Final Agenda

Molecular Med TRI-CON 2013

February 11-15 • Moscone North Convention Center • San Francisco, CA

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20 YEARS OF | ADVANCING APPLIED SCIENCE & TECHNOLOGY

Conference Programs: Feb 13-15

Diagnostics Channel
Molecular Diagnostics
Personalized Diagnostics
Cancer Molecular Markers
Circulating Tumor Cells
Digital Pathology – NEW
Companion Diagnostics – NEW

Therapeutics Channel
Mastering Medicinal Chemistry
Cancer Biologics
Clinical and Translational Science

Clinical Channel
Oncology Clinical Trials
Clinical and Translational Science
Clinical Sequencing – NEW

Informatics Channel
Bioinformatics in the Genome Era
Integrated R&D Informatics and Knowledge Management

Cancer Channel
Cancer Molecular Markers
Circulating Tumor Cells
Predictive Pre-Clinical Models in Oncology – NEW
Oncology Clinical Trials
Cancer Biologics

Symposia: Feb 11-12
Targeting Cancer Stem Cells
Genomics in Medicine – NEW
Point-of-Care Diagnostics
Quantitative Real-Time PCR – NEW
Next Generation Pathology

Partnering Forum: Feb 11-12
Emerging Molecular Diagnostics

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Plenary Keynotes

Wednesday, February 13 8:00 – 9:40 am

Personalized Oncology – Fulfilling the Promise for Today's Patients

In honor of the 20th anniversary of the Molecular Medicine Tri-Conference, CHI and Cancer Commons will present a plenary panel on Personalized Oncology. Innovations such as NGS and The Cancer Genome Atlas have revealed that cancer comprises hundreds of distinct molecular diseases. Early clinical successes with targeted therapies suggest that cancer might one day be managed as a chronic disease using an evolving cocktail of drugs. Representing all five conference channels, Diagnostics, Therapeutics, Clinical, Informatics, and Cancer, a panel of experts will lead a highly interactive exploration of what it will take to realize this vision in the near future.

Topics for discussion include:

- Scientific approaches to treating cancer, involving deep molecular profiling and pathway analysis of individual tumors to design custom treatments, and then monitoring the tumor's response to therapy using sequential biopsies and CTCs.
- Open science initiatives to rapidly learn and refine the clinically actionable, molecular subtypes of cancer and how to treat them.
- New models of translational research that can slash the time and cost of developing highly targeted agents for rare subtypes.
- Efficient systems to enable patients affordable investigational drugs for testing in small proof-of-concept studies.
- Complementary computational approaches to identifying cancer pathways, targets, and subtypes.
- Pragmatic approaches for capturing treatment and outcomes data from every cancer patient, to validate and extend the knowledge of molecular subtypes and treatments.
- The industry ecosystem and what's needed to deliver personalized oncology services at scale.

- Moderator: Marty Tenenbaum, Ph.D., Founder and Chairman, Cancer Commons; Prominent AI Researcher; Cancer Survivor
- Tony Blau, M.D., Professor, Department of Medicine/Hematology and Adjunct Professor, Department of Genome Sciences, University of Washington; Attending Physician, Seattle Cancer Care Alliance; Co-Director, Institute for Stem Cell and Regenerative Medicine, University of Washington and the Program for Stem and Progenitor Cell Biology at the UW/FHCRC Cancer Consortium; Founder and Scientific Officer, Partners in Personal Oncology
- Sarah Greene, Executive Director, Cancer Commons
- Laurence Marton, M.D., Adjunct Professor, Department of Laboratory Medicine, University of California San Francisco; Former Dean of Medicine, University of Wisconsin
- Jane Reese-Coulbourne, MS, ChE, Executive Director, Reagan-Udall Foundation for the FDA; Former Board Chair, Lung Cancer Alliance; Cancer Survivor
- Anil Sethi, CEO, Pinch Bio; HL7 Pioneer and Health Informatics Entrepreneur
- Joshua Stuart, Ph.D., Associate Professor, Department of Biomolecular Engineering, University of California Santa Cruz

Thursday, February 14 8:00 – 9:40 am

Plenary Keynote Panel: Emerging Technologies & Industry Perspectives

This session features 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.

- Moderator: To be Announced
- Rudi Pauwels, Ph.D., Chairman & Founder, Biocartis
- Kevin Bobofchak, Ph.D., Pathway Studio Product Manager, Elsevier
- Jeremy Bridge-Cook, Ph.D., Senior Vice President, Research & Development, Luminex Corporation
- Panelist to be Announced, Remedy Informatics
- Harry Glorikian, Managing Partner, Scientia Advisors, LLC
- Lynn R. Zieske, Ph.D., Vice President, Commercial Solutions, Singulex, Inc.

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Sponsorship Opportunities Available

Co-located Event

BAYBIO Entrepreneur & Investor Roundtables

February 14, 2013, 4:00-7:00 pm

Connect with corporate venture, angel investors and VCs

www.baybioroundtables.com

2013 Conference-at-a-Glance

Monday, February 11

7:30 am	Registration and Morning Coffee
8:25-6:00 pm	Symposia
9:00-6:15 pm	Emerging Molecular Diagnostics Partnering Forum

Tuesday, February 12

8:25-12:00 pm	Symposia
8:45-6:00 pm	Emerging Molecular Diagnostics Partnering Forum
12:30 pm	Short Course Registration
1:30-4:30 pm	Afternoon Short Courses*
5:00-8:00 pm	Dinner Short Courses*

Wednesday, February 13

7:00 am	Registration and Morning Coffee
8:00-9:40 am	Plenary Keynote Session
9:40-11:00 am	Refreshment Break in the Exhibit Hall with Poster Viewing
11:00-12:40 pm	Conference Programs
12:40-1:45 pm	Luncheon Presentations or Lunch on Your Own
1:45-2:15 pm	20th Anniversary Cake in the Exhibit Hall with Poster Viewing
2:15-4:20 pm	Conference Programs
4:20-5:20 pm	Networking Reception in the Exhibit Hall with Poster Viewing
5:20-6:20 pm	Breakout Discussions in the Exhibit Hall

Thursday, February 14

7:00 am	Breakfast Presentations or Morning Coffee
8:00–9:40 am	Plenary Keynote Session
9:40-10:40 am	Refreshment Break in the Exhibit Hall with Poster Viewing
10:40-12:15 pm	Conference Programs
12:15-1:15 pm	Luncheon Presentations or Lunch on Your Own
1:15-1:40 pm	Refreshment Break in the Exhibit Hall with Poster Viewing
1:40-3:45 pm	Conference Programs
3:45-4:30 pm	Valentine's Day Celebration & Poster Competition Winner Announced in the Exhibit Hall *(Last Chance for Poster Viewing)*
4:30–6:35 pm	Conference Programs

Friday, February 15

8:00 am	Morning Coffee
8:30-10:35 am	Conference Programs
10:35-11:00 am	Coffee Break
11:00-12:30 pm	Conference Programs
12:30-1:45 pm	Luncheon Presentations or Lunch on Your Own
1:45-3:20 pm	Conference Programs
3:20 pm	Close of Conference

Valentine's Day Soiree!

Bubbly and chocolate anyone? Join us for a Valentine's Day celebration in the exhibit hall on Thursday, February 14 at 3:45. ** Sponsorship opportunities available! See page 47 for details.*

Short Courses: Tuesday, Feb 12

1:30-4:30pm

SC1 Identification & Characterization of Cancer Stem Cells
SC2 Commercialization Boot Camp: Manual for Success in the Molecular Diagnostics Marketplace
SC3 NGS Data and the Cloud
SC4 Best Practices in Personalized and Translational Medicine
SC5 Latest Advances in Molecular Pathology
SC6 Regulatory Approval of a Therapeutic & Companion Diagnostic: Nuts & Bolts
SC7 PCR Part I: qPCR in Molecular Diagnostics
SC8 Data Visualization
SC9 Methods for Synthesis & Screening of Macrocyclic Compound Libraries

5:00-8:00pm (Dinner)

SC10 PCR Part II: Digital PCR Applications and Advances
SC11 Sample Prep and Biorepositories for Cancer Research
SC12 Next-Generation Sequencing in Molecular Pathology: Challenges and Applications
SC13 Strategies for Companion Diagnostics Development
SC14 Patient-Derived Cancer Tissue Xenograph Models
SC16 Microfluidics Technology and Market Trends
SC17 Open Cloud & Data Science
SC18 Human Microbiome Research & Modern Molecular Technologies

Tell Us Your Story!

In 2013, we will be celebrating the 20th Anniversary of the Molecular Medicine Tri-Conference and 20 years of focusing on advancing applied science & technology. With all the breakthroughs and vast improvements and advances in research, technology and medicine during the last 20 years, we want to hear from you!

- **What prompted you to choose a career in the life sciences?**
- **What do you find as the most rewarding part of your job?**
- **Since choosing your career, what milestones have you been part of?**

We will be showcasing our attendees' stories onsite at this year's Tri-Conference. Send us a 45-60 second video sharing your story. Five attendees who submit a video will receive a complimentary registration for the 2014 Tri-Conference in San Francisco.

Please send your video to videos@healthtech.com – due to file size, we ask that you send your email through yousendit.com, a complimentary service for sending large files. Or you can send a DVD of your video to: CHI, 250 First Avenue, Suite #300, Needham, MA 02494 – Attn: MMTC Video Story

If you are in the Boston area; we can schedule a time to come to your office to record your story – email videos@healthtech.com.

For more information, visit: Tri-Conference.com/videostory

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Hotel Information

Conference Venue:
The Moscone North Convention Center
747 Howard Street
San Francisco, CA 94103
www.moscone.com

Host Hotel:
San Francisco Marriott Marquis
55 Fourth Street
San Francisco, CA 94103
(T) 415-896-1600
Reservations: 888-575-8934

Discounted Group Rate: $229 s/d*
Cutoff Date: January 14, 2013

** Room Rate includes complimentary internet access in your guestroom*

Additional Recommended Hotel:
InterContinental San Francisco Hotel
888 Howard Street
San Francisco, CA 94103
(T) 415-616-6500

Discounted Group Rate: $235 s/d
Cut Off Date: January 14, 2013

Please visit TriConference.com to make your reservations online or call the hotel directly to reserve your sleeping accommodations. You will need to identify yourself as a Molecular Med Tri-Con attendee to receive the discounted room rate with the host hotel. Reservations made after the cut-off date or after the group room block has been filled (whichever comes first) will be accepted on a space- and rate-availability basis. Rooms are limited, so please book early.

**We understand that you have many choices when making your travel arrangements, and may ultimately decide to stay at another hotel. Please understand that reserving your room in the CHI room block allows you to take full advantage of the conference sessions, events and networking opportunities, and ensures that our staff will be available to help should you have any issues with your accommodations.

Reserve your hotel and save $100 off your conference registration*

*You must book your reservation under the Tri-Conference room block for a minimum of 4 nights at the Marriott or the Intercontinental Hotel. One discount per hotel room.

Travel Information

Flight Discount:
Special discount have been established with American Airlines. Please use one of the following methods:

- Call 1-800-433-1790 (authorization code 2923BM).
- Go online at www.aa.com/group (enter 2923BM in promotion discount box).
- Contact our designated travel agent Wendy Levine at 1-877-559-5549 or wendy.levine@protravelinc.com

Car Rental Discounts:
Special discount rentals have been established with Hertz for this conference.

- Call Hertz directly at 800-654-3131 and reference our Discount Number 04KL0004

TRI-CON All Access Package

Get the best 5-day value! Our All Access Packages is a convenient, cost-effective way to attend each aspect of Molecular Med TRI-CON 2013. Package includes access to 1 Symposium or Partnering Forum, 2 Short Courses and 1 Conference Program.

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with the TRICON

PHARMA-BIO PARTNERING FORUMS

Emerging Molecular Diagnostics

Program Advisors *(as of September 18, 2012)*

Robert Schueren, Vice President & General Manager, Genomics, Agilent Technologies, Inc.
Kevin Ellison, Director, Business Development, Almac Diagnostics
Cecilia Schott, Ph.D., Director, Business Development, Personalized Healthcare, AstraZeneca
John Meduri, Ph.D., Global Director, Strategic Planning & Business Development, Becton Dickinson
John Beeler, Ph.D., Director, Business Development, Theranostics, BioMerieux
Andrea H. Lauber, Ph.D., Global Head, Transactions for Clinical Biomarkers & Pharmacodiagnostics, Bristol-Myers Squibb Company
Rolf Ehrnstrom, Ph.D., CSO, DAKO (now part of Agilent)
Iain Miller, Ph.D., Global Head, Personalized Healthcare Strategy and Partnerships, GE Healthcare
Premal Shah, Ph.D., Director, Business Development, Genomic Health
Robert Lipshutz, Ph.D., Chief Business Officer & Senior Vice President, Strategic Partnerships, Institute for Systems Biology
Steven Anderson, Ph.D., CSO & Vice President, LabCorp
Jorge Leon, President & CEO, Leomics Consulting
Frederick Pla, Ph.D., Vice President, Corporate Business Development, Life Technologies
Luigi Cantanzariti, Ph.D., GPD Executive Director, Novartis Molecular Diagnostics
Anh Van Le, Director, Franchise Development, Ortho Clinical Diagnostics
Morten Sogaard, Ph.D., Executive Director, Head, Biotechnology & Precision Medicine, External R&D Innovation, Pfizer
Stephen Little, Ph.D., Vice President, Personalized Healthcare, QIAGEN
Nicholas Conti, Ph.D., Vice President, Business Development, Quest
Thomas Li, Ph.D., Senior Director, Technology, Roche Diagnostics
Emily Winn-Deen, Ph.D., President, Rx Dx Advisors, Inc.
Harry Glorikian, Managing Partner, Scientia Advisors
Ali Tinazli, Ph.D., Director, Business Development & Sales, Biosciences North America, SONY-DADC
Eric Lai, Ph.D., Senior Vice President & Head, Pharmacogenomics, Takeda Pharmaceuticals
Brian Atwood, MBA, Managing Director, Versant Ventures
Katherine Tynan, President, Tynan Consulting, Inc.
Maureen Cronin, Ph.D., Consultant

Confirmed Company Presentations *(as of September 18, 2012)*

BronchoGen: A New Genomic Test for Lung Cancer
Michael Webb, CEO, Allegro Diagnostics, Inc.

Structural Biomarkers in Cancer Diagnostics: Technology and Case Studies
Arnon Chait, Ph.D., President, AnalizaDx, LLC

Barcode All Your Biomarkers with 4,096-Plex Digital Beads
Winston Ho, Ph.D., President, Applied BioCode, Inc.

Innovative, Rapid, Easy to Use, High Multiplex, Diagnostic and Research Systems to Enable Personalized Medicine
Koen Van Acker, Ph.D., Scientist, Research & Assay Development, Biocartis NV

Development of Simple, Cost-Effective Isothermic Molecular Diagnostic Assays for Point-of-Care or Near-Patient Settings
Huimin Kong, Ph.D., President & CEO, BioHelix Corp.

The Role of Methylarginine Biomarkers in 21st Century Personalized Medicine
John Aletta, Ph.D., Principle Scientist, CH3 Biosystems LLC

Precision Microfilters Enable Rapid and Efficient Collection followed by Sophisticated Analysis of Circulating Tumor Cells
Cha-Mei Tang, Sc.D., President and CEO, Creatv MicroTech, Inc.

Unyvero LRT - Moving a Highly Multiplexed Infectious Disease Test Cartridge for Lower Respiratory Tract Application through the Clinic towards an FDA Clearance
Oliver Schacht, Ph.D., CEO, Curetis AG

Applications of a Liquid Biopsy Platform for Next-Generation Sequencing of CTC Populations
Paul Dempsey, Ph.D., Vice President, Bioengineering, Cynvenio Biosystems, Inc.

Molecular Analysis of Circulating Tumor Cell Samples for Oncology Diagnostics Using the IsoFlux Rare Cell Access System
Michael Schwartz, Program Director, Business Development, Fluxion Biosystems, Inc.

GeneCentric Diagnostics: Developing Novel Personalized Cancer Diagnostics
Myla Lai-Goldman, Ph.D., CEO, GeneCentric Diagnostics, Inc.

Introducing Cell-Seq: Massively Parallel Single-Cell Genomics
Andro Hsu, Ph.D., Vice President, Products, GigaGen, Inc.

Exploiting the Body's Own Detection Network for Reliable Diagnostics of Cancer and Autoimmune Diseases
Mats Grahn, CEO, Immunovia AB

Accelerating Development of Highly Sensitive Diagnostics Using *in silico* Powered Design
Alice Jacobs, Ph.D., Chairman & CEO, IntelligentMDx

Discovery and Application of an Epigenomic Signature to Generate a Revolutionary New Molecular Diagnostic and to Identify Novel Therapeutic Targets in RA and Other Autoimmune Diseases
Jonathan Lim, Ph.D., CEO, NexDx, Inc.

A Unique MDx Platform and Novel Partnering Strategy for High-Value MDx Development of Molecular Diagnostic and Companion Diagnostic Tests
David Jackson, Vice President, Business Development, PrimeraDx

Flow Chemistry Process Biocompatible Inorganic High Quantum Yield Tetrapod Quantum Dots for the Next Generation of Diagnostic Assays, Multiplexed Drug Delivery Platforms and POC Devices
Stephen B. Squires, President, Quantum Materials Corporation

Applications of Immune Cell Profiling by Next-Generation Sequencing
Tom Willis, Ph.D., CEO, Sequenta, Inc.

Cell Adhesion Matrix-Based Isolation of Invasive Circulating Tumor Cells – iCTCs
Casey Eitner, Senior Vice President, Business Development, Vitatex, Inc.

PARTNER DIRECT

Partner Direct is a networking tool designed to facilitate collaboration amongst emerging companies and potential strategic partners. It is only available to registered attendees of the Pharma-Bio Partnering Forums. CHI employs partnering software so the audience will have the opportunity to sign up for one-on-one meetings ahead of time with company presenters during the conference.

For more information on CHI's Partnering Forums please visit **PharmaBioPartnering.com**

Second Annual

Targeting Cancer Stem Cells

Promising New Therapeutics for Oncology

Monday, February 11

7:30 am Registration and Morning Coffee

8:25 Chairperson's Opening Remarks

Characterizing CSCs and their Niche

8:30 Suppression of Acquired Resistance in Prostate Cancer through Depletion of Notch- and Hedgehog-Dependent Tumor-Initiating Cells

Carlos Cordon-Cardo, M.D., Ph.D., Professor and Chairman, Department of Pathology; Professor, Department of Genetics and Genomic Sciences, The Mount Sinai School of Medicine

9:00 A Restricted Cell Population Propagates Glioblastoma Growth Following Chemotherapy

Luis F. Parada, Ph.D., Diana K. and Richard C. Strauss Distinguished Chair in Developmental Biology, Southwestern Ball Distinguished Chair in Nerve Regeneration Research, University of Texas Southwestern Medical Center

9:30 Radiation-Induced Reprogramming of Breast Cancer Cells

Frank Pajonk, M.D., Ph.D., Associate Professor, Radiation Oncology, David Geffen School of Medicine, University of California Los Angeles

10:00 Coffee Break with Exhibit and Poster Viewing

10:30 The Tumor Microenvironment as a Target for Breast Cancer Stem Cells

Max S. Wicha, M.D., Distinguished Professor of Oncology and Director, University of Michigan Comprehensive Cancer Center

The tumor microenvironment plays an important role in the regulation of breast cancer stem cells. Cytokine loops modulate cancer stem cell microRNAs which effect stem cell self-renewal and EMT/MET transitions. Targeting these pathways provides a novel therapeutic strategy.

Screening Platforms & Assays

11:00 Defining Novel Drugs and Pathways that Selective Target Human Cancer Stem Cells

Mick Bhatia, Ph.D., Director and Senior Scientist, McMaster Stem Cell and Cancer Research Institute, McMaster University

Pathways that regulate self-renewal processes are shared among normal stem cells, as well as rare cancer cells with stem cell properties. In the human, approaches to isolate, interrogate, and define drugs selectively targeting "cancer stem cells" will be discussed.

11:30 Sponsored Presentations *(Opportunities Available)*

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:25 Chairperson's Remarks

1:30 Identification of Specific Cancer Stem Cell Inhibitors by Chemical Genetic Screens

Michael Detmar, M.D., Professor of Pharmacogenomics, Institute of Pharmaceutical Sciences, Swiss Federal Institute of Technology, ETH Zurich

We have carried out chemical library screens in melanoma stem cells derived from human melanoma vs. normal neural crest stem cells and non-stem cell-like melanoma cells. We identified several specific cancer stem cell inhibitors, and potential novel targets for the selective inhibition of cancer stem cells.

2:00 Cancer Stem-Like Cells from Colon and Lung Tumors Provide Tools for Drug Discovery and Development

Jennie Mather, Senior Vice President, Stem Cell Technologies, Macrogenics, Inc.

We have created a series of unique cancer stem cell lines that self renew, reconstitute patient-like tumors from a single cloned cell, and metastasize from xenografts. These lines are used as drug discovery and screening tools.

Pre-Clinical Models

2:30 Targeted Therapy of the Tumor-Initiating Lgr5 Cell in Colorectal Cancer

Melissa R. Juntilla, Ph.D., Scientist, Molecular Biology, Genentech, Inc.

With the availability of both a pharmacologic and genetic means for selective Lgr5 targeting, we aim to explore the feasibility of targeting the tumor-initiating Lgr5 cell in colorectal cancer and furthermore identify potential resistance mechanisms that occur as a result of Lgr5 targeted therapy.

3:00 Refreshment Break with Exhibit and Poster Viewing

3:30 Novel Strategies for the Detection and Therapeutic Eradication of Leukemia Stem Cells

Leslie Crews Robertson, Ph.D., Jamieson Laboratory, Sanford Consortium for Regenerative Medicine & Moores UC San Diego Cancer Center

Leukemia progression and relapse is fueled by leukemia stem cells (LSC) harboring aberrant self-renewal, differentiation and survival capacity. Activation of stem cell pathways promotes LSC generation in chronic myeloid leukemia, and these pathways represent novel therapeutic targets currently under investigation.

4:00 Targeting Quiescent and Proliferating AML Stem Cells

Robert J. Tressler, Ph.D., Vice President, Research & Development, Cellerant Therapeutics, Inc.

Targeting CSCs is required for more effective cancer treatment. We identified antigens expressed on AML stem cells and are developing antibodies against these targets that bind AML patient samples, have antitumor activity *in vitro* and *in vivo* and kill proliferating and quiescent AML cells, making these mAbs promising therapeutic candidates for AML.

4:30 ET-101: A Novel Therapeutic Antibody Targeting Colorectal Cancer Stem Cells

Peter Chu, Vice President, US Operations and Cancer Biology, Bionomics

ET-101 targets a key cancer stem cell (CSC) receptor overexpressed in CRC and other solid tumors. Pre-clinical data support our therapeutic hypothesis that ET-101 targeting of CSCs can lead to durable cures in the clinic by eliminating stem cells at the root of cancer.

5:00 Breakout Discussions *(See Web for Details)*

6:00 Close of Day

Tuesday, February 12

8:00 am Morning Coffee

8:25 Chairperson's Remarks

Translational Considerations

8:30 Targeting FAK, PI3K/mTOR and Wnt Signaling: Clinical Candidates that Selectively Target Cancer Stem Cells
Jonathan Pachter, Ph.D., Vice President & Head, Research, Verastem, Inc.
FAK, PI3K/mTOR , and Wnt/β-catenin pathways have emerged as critical targets for cancer stem cells. Our selective small molecule inhibitors of each of these have been found to reduce CSCs in cellular and *in vivo* tumor models.

9:00 Development of a Wnt Pathway Antagonist Antibody that Inhibits Tumor Growth and Reduces Cancer Stem Cell Frequency
Tim Hoey, Ph.D., Senior Vice President, Cancer Biology, OncoMed Pharmaceuticals

9:30 Sponsored Presentations *(Opportunities Available)*

10:00 Coffee Break with Exhibit and Poster Viewing

Updates from the Clinic

10:30 How to Target Cancer Stem Cells?
Chiang J. Li, M.D., FACP, President, CEO & CMO, Boston Biomedical, Inc; Head, Global Oncology, Dainippon Sumitomo Pharma Group

11:00 Active Immunotherapy for Cancer Stem Cells
John S. Yu, M.D., Professor & Vice Chairman, Neurosurgery, Cedars-Sinai Medical Center; Chairman & CSO, ImmunoCellular Therapeutics
Limitations of present therapies for solid cancers may be due to the resistance of cancer stem cells. Cytotoxic T Lymphocytes generated by vaccinations with dendritic cells pulsed with antigens derived from CSCs could efficiently deplete the tumor of its most virulent population.

11:30 Cycling Toward Leukemia Stem Cell Elimination with a Selective Sonic Hedgehog Antagonist
Wendy J. Levin, M.D., Director, Early Clinical Oncology, Pfizer
Compelling studies suggest that self-renewing leukemia stem cells (LSC), first identified in acute myeloid leukemia (AML), promote therapeutic resistance and relapse—the leading causes of leukemia mortality. Clinical studies with the selective sonic hedgehog inhibitor PF-04449913 have shown clinical benefit as single agent in this group of recalcitrant diseases, suggesting that this class of agents may be useful to consider as therapeutic options in patients with leukemia.

12:00 pm Close of Symposium

Symposium — February 11-12

Inaugural

Genomics in Medicine

Individualized Care for Improved Outcomes

NEW

Monday, February 11

7:30 am Registration and Morning Coffee

8:25 Chairperson's Opening Remarks

Screening for Rare and Difficult to Diagnose Diseases

8:30 KEYNOTE PRESENTATION: Genomically-Supported Diagnostic and Drug Reposition Strategies out of Academia
Hakon Hakonarson, M.D., Ph.D., Director, Center for Applied Genomics, Children's Hospital of Philadelphia
This talk will discuss genomic strategies applied in academia to identify subsets of patients who, based on their genetic make-up, are predicted to have a favorable response profile to drugs that come from reposition opportunities.

9:00 Evolving Approaches to Mutation Detection in Rare Diseases
Tom Scholl, Vice President, Research & Development, Integrated Genetics, LabCorp
Emerging trends in this field that include the expansion of content in clinical tests to include many loci and increased clinical sensitivity by expanding numbers of mutations detected or whole gene sequencing will be presented.

9:30 From Raw Sequencing Data to Functional Interpretation
Daniel MacArthur, Ph.D., Group Leader, Analytic and Translational Genetics Unit, Massachusetts General Hospital
This presentation will discuss the key lessons learned from large-scale sequencing studies in both common and rare diseases with a particular focus on finding mutations underlying severe muscle diseases.

10:00 Coffee Break with Exhibit and Poster Viewing

10:30 Providing Whole Genome Sequencing in the Clinic
David Dimmock, M.D., Assistant Professor, Pediatrics, Medical College of Wisconsin
This presentation will focus on advances in the implementation of genome wide sequencing in clinical practice. It will address counseling and consent issues specific to testing children. Specifically, it will highlight the challenges of execution in the acute care setting.

11:00 Clinical Utility of Whole Exome Sequencing
Christine M. Eng, M.D., Professor, Department of Molecular and Human Genetics, Baylor College of Medicine
This presentation will discuss the role of whole exome sequencing in the diagnostic evaluation of patients with challenging phenotypes of genetic etiology. Examples of clinical utility, directed medical care, and cost-effectiveness of the whole exome approach to clinical diagnostics will be presented.

11:30 A Neuronal Carnitine Deficiency Hypothesis for Autism
Arthur L. Beaudet, M.D., Henry and Emma Meyer Professor and Chair, Department of Molecular and Human Genetics, Baylor College of Medicine
We have published a paper entitled "A common X-linked inborn error of carnitine biosynthesis may be a risk factor for nondysmorphic autism" (PMID: 22566635). We propose a neuronal carnitine deficiency hypothesis as one risk factor or cause for autism whereby 10-20 of autism might be preventable.

12:00 pm Luncheon Presentation
(Sponsorship Opportunity Available) **or Lunch on Your Own**

Predictive Tests for Improved Patient Outcomes

1:25 Chairperson's Remarks

1:30 Implementation of Personalized Healthcare into Clinical Practice: Lessons Learned
Kathryn Teng, M.D., FACP, Director, Center for Personalized Healthcare, Cleveland Clinic
Integrating a pharmacogenetics program into clinical practice requires a vision for the future of healthcare and a roadmap to reach that vision. Pioneering the road to achieving this vision has brought challenges and has allowed for the creation of solutions that might be applied universally.

2:00 Molecular Profiling of Tumors to Select Therapy in Patients with Advanced Refractory Tumors
Ramesh Ramanathan, M.D., Medical Director, The Virginia G. Piper Cancer Center Clinical Trials
This presentation will discuss molecular profiling of tumors using IHC, CGH and whole genome/exome sequencing of tumors to find actionable targets for therapy. Clinical trials and case reports of patients treated by this approach will be presented.

