mike Lang Jr., VP, Director of Ontology Engineering Services, Revelytix*

This topic presents a system for enabling arbitrary analysis across distributed data sources using W3C semantic standards. It shows how the pharma industry can leverage this system for data validation and integration, policy compliance enforcement, and inferencing.

1:45 Dessert in the Exhibit Hall with Poster Viewing

## INTEGRATION OF BIOMARKER, CLINICAL AND PERSONALIZED MEDICINE DATA

2:15 Chairperson's Remarks

*Carol Hill, Ph.D., Duke Clinical Research Institute*

#### 2:20 Creating Informatics Tools and an Organizational Support Paradigm to Facilitate Bi-Directional Translational Research

*Paul A. Harris, Ph.D., Director, Office of Research Informatics Operations; Associate Professor, Biomedical Informatics & Biomedical Engineering, Vanderbilt University*

This presentation will highlight informatics-centered tools leveraging secondary use of clinical data. Topics will include research data warehousing, biorepository integration, participant recruitment and semi-automated population of project research databases.

#### 2:50 Secondary Use of Healthcare Data for the Study of Genomics and Pharmacology

*Shawn Murphy, M.D., Ph.D., Assistant Professor of Neurology, Research IT, Partners HealthCare*

Informatics for Integrating Biology and the Bedside (i2b2) is a project now installed at over 60 hospitals to provide clinical investigators with the software tools necessary to integrate medical record and clinical research data in the genomics age.

#### 3:20 Clinical Research Informatics: Challenges and Opportunities in Translational Research

*Carol Hill, Ph.D., Informatics Project Leader II, Clinical Data Integration, Duke Clinical Research Institute*

Clinical Research Translational Informatics interfaces exploratory and clinical efforts. Integration across source boundaries requires contextual understanding. I will discuss efforts in developing backend standards, defining data sets, and developing cross-project infrastructure for biomarker research.

#### 3:50 Aggregating & Harmonizing Disparate Data Sources: The Key to Pattern Recognition

*Gary Kennedy, Chairman & CEO, Remedy Informatics*Sponsored by  
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#### 4:05 Breaking the Mold: Whole Genome Sequencing as a Diagnostic Assay

*Jill Hagenkord, M.D., CMO, Complete Genomics*

Whole genome sequencing is enabling researchers to identify novel disease-causing variants and to assess multiple pathways in a single assay. This presentation reviews cases of clinical utility, near-term applications.

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4:20 Reception in the Exhibit Hall (Sponsorship Available)

5:20 Breakout Discussions in the Exhibit Hall

6:20 Close of Day

## WEDNESDAY, FEBRUARY 22

## DATA MODELING AND COMPUTATIONAL INTEGRATIVE TOOLS

7:55 am Chairperson's Remarks

#### 8:00 Mastering Complexity of Biosystems without Math and Computing Background

*Corrado Priami, Ph.D., President and CEO, The Microsoft Research - University of Trento Centre for Computational and Systems Biology (CoSBI)*

This talk presents a new bioinformatics approach that speeds up modeling and analysis of complex biological systems. A natural iHuman-computer interaction interface allows biologists with no math or computing background to master modeling and simulation to infer new knowledge and design better experiments.

#### 8:30 Personalized Medicine: Moving from Correlation to Causality in Breast Cancer

*Michael Liebman, Ph.D., Managing Director, Strategic Medicine, Inc.  
Sabrina Molinaro, Ph.D., Institute for Clinical Physiology, National Research Council, Italy*

We have developed a fundamental model of the disease process for breast cancer, from pre-disease through early detection, treatment and outcome, and apply a multi-scalar approach across the risk assessment-enhanced diagnosis-therapeutic decision axis and will present the modeling methodologies.

#### 9:00 Using Public Molecular Measurements to Drive Discovery of Biomarkers and Therapeutics

*Rong Chen, Ph.D., Bioinformatics Specialist, Butte Lab, Division of Systems Medicine, Department of Pediatrics, Stanford University School of Medicine*

This presentation will describe how computational integrative tools can be used to convert more than 15 billion points of molecular, clinical, and epidemiological data measured by researchers and clinicians over the past decade into novel diagnostics, therapeutics, and insights into disease.