2:30 Sponsored Presentations *(Opportunities Available)*

3:00 Refreshment Break with Exhibit and Poster Viewing

3:30 Gene Panels vs. Whole Exome Sequencing in Cancer Molecular Testing
Madhuri Hegde, Ph.D., FACMG, Associate Professor, Senior Director, Emory Genetics Laboratory, Department of Human Genetics, Emory University School of Medicine

4:00 Next Generation Sequencing and Cancer Diagnostics
Phil Stephens, Ph.D., Vice President, Cancer Genomics, Foundation Medicine
Foundation Medicine has developed FoundationOne™, a CLIA-certified, comprehensive cancer genomic test that analyzes routine clinical specimens for somatic alterations in 189 relevant cancer genes. Experience with the initial 1,000 consecutive patients will be presented.

4:30 KEYNOTE PRESENTATION: Clinical Cancer Genotyping – Snapshot
John Iafrate, M.D., Ph.D., Assistant Professor, Pathology, Harvard Medical School; Assistant Pathologist, Massachusetts General Hospital
The challenges and opportunities of implementing a broad genotyping assay in routine clinical management of cancer patients will be discussed. Snapshot was launched over 3 years ago at the Massachusetts General Hospital, with the goal of providing all cancer patients with a genetic fingerprint to guide therapeutic decisions. Lessons learned will be outlined, and a roadmap to effectively move testing forward into the Next Gen sequencing era.

5:00 Breakout Discussions *(See Web for Details)*

6:00 Close of Day

Tuesday, February 12

8:00 am Morning Coffee

Data Management and Analysis

8:25 Chairperson's Remarks

8:30 Under the Hood of the 1000 Genomes Project
Mark A. DePristo, Ph.D., Associate Director, Medical and Population Genetics Analysis, Broad Institute of MIT and Harvard (on behalf of The 1000 Genomes Project Consortium)
This presentation discusses the evolution of the next-generation sequencing (NGS) data underlying the public 1000 Genomes Project resource, from some of the earliest technologies of 2009 to today's state-of-the-art data. It will also highlight key NGS analytic advances originating from the Project.

9:00 Delivering Genomic Medicine: Challenges and Opportunities
Heidi L. Rehm, Ph.D., FACMG, Assistant Professor, Pathology, BWH and Harvard Medical School; Director, Laboratory for Molecular Medicine, Partners Healthcare Center for Personalized Genetic Medicine
This talk will cover the speaker's experience in offering clinical sequencing to patients, from disease-targeted panels to whole genome analyses as well as supporting the interpretation and delivery of those results to physicians. It will also cover approaches to data sharing within the community.

Sponsored by genomatix

9:30 From Sequence Files to Physicians Report and the Tools Needed to Get There
Martin Seifert, Ph.D., CEO, Genomatix Software
Providing actionable biology from NGS data in a report useful to the practicing clinician is difficult. Ensuring the report is accurate, reproducible, and reflects the biology of the patient is an even larger task. We will show examples of Genomatix' approach to these issues and how we successfully ensure a secure, accurate, and reproducible report, bridging the gap from sequencer to clinician.

10:00 Coffee Break with Exhibit and Poster Viewing

Getting Genomic Testing to Clinic

10:30 Sequence Data on Demand: Access, Visualization and Communication of Genome Sequence Data between Physicians, Researchers, and Patients
Sitharthan Kamalakaran, Ph.D., Senior Member, Research Staff, Philips Research North America
Patients' genome sequences are informative for clinical care over the patient's lifetime and not just for the diagnosis at hand. We present a web-accessible interface for clinicians to integrate relevant patient genome data in their routine practice through clinically-framed queries.

11:00 Transitioning New Technologies from the Bench to the Bedside: Direct Fetal Testing Using Circulating Cell-Free DNA
Allan T. Bombard, M.D., CMO, Sequenom
This presentation will address clinical test implementation of new tests in the US, using circulating cell-free DNA for noninvasive prenatal testing (NIPT) of fetal aneuploidy from maternal plasma as an example.

11:30 Moving Genomic Screening to the Clinic: Next Steps
Bruce R. Korf, M.D., Ph.D., Wayne H. and Sara Crews Finley Chair in Medical Genetics; Professor and Chair, Department of Genetics; Director, Heflin Center for Genomic Sciences, University of Alabama at Birmingham
Since the sequencing of the human genome there has been an expectation that a flood of advances would find their way to the clinic, and, indeed, the pace of translation of genomics to clinical application is accelerating. It is likely that the future of medical care will evolve by the convergence of two disruptive technologies – that of information science and genomics, which, in a sense can be viewed as one and the same.

12:00 pm Close of Symposium

Second Annual

Point-of-Care Diagnostics

Innovation for the Future of Personalized Healthcare

NEW

Monday, February 11

7:30 am Registration and Morning Coffee

8:25 Chairperson's Opening Remarks

The POC Testing Landscape: Intro Session

8:30 How Pharma, Point-of-Care, & Molecular Diagnostics Will Work Together Comfortably

Keith F. Batchelder, M.D., CEO, Genomic Healthcare Strategies
Peter S. Miller, COO, Genomic Healthcare Strategies
For decades, pharma business models have been reasonably static. The industry has done well; the blockbuster model has paid off; and hard times have been dealt with through consolidation, new research models/outsourcing research, and layoffs. This session will discuss the new problems and opportunities facing pharma caused by molecular medicine and the increased information required by doctors, payors, labs, patients, and institutions.

- The impact of molecular diagnostics on pharma business models
- Information needs of other participants
- Where companion diagnostics will fit in
- Effects on business models of point-of-care instruments
- How it will all fit together

10:00 Coffee Break with Exhibit and Poster Viewing

Innovation and Diversity in POC

10:30 KEYNOTE PRESENTATION: P4 Medicine: A Platform for Diagnostic Assessment in the New World of Medicine

Clay Marsh, M.D., Executive Director, Center for Personalized Health Care; Vice Dean and Senior Associate Vice President, Research, College of Medicine; Professor, Internal Medicine, Pulmonary, Allergy, Critical Care and Sleep Medicine; Director, Center for Critical Care and Respiratory Medicine, Ohio State University Medical Center
This talk will help attendees understand the rational for transitioning medicine delivery from therapeutics to diagnostic focus, the definition of Wellness and how diagnostic capabilities might impact this field, and what is meant by precision medicine.

11:00 PANEL DISCUSSION: POC Products for Diverse Settings

Moderator: Peter S. Miller, COO, Genomic Healthcare Strategies
Panelists: David Steinmiller, COO, OPKO Diagnostics
Richard Gill, Ph.D., Director & CEO, TruTouch Technologies, Inc.
Shuqi Chen, Ph.D., CEO, IQuum, Inc.
Rahul K. Dhanda, Vice President, Marketing, T2 Biosystems

12:00 pm Luncheon Presentation
(Sponsorship Opportunity Available) **or Lunch on Your Own**

In the Clinic and Around the World

1:25 Chairperson's Remarks

1:30 Clinical and Economic Impact of Point-of-Care Testing

Gyorgy Abel, M.D., Ph.D., Director, Molecular Diagnostics, Immunology & Clinical Chemistry, Department of Laboratory Medicine, Lahey Clinic Medical Center
The talk reviews the economy of POCT in the context of recent technological advancements and the changing healthcare environment, and highlights examples of clinical applications.

2:00 Technology Developer Perspective on POC in the Clinic

John McDonough, CEO & President, T2 Biosystems
This talk will focus on the challenges of developing diagnostic technologies for use in the POC setting. It will also include a review of the reasons why diagnostic testing at the point-of-care is poised for rapid growth and the technological and environmental challenges that could limit adoption.

2:30 Speaker to be Announced

3:00 Refreshment Break with Exhibit and Poster Viewing

3:30 Sophisticated Point-of-Care Diagnostic Devices based on 2D Paper Networks

Paul Yager, Ph.D., The Hunter and Dorothy Simmons Endowed Chair, Department of Bioengineering, University of Washington
Two-dimensional paper networks (2DPNs) can perform complex chemical processes, but at a far lower cost than conventional microfluidic or macrofluidic systems. We lead two ongoing "demonstration projects."

4:00 Implementation of Molecular Point-of-Care HIV-1 Diagnostics in Resource-Limited Settings

Marco L. Schito, Ph.D. (contractor), Henry M. Jackson Foundation, Vaccine Clinical Research Branch, DAIDS, NIAID, NIH
Even with the advantages of near-patient testing, developers and implementers must also consider the environment where the assay is deployed, the technical skill of the operator, and balance the gains by assessing costs beyond the instrument and cartridges.

4:30 PANEL DISCUSSION: How Will POC Save Money?

Moderator: Keith F. Batchelder, M.D., CEO, Genomic Healthcare Strategies
Panelists: Gyorgy Abel, M.D., Ph.D., Director, Molecular Diagnostics, Immunology & Clinical Chemistry, Department of Laboratory Medicine, Lahey Clinic Medical Center
John McDonough, CEO & President, T2 Biosystems

5:30 Breakout Discussions *(See Web for Details)*

6:00 Close of Day

Tuesday, February 12

8:00 am Morning Coffee

Navigating the Rise of POC

8:25 Chairperson's Remarks

8:30 Point-of-Care Diagnostics: A Consumer-Centric View

Stacy Feld, J.D., Partner, Physic Ventures
We will examine the landscape of innovations in the personal health and wellness market and the unique challenges venture investors consider in deploying capital in this sector.

9:00 Paper Point-of-Care Tests Affordable to All

Una Ryan, O.B.E., Ph.D., Managing Partner, Golden Seeds; Board member, AMRI, MSH (Management Sciences for Health), Diagnostics For All
DFA combines a novel business strategy with groundbreaking technology to enable human health and other benefits in both the developing and developed worlds.Two attributes are of vital importance in providing lasting benefits to all whom may need them: the right technology and the right business plan.

9:30 In Point-of-Care, Demand Will Trump Barriers
Peter S. Miller, COO, Genomic Healthcare Strategies
This talk will discuss reasons for optimism for the rapid spread of new point-of-care (POC) diagnostics technology. Traditional barriers (cost, regulation, reimbursement) won't slow down strong demand.

10:00 Coffee Break with Exhibit and Poster Viewing

A Peek at the Future of POC

10:30 Genetic Diagnostics Using Wireless Systems for Global Health
Syed A. Hashsham, Ph.D., Professor, Department of Civil and Environmental Engineering and Center for Microbial Ecology, Michigan State University
In this presentation, potential of low cost point-of-care genetic analysis systems will be discussed. Performance data related to Gene-Z, a hand-held gene analyzer, will be presented.

10:45 LifeLens: A Mobile Diagnostics Solution
Jason Wakizaka, Co-Founder and Managing Member, LifeLens LLC
The prevalence of diabetes and prediabetes is growing at an unprecedented rate. The key to slowing this trend is early detection and life-style interventions. However, during these early stages of development the patient remains asymptomatic, and thus rarely tested. Lifelens provides a low cost, mobile, non-invasive means of screening patients during these critical early stages.

11:00 Beyond Point-of-Care Dx
Ayub Khattak, CEO, Ruubix, Inc.
We are developing an easy-to-use, consumer facing digital diagnostic platform. The mobile device at the heart of our platform helps close the loop between patient-at-home and doctor to enable actionability such as immediate prescription tasking for antiviral and antibiotics depending upon test results.

11:15 Talk Title to be Announced
Dylan Morris, Co-Founder, Integrated Plasmonics Corporation

11:30 Interactive Clinical Guidelines: Bringing the Standard of Care to the Point-of-Care
Borna Safabakhsh, Co-Founder and CEO, Agile Diagnosis
Scott Freedman, Co-Founder, Agile Diagnosis
In this session, we'll discuss simple but powerful techniques for applying information technology to rapidly disseminate best practices using the latest diagnostics and new standards of care to clinicians at the point-of-care.

11:45 CellScope: Smartphone Imaging for Diagnosis
Erik Douglas, Co-Founder and CEO, CellScope
CellScope is bringing imaging to the mobile platform, with simple optical attachments to convert a stand phone into clinical-quality instruments, including an otoscope and a dermatoscope. Our system can be used by clinicians to store and share images, or by patients themselves for telehealth visits.

12:00 pm Close of Symposium

Symposium February 11-12

Inaugural

Quantitative Real-Time PCR

Applications for Molecular Diagnostics

NEW

Monday, February 11

7:30 am Registration and Morning Coffee

8:25 Chairperson's Opening Remarks

Assays of Extraordinarily High Selectivity and Sensitivity

8:30 Anchor Primers for the Detection of Extremely Rare Sequence Variants
Fred Russell Kramer, Ph.D., Professor, Department of Microbiology and Molecular Genetics, Public Health Research Institute, New Jersey Medical School

9:00 Sensitive Platform for FUS-CHOP Transcripts Detection in Human Liposarcoma
Heike Allgayer, M.D., Ph.D., Full Professor and Head, Department of Experimental Surgery, Medical Faculty Mannheim, Ruprecht Karls University Heidelberg; Head, Molecular Oncology of Solid Tumors Unit, DKFZ (German Cancer Research Center) Heidelberg
We describe a method using RT-PCR to identify and differentiate the fusion transcripts formed in the t(12;16)(q13;p11) chromosomal translocation. This was achieved using transcript individualized primers/probes, designed to detect specifically different variants in both frozen and FFPE tissues.

9:30 Quantification of RNA Degradation and its Use for Correct Quantification of RNA Transcript Number
Alexander Morley, M.D., Professor, Head, Minimal Residual Disease Group, Haematology & Genetic Pathology, Flinders University
We developed a simple PCR-based method for quantification of degradation and using the result to obtain the true level of mRNA transcripts in a sample. Compared to electrophoretic methods this is quantitative, more sensitive, quicker, cheaper and informative over a broader range of degradation.

10:00 Coffee Break with Exhibit and Poster Viewing

10:30 Use of RT-qPCR as a CMC Potency Assay
Chaminda Selgado, Ph.D., Head of Department, CMC Bioassay & Genomics, NDA-Analytics
The talk is based on my experience in using Reverse Transcriptase quantitative Polymerase Chain Reaction as an end-point read for a bioassay. Such assays can be considered for a wide range of drug molecules, both biologics and small molecules.

11:00 Harmonized Quantification of the BCR-ABL Transcripts using Certified Reference Materials
Philippe Corbisier, Ph.D., Scientific Project Manager, Reference Material Unit, European Commission
For the first time DNA material has been certified for its absolute copy number at levels of 10 copies /µL. This material will allow to harmonize the quantification of BCR-ABL transcripts and allow a reliable diagnostic of chronic myeloid leukemia.

11:30 Democratization of Molecular Diagnostics: Bringing Simplified Multiplex Real Time PCR Assays to a Hospital Near You
Sponsored by Luminex
Scott C. Johnson, Ph.D., Vice President, Product Development & Manufacturing, Luminex Corporation
The latest developments of Luminex's upcoming open-platform sample-to-answer molecular diagnostic system will be discussed, including how a clear focus on end-user needs will enable this technology to bring Molecular Dx capabilities to more hospitals and labs than before.

12:00 pm Luncheon Presentation
(Sponsorship Opportunity Available) **or Lunch on Your Own**

Assays of Enhanced Multiplicity

1:25 Chairperson's Remarks

1:30 Highly Divergent Gene Families are Efficiently Amplified Using Low-Concentration Initiator Primers
Kenneth E. Pierce, Ph.D., Senior Research Scientist, Department of Biology, Brandeis University
Detecting sequences of divergent bacterial or viral genes can be challenging. We demonstrate consistent amplification of each subfamily of the CTX-M antibiotic resistance genes using low concentration initiator primers (i Primers) in combination with a single pair of consensus LATE-PCR primers.

2:00 TOCE: A Technology for Changing the Molecular Diagnostics Paradigm
Sponsored by Seegene
David L. Dolinger, Ph.D., Executive Vice President, Business Development & Technology Realization, Seegene, Inc.
A new chemistry has been developed to fully exploit real-time PCR in high multiplex analysis. This chemistry provides the ability to detect multiple targets in a single fluorescence channel. TOCE is a highly specific and versatile chemistry that greatly expands the capabilities of currently installed widely-used real-time platforms.

2:30 New Developments in Detection of Rare Mutations Using Real Time COLD-PCR and DiSSeCT Technology
G. Mike Makrigiorgos, Ph.D., Director, Biophysics Laboratory and Medical Physics Division, Dana Farber Cancer Institute, Harvard Medical School
Multiplex detection of low-level mutant alleles in the presence of wild-type DNA is very useful e.g. for cancer, prenatal diagnosis and infectious diseases. We present new technologies, DiSSeCT and COLD-PCR that, when combined lead to detection of traces of mutations in cancer and circulating DNA.

3:00 Refreshment Break with Exhibit and Poster Viewing

3:30 Sloppy Molecular Beacon®: A New Paradigm in Rapid Pathogen Identification and Molecular Drug Susceptibility Testing
Soumitesh Chakravorty, Ph.D., Instructor, Center for Emerging Pathogens, NJMS, UMDNJ
Sloppy molecular beacons are mis-match tolerant fluorescent DNA probes which can identify a wide range of DNA sequences by generating probe-target hybrid "Tm signatures". This approach enables rapid and definitive identification of bacterial pathogens and MDR and XDR tuberculosis.

Digital PCR

4:00 Considerations for Using Digital PCR as a Diagnostics Tool
Alexandra S. Whale, Ph.D., Researcher, LGC Ltd.
dPCR offers the potential to revolutionize molecular diagnostics by improving technical reproducibility and analytical sensitivity, all using an unambiguous digital output. We are defining dPCR efficacy to provide guidelines for using this approach in order to facilitate maximum diagnostic impact.

4:30 Digital PCR Capabilities vs. Cost
Reginald Beer, Ph.D., Medical Diagnostics Initiative Leader, Center for Micro and Nanotechnologies, Lawrence Livermore National Laboratories
Digital PCR has shown promise in tumor and metastasis detection, copy number variation, and absolute quantitation, but it is still widely misunderstood, expensive, and dependent on the prerequisite amplification. In this talk we discuss costs and benefits of digital PCR.

5:00 Breakout Discussions *(See Web for Details)*

6:00 Close of Day

Tuesday, February 12

8:00 am Morning Coffee

CASE STUDIES

8:25 Chairperson's Remarks

8:30 Detection of Bacterial and Fungal Pathogens Using Novel Platform Molecular Diagnostics Target Technologies
Terry Smith, Ph.D., Professor and Vice President for Research, Natural Sciences, National University of Ireland Galway
Detection and identification of bacterial and fungal pathogens using quantitative real time PCR assays provide a rapid, sensitive and specific alternative to traditional infectious disease diagnostic test methods. The Molecular Diagnostics Research Group (MDRG) at NUI Galway, Ireland, have identified, exemplified and patented a suite of novel molecular targets for microorganism identification. Using the molecular targets identified, including the ssrA (RiboSEQ), rps 7 (MycoSEQ) and LepA (RiboTech) gene targets, a number of nucleic acid tests (NAT) for the sensitive and specific identification of bacterial and fungal pathogens of clinical significance have been developed. While numerous assays for organisms from a range of clinical fields have been developed, this presentation will outline real-time PCR –based assays for the organisms associated with hospital acquired and respiratory tract infections, including for example: Pseudomonas aeruginosa; Klebsiella pneumonia; Enterobacter aerogenes; Bordetella pertussis; Staphylococcus aureus; Candida species; and Aspergillus species.

9:00 Next-Generation PCR
Uffe Vest Schneider, M.D., Ph.D., CSO, QuantiBact A/S
TINA modified PCR primers improves efficacy and robustness of end-point as well as real-time PCR. The efficacy is improved in terms of stable PCR performance over a wide range of primer concentrations and annealing temperatures, shorter cycling time and improved sensitivity. The design rules for TINA modified primers are very simple, sequence independent, constant and reproducible. TINA modified primers are synthesized by conventional oligonucleotide synthesis. This presentation outlines when, why and how to use TINA modified primers in PCR.

9:30 Sponsored Presentations *(Opportunities Available)*

10:00 Coffee Break with Exhibit and Poster Viewing

10:30 Intraoperative PCR for Detection of Metastatic Head and Neck Cancer
Robert L. Ferris, M.D., Ph.D., FACS, Professor and Chief, Division of Head and Neck Surgery; Associate Director, Translational Research; Co-Leader, Cancer, Immunology Program, University of Pittsburgh Cancer Institute
This outlines the selection of relevant tumor gene markers, design and validation of their concordance using PCR with standard pathologic detection of metastatic carcinoma in regional lymph nodes, and the potential clinical application of PCR for nodal assessment within an intraoperative time frame.

11:00 Application of Taqman Array Cards (TAC) for Multipathogen Detection in Clinical Specimens
Jonas Winchell, Ph.D., Laboratory Chief, Pneumonia Response and Surveillance Laboratory, Division of Bacterial Diseases, Respiratory Diseases Branch, Centers for Disease Control and Prevention (CDC)
TAC is a microfluidic, RT-PCR multipathogen detection technology which the CDC used to rapidly screen for potential etiologies of unexplained respiratory disease outbreaks. CDC is spearheading a variety of studies designed to assess the utility of this technology in both domestic and international settings.

11:30 QPCR Testing using ViveST™, a Novel Sample Storage and Transport Device
Daniel McClernon, Ph.D., President, CSO, Virology, bioMONTR
We will describe performance of ViveST, a novel dried ambient transportation matrix, compared to frozen plasma for use with commercially available qPCR assays for HIV and HCV viral load determination and sequencing based genotypic assays for determination of drug resistance.

12:00 pm Close of Symposium

Second Annual

Next Generation Pathology

New Perspective on Tissue: Converting Complexity into Action

Monday, February 11

7:30 am Registration and Morning Coffee

8:25 Chairperson's Opening Remarks

Next Generation Biospecimen Science

8:30 Next Generation Biospecimen Sciences: Systems Pathology and Pushing the Frontier of Personalized Clinical Trials
Michael Roehrl, M.D., Ph.D., Associate Professor of Pathology, University of Toronto

9:00 Biospecimen Science: Quantitative Assessment of Pre-Analytic Variables
David L. Rimm, M.D., Ph.D., Professor, Pathology, Yale University
Companion diagnostic tests are critically dependent on tissue quality. Cold Ischemic time is amongst the most important variable. We will show data on the effects of this variable in the diagnostic setting and show data on analytes that are particularly sensitive to this issue.

9:30 Establishing a Specialist National Breast Cancer Biobank
Valerie Speirs, Ph.D., Associate Professor, Leeds Institute of Molecular Medicine, University of Leeds
Research institutions often face barriers in gaining access to this resource as collections typically have restrictive access policies or an over burdensome application process. We will describe the steps taken to overcome these issues in establishing the first national Breast Biobank in the UK.

10:00 Coffee Break with Exhibit and Poster Viewing

10:30 Enhancing Accuracy When Using DNA from Formalin Fixed Biopsies in Clinical Diagnostics
Alexander Dobrovic, M.D., Head, Molecular Pathology R&D, Pathology, Peter MacCallum Cancer Centre
To overcome the issue of sequence artifacts in FFPE DNA, we show that pre-treatment with Uracil DNA glycosylase dramatically reduces C>T:G>A sequence artifacts using high resolution melting and Sanger sequencing approaches.

11:00 Multiplexing for CTC's and Tissue Diagnostics: Using Antibody Engineering to Develop Sensitive and Specific Immunoassay
Sponsored by Cell Signaling Technology
Herbert Haack, Ph.D., Head, Clinical Assay Development, Cell Signaling Technology
There is unmet need to identify the multitude of new targets with clinical utility. Multiplexed immuno-assays of high specificity and sensitivity could be part of the diagnostics solution. A lung cancer assay for ALK, ROS1 and MET based on antibody engineering will be described.

11:30 Sponsored Presentation *(Opportunity Available)*

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

Novel Biomarker Assays

1:25 Chairperson's Remarks

1:30 Qualifying Ligand Binding Assays in Tissues—The Future of Proteomics or Impossible Dream?
Robert Dunstan, Distinguished Scientist, Investigative Histology, BiogenIdec
With sophisticated immunostainers, digitization, high throughput morphometric methods and the development of tissue based reference standards the reality of true quantitation of tissue changes is not far away.

2:00 microRNAs as Biomarkers in Solid Tumors: Potential Role in Diagnosis, Prognosis and Therapy
Laura J. Tafe, M.D., Assistant Director, Molecular Pathology; Assistant Professor, Department of Pathology, Dartmouth-Hitchcock Medical Center
With the rapid advances in targeted therapeutics, it is becoming more crucial to characterize molecular changes in cancers. Micro RNAs (miRNAs) are potential new biomarkers with respect to solid tumors.

2:30 Ultrasensitive RNA *in situ* Hybridization for Tissue Diagnostics
Sponsored by ACD Advanced Cell Diagnostics, Inc.
Yuling Luo, Ph.D., Founder, President & CEO, Advanced Cell Diagnostics, Inc.
RNA biomarkers are traditionally analyzed by "grind-and-bind" assays such as RT-PCR, which loses critical cellular and tissue context for clinical interpretation. Recent advances in in situ RNA analysis capable of detecting single RNA molecules in routine clinical specimens may finally enable more advanced RNA-based tissue diagnostics.

3:00 Refreshment Break with Exhibit and Poster Viewing

Predictive Tests for Improved Patient Outcomes

3:30 Gene Panels vs. Whole Exome Sequencing in Cancer Molecular Testing
Madhuri Hegde, Ph.D., FACMG, Associate Professor, Senior Director, Emory Genetics Laboratory, Department of Human Genetics, Emory University School of Medicine

4:00 Next Generation Sequencing and Cancer Diagnostics
Phil Stephens, Ph.D., Vice President, Cancer Genomics, Foundation Medicine
Foundation Medicine has developed FoundationOne™, a CLIA-certified, comprehensive cancer genomic test that analyzes routine clinical specimens for somatic alterations in 189 relevant cancer genes. Experience with the initial 1,000 consecutive patients will be presented.

4:30 KEYNOTE PRESENTATION: Clinical Cancer Genotyping – Snapshot
John Iafrate, M.D., Ph.D., Assistant Professor, Pathology, Harvard Medical School; Assistant Pathologist, Massachusetts General Hospital
The challenges and opportunities of implementing a broad genotyping assay in routine clinical management of cancer patients will be discussed. Snapshot was launched over 3 years ago at the Massachusetts General Hospital, with the goal of providing all cancer patients with a genetic fingerprint to guide therapeutic decisions. Lessons learned will be outlined, and a roadmap to effectively move testing forward into the Next Gen sequencing era.

5:00 Breakout Discussions *(See Web for Details)*

6:00 Close of Day

Tuesday, February 12

7:45 am Morning Coffee

Tumor-Stromal Interactions and Host Response in Cancer Patients

7:55 Chairperson's Remarks

8:00 KEYNOTE PRESENTATION: Tumor-Stromal Interactions: A New Target for Cancer Therapy with Radically New Methods for Delivery of Treatment

David Tarin, M.D., Ph.D., Professor of Pathology, Director, UCSD Comprehensive Cancer Center

Cancer cells have an obligate dependency on the host stroma for growth and survival. Without such stromal support they will regress or die. Support is critically dependant on cross-communication between the partners. This exposes a major vulnerability to target therapeutically. Radically new methods to deliver and focus such treatment will be described.

8:30 Quantitative, Spatial Analysis of Cell Populations in Tissue

Peter P. Lee, M.D., Professor and Associate Chair, Cancer Immunotherapeutics & Tumor Immunology (CITI), City of Hope and Beckman Research Institute, Beckman Center

We developed a quantitative image analysis approach incorporating 1) multi-color tissue staining, 2) high-resolution, automated whole-section imaging, 3) analysis software that identifies cell types and locations, and 4) spatial statistical analysis.

9:00 Stromics: The Other Side of Personalized Medicine and Pathology

Richard Levenson, M.D., Professor and Vice Chair for Strategic Technologies, Department of Pathology & Laboratory Medicine, University of California Davis Medical Center

Recent data from multiple investigators suggest that host factors rather than specific tumor characteristics may determine clinical outcomes. How should these perspectives be reflected in research and clinical practice, particularly with respect to pathology-based tools?

9:30 Cancer Stromal Targeting (CAST) Therapy in Oncology

Yasuhiro Matsumura, M.D., Ph.D., Division of Developmental Therapeutics, National Cancer Center Hospital East, Tokyo, Japan

Most human solid tumors possess abundant stroma, hindering diffusion of macromolecules including antibody drug conjugates (ADC). Stroma-targeting immunconjugates bound to the stroma to create a scaffold, from which sustained release of cytotoxic agent occurred and subsequently diffused throughout the tumor tissue to damage both tumor cells and tumor vessels.

10:00 Coffee Break with Exhibit and Poster Viewing

10:30 3D Microtumors: Enabling Microenvironmental Studies in 384-Well Formats

Eric A. Murphy, Ph.D., Research Investigator in Oncology Pharmacology Genomics Institute of the Novartis Research Foundation

11:00 RON Overexpression Accelerates Tumorigenesis and Drives Macrophage Differentiation Towards an Alternatively Activated (M2) Phenotype in a Mouse Model of Spontaneous Pancreatic Cancer

Michele Babicky, M.D., Department of Surgery, University of California San Diego

RON overexpression shifts macrophage differentiation toward the M2 phenotype mouse model of spontaneous pancreatic cancer driven by RON overexpression and oncogenic KRAS, suggesting a direct connection between aberrant signaling in cancer cells and inflammatory changes in the tumor microenvironment.

11:30 PANEL DISCUSSION: Cell-Based Approach vs. Tumor-Stromal Approach to Cancer Diagnostics and Drug Development

Moderator: Richard Levenson, M.D., Professor and Vice Chair for Strategic Technologies, Department of Pathology & Laboratory Medicine, University of California Davis Medical Center

12:00 pm Close of Symposium

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Afternoon
Short Courses 1:30-4:30pm*

SC1 Identification & Characterization of Cancer Stem Cells
This course will provide an overview of the unique challenges of isolation and characterization of cancer stem cells, including identification and validation of surface markers, isolating CSCs from tumor cell populations and adult stem cells, and establishing, maintaining and working with cell lines.

Jaspal Khillan, Ph.D., Associate Professor, Microbiology and Molecular Genetics, University of Pittsburgh
Marek Malecki, M.D., Ph.D., Associate Professor of Genetics, Genomics, and Gene Therapy, College of Osteopathic Medicine of the Pacific, Western University of Health Sciences
Jennie Mather, Senior Vice President, Stem Cell Technologies, Macrogenics, Inc.
Kristen Smith, Ph.D., Scientist, Eclipse Pharmaceuticals

SC2 Commercialization Boot Camp: Manual for Success in the Molecular Diagnostics Marketplace
This workshop will define the priority checklist for executing a successful strategy and operational plan for commercializing molecular diagnostics.

Sue E. Siegel, Corporate Officer and CEO, healthymagination, GE
Maureen Cronin, Ph.D., Industry Consultant
Harry Glorikian, Managing Director, Scientia Advisors

SC3 NGS Data and the Cloud
Sponsored by BioTeam Enabling Science

This course will compare cloud computing to internal infrastructure as well as give a cost-benefit analysis of cloud computing by platform type and application type. Data management and integration will also be discussed.

Adam Kraut, Scientific Consultant, BioTeam, Inc.
Jacob Glanville, Scientific Director, Distributed Bio

SC4 Best Practices in Personalized and Translational Medicine
Award-winning speakers from the 2012 Bio-IT World Best Practices competition will give attendees an in-depth look at cutting edge solutions and techniques for advancing translational medicine research. Going beyond the original entries, Best Practices winners will give updates, answer questions, and share the secrets to their programs' success. This course provides you with an opportunity to "go behind the curtain" and see why our judges chose these entries as the best of the best.

Kevin Davies, Ph.D., Chief Editor, Bio-IT World
Elizabeth Worthey, Ph.D., Assistant Professor, Human and Molecular Genetics Center, Department of Pediatrics, Medical College of Wisconsin
Speaker to be Announced, University of Utah & Omicia, Inc.

SC5 Latest Advances in Molecular Pathology
cap

This course is designed to educate practicing pathologists on the current molecular diagnostics technologies, including an introduction to molecular pathology methods, diagnostics of cancer, and microarray Comparative Genomic Hybridization (CGH). The course is created in collaboration between Cambridge Healthtech Institute and the College of American Pathologists.

Iris Schrijver, M.D., Associate Professor of Pathology and Pediatrics; Director, Molecular Pathology Laboratory, Stanford University Medical Center, Lucile Packard Children's Hospital
Athena Cherry, Ph.D., Director, Cytogenetics Laboratory; Professor, Pathology and Pediatrics, Stanford Comprehensive Cancer Center
Madhuri Hegde, Ph.D., FACMG, Associate Professor, Senior Director, Emory Genetics Laboratory, Department of Human Genetics, Emory University School of Medicine

SC6 Regulatory Approval of a Therapeutic & Companion Diagnostic: Nuts & Bolts
This course will cover some important topics related to regulatory compliance in companion diagnostics such as US requirements and processes, US government oversight of diagnostics, diagnostic clearance and approval pathways, co-development process & timelines, integration of Rx and Dx development plans, navigating the development process, co-development examples and lessons learned, approval path for devices ex-US and more.

Maham Ansari, MS, RAC, Senior Associate, Regulatory Affairs, Strategic Regulatory Services, OptumInsight, Inc. (UnitedHealth Group)
Pamela L. Swatkowski, Director, Regulatory Affairs, Abbott Molecular, Inc.

SC7 PCR Part I: qPCR in Molecular Diagnostics
This course will cover aspects of incorporating qPCR into standard diagnosis including the challenges involved, an overview of the technology available, and next steps.

Steve Miller, M.D., Ph.D., Director, UCSF Clinical Microbiology Laboratory
Additional Instructors to be Announced

SC8 Data Visualization in Biology: From the Basics to Big Data
This course will cover essential data visualization principles, the most common visualization methods for genomics data and tools that implement them, as well as solutions for visualizing big data. You will learn how to choose appropriate methods for your visualization problems and how to address the visualization challenges of large and complex data sets that are now common in biology.

Nils Gehlenborg, Ph.D., Research Associate, Center for Biomedical Informatics, Harvard Medical School

SC9 Methods for Synthesis and Screening of Macrocyclic Compound Libraries
Macrocyclic compounds fill an important chemical space between small molecules and biologics. This course will discuss the recent developments in the field of macrocycle synthesis and screening, including current methods for synthesizing and screening macrocyclic compound libraries, pros, cons and challenges of different methodologies, and examples of successful macrocyclic inhibitors.

Dehua Pei, Ph.D., Professor of Chemistry and Biochemistry, The Ohio State University
Additional Instructor to be Announced

**Separate registration required for a la carte pricing*

Short Courses Maximize Your Productivity
Continued training and education are essential for staying competitive. Molecular Med TRI-CON Short Courses are designed to be instructive and interactive. These courses are a great introduction for those who are new to a particular discipline or as a refresher for those who want to brush up on their knowledge or expand their horizons. Attendance is limited to ensure an interactive environment. Group discussions are a key component in which course participants will have the opportunity to ask questions of the expert instructors and other participants. Course materials are included.

Short Courses are held prior to the main conference events so you won't miss a moment of Molecular Med TRI-CON 2013.

Dinner
Short Courses 5-8pm*

SC10 PCR Part II: Digital PCR Applications and Advances
This course will provide an introduction to digital PCR while showcasing novel technologies for research, innovative amplification techniques, and strategies for solving common research bottlenecks.

Bruce K. Gale, Ph.D., Associate Professor and Director, State of Utah Center of Excellence for Biomedical Microfluidics, Department of Mechanical Engineering, University of Utah
Frank Diehl, Ph.D., Managing Director, Chief Scientific Officer, Inostics GmbH

SC11 Sample Prep and Biorepositories for Cancer Research
This course will educate the participants on the basics of biorepositories for cancer research. It will cover the use of different types of cancer specimens, including liquid and tissue samples. Standard operating procedures for collecting, banking and distributing clinical samples will be reviewed.

Irina A. Lubensky, M.D., Chief, Resources Development Branch, Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis NCI, NIH
Christopher A. Moskaluk, M.D., Ph.D., Walter Reed Professor and Chair of Pathology, University of Virginia Health System
Nilsa C. Ramirez, M.D., Director, Surgical Pathology, Department of Pathology and Laboratory Medicine, Nationwide Children's Hospital; Medical Director, Biopathology Center, Co-Investigator and Lead Pathologist, TCGA BCR, The Research Institute at Nationwide Children's Hospital
Elisabeth Paietta, Ph.D., Professor of Medicine, Albert Einstein College of Medicine, Director, ECOG Leukemia Translational Research Laboratory and Leukemia Tissue Bank, Montefiore Medical Center-North Division

SC12 Next-Generation Sequencing in Molecular Pathology: Challenges and Applications
The focus of this short course will be on understanding the use of NGS in clinical diagnosis, practical implementation of NGS in clinical laboratories and analysis of large data sets by using bioinformatics tools to parse and interpret data in relation to the clinical phenotype. The course is created in collaboration between Cambridge Healthtech Institute and the College of American Pathologists.

Wayne Grody, M.D., Ph.D., FCAP, FACMG, Professor, Departments of Pathology & Laboratory Medicine, Pediatrics, and Human Genetics, University of California Los Angeles School of Medicine
Karl Voelkerding, M.D., Associate Professor, Pathology, University of Utah; Medical Director, Advanced Technology & Bioinformatics, ARUP Laboratories
Nazneen Aziz, Ph.D., Director, Molecular Medicine, College of American Pathologists

SC13 Strategies for Companion Diagnostics Development
Global IVD leaders and experienced consultants will present lessons learned in the development of companion diagnostics, strategies for companion diagnostic development and commercialization, and design of drug clinical trials incorporating a companion diagnostic.

Theo McCormick, Director, RxDx Services, Management Science Associates, Inc.
John F. Beeler, Ph.D., Director, Theranostics & Business Development, bioMerieux
Sabah Malek, Senior Regulatory Scientist, IVD/Medical Devices, Voisin Consulting Life Sciences
Cecilia Schott, Pharm.D., M.B.A., Executive Business Development Director, Personalized Healthcare, AstraZeneca

SC14 Patient-Derived Cancer Tissue Xenograft Models Sponsored by The Jackson Laboratory
Neal Goodwin, Ph.D., Director, Research and Development, in vivo Pharmacology Services, The Jackson Laboratory
Byron C. Hann, M.D., Ph.D., Associate Researcher, Manager of Pre-Clinical Therapeutics Core, UCSF Helen Diller Family Comprehensive Cancer Center
Regina Gandour-Edwards, M.D., Director, Cancer Center Biorepository, Department of Pathology and Laboratory Medicine, UC Davis

SC16 Microfluidics Technology and Market Trends
In recent years, microfluidic and micro/nano technologies have transformed research and experienced impressive market growth allowing novel applications and market avenues. This course will provide an overview of the microfluidic market for *in vitro* diagnostics as well as keys to market entry and future perspectives.

Richard Selden, M.D., Ph.D., CEO, NetBio
Ali Tinazli, Director, Business Development & Sales, Sony DADC
Leanna Levine, Ph.D., President and CEO, ALine, Inc.
Andrew Dallas, President & CTO, Full Spectrum Software, Inc.

SC17 Open Cloud & Data Science: Understanding Key Concepts to Collaborate and Build Solutions for the Patient
This course will enable participants to learn open cloud concepts and applications around data intensive science, broad data, and SMART Architecture to enable substitutable medical applications. Case studies will be presented.

Matt Wood, Ph.D., Program Manager, Data-intensive Computing, Amazon Web Services
Jim Hendler, Ph.D., Tetherless World Professor of Computer and Cognitive Science and Assistant Dean of Information Technology and Web Science, Rennselaer Polytechnic Institute
Joshua Mandel, M.D., S.B. Research Faculty, Harvard Medical School/Children's Hospital Informatics Program; Lead Architect for the SMART project, Harvard Medical School/Office of the National Coordinator for Health IT

SC18 Human Microbiome Research and Modern Molecular Technologies
A variety of microbial organisms exist throughout the human body, with important roles in human health and disease. Human microbiome research aims to characterize the microbial communities from the genomic point of view. This short course is designed to give a comprehensive overview of molecular technologies employed by Human Microbiome Project as well as to discuss future diagnostics and therapeutic implications related to human microbiome.

Tenth Annual

Molecular Diagnostics

Streamlining Companion Diagnostics

The Industry Leaders Networking Event

Wednesday, February 13

7:00 am Registration and Morning Coffee

Plenary Keynote Session

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

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

Keynote Session

11:00 Chairperson's Opening Remarks

11:10 Investing in Molecular Diagnostics
Sue E. Siegel, Corporate Officer and CEO, healthymagination, GE

11:40 KEYNOTE PRESENTATION In Honor of Dr. Jeffrey Kant, Former Chair, AMP Economic Affairs Committee "May You Live in Interesting Times:" The Evolving Landscape of CPT Coding for Molecular Testing
Roger Klein, M.D., J.D., Department of Molecular Pathology, Cleveland Clinic Foundation
2013 will herald broad implementation of more transparent CPT coding for higher volume molecular pathology tests in the oncology and genetics arenas. A number of salient issues to include fee schedule placement and valuation of new molecular pathology CPT codes should be at least partially resolved. Advancements in new technologies such as next generation sequencing of gene panels, exomes and even full genomes pose new challenges for transparent and rational coding for labs and payers. This presentation will update and review developments on these and other topics of current interest.

Dr. Jeff Kant was a dedicated College of American Pathology member and was the Vice Chair of Scientific Affairs Council, a member of the CAP Economic Affairs Committee, the Personalized Health Committee, and the Next Generation Sequencing Work group. He was also a member of the AMA Molecular Pathology CPT WorkGroup; And the Chair of the AMP Economic Affairs Committee.

Industry Update

12:10 pm DxInsights: Advancing Molecular Medicine
Kristin Pothier, Founder, DxInsights; Partner, Health Advances
Delivered by one of its founders, this presentation will address the changing face of diagnostics in the healthcare system today, the role DxInsights is playing to take these challenges head on, and how all stakeholders can participate.

End-to-End Companion Diagnostics Development

12:40 Luncheon Presentation I: Novel Multimodal cMET Panel: Simultaneous and Quantitative Analysis of Copy Number Variation and Gene Expression in a Single Reaction
Sponsored by PrimeraDx
Lily Kong, CSO, PrimeraDx

1:10 Luncheon Presentation II: A Fully Automated Molecular Diagnostics Platform for Companion Diagnostics and Personalized Medicine
Sponsored by Rheonix
Richard A. Montagna, Ph.D., Senior Vice President, Corporate Business Development, RHEONIX, Inc.

1:45 20th Anniversary Cake in the Exhibit Hall with Poster Viewing

2:20 PANEL DISCUSSION: End-to-End Companion Diagnostics Development
This panel will assemble experts from each phase of the companion diagnostics value chain to examine all aspects of end-to-end development, and explore the changing landscape.

Moderator: Harry Glorikian, Founder and Managing Partner, Scientia Advisors
Panelists: Jian Wang, Ph.D., President & CEO, BioFortis, Inc.
Gregory Zdechlik, COO, Eli Lilly & Co.
Pia Maria Gargiulo, Ph.D., Vice President, Pharma Partnerships, QIAGEN
Stephen Little, Ph.D., Vice President, Personalized Healthcare, QIAGEN

3:35 Commercialization of Smart Consumables for *in vitro* Diagnostics
Sponsored by Sony DADC
Ali Tinazli, Ph.D., Director, Business Development & Sales, Sony DADC
Smart Consumables with nanoscale, microfluidic or optical features are prerequisites for emerging applications in the biomedical markets. The increasing complexity of such new products requires new manufacturing avenues. Sony DADC is applying its excellence in customized mass manufacturing to these highly sophisticated consumables in its new OEM business.

3:50 Solutions for the Outsourcing of Companion Diagnostics Development
Sponsored by ResearchDX
Philip D. Cotter, Ph.D., Principal, ResearchDx

4:05 Multiplex Molecular Assays from Discovery to the Clinic on FFPE Samples: Extraction-Free
Sponsored by htg Molecular
BJ Kerns, SVP, Translational Medicine, HTG Molecular Diagnostics, Inc.
The session will detail HTG's new automation for RNA and miRNA analysis from FFPE and HTG's qNPA® technology that enables quantitative, multiplexed extraction-free RNA analysis on FFPE tissue using < a single 5µm section.

4:20 Networking Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunities Available)*

5:20 Breakout Discussions in the Exhibit Hall *(See Web for Details)*

6:20 Close of Day

Thursday, February 14

7:00 am Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

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

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

NGS Diagnostics onto the iPAD: Understanding the Physician Workflow

10:40 Chairperson's Remarks
Alan Carter, Chief Business Officer, PanGenX

10:45 The Clinical Utility of T2DM and Other Genetic Risk Testing in Primary Care?
Alex Cho, M.D., MBA, Assistant Professor, Department of Medicine, General Internal Medicine, DUHS Center for Personalized Medicine, Duke University
Through specific use cases relevant to primary care, the potential utility, limitations, and practical challenges to employing genomics in this manner will be explored.

11:15 Decision Support for Personalized Genomic Medicine
Mark S. Boguski, Ph.D., Associate Professor, Center for Biomedical Informatics, Harvard Medical School

11:45 Turn-Key and Precise Clinical Genome Interpretation
Dietrich Stephan, Ph.D., Founder & CEO, Silicon Valley Biosystems (SVBio)
Genomes are making their way into the practice of medicine. Clinical diagnostics requires a level of accuracy and simplicity that is far different from the research uses of genomic data. We provide a turn-key service to interpret the human genome to improve patient outcomes in several clinical areas.

12:15 pm Luncheon Presentation I: Multiplexed Molecular Testing for Infectious Diarrhea: A Paradigm Shift Microbiology Testing in the Hospital

Sponsored by Luminex

Kimberle C. Chapin, M.D., Lifespan Academic Medical Centers and Brown Medical School

A discussion on the evaluation of a multiplex molecular test to rapidly identify the top pathogens involved in gastroenteritis and its potential impacts across the various hospital care continuum.

12:45 Luncheon Presentation II *(Sponsorship Opportunity Available)*

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

How Will New Molecular Diagnostic Technologies Affect Clinical Practice?

1:45 PANEL DISCUSSION

How does the cost of new technologies influence use and when can we expect to use in clinical trials?

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

Panelist: Jeremy Bridge-Cook, Ph.D., Senior Vice President, Research & Development, Luminex Corporation

David A. Flockhart, M.D., Ph.D., Harry and Edith Gladstein Chair in Cancer Genomics, Professor of Medicine, Genetics and Pharmacology; Director, Division of Clinical Pharmacology, Indiana Institute for Personalized Medicine

Additional Panelists to be Announced

3:15 Randox Biochip Array Technology (BAT) A Revolutionary Multiplex PCR Platform for Infectious Disease Molecular Diagnostics (MDx)

Sponsored by RANDOX

Scott McKeown, Ph.D., R&D Consultant, Export Sales, Randox Pharmaceutical Services, Randox Labs Ltd.

Nucleic acid amplification tests (NAATs) have become integral to the modern microbiology lab. Randox has utilized award winning biochip array technology to develop comprehensive ease-of-use multiplex PCR arrays with unparalleled assay sensitivity and specificity for sexually transmitted and respiratory infections.

3:30 Partnering in Biomarker Driven Clinical Trials

Sponsored by ALMAC

Austin Tanney, Ph.D., Scientific Liaison Manager, Almac Group

Almac has significant experience in the discovery, development and delivery of biomarkers. This presentation will incorporate Almac's experiences in translating pre-clinical biomarkers into clinical tests for the application in early phase clinical trials.

3:45 Valentine's Day Celebration and Poster Competition Winner Announced in the Exhibit Hall *(Last Chance for Poster Viewing)*

How Academic Medical Centers are Leading Personalized Medicine Research

Co-Organized by the Personalized Medicine Coalition

PMC Personalized Medicine Coalition

4:30 Chairperson's Remarks

Edward Abrahams, President, Personalized Medicine Coalition

4:35 Clinical Implementation of Pharmacogenomic Testing on a Large Scale

David A. Flockhart, M.D., Ph.D., Harry and Edith Gladstein Chair in Cancer Genomics, Professor of Medicine, Genetics and Pharmacology; Director, Division of Clinical Pharmacology, Indiana Institute for Personalized Medicine

Increasing evidence supports the use of pharmacogenetic testing in conditions where the adverse effects of medications can be preemptively avoided or effective therapy can be more reliably delivered. The rationale for using this approach and the practical realities of large scale implementation on a system wide scale be discussed.

5:05 Talk Title to be Announced

Evian Gordon, M.D., CEO, Brain Resource Company Limited

5:35 Pathways to Implementing Personalized Cardiovascular Medicine

Dan Roden, M.D., Assistant Vice Chancellor of Personalized Medicine, Vanderbilt University

There is strong evidence that genomic variation can contribute to variable susceptibility to cardiovascular disease and response to drug treatment. Challenges in implementing this knowledge will be discussed in the context of implementation efforts underway at Vanderbilt and other medical centers.

6:05 Sponsored Presentations *(Opportunities Available)*

6:35 Close of Day

Friday, February 15

8:00 am Morning Coffee

It Is Brain Surgery: Changing the Standard of Care to Include Molecular Diagnostics

8:35 PANEL DISCUSSION

How to improve diagnostic accuracy and clinical outcomes using the latest molecular tests available including NGS and PCR.

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

Panelists: Leonard S. Sender, M.D., Medical Director, Hyundai Cancer Institute, CHOC Children's; Medical Director, Clinical Operations and Program Development, UC Irvine Medical Center Chao Family Comprehensive Cancer Center

Jing Wu, M.D., Ph.D., Assistant Professor, Department of Neurology and Neurosurgery; Co-Director, Neuro-Oncology Program, UNC Lineberger Comprehensive Cancer Center, University of North Carolina

Bob S. Carter M.D., Ph.D., Professor and Division Chief, UCSD Neurosurgery

10:05 Sponsored Presentations *(Opportunities Available)*

10:35 Coffee Break

Cost/Benefit Analysis of Companion Diagnostics

11:00 PANEL DISCUSSION

Economic factors driving pharma's decision-making regarding the companion diagnostic route, as well as the perspectives of the payer and regulator.

Moderator: Bruce Quinn, M.D., Ph.D., Senior Health Policy Specialist. Life Science & Government Strategy & Medical Coverage & Reimbursement, Foley Hoag

Emily S. Reese, MPH, Pharmaceutical Health Services Research, University of Maryland School of Pharmacy

Larry J. Lesko, Ph.D., FCP, Professor, Department of Pharmaceutics, University of Florida College of Pharmacy

12:30 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

Companion Diagnostics Post-Approval

1:45 PANEL DISCUSSION: Companion Diagnostics Post-Approval: Communicating Information to the Patient in a Global Environment

Remaining challenges of selling and marketing a companion diagnostic in the global marketplace and communicating information to the patient.

Moderator: Glenn A. Miller, Ph.D., Vice President and Head, Personalized Healthcare and Biomarkers, Strategy, Portfolio and Alliances, AstraZeneca Pharmaceuticals LP

Panelists: Richard E. Buller, M.D., Ph.D., Vice President, Translational Oncology, Pfizer, La Jolla

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

William Pignato, Global Head, Regulatory Affairs, Novartis Institutes for BioMedical Research, Inc.

3:20 Close of Conference

Fourth Annual

Personalized Diagnostics

Getting Ready for Clinical Use

Wednesday, February 13

7:00 am Registration and Morning Coffee

Plenary Keynote Session

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

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

Keynote Session

11:00 Chairperson's Opening Remarks

11:10 Talk Title to be Announced
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11:40 KEYNOTE PRESENTATION IN HONOR OF Dr. Jeffrey Kant, Former Chair, AMP Economic Affairs Committee"May You Live in Interesting Times:" The Evolving Landscape of CPT Coding for Molecular Testing
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2013 will herald broad implementation of more transparent CPT coding for higher volume molecular pathology tests in the oncology and genetics arenas. A number of salient issues to include fee schedule placement and valuation of new molecular pathology CPT codes should be at least partially resolved. Advancements in new technologies such as next generation sequencing of gene panels, exomes and even full genomes pose new challenges for transparent and rational coding for labs and payers. This presentation will update and review developments on these and other topics of current interest.

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Regulatory Update

12:10 pm Microarray/Next-Generation Sequencing Quality Control Project
Leming Shi, Ph.D., National Center for Toxicological Research, U.S. Food and Drug Administration

12:40 CDx Development-Are you ready? Key considerations for Rx/Dx Co-Development from the Dx Partner Perspective
Sponsored by life technologies
Todd Krueger, Strategy Leader, Medical Sciences, Life Technologies
Successful co-development of CDx products requires many decisions be made long before development begins. Key considerations from the IVD development partner perspective will be explored including locking down the marker set, choosing the right platforms and reagents, when to move from RUO to IUO, what is proper commercialization strategy to match the needs of the drug.

1:45 20th Anniversary Cake in the Exhibit Hall with Poster Viewing

Getting Personalized Diagnostics Ready for Clinical Use

2:15 Chairperson's Remarks

2:20 Implementation of Deep (Next-Gen) Sequencing in a Clinical Lab
Toumy Guettouche, Ph.D., Hussman Institute for Human Genomics, Dr. John T. MacDonald Foundation Department of Human Genetics; Center for Genome Technology; Oncogenomics Core Facility, Sylvester Comprehensive Cancer Center, University of Miami, School of Medicine
The presentation will cover the implementation of deep (next-gen) sequencing in a clinical lab. This includes sample preparation and quality control from different types of starting material and workflow examples using different types of targeted panels.

2:50 Quality Control Parameters and Software Tools to Enable Clinical Sequencing on High-Performance Sequencing Platforms
Shawn Levy, Ph.D., Faculty Investigator, HudsonAlpha Institute for Biotechnology
This presentation details the use of advanced sample registration and identification capabilities as well as rapid sample contamination screens using inexpensive sequencing tools. Additionally, software tools to complement existing instrument control software to improve instrument reliability and communication will be described.

3:20 Rapid Whole Genome Sequencing: From DNA to Diagnosis in 50 Hours
Darrell Dinwiddie, Ph.D., Director, Lab Operations, Center for Pediatric Genomic Medicine, Children's Mercy Hospitals and Clinics
Disease progression in newborns is often fast and heterogeneous, so molecular diagnosis must occur rapidly. Here, we describe 50-hour differential diagnosis of genetic disorders by WGS, featuring substantially automated bioinformatic analysis.

3:50 Solving the Challenges of DNA Sequencing for Molecular Diagnostics
Sponsored by genia
Stefan Roever, CEO & Founder, Genia Technologies
There is no debate that genetic information is needed to truly realize the promise of personalized medicine. The problem is that today's DNA sequencers cost anywhere from $50K - $1M, rely on complicated optics, and utilize a complex workflow that does not lend itself to clinical utility.

4:20 Networking Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunities Available)*

5:20 Breakout Discussions in the Exhibit Hall *(See Web for Details)*

6:20 Close of Day

Thursday, February 14

7:00 am Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

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

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

Real Data and Practical Challenges in Implementing NGS

10:40 Chairperson's Remarks
German Pihan, M.D., Director, Hematopathology Lab, Department of Pathology, Beth Israel Deaconess Medical Center and Harvard Medical School

10:45 Mapping the Hallmarks of Lung Adenocarcinoma with Massively Parallel Sequencing
Marcin Imielinski, M.D., Ph.D., Pathology, Brigham and Women's Hospital; Meyerson Lab, Broad Institute and Dana Farber Cancer Institute

11:15 Fundamental Insight: The Biology and Targeting of Cancer through the Lens of Exome Sequencing
German Pihan, M.D., Director, Hematopathology Lab, Department of Pathology, Beth Israel Deaconess Medical Center and Harvard Medical School

11:45 Translation of the Cancer Genome
Lynda Chin, M.D., Professor & Chair, Department of Genomic Medicine; Scientific Director, Institute for Applied Cancer Science; M.G. & Lillie A. Johnson Chair for Cancer Treatment and Research, University of Texas MD Anderson Cancer Center

12:15 pm Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

Real Data and Practical Challenges in Implementing NGS

1:40 Chairperson's Remarks
German Pihan, M.D., Director, Hematopathology Lab, Department of Pathology, Beth Israel Deaconess Medical Center and Harvard Medical School

1:45 Computational Programs and Algorithms (Software) for Exome Sequence Analysis
Gaddy Getz, Ph.D., Director, Cancer Genome Computational Analysis, Broad Institute

2:15 Bioinformatics Challenges for Clinical Genome Sequencing
Stuart Brown, Ph.D., Professor of Bioinformatics, New York University
This talk will address the two major classes of challenges that must be overcome in order to apply genome sequencing to clinical diagnostics. First is establishing the accuracy of the data. Second is the functional interpretation of mutation data.

2:45 Recent Insights from Next-Generation Sequencing (NGS) of Advanced Prostate Cancer
Akash Kumar, B.Chem.E, M.S., M.D./Ph.D. Candidate, Genome Sciences, University of Washington
This talk will discuss the results of a recent exome sequencing survey of lethal prostate cancers. Potential challenges associated with the introduction of NGS into oncology will also be discussed.

3:15 What Everyone Working in the Life Sciences Needs to Know About AIA and the Recent SCOTUS/Federal Circuit Decisions
Alan F. Feeney, Esq., Owner, Feeney Law Group
There have been several recent important developments effecting the patenting of life science discoveries. The America Invents Act and recent SCOTUS decision in validating patents directed to drug dosing have changed the standard for patenting biological discoveries. In 2013, SCOTUS will address the patentability of genes. Best patent practices, clever licensing strategies and effective prior art searches will be discussed.

3:30 TeloTest™: A Transformative Telomere Length Assay in Personalized Medicine for Health Monitoring and Disease Interception
Sponsored by telome health
Calvin B. Harley, Ph.D., CSO, Telome Health, Inc.
Short telomeres at chromosome ends signal aging, loss of regenerative capacity, and increased disease and mortality risk. TeloTest™ is an accurate, high throughput, non-invasive qPCR assay to monitor telomere length in saliva, and improve health, and healthspan, by early intervention.