**9:30 Prediction of Downstream Effects and Transcription Factor Activation of Breast Cancer Cell Lines Using IPA (Ingenuity Pathway Analysis)**

*Stuart Tugendreich, Ph.D., Product Management Director, Ingenuity Systems*  
The epithelial to mesenchymal transition (EMT) that normal cells undergo during development is partially mirrored among different breast cancers and cell lines. IPA's new Downstream Effects Analysis, Transcription Factor Analysis tool, and Human Isoform Viewer are used to explore the molecular differences between breast cancer-derived cell lines using RNA-Seq data.

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on radiation oncology data. Attendees will learn how MAQuery will help in the search for genes with particular expression profiles in cancers.

**6:30 Close of Day**

**THURSDAY, FEBRUARY 23**

**TRANSLATING BIOMARKER DRIVEN CANCER TREATMENTS INTO PRACTICE**

**8:30 am Chairperson's Remarks**

**8:35 The Road to Personalized Medicine is Paved with Data and Information**

*John Quackenbush, Ph.D., Professor, Biostatistics and Computational Biology, Cancer Biology Center for Cancer, Dana-Farber Cancer Institute*  
This presentation will explore the elements necessary to successfully develop an integrated program using genomics and medical data, together with other sources of information, to arrive at robust biomarkers that can be reliably used in a clinical setting.

**9:05 Oral Chemotherapy Translation: Why a Web-Based Data Repository is Essential for Pharmacist Use of Oral Anticancer Treatments**

*Tibor van Rooij, Ph.D. Candidate, Faculty of Pharmacy and Pharmaceutical Sciences, University of Alberta*

Increasingly chemotherapeutic options are available in oral form and it is expected this trend will continue. The use of uninformed oral chemotherapy can result in misunderstandings, preventable toxicities, or inadequate therapy. We created a practical and targeted e-reference for healthcare use.

**9:35 Clinical Information Systems for Genome Directed Cancer Treatment**

*Mia Levy, M.D., Ph.D., Assistant Professor, Biomedical Informatics and Medicine, Vanderbilt University; Cancer Clinical Informatics Officer, Vanderbilt Ingram Cancer Center*

We describe the clinical information systems that support our genome directed cancer treatment. This includes integrating tumor gene mutation testing results into the electronic health record and decision support genome directed cancer treatment including standard of care and clinical trials.

**10:05 Sponsored Presentation (Opportunity Available)**

**10:20 Coffee Break**

**11:00 How to Translate Next-Generation Sequencing Data into Clinically Useful Information**

*Fuad Gwadry, Bioinformatics Consultant, Sequenom Center for Molecular Medicine*  
One of the main challenges facing the implementation of next-generation sequencing in clinical practice is the bioinformatic data analysis. This talk will illustrate bioinformatic strategies used to identify the novel variants that may be clinically relevant.

**11:30 Skinomics - Part I**

*Miroslav Blumenberg, Ph.D., Associate Professor, Dermatology and Biochemistry, NYU Langone Medical Center*

'SKINOMICS' is a field of Bioinformatics specifically applied to Dermatology and Skin Biology. It's primed to enter individualized medicine. Because of its accessibility, skin has been among the first organs analyzed using DNA microarrays. Melanomas, carcinomas, psoriasis, and wound healing have been intensely investigated.

**12:00 pm Skin-Based Genomic Biomarkers for Disease Detection - Part II**

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

The skin is an underutilized source of biomarkers. This presentation will discuss proof-of-concept studies, the development of a clinical test for melanoma detection, and other uses of Epidermal Genetic Information Retrieval (EGIRT), for genomic-based assays of dermatologic and systemic disease.