3:45 Valentine's Day Celebration and Poster Competition Winner Announced in the Exhibit Hall *(Last Chance for Poster Viewing)*

Case Studies in Implementation of Genomic Medicine

4:30 Chairperson's Remarks
Mark S. Boguski, Ph.D., Associate Professor, Center for Biomedical Informatics, Harvard Medical School

4:35 Genomics and the Personalization of Ovarian Cancer Care
David Huntsman, M.D., FRCPC, FCCMG, Medical Director, Center for Translational & Applied Genomics, British Columbia Cancer Agency
In addition to being used to select treatment options the mutation profiles of ovarian cancer can readily be used to develop patient specific monitoring tools.

5:05 Making a Definitive Diagnosis: Opportunities and Challenges Associated with Clinical Application of Whole Genome Sequencing
Elizabeth Worthey, Ph.D., Assistant Professor, Pediatrics & Bioinformatics Program, Human & Molecular Genetics Center, Medical College of Wisconsin
A pilot program aimed at developing a clinically appropriate system for WGS MDx was recently completed. A permanent WGS based clinic is now in place. I will discuss the types of opportunities and challenges associated with each aspect of this process, and will review details from specific cases.

5:35 Case Study in Autism
Timothy W. Yu, M.D., Ph.D., Instructor in Pediatrics, Children's Hospital Boston and Department of Neurology, Lurie Center for Autism, Mass General Hospital for Children

6:05 Sponsored Presentations *(Opportunities Available)*

6:35 Close of Day

Friday, February 15

8:00 am Morning Coffee

Cancer Molecular Markers

8:30 Chairperson's Remarks
Rob Mohney, Ph.D., Director, Projects (North American Pharma-Biotech), Metabolon, Inc.

8:35 NGS of Immune Repertoire for Cancer Biomarker Discovery
Jian Han, M.D., Ph.D., Faculty Investigator, HudsonAlpha Institute for Biotechnology, Director, R10K Project
iCubate is a fully integrated molecular differential diagnostic platform. It performs DNA/RNA extraction, amplification, detection, multiplexed, automated, and in a closed system. We also open the platform for any developers to help bring their diagnostics to market.

9:05 Epigenetically Modified Highly Methylated Coding and Non-Coding RNA Promoter CpG Islands as Early Diagnostics Markers for Human Melanomas
Ranjan Perera, Ph.D., Associate Professor and Scientific Director, Analytical Genomics and Bioinformatics, Metabolic Signaling & Disease, Sanford-Burnham Medical Research Institute
Identification of previously uncharacterized methylated CpG islands in the regulatory regions as well as gene bodies of coding and non-coding genes in melanoma genome opens the possibility of using this extensive genome-wide epigenetic information for future melanoma stratification in patients.

9:35 Mutation Detection in Plasma Tumor DNA
Andrea L. Richardson, M.D., Ph.D., Associate Professor, Pathology, Harvard Medical School; Department of Cancer Biology, Dana-Farber Cancer Institute; Senior Staff Pathologist, Brigham and Women's Hospital, Department of Pathology
The presentation will describe BEAMING technology for mutation detection from free tumor DNA in plasma, present data from published studies on specificity and sensitivity, describe the potential applications to clinical management, and discuss the limitations.

10:05 Sponsored Presentations *(Opportunities Available)*

10:35 Coffee Break

Gene Panels in Oncology and Inherited Disorders

11:00 Advances in Application of Next-Generation Sequencing to Cancer Diagnostics
Shashikant Kulkarni, Ph.D., Associate Professor, Department Pathology & Immunology, Washington University School of Medicine
The challenges that are specific to clinical adaptation of NGS in cancer diagnostics will be discussed. Specific topics include the importance of tumor enrichment, need for ultra-deep sequence coverage and clinical validation.

11:30 The Impact of Expanded Next-Generation Sequencing Panel Testing for Inherited Cardiomyopathies on Disease Diagnosis: Lessons from the First 500 Cases
Birgit H. Funke, Ph.D., FACMG, Assistant Professor of Pathology, MGH/Harvard Medical School; Director of Clinical Research and Development, Laboratory for Molecular Medicine, PCPGM
This presentation will review the evolution of medical sequencing for inherited cardiomyopathies and review results from next generation sequencing for 46 cardiomyopathy genes on over 500 cases.

12:00 pm Exome Sequencing for Candidate Gene Discovery in Inherited Disorders
Karl Voelkerding, M.D., Associate Professor, Pathology, University of Utah; Medical Director, Advanced Technology and Bioinformatics, ARUP Laboratories
Translation of exome sequencing into clinical diagnostics requires appropriate methodological characterization and validation to achieve standards necessary for clinical care. The diagnostic advantages, utility and limitations of exome sequencing will be discussed.

12:30 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

Window On Cancer: Exosome Diagnostics

1:45 Chairperson's Remarks

1:50 Utilizing Exosomes as Biomarkers in Disease
Jan Lötvall, M.D., Ph.D., Professor, Chairman, Krefting Research Centre; President, International Society for Extracellular Vesicles (ISEV)

2:20 Development of Exosome-Based Blood, Urine, and CSF Molecular Diagnostics
Hannah Mamuszka, Vice President, Business Development, Exosome Diagnostics
Exosome Diagnostics is developing biofluid-based molecular diagnostic tests for use in personalized medicine. Recent clinical data has demonstrated significant utility in brain cancer, prostate cancer, and lung cancer.

2:50 Novel Biomarkers in Monocytes and Monocyte-Derived Microvesicles Related to Obesity, and Metabolic and Cardiovascular Disorders
Paul Holvoet, Ph.D., FAHA, FESC, Professor Biomedicine, Cardiovascular Diseases, KULeuven
This presentation will discuss novel biomarkers related to RNA and regulating microRNA obtained by pathway analysis and functional characterization. It demonstrates that microvesicles can be used as proxy for activated monocytes making plasma useful for analysis.

3:20 Close of Conference

Seventh Annual

Cancer Molecular Markers

Advancing Personalized Medicine

Wednesday, February 13

7:00 am Registration and Morning Coffee

Plenary Keynote Session

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

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

Keynote Session

11:00 Chairperson's Opening Remarks

11:10 Biomarkers in Circulating Tumor Cells: Current Progress toward Qualifying Molecular Assays
Daniel Danila, M.D., Genitourinary Oncology Service, Department of Medicine,Memorial Sloan-Kettering Cancer Center
Focusing on molecular biomarkers in CTC, this presentation will emphasize the current state of establishing analytical valid biomarkers for specific contexts of use in patients with castration-resistant prostate cancer.

11:40 Chip-Based Characterization of the Molecular Characteristics of CTCs in Prostate and Lung Cancer
Daniel Haber, M.D., Ph.D., Director, Massachusetts General Hospital Cancer, Center; Isselbacher/Schwartz Professor of Oncology, Harvard Medical School; Investigator, Howard Hughes Medical Institute

12:10 pm Circulating Tumor Cells: Challenges and Perspectives
Klaus Pantel, M.D., Director, Institute of Tumor Biology, UKE
Detection and molecular characterization of circulating tumor cells (CTCs) is one of the most active areas of translational cancer research with more than 400 clinical studies including CTCs as biomarker. This presentation will discuss the aims of research on CTCs.

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

1:45 20th Anniversary Cake in the Exhibit Hall with Poster Viewing

Getting Personalized Diagnostics Ready for Clinical Use

2:15 Chairperson's Remarks

2:20 Implementation of Deep (Next-Gen) Sequencing in a Clinical Lab
Toumy Guettouche, Ph.D., Hussman Institute for Human Genomics, Dr. John T. MacDonald Foundation Department of Human Genetics; Center for Genome Technology; Oncogenomics Core Facility, Sylvester Comprehensive Cancer Center, University of Miami School of Medicine
The presentation will cover the implementation of deep (next-gen) sequencing in a clinical lab. This includes sample preparation and quality control from different types of starting material and workflow examples using different types of targeted panels.

2:50 Quality Control Parameters and Software Tools to Enable Clinical Sequencing on High-Performance Sequencing Platforms
Shawn Levy, Ph.D., Faculty Investigator, HudsonAlpha Institute for Biotechnology
This presentation details the use of advanced sample registration and identification capabilities as well as rapid sample contamination screens using inexpensive sequencing tools. Additionally, software tools to complement existing instrument control software to improve instrument reliability and communication will be described.

3:20 Rapid Whole Genome Sequencing: From DNA to Diagnosis in 50 Hours
Darrell Dinwiddie, Ph.D., Director, Lab Operations, Center for Pediatric Genomic Medicine, Children's Mercy Hospitals and Clinics
Disease progression in newborns is often fast and heterogeneous, so molecular diagnosis must occur rapidly for relevant clinical decision making. Here, we describe 50-hour differential diagnosis of genetic disorders by WGS, featuring substantially automated bioinformatic analysis.

3:50 Solving the Challenges of DNA Sequencing for Molecular Diagnostics
Sponsored by genia
Stefan Roever, CEO & Founder, Genia Technologies
There is no debate that genetic information is needed to truly realize the promise of personalized medicine. The problem is that today's DNA sequencers cost anywhere from $50K - $1M, rely on complicated optics, and utilize a complex workflow that does not lend itself to clinical utility.

4:20 Networking Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunities Available)*

5:20 Breakout Discussions in the Exhibit Hall *(See Web for Details)*

6:20 C*lose* **of Day**

Thursday, February 14

7:00 am Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

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

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

FFPE Samples

10:40 Chairperson's Remarks

10:45 Deep Sequencing of DNA and RNA from FFPE Samples
Toumy Guettouche, Ph.D., University of Miami, School of Medicine

11:15 Molecular Tools for Pathology Diagnostics: Requirements in Terms of Turnaround Time, Specimens, and Quality Assurance
Daniëlle A.M. Heideman, Ph.D., Assistant Professor, Department of Pathology, Molecular Pathology Unit, VU University Medical Center
The increasing knowledge about cancer biology and the development of targeted therapies have initiated a revolution in pathology: malignancies are increasingly classified and treated according to their biomarkers.

11:45 Molecular Diagnostic Tests to Augment Cytomorphologic Diagnosis of Lung Cancer
James C. Willey, M.D., Professor, Medicine and Pathology, University of Toledo College of Medicine; Consultant, Accugenomics, Inc.
An approach that overcomes a common obstruction to development and commercialization of new molecular diagnostic tests: lack of robustness sufficient to enable reliable implementation in surgical and needle aspiration cell block FFPE samples.

12:15 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

Single Cell Analyses

1:40 Chairperson's Remarks

1:45 Single Cell Profiling of Circulating Tumor Cells
*Stefanie Jeffrey, M.D., John and Marva Warnock Professor, Department of Surgery, Chief of Surgical Oncology Research, Stanford University School of Medicine***2:15 Microtechnologies to Interrogate Signaling in Single Cells**
Nancy Allbritton, M.D., Ph.D., Professor & Chair, UNC/NCSU Department of Biomedical Engineering; Chair, UNC CASE; Department of Chemistry, Department of Pharmacology, University of North Carolina; Department of Materials Science & Engineering, North Carolina State University
Chemical cytometry is emerging as an important approach to profile signaling at the single-cell level. These microelectrophoretic methods can perform direct

measurements of the activity of normal or oncogenic kinases in single patient cells to aid in tumor cell characterization.

2:45 NanoVelcro-Embedded Microchips for Detection and Isolation of Circulating Tumor Cells: Validation Studies in Oncology Clinic
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
We have been working on a novel single-cell isolation technology, by coupling a NanoVelcro Chip with Laser MicroDissection (LMD) technique with a goal of enabling highly efficient and specific isolation of viable/preservative-free CTCs for sequential molecular and functional analyses.

3:15 Molecular Analyses of Circulating Tumor Cells: Which View for their Use to Improve Follow Up and Treatment of Patients with Cancer?
Sponsored by Rarecells
Patrizia Paterlini-Brechot, Professor, Cell Biology & Oncology, University Paris Descartes, Paris; Director, INSERM Unit 807 & CSO, Rarecells
By using ISET, we have developed molecular methods targeted to CTC to identify non invasively theranostic mutations in patients with NSCLC and to perform NGS analyses. These advances will open the way to new exciting pathways to treat cancer patients.

3:45 Valentine's Day Celebration and Poster Competition Winner Announced in the Exhibit Hall *(Last Chance for Poster Viewing)*

4:35 The Ephesia Magnetic Arrays Technology, towards Quantitative High Content CTC Screening
Jean-Louis Viovy, Ph.D., Research Director, Macromolecules and Microsystems in Biology and Medicine Lab, Institute Curie

5:05 Digital Profiling of Circulating Tumor Cells: Towards Point-of-Care Molecular Diagnostics
Balaji Panchapakesan (Baloo), Ph.D., Associate Professor of Mechanical Engineering, University of Louisville
The presentation will focus on our scientific efforts, opportunities and challenges faced in the development of new generation of electronic devices to profile circulating tumor cells for clinical applications.

5:35 Single-Cell Digital Gene Expression of 800 mRNA Targets: Applications for Circulating Tumor Cells
Sponsored by nanoString TECHNOLOGIES
Joseph M. Beechem, Ph.D., Senior Vice President, Research & Development, NanoString Technologies
NanoString digital, multiplexed nucleic acid counting technology can now use single-cell input. 800-plex single-cell data will be shown, application to CTC's highlighted.

6:05 Advanced Platform for Real-Time Monitoring of Circulating Tumor Cells Beyond the Detection Limits
Vladimir Zharov, Ph.D., D.Sc., Professor, Director, Arkansas Nanomedicine Center, University of Arkansas for Medical Sciences

6:35 Close of Day

Friday, February 15

8:00 am Morning Coffee

Cancer Molecular Markers

8:30 Chairperson's Remarks
Rob Mohney, Ph.D., Director, Projects (North American Pharma-Biotech), Metabolon, Inc.

8:35 NGS of Immune Repertoire for Cancer Biomarker Discovery
Jian Han, M.D., Ph.D., Faculty Investigator, HudsonAlpha Institute for Biotechnology, Director, R10K Project
iCubate is a fully integrated molecular differential diagnostic platform. It performs DNA/RNA extraction, amplification, detection, multiplexed, automated, and in a closed system. We also open the platform for any developers to help bring their diagnostics to market.

9:05 Epigenetically Modified Highly Methylated Coding and Non-Coding RNA Promoter CpG Islands as Early Diagnostics Markers for Human Melanomas
Ranjan Perera, Ph.D., Associate Professor and Scientific Director, Analytical Genomics and Bioinformatics, Metabolic Signaling & Disease, Sanford-Burnham Medical Research Institute
Identification of previously uncharacterized methylated CpG islands in the regulatory regions as well as gene bodies of coding and non-coding genes in melanoma genome opens the possibility of using this extensive genome-wide epigenetic information for future melanoma stratification in patients.

9:35 Mutation Detection in Plasma Tumor DNA
Andrea L. Richardson, M.D., Ph.D., Associate Professor, Pathology, Harvard Medical School; Department of Cancer Biology, Dana-Farber Cancer Institute; Senior Staff Pathologist, Brigham and Women's Hospital, Department of Pathology
The presentation will describe BEAMING technology for mutation detection from free tumor DNA in plasma, present data from published studies on specificity and sensitivity, describe the potential applications to clinical management, and discuss the limitations.

10:05 Sponsored Presentations *(Opportunities Available)*

10:35 Coffee Break

Molecular Profiling for Patient Selection

11:00 Clonal Analysis and Molecular Profiling for Patient Selection
Michael Barrett, Ph.D., Associate Professor, Clinical Translational Research Division; Unit Head, Oncogenomics Laboratory, TGEN
Cancers frequently arise as a result of an acquired genomic instability and the subsequent evolution of neoplastic cells with variable genomes. Thus the behaviors of distinct clonal populations in each patient's tumor underlie the clinical phenotypes of many cancers.

11:30 Molecular Profiling for Patient Selection: MD Anderson Perspective
Apostolia-Maria Tsimberidou, M.D., Ph.D., Associate Professor, Department of Investigational Cancer Therapeutics, University of Texas MD Anderson Cancer Center

12:00 pm Challenges and Issues in the Clinical Execution of a Biomarker Driven Clinical Trial
Jonathan Cheng, M.D., Director, Oncology Clinical Development, Merck

12:30 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

Window on Cancer: Exosome Diagnostics

1:45 Chairperson's Remarks

1:50 Utilizing Exosomes as Biomarkers in Disease
Jan Lötvall, M.D., Ph.D., Professor, Chairman, Krefting Research Centre; President, International Society for Extracellular Vesicles (ISEV)

2:20 Development of Exosome-Based Blood, Urine, and CSF Molecular Diagnostics
Hannah Mamuszka, Vice President, Business Development, Exosome Diagnostics
Exosome Diagnostics is developing biofluid-based molecular diagnostic tests for use in personalized medicine. Recent clinical data has demonstrated significant utility in brain cancer, prostate cancer, and lung cancer.

2:50 Novel Biomarkers in Monocytes and Monocyte-Derived Microvesicles Related to Obesity, and Metabolic and Cardiovascular Disorders
Paul Holvoet, Ph.D., FAHA, FESC, Professor Biomedicine, Cardiovascular Diseases, KULeuven
This presentation will discuss novel biomarkers related to RNA and regulating microRNA obtained by pathway analysis and functional characterization. It demonstrates that microvesicles can be used as proxy for activated monocytes making plasma useful for analysis.

3:20 Close of Conference

Third Annual

Circulating Tumor Cells

Future of Cancer Management

Wednesday, February 13

7:00 am Registration and Morning Coffee

Plenary Keynote Session

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

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

Keynote Session

11:00 Chairperson's Opening Remarks

11:10 Biomarkers in Circulating Tumor Cells: Current Progress toward Qualifying Molecular Assays

Daniel Danila, M.D., Genitourinary Oncology Service, Department of Medicine, Memorial Sloan-Kettering Cancer Center

Focusing on molecular biomarkers in CTC, this presentation will emphasize the current state of establishing analytical valid biomarkers for specific contexts of use in patients with castration-resistant prostate cancer.

11:40 Chip-Based Characterization of the Molecular Characteristics of CTCs in Prostate and Lung Cancer

Daniel Haber, M.D., Ph.D., Director, Massachusetts General Hospital Cancer Center; Isselbacher/Schwartz Professor of Oncology, Harvard Medical School; Investigator, Howard Hughes Medical Institute

12:10 pm Circulating Tumor Cells: Challenges and Perspectives

Klaus Pantel, M.D., Director, Institute of Tumor Biology, UKE

Detection and molecular characterization of circulating tumor cells (CTCs) is one of the most active areas of translational cancer research with more than 400 clinical studies including CTCs as biomarker. This presentation will discuss the aims of research on CTCs.

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

1:45 20th Anniversary Cake in the Exhibit Hall with Poster Viewing

Liquid Biopsy

2:15 Chairperson's Remarks

2:20 Circulating Tumor Cells: Current Clinical Utility and Future Directions

Daniel Hayes, M.D., Professor, Internal Medicine, University of Michigan, Ann Arbor

Recent studies have demonstrated the ability to genotype and phenotype CTC, and at least these studies reflect the heterogeneity of cancer. Ongoing and future studies will address whether CTC can be used to direct general or targeted anti-cancer therapy.

2:50 Sequencing and Monitoring Circulating Free DNA in Colorectal Cancer Patients

Luis Diaz, M.D., Associate Professor of Oncology, Director of Translational Medicine, Ludwig Center at Johns Hopkins, Kimmel Cancer Center, Johns Hopkins

3:20 Digital Profiling of Circulating Tumor Cells: Towards Point-of-Care Molecular Diagnostics

Balaji Panchapakesan (Baloo), Ph.D., Associate Professor of Mechanical Engineering, University of Louisville

In this talk, we will present our efforts on developing hand held electronic devices for profiling molecular surface receptors directly in circulating tumor cells. The presentation will focus on our scientific efforts, opportunities and challenges faced in the development of new generation of electronic devices to profile circulating tumor cells for clinical applications.

3:50 The Capture, Growth and Genetic Analysis of CTC in PDAC: What Can it Tell Us About this Disease?

Sponsored by ScreenCell

Sarah P. Thayer, M.D., Ph.D., Associate Professor, Surgery, W. Gerald Austen Scholar in Academic Surgery & Director, Pancreatic Biology Laboratory, Massachusetts General Hospital

CTC captured by ScreenCell devices were detected in patients with resectable PDAC. These CTC are capable of in vitro growth confirming tumorigenicity. Selective deep sequencing demonstrated the feasibility of identifying mutations present in the primary tumor and their corresponding CTC.

4:20 Networking Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunities Available)*

5:20 Breakout Discussions in the Exhibit Hall *(See Web for Details)*

6:20 Close of Day

Thursday, February 14

7:00 am Breakfast Presentation (*Sponsorship Opportunity Available)* **or Morning Coffee**

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

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

CTCs in Companion Diagnostics

10:40 Chairperson's Remarks

10:45 Capturing and Molecular Analysis of Circulating Tumor Cells to Support Early Clinical Studies

Thomas Krahn, Ph.D., Head, Global Biomarker Research, Bayer HealthCare Pharmaceuticals, Bayer Pharma AG

This talk presents the capturing efficiency of technologies for CTC isolation and the subsequent molecular analysis of captured cells. First results from molecular CTC analysis in clinical studies will be shown.

11:15 Implementation of CTC Assays in Oncology Clinical Trials

Iman Jilani, Ph.D., Associate Director, Clinical Assay Group, Global Clinical Pharmacology, Pfizer, Inc.

This presentation will discuss the incorporation of CTC assays in oncology clinical trials. Content will include choosing a platform, method development, validation, and clinical trial implementation.

11:45 Analysis and Characterization of Subpopulations of Circulating Tumor Cells in Breast Cancer Patients

Haifeng Bao, Ph.D., Principal Scientist, Research & Development Translational Sciences, MedImmune

12:15 pm Assessment of Single Cell Mutational Status Reveals Breast Cancer CTC Heterogeneity

Sponsored by silicon biosystems

Nicolo Manaresi, Ph.D., CTO, Silicon Biosystems

Circulating Tumor Cells can be viewed as a "fluid biopsy" and have the potential to be used as an aid in cancer diagnosis and the monitoring of patient response to therapy. Results of genetic analysis of individual CTCs from breast cancer patient samples show significant heterogeneity amongst the cells and supports the position that it is possible to obtain a clear picture of mutational heterogeneity at the single cell level.

12:30 pm Luncheon Presentation: High Density Protein Microarray and its Application in Developing Ultra-Specific mAbs

Sponsored by ORIGENE

Weiwu He, Ph.D., CEO & President, OriGene Technologies, Inc

Antibody specificity is of pivotal importance for its use, especially in diagnostic and therapeutic applications.Currently no technologies have been established for antibody specificity validation. Here we will showcase OriGene's novel platform of high density protein microarray technology to test antibody specificity. Using such platform, OriGene has successfully created a new line of ultra-specific mAbs, UltraMAB®, for multiple diagnostic targets, including HER2 and ERCC1. Sample cases will be discussed.

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

Single Cell Analyses

1:40 Chairperson's Remarks

1:45 Single Cell Profiling of Circulating Tumor Cells

Stefanie Jeffrey, M.D., John and Marva Warnock Professor, Department of Surgery, Chief of Surgical Oncology Research, Stanford University School of Medicine

2:15 Microtechnologies to Interrogate Signaling in Single Cells

Nancy Allbritton, M.D., Ph.D., Professor & Chair, UNC/NCSU Department of Biomedical Engineering; Chair, UNC CASE; Department of Chemistry, Department of Pharmacology, University of North Carolina; Department of Materials Science & Engineering, North Carolina State University

Chemical cytometry is emerging as an important approach to profile signaling at the single-cell level. These microelectrophoretic methods can perform direct measurements of the activity of normal or oncogenic kinases in single patient cells to aid in tumor cell characterization.

2:45 NanoVelcro-Embedded Microchips for Detection and Isolation of Circulating Tumor Cells: Validation Studies in Oncology Clinic

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We have been working on a novel single-cell isolation technology, by coupling a NanoVelcro Chip with Laser MicroDissection (LMD) technique with a goal of enabling highly efficient and specific isolation of viable/preservative-free CTCs for sequential molecular and functional analyses.

3:15 Molecular Analyses of Circulating Tumor Cells: Which View for their Use to Improve Follow Up and Treatment of Patients with Cancer?

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Patrizia Paterlini-Brechot, Professor, Cell Biology & Oncology, University Paris Descartes, Paris; Director, INSERM Unit 807 & CSO, Rarecells

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4:35 The Ephesia Magnetic Arrays Technology, towards Quantitative High Content CTC Screening

Jean-Louis Viovy, Ph.D., Research Director, Macromolecules and Microsystems in Biology and Medicine Lab, Institute Curie

5:05 Expanding the Definition of Traditional CTCs: Cells Associated with Cancer in the Blood of Patients with Solid Tumors

Jeffrey J. Chalmers, Ph.D., Professor, Chemical & Biomolecular Engineering; Director, Analytical Cytometry Shared Resource, The Ohio State University Comprehensive Cancer Center

The currently accepted definition of CTCs are cells that have: a nuclei, cytokeratin+ EpCAM+, and CD45-. Emerging evidence suggests that other rare, cancer associated circulating cells are present in the blood of metastatic cancer patients including CD45+ cytokeratin+ cells. In this presentation, results will be presented on further characterization of both traditional CTC as well as these CD45+, CK+ cells using flow cytometry and multispectral, deconvolution fluorescence spectroscopy and relate this characterization to patient status. A comparison with and without negative, magnetic pre-enrichment will be discussed.

5:35 Single-Cell Digital Gene Expression of 800 mRNA Targets: Applications for Circulating Tumor Cells

Sponsored by nanoString TECHNOLOGIES

Joseph M. Beechem, Ph.D., Senior Vice President, Research & Development, NanoString Technologies

NanoString digital, multiplexed nucleic acid counting technology can now use single-cell input. 800-plex single-cell data will be shown, application to CTC's highlighted.

6:05 Advanced Platform for Real-Time Monitoring of Circulating Tumor Cells Beyond the Detection Limits

Vladimir Zharov, Ph.D., D.Sc., Professor, Director, Arkansas Nanomedicine Center, University of Arkansas for Medical Sciences

6:35 Close of Day

Friday, February 15

8:00 am Morning Coffee

Detection Systems

8:30 Chairperson's Remarks

Lynn Sorbara, Ph.D., Program Director, NIH/NCI/Division of Cancer Prevention, Cancer Biomarker Research Group

8:35 Application of iCTC Detection and Culture in Personalized Cancer Management

Wen-Tien Chen, Ph.D., Research Professor, Gynecologic Oncology, Stony Brook University Medical Center

Isolation and culture of invasive CTCs (iCTCs) by their interaction with cell adhesion matrix (CAM), rather than cell surface antibodies or physical properties, results in capture of functional metastasis-initiating tumor cells with greater sensitivity.

9:05 Microfluidic Sorting of Blood Cells for Cellular and Molecular Analysis

David A. Lawrence, Ph.D., Chief, Laboratory of Immunology, Wadsworth Center, NYSDOH

A microfluidic, size-based sorting array has been adapted to accommodate a 1 cm2 GCSPR chip spotted to capture hundreds of different analytes or cells. Cells can be quantified by GCSPR and plasma or cell-released analytes.

9:35 Cancer Sample Preparation with Micromachined Magnetic Sifter and Nanoparticles

Shan X. Wang, Ph.D., Professor of Materials Science & Engineering, jointly of Electrical Engineering, and by courtesy of Radiology (Stanford School of Medicine), Director, Stanford Center for Magnetic Nanotechnology

Rare cell enrichment and post analysis of peripheral blood samples from cancer patients hold promises for prognosis and personalized therapy. We present a micromachined magnetic sifter device which can capture circulating tumor cells at a high flow rate of 10 mL/hour.

10:05 Sponsored Presentations *(Opportunities Available)*

10:35 Coffee Break

▶ *Continued on page 48.*

Inaugural

Digital Pathology

Defining a New Standard

NEW

Wednesday, February 13

7:00 am Registration and Morning Coffee

Plenary Keynote Session

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

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

Introduction

11:00 Chairperson's Opening Remarks

11:10 Digital Pathology: The Big Picture

Liron Pantanowitz, M.D., Associate Professor of Pathology, University of Pittsburgh Medical Center; Department of Pathology, UPMC Shadyside

Pathology digital images are becoming more integrated with information systems, imaging standards are evolving, and new regulatory issues are arising. This talk provides an overview of all key aspects of the emerging field of Digital Pathology.

Image Analysis & Advanced Imaging

11:40 Workflow Management: From Imaging to Analysis and Database Curation

BS Manjunath, Ph.D., Director, Center for Bio-image Informatics; Vice Chair and Undergraduate Program Director, Department of Electrical and Computer Engineering, University of California Santa Barbara

12:10 pm Multiplexed Imaging, Pathology and Personalized Medicine: Keeping Sight of the Forest

Richard Levenson, M.D., Professor and Vice Chair for Strategic Technologies, Department of Pathology & Laboratory Medicine, University of California Davis Medical Center

Molecular analysis has revealed immense complexity in cancer genomes and expression profiles, critical aspects of which can be captured using spatially resolved, multiplexed molecular techniques now available to research and clinical pathology communities.

Sponsored by EXEMPLAR GENETICS

12:40 Luncheon Presentation I: Genetically Engineered Miniature Swine Models of Cancer: Bridging the Pre-Clinical Gap from Rodents to Humans

John Swart, Ph.D., President, Exemplar Genetics

The development and characterization status of the first two genetically engineered miniature swine models of cancer, a model that should have significant advantages over the currently available rodent models for preclinical predictive efficacy, will be presented during this session.

1:10 Luncheon Presentation II: *(Opportunity Available)* **or Lunch on Your Own**

1:45 20th Anniversary Cake in the Exhibit Hall with Poster Viewing

2:20 Ephemeral Images, Indelible Data: The Promises and Challenges of Digital Imaging as Applied to Pathology

Ulysses Balis, M.D., Ph.D., Associate Professor, Pathology, University of Michigan

This presentation will highlight several promising areas of digital image algorithm development that can help to span the divide between life scientist and imaging informaticist, with a focus on actual discovery and workflow models.

2:50 Filling the Training Gap for Future Pathologists: How Does a Novice like Me Catch Up?

Lewis A. Hassell, M.D., Department of Pathology, University of Oklahoma College of Medicine

This session will focus on the learning models and methods appropriate to bringing on line sophisticated image analysis tools, with particular reference to differences between early and late adopters, as well as laboratory validation and credentialing issues that may be raised by these new technologies. Generational differences in learners will also be addressed.

3:20 Q&A with Speakers

Sponsored by DEFINIENS Understanding Images

3:50 Accelerating and Advancing Dx and CDx Biomarker Development from Discovery to Clinical Trials by Seamlessly Integrating Image Analysis with Data Mining

Martin Baatz, Ph.D., Vice President, Marketing, Definiens

Automating the analysis of histological slides for biomarker development supports comprehensive biomarker expression profiling and morphological fingerprinting in unsurpassed detail and accuracy. Workflow automation and highly efficient data correlation, predictive modeling and validation reduce study length from weeks to days.

4:20 Networking Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunities Available)*

5:20 Breakout Discussions in the Exhibit Hall *(See Web for Details)*

6:20 Close of Day

Thursday, February 14

7:00 am Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

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

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

Image Analysis & Advanced Imaging

10:40 Chairperson's Remarks

10:45 Breast Cancer Predictive Factor Testing: The Challenge and Importance of Standardizing Pre-Analytic Variables

David G. Hicks, M.D., FCAP, Professor and Director, Surgical Pathology Unit, Department of Pathology and Laboratory Medicine, University of Rochester Medical Center

The introduction of biomarkers into clinical practice and their increased use in adjuvant treatment decisions has created new challenges for the laboratory. The quality of routine diagnostic samples can be improved by regulating specimen handling, which will in turn ensure more accurate testing.

11:15 Quantitative in situ Measurement of Biomolecules for Companion Diagnostics

David L. Rimm, M.D., Ph.D., Professor, Pathology, Yale University

New methods of in situ hybridization using paired sets of primers or locked nucleic acids have made in situ measurement of mRNA and microRNAs reproducible and quantifiable. Here we show examples of these tools to predict outcome or response to therapy in cancer.

11:45 Advanced Optical Imaging Tools for Pathologists

Sushmita Mukherjee, Ph.D., M.S., Assistant Professor, Biochemistry, Director, Multiphoton Microscopy Facility, Weill Medical College of Cornell University

This talk will focus on optical imaging technologies that are capable of generating cellular-resolution images from fresh, unprocessed and unstained tissues such as biopsies and surgical margins.

12:15 pm Luncheon Presentations *(Sponsorship Opportunities*

Available) **or Lunch on Your Own**

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

1:45 3D Imaging for Tumor Vasculature
Raul Brauner, Founder and CEO, Oncotree and Biotree

2:15 Digital Imaging in Hematology- Emerging Technologies
James Linder, M.D., Senior Associate to the President for Innovation and Economic Competitiveness; President, University Technology Development Corp.; Professor, Pathology and Microbiology, University of Nebraska
Technology now allows capture of digital images of blood cells on a glass microscope slide so that a complete blood count or white blood cell differential count can be determined. These approaches may improve laboratory workflow or provide new insight into hematologic disorders. Image-based reporting also may enhance hematology education, collaboration, and communication of results to clinicians.

2:45 Q&A with Speakers

Sponsored by EMC® ISILON

3:15 DNA as Storage Platform: An Overview
Sanjay Joshi, CTO, Life Sciences, Isilon Storage Division, EMC Corporation
With recent advancements in chemistry and synthetic DNA creation, the world of using DNA as a storage platform is becoming feasible. We will present recent developments in the field along with practical issues.

3:45 Valentine's Day Celebration and Poster Competition Winner Announced in the Exhibit Hall *(Last Chance for Poster Viewing)*

Image Applications

4:30 Chairperson's Remarks

4:35 Practical ePathology Solutions for Community Pathologists: What a Difference a Letter Makes
Eric F. Glassy, M.D., Medical Director, Pathology, Inc.
Whole Slide Imaging has followed a niche adoption pattern particularly for community pathologists who have been slow to embrace the technology. This talk will discuss practical examples of WSI for the non-academic pathologist, focusing on branding, workflow, and diagnostics.

5:05 Developing Infrastructure which Enables the Insourcing of Telepathology Consultation into a Subspecialty Practice
David C. Wilbur, M.D., Professor, Pathology, Harvard Medical School and Massachusetts General Hospital
Subspecialty teleconsulatations require the development of an infrastructure which allows for rapid acceptance of whole slide image, demographic and patient historical data in a secure manner. This talk will review the particular elements of the system and caveats for development and implementation.

5:35 Digital Pathology with China: Waking the Sleeping Giant
Jian Yu Rao, M.D., Professor, Pathology and Laboratory Medicine, UCLA Program on Genomics and Nutrition
The challenges and rewards of establishing a second opinion Telepathology Consult service with a tier one Chinese academic medical center are discussed. Infrastructure needs are discussed, as are the workflow issues, bridging different cultures, and dealing with quality and personnel challenges.

6:05 Sponsored Presentations *(Opportunities Available)*

6:35 Close of Day

Friday, February 15

8:00 am Morning Coffee

Image Applications

8:30 Chairperson's Remarks

8:35 Telepathology Initiative for Improved Patient Care in VISN 8 Veteran's Administration Network
Drazen Jukic, M.D., Chief of Dermatopathology, Pathology and Laboratory Medicine Services, James A. Haley Veterans' Hospital
The James A. Haley Veterans' Hospital has established a Telepathology/ Digital Pathology Center of Excellence which helps identify requirements, obstacles and solutions for interoperable digital pathology systems. We discuss implementation through the area of expertise.

9:05 A Systems Approach: Integrating Molecular and other Novel Diagnostics into Comprehensive Pathology Consultations
Sylvia L. Asa, M.D., Ph.D., Medical Director, Laboratory Medicine Program, University Health Network and Lakeridge Health; Senior Scientist, Ontario Cancer Institute; Professor, Department of Laboratory Medicine & Pathobiology, University of Toronto
Pathology reports are becoming more complex and require integration of information from multiple types of analyses to provide the correct diagnosis, prognosis and prediction for optimal therapeutic approaches. This talk reviews approaches to consolidate information into a single consultation report.

9:35 A Better View Ahead: Next Generation Approaches to Cellular Analysis
Kenneth J. Bloom, M.D., CMO, Clarient, Inc.

10:05 Sponsored Presentations *(Opportunities Available)*

10:35 Coffee Break

Imaging Workflow

11:00 Essential Digital Pathology: Perfecting Digital Image Acquisition
Yukako Yagi, Ph.D., Director, MGH Pathology Imaging & Communication Technology (PICT) Center, Massachusetts General Hospital; Affiliated Faculty, Wellman Center for Photomedicine, Massachusetts General Hospital; Assistant Professor of Pathology, Harvard Medical School
This talk will address important technical and clinical aspects of digital pathology as well as offer an introduction to imaging research.

11:30 Real-Time Deformable Registration of Multi-Modal Whole Slides for Digital Pathology
Dirk Vossen, Ph.D., Director, Applications and Q&R, Philips Digital Pathology
This presentation presents a method for the spatial alignment of multi-modal whole slide digital microscopy images.

12:00 pm How Do You Make Sure WSI are Safe to Use?
Elizabeth A. Krupinski, Ph.D., Professor & Vice Chair of Research, Department of Medical Imaging, University of Arizona
The pathology reading environment looks very different; glass slides and microscopes are being replaced by digital "virtual slides" and computer displays. This talk will address safety concerns, with respect to making sure an image is safe to use and has been displayed properly to avoid misdiagnosis.

12:30 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

1:45 Chairperson's Remarks

1:50 Validation of Digital Whole Slide Images (WSI) for Diagnosis and Correlation Studies
Anil V. Parwani, M.D., Ph.D., Director, Division of Pathology Informatics, University of Pittsburgh
This talk will provide an overview of capabilities and limitations of WSI in terms of diagnostic consistency, review past and current data on diagnostic accuracy and how this information can be incorporated in clinical trials to assess the potential of WSI for diagnostic use.

2:20 Regulatory Issues & the Practice of Digital Pathology
Keith Kaplan, M.D., Pathologist and CIO, Carolinas Pathology Group

2:50 Wrap-Up
Liron Pantanowitz, M.D., Associate Professor of Pathology, University of Pittsburgh Medical Center; Department of Pathology, UPMC Shadyside

3:20 Close of Conference

Inaugural

Companion Diagnostics

Strategies and Solutions to Streamline Development

NEW

Wednesday, February 13

7:00 am Registration and Morning Coffee

Plenary Keynote Session

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

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

Keynote Session

11:00 Chairperson's Opening Remarks

11:10 Talk Title to be Announced
Sue E. Siegel, Corporate Officer and CEO, healthymagination, GE

11:40 KEYNOTE PRESENTATION IN HONOR OF Dr. Jeffrey Kant, Former Chair, AMP Economic Affairs Committee"May You Live in Interesting Times:" The Evolving Landscape of CPT Coding for Molecular Testing
Roger Klein, M.D., J.D., Department of Molecular Pathology, Cleveland Clinic Foundation
2013 will herald broad implementation of more transparent CPT coding for higher volume molecular pathology tests in the oncology and genetics arenas. A number of salient issues to include fee schedule placement and valuation of new molecular pathology CPT codes should be at least partially resolved. Advancements in new technologies such as next generation sequencing of gene panels, exomes and even full genomes pose new challenges for transparent and rational coding for labs and payers. This presentation will update and review developments on these and other topics of current interest.

Dr. Jeff Kant was a dedicated College of American Pathology member and was the Vice Chair of Scientific Affairs Council, a member of the CAP Economic Affairs Committee, the Personalized Health Committee, and the Next Generation Sequencing Work group. He was also a member of the AMA Molecular Pathology CPT WorkGroup; And the Chair of the AMP Economic Affairs Committee.

Industry Update

12:10 pm DxInsights: Advancing Molecular Medicine
Kristin Pothier, Founder, DxInsights; Partner, Health Advances
Delivered by one of its founders, this presentation will address the changing face of diagnostics in the healthcare system today, the role DxInsights is playing to take these challenges head on, and how all stakeholders can participate.

End-to-End Companion Diagnostics Development

12:40 Luncheon Presentation I: Novel Multimodal cMET Panel: Simultaneous and Quantitative Analysis of Copy Number Variation and Gene Expression in a Single Reaction
Sponsored by PrimeraDx
Lily Kong, CSO, PrimeraDx

1:10 Luncheon Presentation II: A Fully Automated Molecular Diagnostics Platform for Companion Diagnostics and Personalized Medicine
Sponsored by Rheonix
Richard A. Montagna, Ph.D., Senior Vice President, Corporate Business Development, RHEONIX, Inc.

1:45 20th Anniversary Cake in the Exhibit Hall with Poster Viewing

2:20 PANEL DISCUSSION: End-to-End Companion Diagnostics Development
This panel will assemble experts from each phase of the companion diagnostics value chain to examine all aspects of end-to-end development, and explore the changing landscape.

Moderator: Harry Glorikian, Founder and Managing Partner, Scientia Advisors
Panelists: Jian Wang, Ph.D., President & CEO, BioFortis, Inc.
Gregory Zdechlik, COO, Eli Lilly & Co.
Pia Maria Gargiulo, Ph.D., Vice President, Pharma Partnerships, QIAGEN
Stephen Little, Ph.D., Vice President, Personalized Healthcare, QIAGEN

3:35 Commercialization of Smart Consumables for *in vitro* Diagnostics
Sponsored by Sony DADC
Ali Tinazli, Ph.D., Director, Business Development & Sales, Sony DADC
Smart Consumables with nanoscale, microfluidic or optical features are prerequisites for emerging applications in the biomedical markets. The increasing complexity of such new products requires new manufacturing avenues. Sony DADC is applying its excellence in customized mass manufacturing to these highly sophisticated consumables in its new OEM business.

3:50 Solutions for the Outsourcing of Companion Diagnostics Development
Sponsored by ResearchDx
Philip D. Cotter, Ph.D., Principal, ResearchDx

4:05 Multiplex Molecular Assays from Discovery to the Clinic on FFPE Samples: Extraction-Free
Sponsored by htg Molecular
Speaker to be Announced
The session will detail HTG's new automation for RNA and miRNA analysis from FFPE and HTG's qNPA® technology that enables quantitative, multiplexed extraction-free RNA analysis on FFPE tissue using < a single 5µm section.

4:20 Networking Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunities Available)*

5:20 Breakout Discussions in the Exhibit Hall *(See Web for Details)*

6:20 Close of Day

Thursday, February 14

7:00 am Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

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

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

CTCs In Companion Diagnostics

10:40 Chairperson's Remarks

10:45 Capturing and Molecular Analysis of Circulating Tumor Cells to Support Early Clinical Studies
Thomas Krahn, Ph.D., Head, Global Biomarker Research, Bayer HealthCare Pharmaceuticals, Bayer Pharma AG
This talk presents the capturing efficiency of technologies for CTC isolation and the subsequent molecular analysis of captured cells. First results from molecular CTC analysis in clinical studies will be shown.

11:15 Implementation of CTC Assays in Oncology Clinical Trials
Iman Jilani, Ph.D., Associate Director, Clinical Assay Group, Global Clinical Pharmacology, Pfizer, Inc.
This presentation will discuss the incorporation of CTC assays in Oncology clinical trials. Content will include choosing a platform, method development, validation, and clinical trial implementation.

11:45 Analysis and Characterization of Subpopulations of Circulating Tumor Cells in Breast Cancer Patients
Haifeng Bao, Ph.D., Senior Scientist, Research & Development Translational Sciences, MedImmune

12:15 pm Assessment of Single Cell Mutational Status Reveals Breast Cancer CTC Heterogeneity

Sponsored by silicon biosystems

Nicolo Manaresi, Ph.D., CTO, Silicon Biosystems

Circulating Tumor Cells can be viewed as a "fluid biopsy" and have the potential to be used as an aid in cancer diagnosis and the monitoring of patient response to therapy. Results of genetic analysis of individual CTCs from breast cancer patient samples show significant heterogeneity amongst the cells and supports the position that it is possible to obtain a clear picture of mutational heterogeneity at the single cell level.

12:30 pm Luncheon Presentation: High Density Protein Microarray and its Application in Developing Ultra-Specific mAbs

Sponsored by ORIGENE

Weiwu He, Ph.D., CEO & President, OriGene Technologies, Inc

Antibody specificity is of pivotal importance for its use, especially in diagnostic and therapeutic applications.Currently no technologies have been established for antibody specificity validation. Here we will showcase OriGene's novel platform of high density protein microarray technology to test antibody specificity. Using such platform, OriGene has successfully created a new line of ultra-specific mAbs, UltraMAB®, for multiple diagnostic targets, including HER2 and ERCC1. Sample cases will be discussed.

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

How Will New Molecular Diagnostic Technologies Affect Clinical Practice?

1:45 PANEL DISCUSSION

How does the cost of new technologies influence use and when can we expect to use in clinical trials?

Moderator: Hakan Sakul, Ph.D., Executive Director & Head, Diagnostics, Worldwide Research & Development, Clinical Research and Precision Medicine, Pfizer, Inc.
Panelist: Jeremy Bridge-Cook, Ph.D., Senior Vice President, Research & Development, Luminex Corporation
David A. Flockhart, M.D., Ph.D., Harry and Edith Gladstein Chair in Cancer Genomics, Professor of Medicine, Genetics and Pharmacology; Director, Division of Clinical Pharmacology, Indiana Institute for Personalized Medicine
Additional Panelists to be Announced

3:15 Molecular Diagnostic Assays Multiplexed with Randox Biochip Array Technology

Sponsored by RANDOX

Scott McKeown, Ph.D., R&D Consultant, Randox Pharmaceutical Services, Randox Labs Ltd

3:30 Partnering in Biomarker Driven Clinical Trials

Sponsored by ALMAC

Austin Tanney, Ph.D., Scientific Liaison Manager, Almac Group

Almac has significant experience in the discovery, development and delivery of biomarkers. This presentation will incorporate Almac's experiences in translating pre-clinical biomarkers into clinical tests for the application in early phase clinical trials.

3:45 Valentine's Day Celebration and Poster Competition Winner Announced in the Exhibit Hall *(Last Chance for Poster Viewing)*

How Academic Medical Centers are Leading Personalized Medicine Research

Co-Organized by the Personalized Medicine Coalition PMC Personalized Medicine Coalition

4:30 Chairperson's Remarks

Edward Abrahams, President, Personalized Medicine Coalition

4:35 Clinical Implementation of Pharmacogenomic Testing on a Large Scale

David A. Flockhart, M.D., Ph.D., Harry and Edith Gladstein Chair in Cancer Genomics, Professor of Medicine, Genetics and Pharmacology; Director, Division of Clinical Pharmacology, Indiana Institute for Personalized Medicine

Increasing evidence supports the use of pharmacogenetic testing in conditions where the adverse effects of medications can be preemptively avoided or effective therapy can be more reliably delivered. The rationale for using this approach and the practical realities of large scale implementation on a system wide scale be discussed.

5:05 Talk Title to be Announced

Evian Gordon, M.D., CEO, Brain Resource Company Limited

5:35 Pathways to Implementing Personalized Cardiovascular Medicine

Dan Roden, M.D., Assistant Vice Chancellor of Personalized Medicine, Vanderbilt University

There is strong evidence that genomic variation can contribute to variable susceptibility to cardiovascular disease and response to drug treatment. Challenges in implementing this knowledge will be discussed in the context of implementation efforts underway at Vanderbilt and other medical centers.

6:05 Sponsored Presentations *(Opportunities Available)*

6:35 Close of Day

Friday, February 15

8:00 am Morning Coffee

8:05 Successful Development and Commercialization of Precision Medicines: "It Takes a Village"

Hakan Sakul, Ph.D., Executive Director & Head, Diagnostics, Worldwide R&D, Clinical Research and Precision Medicine, Pfizer

Companion Diagnostics: Development and Implementation

8:35 Clinical Development of an Oncology Drug with a Companion Diagnostic: It's Not Just About the Drug!

Kenneth Emancipator, M.D., Director, Companion Diagnostics, Merck

9:05 Emerging Regulatory Trends in Drug-Diagnostic Co-Development

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

9:35 From Biomarker to Companion Diagnostics: The Process Starts Early

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

10:05 Sponsored Presentations *(Opportunities Available)*

10:35 Coffee Break

Cost/Benefit Analysis of Companion Diagnostics

11:00 PANEL DISCUSSION

Economic factors driving pharma's decision-making regarding the companion diagnostic route, as well as the perspectives of the payer and regulator.

Moderator: Bruce Quinn, M.D., Ph.D., Senior Health Policy Specialist. Life Science & Government Strategy & Medical Coverage & Reimbursement, Foley Hoag
Emily S. Reese, MPH, Pharmaceutical Health Services Research, University of Maryland School of Pharmacy
Larry J. Lesko, Ph.D., FCP, Professor, Department of Pharmaceutics, University of Florida College of Pharmacy

12:30 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

Companion Diagnostics Post-Approval

1:45 PANEL DISCUSSION: Companion Diagnostics Post-Approval: Communicating Information to the Patient in a Global Environment

Remaining challenges of selling and marketing a companion diagnostic in the global marketplace and communicating information to the patient.

Moderator: Glenn A. Miller, Ph.D., Vice President and Head, Personalized Healthcare and Biomarkers, Strategy, Portfolio and Alliances, AstraZeneca Pharmaceuticals LP
Panelists: Richard E. Buller, M.D., Ph.D., Vice President, Translational Oncology, Pfizer, La Jolla
Walter H. Koch, Ph.D., Vice President and Head, Global Research, Roche Molecular Diagnostics
William Pignato, Global Head, Regulatory Affairs, Novartis Institutes for BioMedical Research, Inc.

3:20 Close of Conference

Tenth Annual

Mastering Medicinal Chemistry

In an Era of Tough Targets

Wednesday, February 13

7:00 am Registration and Morning Coffee

Plenary Keynote Session

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

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

Increasing Complexity, Macrocycles, 3-D Structure, Shape & Chirality

11:00 Chairperson's Opening Remarks
Nick Terrett, Ph.D., CSO, Ensemble Therapeutics Corp.

11:10 Opening Address: Using Synthetic Chemistry to Answer the Challenge of Increasing Molecular Complexity in Small Molecule Drug Discovery
Simon Bailey, Ph.D., Sr. Director, Worldwide Medicinal Chemistry Oncology, Pfizer
This presentation will provide examples of the positive benefits of increased molecular complexity in small molecule drug candidates and illustrate how medicinal chemists can adopt innovative new synthetic chemistry strategies to access molecularly complex compounds.

11:40 Beyond the Rule of Five – Novel Strategies for Accessing Macrocyclic Chemical Space
Keith James, President, Ferring Research Institute; Visiting Investigator, The Scripps Research Institute
Macrocycle-based drug design represents a compelling strategy for addressing challenging molecular targets, and an exciting new frontier in drug discovery. This presentation will describe both novel strategies for accessing this intriguing region of chemical space, and some unique properties of macrocyclic systems.

12:10 pm Moving in New Circles – An Introduction to Macrocycles in Drug Discovery
Nick Terrett, Ph.D., CSO, Ensemble Therapeutics Corp.
Recently there has been a rapid growth in interest in small molecules outside of Lipinski 'Rule of 5' space. Macrocycles in particular can bind to challenging protein targets and maintain good drug-like properties offering a new fertile direction for drug discovery.

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

1:45 20th Anniversary Cake in the Exhibit Hall with Poster Viewing

Next Generation Payload Linker and Conjugation Technologies

2:15 Chairperson's Remarks

2:20 Design of Novel Linkers, Payloads and Antibody-Drug Conjugates for the Treatment of Cancer
Christopher J. O'Donnell, Ph.D., Sr. Director, Oncology Medicinal Chemistry, Pfizer
ADCs are an emerging modality for the treatment of cancer. This talk will focus on Pfizer's innovative chemistry strategy to discover and develop new linker-payload classes that will yield more efficacious and potentially better tolerated conjugates to advance this area of research.

2:50 Antibody-Drug Conjugates for the Treatment of Cancer
John Flygare, Ph.D., Senior Scientist, Discovery Chemistry, Genentech
Combining the specificity of a monoclonal antibody with the cell killing ability of a cytotoxic agent is an outstanding method for treating cancer. This presentation will review successful applications of this technology and discuss future directions of linkers and cytotoxic drugs used in this approach.

3:20 Using Small Molecules to Engineer and Explore Human Immunity
David A. Spiegel, Ph.D., Associate Professor of Chemistry, Yale
This talk describes research efforts in our laboratories toward the design, synthesis, and characterization of small molecule antibody recruiting therapeutics. It is our hope that this strategy will serve as a starting point toward entirely novel scientific insights and therapeutic approaches.

3:50 Rationalizing Non-Standard Interactions in Ligand Design: The Duality of Halogens
Sponsored by CHEMICAL COMPUTING GROUP
Chris Williams, Ph.D., Principal Scientist, Chemical Computing Group
Non-standard intermolecular interactions are significant in ligand binding, but they are inadequately modeled using molecular mechanics. An Extended Hückel Theory (EHT) model is proposed, which accounts for electronic effects on interaction strengths. Model accuracy is demonstrated using case studies.

4:20 Networking Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunities Available)*

5:20 Breakout Discussions in the Exhibit Hall *(See Web for Details)*

6:20 Close of Day

Thursday, February 14

7:00 am Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

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

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

Increasing Complexity

10:40 Chairperson's Remarks
Michael Foley, Ph.D., Director, Chemical Biology, Broad Institute

10:45 Membrane Permeability and Oral Bioavailability of Macrocycles
Matthew P. Jacobson, Ph.D., Professor, Pharmaceutical Chemistry, Department of Bioengineering and Therapeutic Science, University of California San Francisco
I will discuss the emerging understanding of how synthetic and natural product macrocycles achieve membrane permeability and oral bioavailability, despite not being considered drug-like by many simple criteria. Examples will include cyclic peptides and polyketides, emphasizing design strategies.

11:15 Synthetic Macrocycles: Leveraging Natures Design Strategy
Michael Foley, Ph.D., Director, Chemical Biology, Broad Institute
This presentation will describe progress towards creating a macrocycle collection at the Broad Institute using the build-couple-pair strategy for diversity-oriented synthesis. Case studies of several DOS-derived macrocycles will be presented as an example of the utility of this screening collection against 'undruggable' targets.

11:45 Molecular Complexity and Promiscuity
Frank Lovering, Ph.D., Principle Scientist II, Computational Chemistry, Pfizer
Complexity, as measured by fraction sp3 and the presence of chiral centers, impacts success in the clinic. We illustrate the relationship between complexity and promiscuity as well as Cyp450 inhibition - factors that are critical to success in drug discovery.

12:15 pm Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

Hot Targets to Watch: Epigenetic Targets

1:40 Chairperson's Remarks
Ed Olhava, Ph.D., Associate Director, Pre-Clinical Development, Epizyme, Inc.

1:45 Chemically Targeting the Histone Lysine Methyltransferase EZH2 (Enhancer of Zeste Homolog 2)
Sharad K. Verma, Ph.D., Investigator, Medicinal Chemistry, GlaxoSmithKline
The histone lysine methyltransferase EZH2 is frequently over-expressed in a variety of cancerous tissues. The synthesis and development of highly potent and selective small molecule inhibitors of EZH2 will be described from a medicinal chemistry perspective.

2:15 Inhibition of BET Bromodomains for the Treatment of Cancer
Brian K. Albrecht, Ph.D., Sr. Dir., Medicinal Chemistry, Constellation Pharmaceuticals
Inhibition of the BET bromodomain family of chromatin readers leads to effective tumor growth inhibition in xenograft models. The discovery and optimization of a series of potent and selective isoxazoloazepine BET inhibitors will be presented.

2:45 From Protein to Candidate: Discovery of EPZ-5676, A Potent and Selective Inhibitor of the Histone Methyltransferase DOT1L
Ed Olhava, Ph.D., Associate Director, Pre-Clinical Development, Epizyme, Inc.
The clinical candidate EPZ-5676, a DOT1L inhibitor for treatment of MLL-rearranged leukemia, is described. The lead series was discovered via structure guided design. Crystallography aided optimization of the pharmacokinetic properties and potency of this series led to EPZ-5676.

3:15 Advances in the Treatment of Water Molecules for Assessing Druggability, Understanding SAR, and Computing Binding Energies
Sponsored by SCHRÖDINGER.
Chris Higgs, Senior Applications Scientist, Schrödinger
Significant progress has recently been made in the treatment of water molecules in drug design. Specifically, the ability to compute the thermodynamic properties of individual waters has allowed researchers to gain insights into the biomolecular recognition process that was not previously possible. Here, we present the latest advances in the WaterMap method and applications to assessing druggability, SAR, affinity, and selectivity. We highlight examples where knowledge of explicit water thermodynamics is essential in understanding the molecular recognition process.

3:45 Valentine's Day Celebration and Poster Competition Winner Announced in the Exhibit Hall *(Last Chance to View Posters)*

Hot Targets To Watch: GPCRs

4:30 Chairperson's Remarks
Graeme Semple, Ph.D., Vice President, Discovery Chemistry, Arena Pharmaceuticals, Inc.

4:35 Meeting Key Challenges in the Discovery of APD811: An Orally Available Prostacyclin Receptor Agonist for the Treatment of Pulmonary Arterial Hypertension
Graeme Semple, Ph.D., Vice President, Discovery Chemistry, Arena Pharmaceuticals, Inc.
Our design and SAR of new prostacyclin receptor agonists for PAH will be described. Special attention was paid to pharmacokinetic behavior and pharmaceutical properties of prospective candidates.