**12:30 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own**

**BIOINFORMATICS IN THE CLOUD**

**1:45 Chairperson's Remarks**

**1:50 Bioinformatics in the Cloud: An Affordable Alternative**

*Giles Day, Co-Founder and Managing Director, Distributed Bio, LLC*

**2:20 Translational Bioinformatics: A Multidisciplinary Approach to Biomedical Research**

*Speaker to be Announced*

**2:50 Bioinformatics on Cloud Cyberinfrastructure**

*Speaker to be Announced*

**3:20 Close of Conference**

**10:00 Transition to Plenary Keynote**

**PLENARY KEYNOTE**

**10:10 Plenary Keynote Presentation (See Page 3 for Details)**

**11:00 Refreshment Break in the Exhibit Hall with Poster Viewing**

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**GENOMICS AND INTEGRATING MULTIPLE-OMIC DATA TYPES**

**12:00 pm Clinical Grade Genomics: The Informatics Challenge**

*Peter J. Tonellato, Ph.D., Visiting Professor, Senior Research Scientist, Pathology, BIDMC & Center for Biomedical Informatics, Harvard Medical School*

**12:30 Integrative Network Biology Provides Novel Predictors of Human Disease**

*Rod Nibbe, Ph.D., Senior Scientist & Director of Product Development, NEO Proteomics, Inc.*

Network biology approaches are described that integrate multiple -omic data types to identify parsimonious candidate markers in cancer and Alzheimer's. Network based markers are powerful features for classification and can identify new drug target candidates.

**1:00 Luncheon Presentations (Sponsorship Opportunities Available) or Lunch on Your Own**

**2:00 Ice Cream Refreshment Break in the Exhibit Hall with Poster Viewing**

**PLENARY KEYNOTE PANEL**

**2:30 Plenary Keynote Panel (See Page 2 for Details)**

**3:50 Refreshment Break & Poster Awards in the Exhibit Hall**

**GENE EXPRESSION & DATA ANALYSIS**

**4:25 Chairperson's Remarks**

**4:30 Detection of Lung Cancer Molecular Subtypes by Gene Expression Arrays, Protein Immunohistochemistry and PCR from Paraffin Based Assays**

*David Neil Hayes, M.D., M.P.H., Assistant Professor, Clinical Research, Hematology/Oncology, University of North Carolina, Chapel Hill*

Gene expression profiling has revealed reproducible subtypes of lung cancer not detectable by routine clinical diagnostic methods. We investigate the nature of the tumor subtypes in terms of clinical relevance and biologic underpinnings such as associated mutations and potential cell of origin.

**5:00 Recovering Upstream Regulatory Pathways and Predicting Side Effects from Gene Expression Signatures**

*Avi Ma'ayan, Ph.D., Assistant Professor, Department of Pharmacology & Systems Therapeutics, Mount Sinai School of Medicine*

This talk discusses analysis of gene expression signatures from individual patient tissues to uniquely identify upstream transcription factors, protein complexes, and protein kinases, as well as a method to predict new indications and side effects for approved and experimental drugs from gene expression signatures.

**5:30 Comparing Two Microarray Covariance Matrices Based on a Novel Conjugate Bayes Factor**

*James Zhou, Ph.D., Director, Statistical Operations, Clinical Development, Social & Scientific Systems, Inc.*

A novel conjugate Bayes factor is developed to assess the equality of two multivariate normal covariance matrices in microarray gene expression data analysis. We illustrate this test and implement it using prior parameters estimated empirically from a large collection of gene sets.

**6:00 Web Portal for Integrated Analysis of Radiation Responsive Cancer Gene Expression Profiles**

*Uma Shankavaram, Ph.D., Staff Scientist, National Cancer Institute & NIH*

This presentation will describe a web portal called MAQuery we have created that would house cancer related microarray expression data focusing primarily



# Pricing and Registration Information

## Regular Pricing – A La Carte Options

### PARTNERING FORUMS (FEB 19-20)

\$1395

Emerging Targeted Oncology Partnering Forum  
Early Stage Molecular Diagnostics Partnering Forum

### SYMPOSIA (FEB 19-20)

\$1395

\$995

Targeting Cancer Stem Cells in Oncology	Point-of-Care Diagnostics
Cloud Computing	Next-Generation Pathology
Phage and Yeast Display of Difficult Targets	