5:05 The New Era of Structure-Based Drug Design GPCRs
Jonathan S. Mason, Ph.D., Drug Design & Computational Chemistry, Heptares Therapeutics Ltd.
The wealth of new GPCR structures enables full SBDD for this important target class. Druggability analyses will be presented, and multiple structure-based candidate designs from the mutationally stabilized receptors (StaRs) used at Heptares that uniquely exist in precisely defined biologically-relevant conformations.

Hot Targets to Watch: Protein-Protein Interactions

5:35 Has Fragment Discovery Helped Us Solve the Protein-Protein Interactions Challenge?
Michelle R. Arkin, Ph.D., Associate Adjunct Professor, Pharmaceutical Chemistry, University of California San Francisco School of Pharmacy
We will describe some of the issues and advances in tackling protein-protein interactions by fragment-based lead discovery. We utilize a range of approaches to understand molecular recognition features that lead to binding to protein interfaces and to develop inhibitors of these challenging targets.

6:05 Sponsored Presentations *(Opportunities Available)*

6:35 Close of Day

Friday, February 15

8:00 am Morning Coffee

Hot Targets to Watch: Protein-Protein Interactions (cont'd)

8:30 Chairperson's Remarks
Stephen Hale, Ph.D., Vice President, Drug Discovery, Ensemble Therapeutics
This talk will include details of a rational design, synthesis, *in vitro* and *in vivo* biological profiling of potent oncology candidates. An integrated approach was employed using X-ray, NMR, computational chemistry, medicinal chemistry, *in vitro* biology and pharmacology among others.

8:35 Monomeric and Dimeric SMAC Mimetics as Pro-Apoptotic Agents in Anticancer Therapy
Pierfausto Seneci, Ph.D., Professor, Chemistry, University of Milan
This talk will include details of a rational design, synthesis, *in vitro* and *in vivo* biological profiling of potent oncology candidates. An integrated approach was employed using X-ray, NMR, computational chemistry, medicinal chemistry, *in vitro* biology and pharmacology among others.

9:05 The Solution to "Tough-to-Drug" Targets: An Integrated Discovery Engine Leveraging the Unique Properties of Synthetic Macrocycles
Stephen Hale, Ph.D., Vice President, Drug Discovery, Ensemble Therapeutics
Many high-value targets have proven to be intractable to traditional "small-molecule" discovery efforts. Ensemble has a discovery platform that allows for the rapid identification of novel macrocyclic compounds active against challenging targets, including protein:protein interaction targets.

Novel Approaches: Novel Technologies for Synthesis

9:35 Development of Macrocyclic Inhibitors against K-Ras Protein
Dehua Pei, Ph.D., Professor of Chemistry and Biochemistry, The Ohio State University
Developing small-molecule inhibitors against Ras has met with many challenges. A high-throughput method has been developed to synthesize, screen, and decode macrocyclic compound libraries of 107 diversity. Screening of such libraries has identified compounds that disrupt Ras-effector complexes at high nanomolar to low micromolar concentrations.

10:05 Sponsored Presentations *(Opportunities Available)*

10:35 Coffee Break

Novel Approaches: Phenotypic Screening & Chemical Biology

11:00 Development of Isoform Selective Inhibitors of Class I and Class II HDACs for CNS and Metabolic Disorders

Edward, Holson, Ph.D., Director, Stanley Center for Psychiatric Research, Broad Institute of MIT and Harvard

Taking a chemical genetics approach, we have developed a "toolkit" of HDAC inhibitors which includes a variety of highly potent and selective inhibitors. These novel inhibitors include HDAC 1: HDAC1,2: HDAC 3: HDAC 1,2,3: HDAC 6: and the first demonstration of HDAC 6,8 inhibitors.

Novel Approaches: Medicinal Chemistry Design

11:30 Delta-Selective Opioid Agonists for the Treatment of Chronic Pain

Robin Polt, Ph.D., Professor of Chemistry & Biochemistry, BIO5, University of Arizona

Here we report the synthesis of a series of glycosylated deltorphin-based peptides that possess selectivity and efficacy for the delta opioid receptor (DOR). From this series, a lead candidate compound (BBI 11008) was identified.

12:00 pm Discovery and Optimization of Selective JAK1 Inhibitors as Potential Treatments for Rheumatoid Arthritis

Mark Zak, Ph.D., Scientist, Discovery Chemistry, Genentech

We wished to identify JAK1 inhibitors as prospective therapeutics for rheumatoid arthritis (RA) and other immunologic disorders. Details of the design and optimization efforts, as well as the biological characterization and chemical structure of the lead compound will be presented.

12:30 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

Novel Approaches: Matched Pairs

1:45 Chairperson's Remarks

Elizabeth Farrant, Ph.D., Chief Business Officer, Cyclofluidic Ltd

1:50 Mastering Medicinal Chemistry with Molecular Matched-Pairs

Jonas Boström, Ph.D., Computational Chemist, Medicinal Chemistry, AstraZeneca

We will present novel and efficient matched-pair approaches, combined with important medicinal chemistry data, and demonstrate use in drug design. Observations affecting lipophilicity will be given extra attention.

Novel Approaches: Flow Chemistry

2:20 Generation of Kinase Structure Activity Data Using Integrated Microfluidic Synthesis, Screen and Design

Elizabeth Farrant, Ph.D., Chief Business Officer, Cyclofluidic Ltd

This presentation describes the application of an integrated microfluidic platform where potential lead molecules are designed, synthesized, purified and screened in fast serial mode.

2:50 Integrating Flow Chemistry in Drug Discovery

Noel S. Wilson, Ph.D., Senior Scientist I, Global Pharmaceutical Discovery, Hit to Lead, Abbott Laboratories

3:20 Close of Conference

Fourth Annual

Cancer Biologics

Approaches Changing the Treatment of Cancer

Wednesday, February 13

7:00 am Registration and Morning Coffee

Plenary Keynote Session

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

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

Biomarkers for Patient Selection and Diagnostics

11:00 Chairperson's Opening Remarks

11:10 FEATURED PRESENTATION: The Yin and Yang of Personalized Medicine
Stefan Scherer, M.D., Ph.D., Vice President, Clinical Development & Medical Affairs, Boehringer Ingelheim Pharma GmbH & Co. KG

Advances with Antibody-Drug Conjugates

11:40 KEYNOTE PRESENTATION: Empowered Antibodies for Cancer Therapy
Peter Senter, Ph.D., Vice President, Chemistry, Seattle Genetics, Inc.
The technology surrounding antibody drug conjugates has advanced significantly in the past two years, with developments in antibody, drug, linker and conjugation technologies. This presentation will overview some of the recent technical achievements surrounding antibody drug conjugates, and include the development of a clinically approved drug.

12:10 pm Potent-Payload Linker-Drug Technology – Development of Novel Duocarmycin-Based ADCs
Marco Timmers, Ph.D., CSO, Synthon BV
This presentation will highlight optimization of Synthon's unique linker chemistry and its complementarity with novel proprietary duocarmycin drugs. Latest pre-clinical results will be discussed, including CMC and *in vivo* therapeutic window.

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

1:45 20th Anniversary Cake in the Exhibit Hall with Poster Viewing

ADCs: Pre-Clinical Development

2:15 Chairperson's Remarks

2:20 Challenges Associated with Research & Development of ADCs
Paul Polakis, Ph.D., Director & Staff Scientist, Cancer Targets, Genentech, Inc.
I will include preclinical studies designed to anticipate the nature of inevitable drug resistance and emphasize the potential for combining existing targeted therapies with ADCs in the clinic.

2:50 Pre-Clinical Development of IMGN529: A Novel CD37-Targeting Antibody-Maytansinoid Conjugate for the Treatment of B-Cell Malignancies
Jutta Deckert, Ph.D., Principal Scientist, Discovery Research, ImmunoGen, Inc.
IMGN529, a CD37-directed ADC designed to kill malignant B cells using multiple, targeted mechanisms, is currently in clinical testing in non-Hodgkin's lymphoma patients. Its preclinical evaluation will be discussed with a focus on *in vitro* safety studies.

3:20 Predicting Clinical Efficacy of ADCs from PK/PD Modeling of Pre-Clinical Data: Can We Really Extrapolate from Mouse to Man?
Alison Betts, Ph.D., Associate Research Fellow, Pharmacokinetics, Dynamics and Metabolism (PDM), Pfizer Worldwide Research & Development
In this presentation, a multiscale-mechanism based PK/PD model for ADCs is proposed which can integrate *in vitro* biomeasures and pre-clinical PK/PD data, to predict a clinical efficacious response. A case study is shown with Brentuximab-vedotin (SGN-35).

3:50 Sponsored Presentations *(Opportunities Available)*

4:20 Networking Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunities Available)*

5:20 Breakout Discussions in the Exhibit Hall *(See Web for Details)*

6:20 Close of Day

Thursday, February 14

7:00 am Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

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

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

ADCs: Pre-Clinical and Clinical Progress

10:40 Chairperson's Remarks

10:45 Anti-Müllerian Inhibiting Substance Type II Receptor Antibodies for Ovarian Cancer Therapy
Gregory P. Adams, Ph.D., Co-Leader, Developmental Therapeutics Program, Fox Chase Cancer Center
Antibodies with agonistic activity have been difficult to develop. Our efforts at isolating anti-MISIIR antibodies by phage display and using homology modeling to rationally design antibodies capable of binding to the highly conserved ligand binding site will be presented.

11:15 Improvements to ADC Safety with Calicheamicin
Hans-Peter Gerber, Ph.D., Executive Director, BioConjugate Discovery and Development, Oncology Research Unit East, Pfizer Worldwide R&D
The ADC modality and its components, essential aspects of tumor cell biology and their impact on pharmacology and safety of ADC's will be discussed, with particular focus on clinical dose fractionation studies conducted with two calicheamicin conjugates in the clinic.

11:45 Clinical Development of a Novel Auristatin E-Based Antibody Drug Conjugate against SLC44A4 in Resistant Prostate Cancer
Leonard M. Reyno, M.D., Senior Vice President & CMO, Agensys, Inc.
ASG-5ME is a fully human antibody against SLC44A4 (expressed in 95% of prostate tumors) conjugated to monomethyl auristatin E. Phase I study will be discussed including challenges defining proof of concept in light of evolving standards of care.

12:15 pm Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

New Targets and Measures to Reach Difficult Targets

1:40 Chairperson's Remarks

1:45 Predictive Drug Discovery for Novel Cancer Biologics
John Hunter, Ph.D., Vice President, Antibody Research & Development, Compugen, Inc.
Compugen has applied its Predictive Discovery platform to identify novel members of the B7/CD28 family for targeted antibody immunotherapy in cancer. Validation data for representative targets will be presented.

2:15 Function-Orientated Screening Strategies to Identify Novel and More Effective Cancer Therapeutics
Mary Haak-Frendscho, Ph.D., CEO, Igenica, Inc.
I will highlight Igenica's two innovative technology platforms, sTAg (surface-tagged tumor antigen profiling) and iTAb (*in vivo* anti-tumor antibody screening) that collectively offer function-orientated strategies to identify novel tumor antigens and effective antibody-based therapeutic candidates.

2:45 Proteomics for Trans-Membrane Targets for ADCs
John Terrett, Ph.D., CSO, Oxford Biotherapeutics, Inc.
Proteins with high expression on cancer plasma membranes are identified directly by mass spectrometric analysis of membranes from clinical samples. Targetability, prevalence, antigen density, and appropriate ADC development can be determined from a comprehensive proteomics database built at OBT.

3:15 Sponsored Presentations *(Opportunities Available)*

3:45 Valentine's Day Celebration and Poster Competition Winner Announced in the Exhibit Hall *(Last Chance to View Posters)*

Immunotherapy Approaches

4:30 Chairperson's Remarks

4:35 Understanding the Role of B Cells in Ovarian Cancer and Implications for Targeted Therapy
Nathalie Scholler, M.D., Ph.D., Assistant Professor, Obstetrics and Gynaecology, Gyn University of Pennsylvania
Anti-tumor effector T cells are inhibited by the tumor microenvironment. Recent experimental evidence demonstrates that B cell responses can regulate T cell functions in cancer patients, thus potentially enabling translational research with existing B cell-modifying drugs.

5:05 Adoptive Therapy of Cancer with Genetically Modified T Cells
Renier J. Brentjens, M.D., Ph.D., Associate Attending Physician, Associate Member, Department of Medicine, Memorial Sloan-Kettering Cancer Center
Production and clinical application of tumor targeted CAR T cells will be presented. Potential obstacles as well as approaches to address these limitations, including the use of IL-12 secreting T cells, will be discussed.

5:35 Allovectin®: *In vivo* Studies and Potential Synergy with Other Advanced Melanoma Immunotherapeutics
John Doukas, Ph.D., Senior Director, Pre-Clinical Safety and Efficacy, Vical, Inc.
Allovectin® is an immunotherapeutic currently completing evaluation in a pivotal Phase 3 study for metastatic melanoma. This presentation will review its proposed mechanisms of action and potential synergy with other immunotherapies, drawing supporting data from preclinical and clinical studies.

6:05 Sponsored Presentations *(Opportunities Available)*

6:35 Close of Day

Friday, February 15

8:00 am Morning Coffee

Bi- and Multi-Specific Antibodies

8:30 Chairperson's Remarks

8:35 Improving Potency & Manufacturability of Bi-Specific Antibodies
Jason Baum, Ph.D., Principal Scientist, Research, Merrimack Pharmaceuticals, Inc.
Here we describe an optimization approach for multi-specific molecules targeting growth factor receptor signaling pathways that has been successfully applied to the design of MM-141, a stable high affinity bispecific antibody targeting IGF-1R and ErbB3.

9:05 Multi-Targeting Approaches in Oncology and Angiogenesis by Multi-Specific Darpins
Ulrike Fiedler, Ph.D., Principle Scientist, Disease Biology, Molecular Partners AG
This platform enables novel therapeutic concepts in which efficacy, PK, and mechanism of action are tailored to address unmet medical needs. We will highlight different pre-clinical programs.

9:35 BiTE® Antibodies for Cancer Therapy
Roman Kischel, M.D., Principal Scientist, BiTE Technology, Amgen Research (Munich) GmbH

10:05 Sponsored Presentations *(Opportunities Available)*

10:35 Coffee Break

11:00 Targeting Multiple Oncology Sites with Multi-Specific Antibody-Like Molecules
Peter Kiener, Ph.D., President & CEO, Zyngenia, Inc.
The Zybody platform generates multi-specific antibodies with 2-5 specificities that can simultaneously engage multiple targets. This can give rise to "better than additive" responses to modulation of cell growth and signaling receptors and internalization. We will discuss some examples.

11:30 Genetically Engineered Mice to Develop and Test Bi-Specific Antibodies
Eric Smith, Ph.D., Associate Director, Bispecific Antibodies, Regeneron Pharmaceuticals, Inc.
Using mouse genetic engineering platforms at (Velocigene, VelocImmune), together with a novel approach to generate fully human bi-specific antibodies, we have evaluated the anti-tumor effects of different classes of bi-specifics *in vivo*.

12:00 pm Employing the Bispecific RECRUIT TandAb Platform
Eugene Zhukovsky, Ph.D., CSO, Research, Affimed Therapeutics AG
This technology comprises CD3 RECRUIT and CD16 RECRUIT modules for respective T and NK cell recruitment and killing of cancer cells. We will report on safety and efficacy, and activity in the clinic.

12:30 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

Combination Therapies

1:45 Chairperson's Remarks

1:50 Combination Strategies to Enhance Anti-Tumor ADCC
Holbrook Kohrt, M.D., Ph.D., Assistant Professor, Oncology, University of Stanford
Here I discuss strategies that increase total target–monoclonal antibody–effector binding, strategies that trigger effector cell 'activating' signals, and strategies that block effector cell 'inhibitory' signals.

2:20 Observations with the ADC Trastuzumab Emtansine (T-DM1) Alone and in Combination
Steve Olsen, M.D., Ph.D., Global Development Team Leader, Trastuzumab Emtansine Product Development-Oncology, Genentech, Inc.
T-DM1 has demonstrated promising safety and efficacy as single-agent therapy for HER2-positive metastatic breast cancer. Combining T-DM1 with other HER2-directed therapy and/or chemotherapy has the potential to improve clinical efficacy. Pre-clinical and emerging clinical data will be discussed.

2:50 Novel Strategy to Target Tyrosine Kinase Receptors: From Bench to Clinic
Ivan D. Horak, M.D., F.A.C.P., CSO/CMO, R&D, Symphogen A/S

3:20 Close of Conference

Third Annual

Oncology Clinical Trials

Bringing Effective and Safe Cancer Therapy to Patient

Wednesday, February 13

7:00 am Registration and Morning Coffee

Plenary Keynote Session

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

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

Cancer Drug Resistance and its Impact on Oncology Clinical Development

11:00 Chairperson's Opening Remarks

11:10 KEYNOTE PRESENTATION: Challenges in Understanding Resistance to Targeted Therapies
Jamey Skillings, M.D., Vice President, Global Medical Affairs, Pfizer
This presentation will describe the evolution of clinical and molecular data which describe resistance to Xalkori. Case examples from this program and other targeted therapies will be used to discuss how evidence can be developed to support treatment decisions after RECIST progression.

11:40 Epithelial to Mesenchymal Transition (EMT): Diagnostics, Drug Resistance and Impact in Clinical Trials
Branimir I. Sikic, M.D., Professor of Medicine, Division of Oncology, Stanford University School of Medicine
EMT is associated with stem cell markers in cancer cells, as well as resistance to various chemotherapies. Characteristic biomarkers of EMT include decreased E-cadherin, and increased vimentin, fibronectin, MMP2 and MMP9. Among the consequences of EMT is an upregulation of TUBB3, the beta tubulin isoform that confers resistance to microtubule stabilizing drugs such as taxanes.

12:10 pm Combining BRAF Inhibitor and Adoptive Cell Immunotherapy Increases Antitumor Activity and Reduces Risk of Resistance in Metastatic Melanoma
Richard C. Koya, M.D., Ph.D., Assistant Professor, Department of Surgery, Surgical Oncology, Member, JCCC Tumor Immunology Program Area
Recently various targeted kinase inhibitors showed promising outcomes in metastatic melanoma patients, but recurrence is still an issue. Adoptive transfer of anti-melanoma reactive T cells can induce long-term response in selected patients, thus a combination of both is an attractive therapeutic approach our group is pursuing.

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

1:45 20th Anniversary Cake in the Exhibit Hall with Poster Viewing

2:15 Chairperson's Remarks

2:20 Translational and Clinical Pharmacologic Considerations for Combination Therapy Development in Oncology
Stephanie Faucette, Pharm.D., Ph.D., Senior Manager, Clinical Pharmacology, Millennium Pharmaceuticals

Adverse Events Reporting and Pharmacovigilance

2:50 NCI's Approach to Expedited and Routine Adverse Event Reporting as it Relates to the New FDA Guidance on AE Reporting for IND Agents
S. Percy Ivy, M.D., Associate Branch Chief, IDB, CTEP, National Cancer Institute

3:20 System Approach to Serious Adverse Events Reporting in Cancer Clinical Trials
Patrick Schnell, M.D., Safety Risk Management Lead, Pfizer

3:50 Sponsored Presentations *(Opportunities Available)*

4:20 Networking Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunities Available)*

5:20 Breakout Discussions in the Exhibit Hall *(See Web for Details)*

6:20 Close of Day

Thursday, February 14

7:00 am Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

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

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

Cancer Clinical Trials in the Era of Personalized Medicine

10:40 Chairperson's Remarks
John A. Todd, Ph.D., Vice President, Research & Development, Singulex, Inc.

10:45 Case Study of I-SPY2 Trial
Laura Jean Esserman, M.D., MBA, Director, Carol Franc Buck Breast Care Center; Professor of Surgery and Radiology, University of California San Francisco
Screening phase II agents for neoadjuvant breast cancer, matching drugs with patients depending on biomarker subsets, including modeling longitudinal information about individual patients and using adaptive randomization.

11:15 Personalizing NSCLC Therapy: The BATTLE-2 Program
Vassiliki Papadimitrakopoulou, M.D., Professor, Department of Thoracic/Head and Neck Medical Oncology, Medical Oncology, The University of Texas MD Anderson Cancer Center
Comparing the efficacy of experimental therapies within biomarker subsets of non-small-cell lung cancer using adaptive randomization with primary endpoint 8-week disease control.

11:45 Beyond I-SPY 2 and BATTLE
Donald Berry, Ph.D., Professor, Department of Biostatistics, The University of Texas MD Anderson Cancer Center
Extending the I-SPY 2 and BATTLE trial designs beyond breast and non-small-cell cancer, incorporating combinations of experimental agents and adapting therapies within as well as across patients.

12:15 pm Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

1:40 Chairperson's Remarks

1:45 Novel Strategies in Oncology Clinical Development
Emmett V. Schmidt, M.D., Ph.D., Senior Principal Scientist, Clinical Research, Merck Research Laboratories - Oncology

2:15 KEYNOTE PRESENTATION: Novel Strategies for Biomarker-Driven Clinical Trials
Sandra J. Horning, M.D., Senior Vice President, Global Head, Clinical Development Hematology/Oncology, Genentech

2:45 Sponsored Presentations *(Opportunities Available)*

3:15 Panel Diacussion: Bringing Targeted and Tailored Therapies to Patient
Panelists: Speakers of The Session

3:45 Valentine's Day Celebration and Poster Competition Winner Announced in the Exhibit Hall *(Last Chance for Poster Viewing)*

Quality of Pre-Clinical Evidence Matters

4:30 Chairperson's Remarks

4:35 Challenges in Translating Pre-Clinical Research into Benefit for Patients: Raising the Bar for Pre-Clinical Cancer Research
C. Glenn Begley, Ph.D., Senior Vice President, TetraLogic
There are multiple challenges translating research findings into drugs that ultimately benefit patients. Some are inherent in the disease and the models we employ, and are extremely difficult to address. Others are inherent to our processes, and may be more readily overcome.

5:05 Building More Predictive *in vitro* and *in vivo* Models to Identify Responder Populations Pre-Clinically
Emma Lees, Ph.D., Vice President, Oncology, NIBR Site Head Emeryville, Novartis Institutes for Biomedical Research

5:35 Challenges to Accurately Translating Results from Pre-Clinical Cancer Models to the Clinic
Peter Houghton, Ph.D., Director, Center for Childhood Cancer, Nationwide Children's Hospital
Human tumor xenografts have been the predominant models for cancer drug development for about 30 years. However, there are concerns that results from such pre-clinical models do not translate into clinical reality.

6:05 Sponsored Presentations *(Opportunities Available)*

6:35 Close of Day

Friday, February 15

8:00 am Morning Coffee

Companion Diagnostics: Development and Implementation

8:30 Chairperson's Remarks

8:35 Successful Development and Commercialization of Precision Medicines: "It Takes a Village"
Hakan Sakul, Ph.D., Executive Director & Head, Diagnostics, Worldwide R&D, Clinical Research and Precision Medicine, Pfizer

9:05 Clinical Development of an Oncology Drug with a Companion Diagnostic: It's Not Just About the Drug!
Kenneth Emancipator, M.D., Director, Companion Diagnostics, Merck

9:35 Use of NGS as a Biomarker Tool for Oncology Drug Development: A Diagnostic Company's Perspective
Premal Shah, Ph.D., Director, Business Development, Genomic Health, Inc.
The ability to effectively use Next Generation Sequencing techniques for biomarker discovery provides therapeutic manufacturers an important tool to develop effective and safe drugs. But unlike the past where pharma companies spent money and invested in nascent technologies themselves, there is a capable and robust infrastructure, led by diagnostics companies, that will enable low-cost and powerful biomarker discovery for every drug development program. In oncology, where low number of NMEs, high development time and costs are pervasive, biomarker discovery using NGS is not just a nice-to-have, but a must have. NGS techniques such as whole transcriptome profiling, or DNA-seq can help identify simple to complex signatures (e.g., multi-gene panel that includes gene fusions). And while the industry has historically focused on single gene markers since they are easier to deploy in "kit" form, the reality is that the biomarkers of the future will have to be complex. And complex biomarkers, by definition, will have to be delivered by emerging companies such as Genomic Health, Foundation Medicine, and Myriad. The future is here and the tools are there.

10:05 Sponsored Presentations (Opportunities Available)

10:35 Coffee Break

Molecular Profiling for Patient Selection

11:00 Clonal Analysis and Molecular Profiling for Patient Selection
Michael Barrett, Ph.D., Associate Professor, Clinical Translational Research Division; Unit Head, Oncogenomics Laboratory, TGEN
Cancers frequently arise as a result of an acquired genomic instability and the subsequent evolution of neoplastic cells with variable genomes. Thus the behaviors of distinct clonal populations in each patient's tumor underlie the clinical phenotypes of many cancers.

11:30 Molecular Profiling for Patient Selection: MD Anderson Perspective
Apostolia-Maria Tsimberidou, M.D., Ph.D., Associate Professor, Department of Investigational Cancer Therapeutics, University of Texas MD Anderson Cancer Center

12:00 pm Challenges and Issues in the Clinical Execution of a Biomarker Driven Clinical Trial
Jonathan Cheng, M.D., Director, Oncology Clinical Development, Merck

12:15 pm Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

Clinical Trial Specimens in Cancer Research

1:45 Chairperson's Remarks

1:50 Cooperative Oncology Group Banks (CGBS)
Irina A. Lubensky, M.D., Chief, Resources Development Branch, Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis, NCI, NIH
CGBs collect, store and distribute specimens from patients treated in phase III and large phase II NCI-funded randomized clinical trials. These well-annotated specimen collections are unique because they have associated uniform clinical, treatment, and outcome data.

2:20 The Role of the Biorepository in Cancer Clinical Trials: "From Bed to Bench"
Nilsa C. Ramirez, M.D., Director, Surgical Pathology, Department of Pathology and Laboratory Medicine, Nationwide Children's Hospital; Medical Director, Biopathology Center, Co-I and Lead Pathologist, TCGA BCR, The Research Institute at Nationwide Children's Hospital
Biorepositories directly influence the outcome of translational research in clinical trials.They oversee procurement, banking, testing and distribution of quality clinical trial samples to approved investigators. The role of the biorepository in the cancer cooperative group organization is discussed.

2:50 National Breast Cancer Biobank and Oncology Research
Valerie Speirs, Ph.D., Associate Professor, Leeds Institute of Molecular Medicine, University of Leeds

3:20 The Role of the Tissue Bank in Academic Cancer Centers
Teri A. Longacre, M.D., Professor of Pathology, Director, Tissue Procurement Facility, Stanford Cancer Center, Stanford, California
The various functions of the tissue bank in academic cancer centers have increased in complexity in the last decade. In this lecture, key problem areas faced by academic cancer centers in the areas of tissue procurement, tissue distribution, quality metrics, accommodation of SPORE and other specific programmatic projects, clinical annotation, and data tracking are discussed.
In addition, the concept of a "clinical biobank" as opposed to the traditional "research biobank" is introduced.

▶ *Continued on page 49.*

Ninth Annual

Clinical and Translational Science

Strategies to Accelerate and De-Risk Clinical Development

Wednesday, February 13

7:00 am Registration and Morning Coffee

Plenary Keynote Session

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

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

Strategies to De-Risk Clinical Development

11:00 Chairperson's Opening Remarks

11:10 Leveraging the Intersection of Mechanism and Disease Biology to De-Risk Early Clinical Development
Scott Kennedy, Ph.D., Global Head, Biomarker Development, Novartis Institutes for BioMedical Research
This presentation will discuss challenges and opportunities for leveraging stratification biomarkers which inform a biological understanding of targeted and disease pathways to enable increased success of early clinical development and the identification of additional treatable disease populations.

11:40 Safety of Targeted Immunotherapy in Cancer: Early Toxicity Risk Mitigation Strategies
Rakesh Dixit, Ph.D., Vice President, Research & Development; Global Head, Biologics Safety Assessment, MedImmune
Biologics immunotherapies have revolutionized cancer treatment but there is increasing concern that certain toxicities may limit their long-term benefits. We will discuss the early risk mitigation approaches to reduce toxicities and better manage safety of these therapies in clinical trials.

12:10 pm Translating Therapeutic Index into Probability of Success for Clinical Drug Candidates
Patrick Y. Mueller, Ph.D., Director, Global Coordinator, Novartis Institutes for BioMedical Research
A balanced safety/efficacy profile is key for the clinical success of drug candidates. The therapeutic index is an important parameter in efforts to achieve this goal in a translational drug development setting.

12:40 Luncheon Presentation
Speaker to be Announced
Sponsored by ELSEVIER

1:10 Luncheon Presentation *(Sponsorship Opportunity Available)*

1:45 20th Anniversary Cake in the Exhibit Hall with Poster Viewing

Innovation in Clinical Development

2:15 Chairperson's Remarks

2:20 Human Target Validation and Patient-Centric, Novel Therapeutic Strategies to Improve Clinical Outcomes in R&D
Harsukh Parmar, M.D., Vice President and Head, Translational and Experimental Medicine, F. Hoffmann La Roche
R&D productivity has continued to decline despite the readout of the human genome project. We need a change in the quality and rigor of experimental methods using human clinical studies as a paradigm shift in improving the success rate of R&D.

2:50 Innovation in Clinical Trials: Theory vs. Practice
Jean-Pierre Bizzari, M.D., Executive Vice President, Clinical Oncology/Hematology, Celgene Corporation
The biomarker approach is now being fully implemented in most of the clinical development plans for oncology compounds in Celgene. We will show examples and will focus on the various methodological issues.

3:20 The Difference Between Generating and Understanding Research Data: Ontology-Driven Approaches to Advancing Research
Sponsored by REMEDY INFORMATICS
Mike Cummens, M.D., Chief Medical Officer, Remedy Informatics
Remedy's CMO, Dr. Michael Cummens, will demonstrate why an ontology-based registry is essential to advance your research by accelerating pattern discovery. Employing an ontology will allow you to aggregate, map, and harmonize data from disparate sources and enable intelligent queries.

3:50 Never Send a Gene to do a Protein's Job: Dissecting Biological Complexity to Impact Drug Development
Sponsored by SomaLogic
Stephen A. Williams, M.D., Ph.D., CMO, SomaLogic, Inc
The well-documented failures across the drug development pipeline are almost all a result of our current technological inability to understand complex biology. We present here a powerful new proteomics "scalpel" for dissecting complex and real-time biology and pharmacology in drug discovery and development. We also demonstrate multiple successful applications of this technology to understanding disease biology, validating targets, uncovering the pharmacology of new compounds, and accelerating the development pipeline.

4:05 Establishing Clinically Relevant Biomarkers Through Advanced Single Molecule Counting
Sponsored by Singulex
Cleland C. Landolt, M.D., CMO, Singulex, Inc.
- Singulex's proprietary digital immunoassay technology helps to overcome challenges in the translation of biomarkers to the clinic, due to improved assay precision and sensitivity which has enabled the measurement of endogenous biomarker levels and the precise monitoring over time.
- Review the recent development of ultra-sensitive cardiac troponin I (cTnI) as a clinically relevant biomarker for CVD risk characterization and chronic disease management.
- Present a case study demonstrating the clinical application of ultra-sensitive cTnI.

4:20 Networking Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunities Available)*

5:20 Breakout Discussions in the Exhibit Hall *(See Web for Details)*

6:20 Close of Day

Thursday, February 14

7:00 am Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

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

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

Integrating Biomarkers and Genomics into Clinical Development

10:40 Chairperson's Remarks

10:45 Clinical Trials in Genetically Defined Patient Populations
Tim Harris, Ph.D., Senior Vice President, Translational Medicine, Biogen Idec
There is an increasing realization that proof-of-concept for new therapies can be obtained by clinical trials in genetically well characterized patients.

The prospect of using whole genome sequencing to stratify patients into different subsets for more efficient clinical trials is an enticing one.

11:15 From Biomarker to Companion Diagnostic: Different Bumps in Different Roads
Richard Buller, M.D., Ph.D., Vice President, Translational Oncology, Pfizer
There are usually multiple options for biomarker development and no two development plans are likely to be identical. Perspectives on the variables influencing diagnostic development for three different Pfizer compounds will be discussed including assay selection and post-marking activities.

11:45 Using Biomarkers in Clinical Trials – Perspectives from the FNIH Biomarkers Consortium
Maria Vassileva, Ph.D., Scientific Program Manager, Metabolic Disorders, The Biomarkers Consortium
The Biomarkers Consortium is involved in clinical trial execution and data compilation for biomarker qualification. This presentation will focus on two projects to demonstrate that data from multiple studies, once integrated, can answer questions that would otherwise be impossible to address.

12:15 pm Luncheon Presentations ***(Sponsorship Opportunities Available)*** or Lunch on Your Own

12:15 pm Luncheon Presentation I: Metabolomics for Improved Translation through New Targets and Biomarkers
Sponsored by METABOLON
Rob Mohney, Ph.D., Director, Projects (North American Pharma-Biotech), Metabolon, Inc.
Technology advancements enable rapid, simultaneous assessment of >2800 metabolites to derive novel biomarkers and targets. A GWAS study demonstrates metabolomics provides insight regarding gene function and biomarkers of disease or drug response to develop biomarkers for prostate cancer progression.

12:45 pm Luncheon Presentation II *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

1:40 Chairperson's Remarks

1:45 Multifaceted Impact Potential of Biomarkers and Translational Research in Oncology Drug Development
Shirin Khambata Ford, Ph.D., Executive Director and Global Head, Oncology Correlative Sciences, Novartis

2:15 Presentation to be Announced

2:45 Role of Biomarkers in Clinical Drug Development and Drug Approval: FDA Experience
Jingyu Jerry Yu, Ph.D., Pharmacometrics Reviewer, FDA
The critical role of biomarkers in clinical development and drug approval will be discussed based on FDA experience. Cases will be presented to illustrate how quantitative analysis based on biomarker data can facilitate drug approval.

3:15 Sponsored Presentation
Sponsored by MYRIAD RBM
Speaker to be Announced

3:30 Sponsored Presentation *(Opportunity Available)*

3:45 Valentine's Day Celebration and Poster Competition Winner Announced in the Exhibit Hall (Last Chance for Poster Viewing)

Quality of Pre-Clinical Evidence Matters

4:30 Chairperson's Remarks

4:35 Challenges in Translating Pre-Clinical Research into Benefit for Patients: Raising the Bar for Pre-Clinical Cancer Research
C. Glenn Begley, Ph.D., Senior Vice President, TetraLogic
There are multiple challenges translating research findings into drugs that ultimately benefit patients. Some are inherent in the disease and the models we employ, and are extremely difficult to address. Others are inherent to our processes, and may be more readily overcome.

5:05 Building More Predictive *in vitro* and *in vivo* Models to Identify Responder Populations Pre-Clinically
Emma Lees, Ph.D., Vice President, Oncology, NIBR Site Head Emeryville, Novartis Institutes for Biomedical Research

5:35 Challenges to Accurately Translating Results from Pre-Clinical Cancer Models to the Clinic
Peter Houghton, Ph.D., Director, Center for Childhood Cancer, Nationwide Children's Hospital
Human tumor xenografts have been the predominant models for cancer drug development for about 30 years. However, there are concerns that results from such pre-clinical models do not translate into clinical reality.

6:05 Panel Discussion: Improving Reproducibility and Predictability of Preclinical Research
Moderator: Peter Houghton, Ph.D., Director, Center for Childhood Cancer, Nationwide Children's Hospital
Panelists:
C. Glenn Begley, Ph.D., Senior Vice President, TetraLogic
Emma Lees, Ph.D., Vice President, Oncology, NIBR Site Head Emeryville, Novartis Institutes for Biomedical Research
Terry A. Van Dyke, Ph.D., Head, Mouse Cancer Genetics Program; Program Director, Cancer Pathways and Mechanisms, National Cancer Institute

6:35 Close of Day

Friday, February 15

8:00 am Morning Coffee

Data Integration Strategies to Support Clinical & Translational Research

8:30 Chairperson's Remarks
Ajay Shah, Ph.D., Director, Research Informatics Division, City of Hope

8:35 Translational Research Informatics Platform at City of Hope
Ajay Shah, Ph.D., Director, Research Informatics Division, City of Hope
City of Hope (COH) is implementing several components of its Translational Research Informatics Platform. This platform leverages COH Enterprise Data Warehouse. Natural language processing components of the platform allows for analysis of EMRs, and extraction of coded fields from these records.

9:05 Path to Develop Integrated Data for Biomarker Research
Carol Bova Hill, Ph.D., Informatics Project Leader II, Clinical Research Informatics, Duke Clinical Research Institute
Integration of data to support translational research requires rigorous understanding of data and highlights the crucial role of the Informaticist. I will outline efforts and challenges to create a robust systematic environment to support the utilization of biospecimens at DCRI.

9:35 Data Visualization in Clinical Research
Dimitris Agrafiotis, Janssen R&D, Johnson & Johnson

▶ *Continued on page 49.*

Inaugural

Clinical Sequencing

Translating NGS from Research to Practice

NEW

Wednesday, February 13

7:00 am Registration and Morning Coffee

Plenary Keynote Session

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

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

NGS Platforms and Workflows: Data Analysis and Implementation

11:00 Chairperson's Opening Remarks

11:10 The Impact of Novel Sequencing Technologies on Antibody Discovery and Development
Jacob Glanville, Ph.D., Science Director, Distributed Bio

11:40 From Data to Discovery: Case Studies, Lessons Learned, and Next Steps
Joseph Szustakowski, Ph.D., Senior Group Head, Bioinformatics, Biomarker Discovery, Novartis Institutes for BioMedical Research
This presentation will describe several case studies to highlight the bioinformatics challenges we face when analyzing NGS data, the computational infrastructure required to enable such analyses, and the analysis algorithms and strategies used to solve the problems at hand.

12:10 pm Toward an Open Translational Research System: Leveraging tranSMART to Drive the Management of Clinical and Molecular Information
Jay Bergeron, Program Manager, Pfizer

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

1:45 20th Anniversary Cake in the Exhibit Hall with Poster Viewing

Getting Personalized Diagnostics Ready for Clinical Use

2:15 Chairperson's Remarks

2:20 Implementation of Deep (Next-Gen) Sequencing in a Clinical Lab
Toumy Guettouche, Ph.D., Hussman Institute for Human Genomics, Dr. John T. MacDonald Foundation Department of Human Genetics; Center for Genome Technology; Oncogenomics Core Facility, Sylvester Comprehensive Cancer Center, University of Miami, School of Medicine
The presentation will cover the implementation of deep (next-gen) sequencing in a clinical lab. This includes sample preparation and quality control from different types of starting material and workflow examples using different types of targeted panels.

2:50 Quality Control Parameters and Software Tools to Enable Clinical Sequencing on High-Performance Sequencing Platforms
Shawn Levy, Ph.D., Faculty Investigator, HudsonAlpha Institute for Biotechnology
This presentation details the use of advanced sample registration and identification capabilities as well as rapid sample contamination screens using inexpensive sequencing tools. Additionally, software tools to complement existing instrument control software to improve instrument reliability and communication will be described.

3:20 Rapid Whole Genome Sequencing: From DNA to Diagnosis in 50 Hours
Darrell Dinwiddie, Ph.D., Director, Lab Operations, Center for Pediatric Genomic Medicine, Children's Mercy Hospitals and Clinics
Disease progression in newborns is often fast and heterogeneous, so molecular diagnosis must occur rapidly. Here, we describe 50-hour differential diagnosis of genetic disorders by WGS, featuring substantially automated bioinformatic analysis.

3:50 Solving the Challenges of DNA Sequencing for Molecular Diagnostics
Sponsored by genia
Stefan Roever, CEO & Founder, Genia Technologies
There is no debate that genetic information is needed to truly realize the promise of personalized medicine. The problem is that today's DNA sequencers cost anywhere from $50K - $1M, rely on complicated optics, and utilize a complex workflow that does not lend itself to clinical utility.

4:20 Networking Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunities Available)*

5:20 Breakout Discussions in the Exhibit Hall *(See Web for Details)*

6:20 Close of Day

Thursday, February 14

7:00 am Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

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

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

NGS Diagnostics onto the iPad: Understanding the Physician Workflow

10:40 Chairperson's Remarks
Alan Carter, Chief Business Officer, PanGenX

10:45 The Clinical Utility of T2DM and Other Genetic Risk Testing in Primary Care?
Alex Cho, M.D., MBA, Assistant Professor, Department of Medicine, General Internal Medicine, DUHS Center for Personalized Medicine, Duke University
Through specific use cases relevant to primary care, the potential utility, limitations, and practical challenges to employing genomics in this manner will be explored.

11:15 Decision Support for Personalized Genomic Medicine
Mark S. Boguski, Ph.D., Associate Professor, Center for Biomedical Informatics, Harvard Medical School

11:45 Turn-Key and Precise Clinical Genome Interpretation
Dietrich Stephan, Ph.D., Founder & CEO, Silicon Valley Biosystems (SVBio)
Genomes are making their way into the practice of medicine. Clinical diagnostics requires a level of accuracy and simplicity that is far different from the research uses of genomic data. We provide a turn-key service to interpret the human genome to improve patient outcomes in several clinical areas

12:15 pm Luncheon Presentation I: Multiplexed Molecular Testing for Infectious Diarrhea: A Paradigm Shift Microbiology Testing in the Hospital
Sponsored by Luminex
Jeremy Bridge-Cook, Ph.D., Senior Vice President, Research & Development, Luminex Corporation

12:45 Luncheon Presentation II (Sponsorship Opportunity Available)

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

Real Data and Practical Challenges in Implementing NGS

1:40 Chairperson's Remarks
German Pihan, M.D., Director, Hematopathology Lab, Department of Pathology, Beth Israel Deaconess Medical Center and Harvard Medical School

1:45 Computational Programs and Algorithms (Software) for Exome Sequence Analysis
Gaddy Getz, Ph.D., Director, Cancer Genome Computational Analysis, Broad Institute

2:15 Bioinformatics Challenges for Clinical Genome Sequencing
Stuart Brown, Ph.D., Professor of Bioinformatics, New York University
This talk will address the two major classes of challenges that must be overcome in order to apply genome sequencing to clinical diagnostics. First is establishing the accuracy of the data. Second is the functional interpretation of mutation data.

2:45 Recent Insights from Next-Generation Sequencing (NGS) of Advanced Prostate Cancer
Akash Kumar, B.Chem.E, M.S., M.D./Ph.D. Candidate, Genome Sciences, University of Washington
This talk will discuss the results of a recent exome sequencing survey of lethal prostate cancers. Potential challenges associated with the introduction of NGS into oncology will also be discussed.

3:15 Sponsored Presentations *(Opportunities Available)*

3:45 Valentine's Day Celebration and Poster Competition Winner Announced in the Exhibit Hall *(Last Chance for Poster Viewing)*

Case Studies in Implementation of Genomic Medicine

4:30 Chairperson's Remarks
Mark S. Boguski, Ph.D., Associate Professor, Center for Biomedical Informatics, Harvard Medical School

4:35 Genomics and the Personalization of Ovarian Cancer Care
David Huntsman, M.D., FRCPC, FCCMG, Medical Director, Center for Translational & Applied Genomics, British Columbia Cancer Agency
In addition to being used to select treatment options the mutation profiles of ovarian cancer can readily be used to develop patient specific monitoring tools.

5:05 Making a Definitive Diagnosis: Opportunities and Challenges Associated with Clinical Application of Whole Genome Sequencing
Elizabeth Worthey, Ph.D., Assistant Professor, Pediatrics & Bioinformatics Program, Human & Molecular Genetics Center, Medical College of Wisconsin
A pilot program aimed at developing a clinically appropriate system for WGS MDx was recently completed. A permanent WGS based clinic is now in place. I will discuss the types of opportunities and challenges associated with each aspect of this process, and will review details from specific cases.

5:35 Case Study in Autism
Timothy W. Yu, M.D., Ph.D., Instructor in Pediatrics, Children's Hospital Boston and Department of Neurology, Lurie Center for Autism, Mass General Hospital for Children

6:05 Sponsored Presentations *(Opportunities Available)*

6:35 Close of Day

Friday, February 15

8:00 am Morning Coffee

Companion Diagnostics: Development and Implementation

8:30 Chairperson's Remarks

8:35 Successful Development and Commercialization of Precision Medicines: "It Takes a Village"
Hakan Sakul, Ph.D., Executive Director & Head, Diagnostics, Worldwide R&D, Clinical Research and Precision Medicine, Pfizer

9:05 Emerging Regulatory Trends in Drug-Diagnostic Co-Development
Erling Thor Donnelly, Ph.D., R.A.C., Director, Worldwide Regulatory Strategy, Pfizer, Inc.

9:35 From Biomarker to Companion Diagnostics: The Process Starts Early
Premal Shah, Ph.D., Director, Business Development, Genomic Health, Inc. (tentative)

10:05 Sponsored Presentations *(Opportunities Available)*

10:35 Coffee Break

Molecular Profiling for Patient Selection

11:00 Clonal Analysis and Molecular Profiling for Patient Selection
Michael Barrett, Ph.D., Associate Professor, Clinical Translational Research Division; Unit Head, Oncogenomics Laboratory, TGEN
Cancers frequently arise as a result of an acquired genomic instability and the subsequent evolution of neoplastic cells with variable genomes. Thus the behaviors of distinct clonal populations in each patient's tumor underlie the clinical phenotypes of many cancers.

11:30 Molecular Profiling for Patient Selection: MD Anderson Perspective
Apostolia-Maria Tsimberidou, M.D., Ph.D., Associate Professor, Department of Investigational Cancer Therapeutics, University of Texas MD Anderson Cancer Center

12:00 pm Challenges and Issues in the Clinical Execution of a Biomarker Driven Clinical Trial
Jonathan Cheng, M.D., Director, Oncology Clinical Development, Merck

12:30 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

Clinical Trial Specimens in Cancer Research

1:45 Chairperson's Remarks

1:50 Cooperative Oncology Group Banks (CGBS)
Irina A. Lubensky, M.D., Chief, Resources Development Branch, Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis, NCI, NIH
CGBs collect, store and distribute specimens from patients treated in phase III and large phase II NCI-funded randomized clinical trials. These well-annotated specimen collections are unique because they have associated uniform clinical, treatment, and outcome data.

2:20 The Role of the Biorepository in Cancer Clinical Trials: "From Bed to Bench"
Nilsa C. Ramirez, M.D., Director, Surgical Pathology, Department of Pathology and Laboratory Medicine, Nationwide Children's Hospital; Medical Director, Biopathology Center, Co-I and Lead Pathologist, TCGA BCR, The Research Institute at Nationwide Children's Hospital
Biorepositories directly influence the outcome of translational research in clinical trials.They oversee procurement, banking, testing and distribution of quality clinical trial samples to approved investigators. The role of the biorepository in the cancer cooperative group organization is discussed.

2:50 National Breast Cancer Biobank and Oncology Research
Valerie Speirs, Ph.D., Associate Professor, Leeds Institute of Molecular Medicine, University of Leeds

3:20 The Role of the Tissue Bank in Academic Cancer Centers
Teri A. Longacre, M.D., Professor of Pathology, Director, Tissue Procurement Facility, Stanford Cancer Center, Stanford, California
The various functions of the tissue bank in academic cancer centers have increased in complexity in the last decade. In this lecture, key problem areas faced by academic cancer centers in the areas of tissue procurement, tissue distribution, quality metrics, accommodation of SPORE and other specific programmatic projects, clinical annotation, and data tracking are discussed. In addition, the concept of a "clinical biobank" as opposed to the traditional "research biobank" is introduced.

3:50 Close of Conference

Second Annual

Bioinformatics in the Genome Era

Understanding the Evolving Role of Bioinformatics in Molecular Medicine

Wednesday, February 13

7:00 am Registration and Morning Coffee

Plenary Keynote Session

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

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

NGS Platforms and Workflows: Data Analysis and Implementation

11:00 Chairperson's Opening Remarks

11:10 The Impact of Novel Sequencing Technologies on Antibody Discovery and Development
Jacob Glanville, Ph.D., Science Director, Distributed Bio

11:40 From Data to Discovery: Case Studies, Lessons Learned, and Next Steps
Joseph Szustakowski, Ph.D., Senior Group Head, Bioinformatics, Biomarker Discovery, Novartis Institutes for BioMedical Research
This presentation will describe several case studies to highlight the bioinformatics challenges we face when analyzing NGS data, the computational infrastructure required to enable such analyses, and the analysis algorithms and strategies used to solve the problems at hand.

12:10 pm Toward an Open Translational Research System: Leveraging tranSMART to Drive the Management of Clinical and Molecular Information
Jay Bergeron, Program Manager, Pfizer

Sponsored by Appistry

12:40 Scaling Science for Performance: Implementing a Cost-Effective "Big Data"
Gordon Springer, Ph.D., Scientific Director, Computer Science, University of Missouri Bioinformatics Consortium
"Fabric computing" has enabled a leading agricultural genomics research consortium to scale automated sequencing pipelines and alleviate the data management burden associated with traditional high-performance computing architectures. The environment facilitates research collaborations by enabling scientists to rapidly and cost effectively develop custom pipelines using their preferred bioinformatics tools.

1:45 20th Anniversary Cake in the Exhibit Hall with Poster Viewing

Integrating Genomic Information

2:15 Chairperson's Remarks

2:20 Integrative Omics Profiling for Personalized Medicine
Rui Chen, Ph.D., Postdoctoral Scholar, Snyder Lab, Genetics, Stanford University School of Medicine
We performed an integrative Personal Omics Profile (iPOP) analysis on one volunteer individual over a 14-month period, combining multiple omics information collected from 20 time points. We observed extensive, dynamic molecular changes across various physiological stages.

2:50 Interactive Medical Decision Trees: Using Up-to-Date Genomics and IT to Bring Personalized Care to Regional Populations
Tibor van Rooij, Ph.D. Candidate, Pharmacy and Pharmaceutical Sciences, University of Alberta; former Director of Bioinformatics, Génome Québec and Montreal Heart Institute Pharmacogenomics Centre
Learn about an innovative approach which uses available genomics data, newly collected data from pgeni.org and its nine affiliated centers worldwide and de-novo generated medical decision trees. This approach allows for personalized medicine at point-of-care for use by country-specific healthcare systems.

3:20 iCTNet: A Data Integration Tool to Facilitate Analysis of Complex Traits and Evaluate Novel Therapeutic Approaches
Sergio E. Baranzini, Ph.D., Associate Professor, Heidrich Family and Friends Endowed Chair in Neurology, Neurology, University of California San Francisco
The talk discusses Integrated Complex Traits Network (iCTNet), a large-scale network assembling human disease-gene association, tissue-gene association, disease-tissue associations, protein-DNA interactions, protein-protein interactions and drug-target information. This network provides a new and comprehensive perspective for human genetic diseases.

Sponsored by INGENUITY SYSTEMS

3:50 Transcriptomics Analysis of Human Muscle Redefines mTOR Role in Growth Regulation
Jamie Timmons, Ph.D., Professor, Systems Biology, Loughborough University
Transcriptomics analysis has evolved to the point that robust experiments can be done in-silico. Using Upstream Regulator Analysis in Ingenuity's IPA, we analyzed human clinical samples and discovered mTor is a new molecular regulator of human muscle growth.

4:20 Networking Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunities Available)*

5:20 Breakout Discussions in the Exhibit Hall *(See Web for Details)*

6:20 Close of Day

Thursday, February 14

7:00 am Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

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

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

Collaborations: Role of Bioinformatics and its Positive Impact on Translational Medicine

10:40 Chairperson's Remarks

10:45 PANEL DISCUSSION: Nationwide Children's Presents a Multifaceted Computational Approach to Pediatric Care
Computational scientists at the Kloczkowski research group, Battelle Center for Mathematical Medicine, have taken the initiative to collaborate with several of the researchers and clinical doctors at The Research Institute (RI) and Nationwide Children's Hospital (NCH). In the past year, these collaborations with clinical researchers, who conduct studies relating to childhood cancer, nephrotic syndrome, cardiovascular and infectious diseases, have brought synergy and determination to combat childhood diseases. This session will share our experiences and perspectives in applying computational techniques to these studies and working together with scientists coming from widely varying fields of research.

Moderator: Andrzej Kloczkowski, Ph.D., Professor, Battelle Center for Mathematical Medicine, The Research Institute at Nationwide Children's Hospital and Pediatrics, The Ohio State University College of Medicine Saras Saraswathi Ph.D., Postdoctoral Research Associate, Battelle Center for Mathematical Medicine, The Research Institute at Nationwide Children's Hospital
Richard Ransom, Ph.D., Principal Investigator, Center for Clinical and Translational Research and Faculty, Nephrology and Urology Research Affinity Group, The Research Institute at Nationwide Children's Hospital
Peter Houghton, Ph.D., Principal Investigator, Hematology/Oncology & Blood and Marrow Transplant (BMT) and Director, Center for Childhood Cancer and Blood Diseases, The Research Institute at Nationwide Children's Hospital
Pam Lucchesi, Ph.D., Director, Center for Cardiovascular and Pulmonary Research and Principal Investigator, Heart Center, The Research Institute at Nationwide Children's Hospital

12:15 pm Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

Implementing the Rapid-Learning Healthcare System for Cancer Care

1:40 PANEL DISCUSSION: Implementing the Rapid-Learning Healthcare System for Cancer Care

This session examines the elements of a rapid-learning system for cancer care, including registries and databases and emerging information technology and bioinformatics tools.

Moderator: Marcia Kean, Chairman, Strategic Initiatives, Feinstein Kean Healthcare

~William S. Dalton, Ph.D., M.D., CEO, M2Gen; Director, Personalized Medicine Institute, Moffitt Cancer Center

~Peter Yu, M.D., Medical Oncologist and Hematologist, Palo Alto Medical Foundation; Chair, Health Information Technology Work Group, The American Society of Clinical Oncology; Co-Chair, Oncology Certification Work Group, Commission for the Certification of Health Information Technology

Dietrich A. Stephan, Ph.D., President and CEO, Silicon Valley Biosystems, Inc.

Sponsored by IMPROVER systemsbiologyverification

3:15 Translational Systems Biology: Understanding the Limits of Animal Models as Predictors of Human Biology

Kahn Rhrissorrakrai, Ph.D., Post-doctoral Researcher, Functional Genomics and Systems Biology, IBM Thomas J. Watson Research Center

Inferring how humans may respond to external stimuli is an essential question in biomedicine. This presentation describes a series of 'competitive crowd sourcing challenges' within the SBV IMPROVER project sbvimprover.com that address the issue of translatability between humans and rodents.

3:45 Valentine's Day Celebration and Poster Competition Winner Announced in the Exhibit Hall *(Last Chance to View Posters)*

Bioinformatics in Translational Medicine: Systems Biology Approaches

4:30 Chairperson's Remarks

Manuel C. Peitsch, Ph.D., Vice President, Biological Systems Research, Philip Morris International Research & Development

4:35 FEATURED PRESENTATION: Systems Approaches to Molecular Diagnostics and Perturbed Network Identification

Nathan Price, Ph.D., Associate Professor, Institute for Systems Biology

This presentation discusses broad sources of inter-study variance that can significantly affect reproducibility and accuracy of molecular diagnostics as they move from lab experiment towards the clinic as well as systems approaches for dealing with these challenges. Also discussed will be network analysis techniques to better link molecular signatures with underlying biological mechanisms. Such integrations are critical to harnessing the tremendous potential of -omics technologies to revolutionize medicine.

5:05 Robust Statistical Approach for Cancer Research

Svetlana Amirova, Ph.D., Assistant Professor, Mathematics, University of Texas at El Paso

We apply a systems biology approach to study genetic aspects of metabolic pathway regulation for cancer research. To demonstrate universality of this approach we apply this computational framework to work with biological data motivated by cancer research.

5:35 Predicting Drug Response from Cancer Cell Lines

Adam Margolin, Ph.D., Computational Biology, Sage Bionetworks

6:05 Structural Bioinformatics Analysis Predicts Superior Kinome Selectivity of Clinical p38 MAPK Inhibitor

Li Xing, Ph.D., Senior Principal Scientist, Pfizer

PH-797804 is a p38 kinase inhibitor derived from a racemic mixture as the more potent atropisomer. Structural bioinformatics mining of human kinase genome identified a selectivity motif on the kinase hinge. PH-797804 exhibited high specificity against MAPK and large kinase panels, which translated well to cellular systems. Safety was proven in Phase I clinical trials. Efficacy was achieved in certain human disease population.

6:35 Close of Day

Friday, February 15

8:00 am Morning Coffee

Bioinformatics in Translational Medicine: Systems Biology Approaches

8:30 Chairperson's Remarks

8:35 Metabolic Diseases: Modulation of Microbiome

Deepak Rajpal, Ph.D., Senior Scientific Investigator, Computational Biology, Medicines Discovery & Development, GlaxoSmithKline

We present a proof-of-concept study where modulation of gut microbiome revealed novel associations with metabolic improvements in rodents. This is an important step in evaluating the gut microbiome changes with metabolic improvements.

9:05 Systems Biology: A Molecular Nutrition Perspective

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

Omics data are often collected in conjunction with markers of clinical health and lifestyle information. A challenge is how to address the impact of diet on health by exploiting a system-level approach that integrates this multilayer data in a coherent, functional, modular and biologically informative view.

9:35 Understanding the Impact of PI3K(p110a) Inactivation in Myocardial Infarction

David Fung, Ph.D., Postdoctoral Research Fellow, School of Biotechnology and Biomolecular Sciences, The University of New South Wales

So far, systems analyses of cardiomyopathy are not as frequent as compared to common cancers. This presentation will showcase analytics that make good use of ontology enrichment combined with network modeling to general insight into the biology of myocardial infarction.

10:05 Sponsored Presentations *(Opportunities Available)*

10:35 Coffee Break

Data Integration Strategies to Support Clinical & Translational Research

11:00 BioAssay Ontology (BAO)and the LINCS Information FramEwork (LIFE) to Integrate and Analyze Diverse High Throughput and Cellular Profiling Assay Data

Stephan Schürer, Ph.D., Center for Computational Science and Molecular and Cellular Pharmacology, Miller School of Medicine, University of Miami

11:30 Secondary Research with Clinical Data

Shoibal Datta, Ph.D., Associate Director, R&D Information Technology, Biogen Idec

Biogen Idec has recently embarked on an ambitious strategy to embed translational approaches into every aspect of its R&D lifecycle. This has required a complete overhaul of processes and systems to support the strategy touching almost all functions within R&D.