### SHORT COURSES (FEB 20)

1 Short Course	\$595	\$295
2 Short Courses	\$895	\$495

<b>Afternoon</b>	<b>Dinner</b>
SC1 Identification, Characterization and Targeting of Cancer Stem Cells	SC10 Digital PCR Applications and Advances
SC2 Roadmap for Accelerating Commercialization of Molecular Diagnostics	SC11 CTCs from Bench to Bed: Streamlining from Research to Clinical Practice
SC3 Understanding EMT: Mechanisms and Metastasis to MET	SC12 First-in-Human Study and Risk Mitigation Strategy for Biologics
SC4 Network Pharmacology	SC13 Scientists: Business Training 101
SC5 Next-Generation Sequencing in the Cloud Era	SC14 Adaptive Oncology Clinical Trials
SC6 Marketing and Sales: Science Training 101	SC15 Latest Advances in Molecular Pathology, Part II (Advanced)
SC7 Latest Advances in Molecular Pathology, Part I (Basic)	SC16 Ontologies for the Bio-Science Industry: Development & Use
SC8 Best Practices in Translational Informatics	SC17 Mastering Physicochemical Properties-Based Analysis to Deliver Improved Drug Candidates
SC9 Pharmacology and Drug Discovery in the Allosteric World	SC18 Regulatory Approval of a Therapeutic & Companion Diagnostic: Nuts & Bolts

### CORE PROGRAMS (FEB 21-23)

Advance Registration until January 20, 2012	\$2055	\$1155
Registration after January 20, 2012, and on-site	\$2195	\$1205

#### Diagnostics Channel

Molecular Diagnostics  
Personalized Diagnostics  
Cancer Molecular Markers  
Circulating Tumor Cells  
Genomic Screening and Diagnosis

#### Drug Discovery & Development Channel

Mastering Medicinal Chemistry  
Translational Science  
Oncology Clinical Trials  
De-Risking Drug Discovery

#### Informatics Channel

Integrated R&D Informatics  
Bioinformatics/  
Cancerinformatics

#### Cancer Channel

Cancer Biologics  
Cancer Molecular Markers  
Circulating Tumor Cells  
Oncology Clinical Trials  
Bioinformatics/Cancerinformatics



### TRI-CON ALL ACCESS PACKAGE- BEST VALUE! (FEB 19-23)

See bottom left for recommended pairings.

**Includes: 1 Symposium OR Partnering Forum, 2 Short Courses, and 1 Conference Program**

**Commercial**

**Academic, Government, Hospital-affiliated**

Advance Registration until January 20, 2012	\$3095	\$1835
Registration after January 20, 2012, and on-site	\$3215	\$1905

#### ADDITIONAL REGISTRATION DETAILS

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

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

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February 19-23, 2012

San Francisco, CA

The Moscone North Convention Center  
& InterContinental San Francisco Hotel

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\*Alumni and BayBio Discount cannot be combined. Discounts not applicable on Event Short Courses

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are due by **January 13, 2012**. Once your registration has been fully processed, we will send an email containing a unique and session-specific link allowing you to submit your poster abstract. If you do not receive your link within 5 business days, please contact [jring@healthtech.com](mailto:jring@healthtech.com).

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If you are unable to attend but would like to purchase the Molecular Medicine Tri-Conference CD for \$795 (plus shipping), please visit [www.triconference.com](http://www.triconference.com). Massachusetts delivery will include sales tax.

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### TRI-CON ALL ACCESS PACKAGE - Recommended Pairings

#### Partnering Forum

Emerging Targeted Oncology Partnering Forum

OR

#### Symposia

Targeting Cancer Stem Cells in Oncology  
Display of Difficult Targets

AND

#### Short Courses

SC1 Identification, Characterization and Targeting of Cancer Stem Cells  
SC10 Digital PCR  
SC12 First-in-Human Study and Risk Mitigation Strategy for Biologics  
SC14 Adaptive Oncology Clinical Trials

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At the InterContinental San Francisco Hotel  
February 19-20, 2012

- Topic-specific poster sessions
- Targeted audience

### Reserve Your Space by Jan. 13th!

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At the Moscone North Convention Center  
February 21-22, 2012

- Your poster will be available to over 3,000 delegates
- Posters will be on display for two full days in the exhibit hall
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