12:00 pm OpenMedNet: Toward a Future of Personalized Medicine-Bridging Genomics, Informatics and Clinical Care

Andreas M. Kogelnik, M.D., Ph.D., Director, Open Medicine Institute

12:30 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

Data Integration

1:45 Chairperson's Remarks

1:50 Synthetic Biology beyond the Firewall: Cloud-Based Computing with Extremely High Value Data

Michael Fero, Ph.D., CEO, TeselaGen Bio

This talk presents a use-case that illustrates the cost and time benefits of using 3rd party cloud based informatics solutions vs keeping high-value data behind corporate firewalls. Recommendations on how to implement secure solutions that ensure data integrity and security will also be presented.

2:20 Berg Interrogative Biology: Personalizing Healthcare by Using Advanced Molecular Analytics

Niven Narain, Ph.D., President and CTO, Berg Pharma

This talk will review implementation and case studies of a top-of-the-art unique analytical platform for healthcare and molecular informatics. Real world application of this Bayesian artificial intelligence based approach to data analysis of massive collections of patient records, clinical information and molecular measurements will be presented.

2:50 HOMER: A Free Software Suite Designed for Biologists to Analyze Next-Generation Sequencing Data of Epigenetics and Long-Range Genomic Interactions

Yin Lin, Ph.D., Assistant Project Scientist, Biological Sciences, University of California, San Diego

This talk will describe a proven free software suite to assist researchers in performing their own analyses on NGS data in a matter of hours for quality control, data visualization, generation of hypothesis, and to hasten the process of discovery.

3:20 Close of Conference

Fifth Annual

Integrated R&D Informatics and Knowledge Management

Leveraging IT and Informatics to Enable Global Information Sharing

Wednesday, February 13

7:00 am Registration and Morning Coffee

Plenary Keynote Session

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

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

Collaboration – What Does it Mean, How do We use it & Measure it?

11:00 Chairperson's Opening Remarks
Manish Muzumdar, Senior Vice President, Products, Remedy Informatics

11:10 Internal Collaboration
Arturo Morales, Ph.D., Global Leader Data Federation Initiative, Informatics Systems Lead, Novartis
The Novartis Data Federation Initiative aims to enable global project teams by providing a seamless collaborative environment that integrates data, information and knowledge generated within and outside NIBR.

11:40 Technology for Collaborative Development of Ontologies for Data Analysis and Integration
Mark A. Musen, M.D., Ph.D., Professor of Medicine, Biomedical Informatics, Stanford Center for Biomedical Informatics Research
Work with "big data" requires well-defined ontologies for annotation, retrieval, integration, and analysis. The National Center for Biomedical Ontology is developing a comprehensive infrastructure to support collaborative authoring, dissemination, open peer review, and use of ontologies over the Web.

12:10 pm Pre-Competitive Collaboration
Sandor Szalma, Head, External Innovation, R&D IT at Janssen Research & Development, LLC
To increase innovation in non-core areas, pharma companies have recently been more open to establish precompetitive partnerships. In this presentation we discuss several improved outcomes from such informatics and IT collaborations.

12:40 Luncheon Presentation I: Liberating the Knowledge in your Biospecimens through Next Generation Biobanking
Sponsored by BioFortis
Mark A Collins, Ph.D., Director, Marketing, BioFortis, Inc.
Traditional biobanking software is sample-centric. However, Next Generation Biobanking software extends support into biomarker-based clinical research carried out in a distributed ecosystem of vendors, partners and collaborators, while ensuring security and compliance. Next Generation Biobanking case studies will be presented

1:10 Luncheon Presentation II *(Sponsorship Opportunity Available)*

1:45 20th Anniversary Cake in the Exhibit Hall with Poster Viewing

Externalization and the Changing Landscape in Pharma

2:15 Chairperson's Remarks: The De-Evolution of Informatics: How Externalization is Radically Changing the Informatics Landscape
Mike Elliott, Ph.D., CEO, Atrium Research & Consulting LLC
The rush toward externalization is transforming traditional approaches to informatics architectures. Increasing business development activity is forcing IT to confront new questions and to modify existing architectures. This session will discuss this trend and how organizations are addressing the challenges.

2:20 Fully Integrated Pharmaceutical Network (FIPnet): AstraZeneca R&D Case Study
Arun Nayar, Global Head, External Collaborations, R&D, Information, AstraZeneca Pharmaceuticals Sebastien Lefebvre, Head, R&D Information Architecture Practice, AstraZeneca Pharmaceuticals
We will share our experiences in deploying Informatics platforms to enable externalization and virtualization of key R&D capabilities in support of Virtual NeuroScience Innovative Medicine and other R&D functions.

2:30 Externalization as a Platform to Enable Integrated Collaboration: A Merck R&D Case Study
Phyllis Post, Executive Director, Merck & Co., Inc.
Merck R&D has implemented an integrated partner portal that is designed to enable consolidated collaboration with our strategic partners to provide a user-centric "window to the world" for our partners to collaborate and interact with Merck R&D in an efficient, agile and effective manner.

3:00 Outsourcing Understanding
Jeremy Packer, Ph.D., Principal Research Scientist, Scientific Informatics, Abbott Laboratories

3:30 PANEL DISCUSSION: Measuring and Showing the Impact of IT and Informatics on Collaboration
Moderator: Martin Leach, Ph.D., CIO, The Broad Institute
Mike Elliott, Ph.D., CEO, Atrium Research & Consulting LLC
HongMei Huang, Ph.D., Director and Site Head, NIBR IT Emeryville, Novartis
Joseph F. Donahue, Senior Vice President, Intellectual Property & Science, Thomson Reuters

3:50 Searchability and Findability in the Brave New World of Big Data
Sponsored by THOMSON REUTERS
Andreas Matern, Vice President, Disruptive Innovation, Thomson Reuters
The data deluge has made the 'findability' of information a priority, especially in the life sciences. This talk will discuss some of the trends in the industry around not just searching for meaningful data, but more importantly, finding answers to questions.

4:20 Networking Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunities Available)*

5:20 Breakout Discussions in the Exhibit Hall *(See Web for Details)*

6:20 Close of Day

Thursday, February 14

7:00 am Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

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

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

Leveraging Information Across Multiple Internal Sources

10:40 Chairperson's Remarks
Chris L. Waller, Ph.D., Director, Cheminformatics, Discovery Merck Research Labs

10:45 Breaking Down Information Silos
Chris L. Waller, Ph.D., Director, Cheminformatics, Discovery Merck Research Labs
Much has been written about the various technologies that can be utilized to empower translational informatics systems. This talk will focus on behavioral barriers that impede the implementation of translational systems in support of the emerging open research and development environment.

11:15 The Path to Linked Data in BioPharma
Tom Plasterer, Ph.D., Principal Informatics Scientist, Semantic Framework Lead, AstraZeneca
As BioPharma adapts to incorporate nimble networks of suppliers, collaborators, and regulators the ability to link data is critical for dynamic interoperability. Adoption of linked data paradigm allows BioPharma to focus on core business: delivering valuable therapeutics in a timely manner.

11:45 Towards a Data-Driven Framework for Life Sciences Integration
Paul Konstant, Manager Informatics, Janssen Pharmaceuticals
Interdisciplinary integration of experimental outcomes continues to face a changing landscape of scientific and technology methods. In this work, we present the Independent Variable Framework designed to manage diversity and change. The framework supports capturing outcomes in their complete context.

Sponsored by ELSEVIER

12:15 Repurposing Scientific Discovery - Delivering Structured Intelligence from Unstructured Text
Kevin Bobofchak, Ph.D., Pathway Studio Product Manager, Elsevier

Sponsored by ACD/Labs

12:45 Breathing Life into Your Analytical Data
Ryan Sasaki, Director, Global Strategy, ACD/Labs
Analytical data from different departments can be spread across different information silos throughout an organization. Despite significant investments in data acquisition and storage, the knowledge and decision-making associated with this data is rarely retained. Bringing this data to life requires systems that can handle all data types and vendor formats as well as a means to extract the information from data as it relates to chemical structure(s).

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

1:40 Chairperson's Remarks
Barry Bunin, Ph.D. CEO, Collaborative Drug Discovery

1:45 Leveraging Information to Drive Drug Discovery: Lessons Learned Over 25 Years
Mic Lajiness, Ph.D., Research Advisor, Eli Lilly
This presentation will cover lessons learned in development of Cousin, ChemLink and Mobius, the main integrated DBs used at Pharmacia and Lilly. This talk highlights key factors that led to success as well as those that have led to failure.

2:15 Registration and Management of Non-Sequenced Based Biological Samples
Christina Lu, Manager, IT, Novartis Pharmaceuticals Corp.

2:45 Applying Lessons Learned from Life Science to Downstream Energy Informatics
Len Koenig, Senior Research Associate Research Computing, Computer Science and Chemistry, ExxonMobil Research and Engineering
As Life Sciences and Downstream Energy face similar challenges of managing research data, we implemented common practices to merge and precondition disparate or complex data. We will describe the benefits of these activities and extend lessons learned and best practices across our mutual industries.

Sponsored by Reverse Informatics

3:15 World's Disclosed Knowledge in Digestible Format: Externalization and Reverse Informatics
Srinivasan Parthiban, Ph.D., CEO & President, Parthys Reverse Informatics

Sponsored by idbs

3:30 Perspectives on Collaboration Models Across the Health Science Ecosystem
Paul Denny-Gouldson, Ph.D., Vice President, Translational Medicine, IDBS
Pharmaceutical companies are moving from centralised organisations to virtual network of internal labs, CROs, academic partners and government agencies. Data is central to these collaborative ecosystems and needs to be consistently captured, integrated, managed, tracked and analysed. This presentation will highlight key case studies to demonstrate how companies can gain competitive advantage from their increasingly complex network of data and partners.

3:45 Valentine's Day Celebration and Poster Competition Winner Announced in the Exhibit Hall *(Last Chance to View Posters)*

Platforms to Enable Internal and External Collaboration and Drive Discovery

4:30 Chairperson's Remarks

4:35 Leveraging the Google Apps Enterprise Platform to Enable Internal and External Collaboration at the Broad Institute
Lukas Karlsson, Head, Administrative Computing, Technology Leader Broad Institute
In the presentation you will learn how the Broad Information Technology Services Group have leveraged the Google Apps Enterprise Platform to facilitate collaboration, challenges we have faced and how we complement other collaboration tools to provide a rich collaboration experience.

Sponsored by CDD COLLABORATIVE DRUG DISCOVERY

5:05 A More Economical, Collaborative Business Model for Drug Discovery: The Collaborative Drug Discovery Paradigm
Barry Bunin, Ph.D. CEO, Collaborative Drug Discovery
Cloud computing and leveraging the Internet for secure collaborations are becoming more important. A more economical, collaborative business model for drug discovery has emerged. Representative commercial and neglected disease NIH, BMGF, industry, and academic case studies will be shared.

5:35 A Roadmap to Successful Collaborations: Lessons from Past and Present
Mary Bradley, Ph.D., MBA, CollaborationFinder
Collaboration is widely viewed as a necessity to improve productivity and increase innovation. Identifying factors and behaviors that contributed to successful collaborations, as well as cultural factors that can impede success, provide insight into what drives the best collaborative outcomes.

6:05 Sponsored Presentations *(Opportunities Available)*

6:35 Close of Day

Friday, February 15

8:00 am Morning Coffee

Data Integration Strategies to Support Clinical & Translational Research

8:30 Chairperson's Remarks
Ajay Shah, Ph.D., Director, Research Informatics Division, City of Hope

8:35 Translational Research Informatics Platform at City of Hope
Ajay Shah, Ph.D., Director, Research Informatics Division, City of Hope
City of Hope (COH) is implementing several components of its Translational Research Informatics Platform. This platform leverages COH Enterprise Data Warehouse. Natural language processing components of the platform allows for analysis of EMRs, and extraction of coded fields from these records.

9:05 Path to Develop Integrated Data for Biomarker Research
Carol Bova Hill, Ph.D., Informatics Project Leader II, Clinical Research Informatics, Duke Clinical Research Institute
Integration of data to support translational research requires rigorous understanding of data and highlights the crucial role of the Informaticist. I will outline efforts and challenges to create a robust systematic environment to support the utilization of biospecimens at DCRI.

9:35 Data Visualization in Clinical Research
Dimitris Agrafiotis, Janssen R&D, Johnson & Johnson

10:05 Sponsored Presentations *(Opportunities Available)*

10:35 Coffee Break

11:00 BioAssay Ontology (BAO)and the LINCS Information FramEwork (LIFE) to Integrate and Analyze Diverse High Throughput and Cellular Profiling Assay Data

Stephan Schürer, Ph.D., Center for Computational Science and Department of Molecular and Cellular Pharmacology, Miller School of Medicine, University of Miami

11:30 Secondary Research with Clinical Data

Shoibal Datta, Ph.D., Associate Director, R&D Information Technology, Biogen Idec

Biogen Idec has recently embarked on an ambitious strategy to embed translational approaches into every aspect of its R&D lifecycle. This has required a complete overhaul of processes and systems to support the strategy touching almost all functions within R&D.

12:00 pm OpenMedNet: Toward a Future of Personalized Medicine- Bridging Genomics, Informatics and Clinical Care

Andreas M. Kogelnik, M.D., Ph.D., Director, Open Medicine Institute

12:30 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

Data Integration

1:45 Chairperson's Remarks

1:50 Synthetic Biology beyond the Firewall: Cloud-Based Computing with Extremely High Value Data

Michael Fero, Ph.D., CEO, TeselaGen Bio

This talk presents a use-case that illustrates the cost and time benefits of using 3rd party cloud based informatics solutions vs keeping high-value data behind corporate firewalls. Recommendations on how to implement secure solutions that ensure data integrity and security will also be presented.

2:20 Berg Interrogative Biology: Personalizing Healthcare by Using Advanced Molecular Analytics

Niven Narain, Ph.D., President and CTO, Berg Pharma

This talk will review implementation and case studies of a top-of-the-art unique analytical platform for healthcare and molecular informatics. Real world application of this Bayesian artificial intelligence based approach to data analysis of massive collections of patient records, clinical information and molecular measurements will be presented.

2:50 HOMER: A Free Software Suite Designed for Biologists to Analyze Next-Generation Sequencing Data of Epigenetics and Long-Range Genomic Interactions

Yin Lin, Ph.D., Assistant Project Scientist, Biological Sciences, University of California, San Diego

This talk will describe a proven free software suite to assist researchers in performing their own analyses on NGS data in a matter of hours for quality control, data visualization, generation of hypothesis, and to hasten the process of discovery.

3:20 Close of Conference

Inaugural

Predictive Pre-Clinical Models in Oncology

Delivering Reproducible and Predictive Results

NEW

Wednesday, February 13

7:00 am Registration and Morning Coffee

Plenary Keynote Session

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

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

11:00 Chairperson's Opening Remarks

11:10 KEYNOTE PRESENTATION: Development of Pre-Clinical Strategies that Accurately Guide Clinical Cancer Research: Progress, Challenges, & Perspective
Terry A. Van Dyke, Ph.D., Head, Mouse Cancer Genetics Program; Program Director, Cancer Pathways and Mechanisms, National Cancer Institute

Novel Animal Models

11:40 Pre-Clinical Models for Prediction of Therapeutic Response in Breast Cancer
Joe W. Gray, Ph.D., Gordon Moore Professor and Chair, Biomedical Engineering, Oregon Health and Science University; Emeritus Professor, UCSF; Visiting Faculty, Lawrence Berkeley National Laboratory; Co-Director, Breast Cancer SPORE

12:10 pm Models of Anaplastic Lymphoma Kinase Activation in Breast Cancer
Fredika Robertson, Ph.D., Professor, Experimental Therapeutics, The University of Texas MD Anderson Cancer Center

12:40 Luncheon Presentation
Sponsored by EXEMPLAR GENETICS
John Swart, Ph.D., President, Exemplar Genetics

1:45 20th Anniversary Cake in the Exhibit Hall with Poster Viewing

2:15 Chairperson's Remarks

2:20 Is the Use of Orthotopic Oncology Models a Necessity or Luxury?
Cedo Bagi, M.D., Ph.D., Senior Research Fellow, Worldwide Comparative Medicine, Global Science & Technology, Pfizer Global R&D

2:50 Non-Germline Genetic Mouse Model Strategies for Retooling of Next- Generation Pre-Clinical Murine GEMMs
Serguei Kozlov, Ph.D., Principal Scientist, Center for Advanced Pre-Clinical Research, SAIC-Frederick, Inc.
CAPR employs orthotopic allografting and embryonic/induced pluripotent stem cell technologies to expedite resource conscious building of cohorts for pre-clinical experimentation using "non-germline" models.

3:20 Complex Models & Polypharmacology: A Fly Approach to Therapeutics
Ross Cagan, Ph.D., Professor, Developmental & Regenerative Biology, Mount Sinai School of Medicine
Cancer presents a challenge due to its genomic and tissue complexity. I will discuss our use of Drosophila cancer models that embrace this complexity to develop novel candidate therapeutics.

3:50 The JAX Patient Derived Xenograft (PDX) Cancer Consortium: Changing the Course of Clinical Advancement
Sponsored by The Jackson Laboratory
Neal Goodwin, Ph.D., Dir., R&D, In Vivo Pharmacology Services, The Jackson Laboratory
A collaborative effort between JAX, the UC-Davis Comprehensive Cancer Center, and other research centers has been established for advancing cancer therapeutic development. Solid and liquid tumor specimens from consenting patients are being transplanted into the JAX-NSG mouse which has been engineered to ideally propagate human tissue.

4:20 Networking Reception in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunities Available)*

5:20 Breakout Discussions in the Exhibit Hall *(See Web for Details)*

6:20 Close of Day

Thursday, February 14

7:00 am Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

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

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

Cell Culture Models

10:40 Chairperson's Remarks

10:45 Leveraging the Molecular Diversity of Large Panel of Cancer Cell Lines to Improve Cancer Therapeutics
Cyril H. Benes, Ph.D., Principal Investigator and Director, Center for Molecular Therapeutics, Massachusetts General Hospital Cancer Center
Some of the complexity of cancer is captured by large panels of cancer cell lines. Using high-throughput screening candidate biomarkers of cancer therapeutic sensitivity can be identified.

11:15 Tumor-Derived Cell Lines as a Model System for Discovery of Predictive Biomarkers and Mechanisms of Drug Resistance
Jeffrey Settleman, Ph.D., Senior Director, Discovery Oncology, Genentech
With the emergence of "pathway-targeted" cancer drug therapies, tumor-derived cell lines are playing an increasingly important role in the discovery of biomarkers for stratifying patients for optimal clinical benefit, and to identify molecular mechanisms of innate and acquired drug resistance.

11:45 Sponsored Presentations (*Opportunities Available*)

12:15 pm Utilization of Predictive *in vivo* TumorGraft Models to Guide Oncology Drug Development
Sponsored by CHAMPIONS ONCOLOGY
Elizabeth Bruckheimer, Ph.D., Vice President, Scientific Operations, Champions Oncology, Inc.
One of the challenges of oncology drug development is the ability to translate preclinical results to the clincial setting. By using Champions TumorGraft models, oncology drug developers can better guide a compounds development from the lab to the clinic.

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

Maximizing Success of Preclinical Development

1:40 Chairperson's Remarks

1:45 Identifying Differentiation Strategies Among Competing Oncology Programs
Gallen Triana-Baltzer, Ph.D., Principal Scientist, Oncology, CovX Research, Pfizer WRD
In order to derisk a compound portfolio there is a growing emphasis on differentiation from internal and external competing programs as early as possible in R&D.

2:15 Maximizing Success of Anticancer Drugs in the Clinic Using Predictive Oncology Pre-Clinical Models
Handan He, Ph.D., Dir., Pre-Clinical PK/PD, DMPK, Translational Sciences, Novartis
Efficacious exposure predictions can be challenging due to poor solubility and/or permeability for BDDCS 2/BDDCS 4 anticancer drugs. The successful use of pre-clinical animal data with PBPK/PD/biomarkers together with ACAT modeling to predict systemic exposure or food effects will be presented.

2:45 Developing Foundation/Academic/Pharmaceutical Platforms to Accelerate Pre-Clinical Studies for Rare and Orphan Diseases
Mila McCurrach, Project Manager, NFPC, Neurofibromatosis Pre-Clinical Consortium, Children's Tumor Foundation, Research Manager, Lustgarten Foundation
Foundations are spearheading, and putting significant resources into, novel platforms that bring together investigators from academic institutions and pharmaceutical companies to rigorously evaluate rational candidate drugs in GEM models.

3:15 New High-Throughput Human MicroTumor Screening Platform To Accelerate Pre-Clinical Drug Development
Sponsored by VIVO BIOSCIENCES ADVANCING DRUG DEVELOPMENT
Raj Singh, Ph.D., President & CEO, Vivo Biosciences, Inc.
VBI's novel 3D MicroTumor screens replicate monotypic (NCI-60) and heterotypic (PDx) biology and functions. *In vivo*-like HTS oncology platform allows real-time analysis of drug uptake, tumor penetration and sensitivity profiles, thus accelerating pre-clinical drug development prior to expensive animal trials.

3:30 Sponsored Presentation *(Opportunity Available)*

3:45 Valentine's Day Celebration and Poster Competition Winner Announced in the Exhibit Hall *(Last Chance to View Posters)*

Quality of Pre-Clinical Evidence Matters

4:30 Chairperson's Remarks

4:35 Challenges in Translating Pre-Clinical Research into Benefit for Patients: Raising the Bar for Pre-Clinical Cancer Research
C. Glenn Begley, Ph.D., Senior Vice President, TetraLogic
There are multiple challenges translating research findings into drugs that ultimately benefit patients. Some are inherent in the disease and the models we employ, and are extremely difficult to address. Others are inherent to our processes, and may be more readily overcome.

5:05 Building More Predictive *in vitro* and *in vivo* Models to Identify Responder Populations Pre-Clinically
Emma Lees, Ph.D., Vice President, Oncology, NIBR Site Head Emeryville, Novartis Institutes for Biomedical Research

5:35 Challenges to Accurately Translating Results from Pre-Clinical Cancer Models to the Clinic
Peter Houghton, Ph.D., Dir., Center for Childhood Cancer, Nationwide Children's Hospital
Human tumor xenografts have been the predominant models for cancer drug development for about 30 years. However, there are concerns that results from such pre-clinical models do not translate into clinical reality.

6:05 Sponsored Presentations *(Opportunities Available)*

6:35 Close of Day

Friday, February 15

7:30 am Morning Coffee

Applying Animal Models of Cancer

8:00 Chairperson's Remarks

8:05 Targeted Kinase Inhibition: Using Pre-Clinical Data to Identify Novel Pathway Inhibitor Combinations
Barry Hart, Ph.D., VP, Project Mgmt. & Business Development, Allostem Therapeutics
Allostem Therapeutic's lead MEK kinase inhibitor, CIP-137401, is in late pre-clinical evaluation. We believe that MEK inhibitors must be dosed in combination with other targeted therapies to have durable efficacy. As novel pathway inhibitor combinations involving MEK are reported we evaluate these for potential clinical development.

8:35 Targeting Replication Initiation in Cancer
Julie Bailis, Ph.D., Senior Scientist, Oncology Research, Amgen, Inc.
Cdc7, an essential serine/threonine protein kinase, regulates the initiation of DNA replication to maintain genome stability. We present characterization of a potent, selective small molecule inhibitor of Cdc7 kinase activity *in vitro* and *in vivo*.

9:05 Effects of Sphingosine Kinase Activity on Tumor Cell Viability
Holger Wesche, Ph.D., Principal Scientist, Amgen, Inc.
Sphingosine kinase (SPHK) activity has been postulated to play a critical role in apoptosis. Here we report the results of studies with novel, potent and specific SPHK inhibitors which elucidate the role of S1P production in whole cells and in animals.

9:35 Applying Genetically Engineered Mouse Modeling to Oncology Drug Development
Melissa R. Junttila, Ph.D., Scientist, Genentech, Inc.

10:05 Sponsored Presentations *(Opportunities Available)*

10:35 Coffee Break

Imaging in Pre-Clinical Cancer Research

11:00 The Utility of Various Imaging Modalities in Cancer Research
Simon Williams, Ph.D., Senior Scientist, Biomedical Imaging, Genentech
This talk will illustrate applications of various imaging modalities (Optical, Ultrasound, PET, CT, and MRI) in cancer research and drug development and emphasize the need to match the modality to the biological question and disease model at hand.

11:30 Metabolic PET Endpoints in Translational Oncologic Imaging: An Amgen Case Study
Charles Glaus, Ph.D., Scientist, Research Imaging Sciences, Amgen
Targeted therapeutics pose unique challenges for PET imaging biomarkers, and selection of response models and appropriate tracers is of critical importance. We present a pre-clinical PET imaging study that resulted in a focused imaging strategy for a first-in-human study.

12:00 pm Diffusion MRI for Early Detection of Treatment Response in a Pre-Clinical Glioma Model
Sharon Ungersma, Ph.D., Research Imaging Sciences, Amgen, Inc.
MRI diffusion measurements can detect cellular changes in tumor tissue. In this pre-clinical case study, we measured significant changes in MRI diffusion before differences between control and treated tumor volumes were apparent, making MRI diffusion a potential early biomarker for glioma therapy.

12:30 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

Clinical Trial Specimens in Cancer Research

1:45 Chairperson's Remarks

1:50 Cooperative Oncology Group Banks (CGBS)
Irina A. Lubensky, M.D., Chief, Resources Development Branch, Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis, NCI, NIH
CGBs collect, store and distribute specimens from patients treated in phase III and large phase II NCI-funded randomized clinical trials. These well-annotated specimen collections are unique because they have associated uniform clinical, treatment, and outcome data.

2:20 The Role of the Biorepository in Cancer Clinical Trials: "From Bed to Bench"
Nilsa C. Ramirez, M.D., Director, Surgical Pathology, Department of Pathology and Laboratory Medicine, Nationwide Children's Hospital; Medical Director, Biopathology Center, The Research Institute at Nationwide Children's Hospital
Biorepositories directly influence the outcome of translational research in clinical trials.They oversee procurement, banking, testing and distribution of quality clinical trial samples to approved investigators.

2:50 National Breast Cancer Biobank and Oncology Research
Valerie Speirs, Ph.D., Associate Professor, Leeds Institute of Molecular Medicine,University of Leeds

3:20 The Role of the Tissue Bank in Academic Cancer Centers
Teri A. Longacre, M.D., Professor of Pathology, Director, Tissue Procurement Facility, Stanford Cancer Center, Stanford, California
The various functions of the tissue bank in academic cancer centers have increased in complexity in the last decade. In this lecture, key problem areas faced by academic cancer centers in the areas of tissue procurement, tissue distribution, quality metrics, accommodation of SPORE and other specific programmatic projects, clinical annotation, and data tracking are discussed. In addition, the concept of a "clinical biobank" as opposed to the traditional "research biobank" is introduced.

3:50 Close of Conference

Circulating Tumor Cells

Continued from page 24.

Capture Technology Improvements

10:55 Chairperson's Remarks
Steven A. Soper, Ph.D., Professor, Biomedical Engineering; Professor, Chemistry; Director, CBMM; Pryor Emeritus Professor (LSU), University of North Carolina, Chapel Hill

11:00 Presentation to be Announced

11:30 The Fluid Phase of Solid Tumors: How Does Cancer Spread?
Peter Kuhn, Ph.D., Associate Processor, Cell Biology, The Scripps Research Institute
Results will be presented that describe technical developments and validation, clinical validation and clinical utility of the HD-CTC Technology.

12:00 pm Utilization of Dielectrophoresis for Antigen Independent Circulating Tumor Cell (CTC) Capture Allows for Detection of Heterogeneous Tumor Cell Populations
Andrew Poklepovic, Ph.D., Assistant Professor, Internal Medicine, Virginia Commonwealth University
The ApoStreamTM antigen independent, dielectrophoresis based CTC enrichment device enables investigators to analyze various populations of tumor cells and has demonstrated clinical applicability in a wide variety of cancers.

12:30 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

Is the Clinical Need for CTCs Evolving?

1:50 PANEL DISCUSSION
How do we go from prognostication to measuring drug response and will clinical applications require live cells, plasma DNA, RNA or protein-based measurements?

Moderator: Daniel Haber, M.D., Ph.D., Director, Massachusetts General Hospital Cancer Center; Isselbacher/Schwartz Professor of Oncology, Harvard Medical School; Investigator, Howard Hughes Medical Institute
Panelists: Daniel Hayes, M.D., Professor, Internal Medicine, University of Michigan, Ann Arbor
Luis Diaz, M.D., Associate Professor of Oncology, Director of Translational Medicine, Ludwig Center at Johns Hopkins, Kimmel Cancer Center at Johns Hopkins
Lyndsay N. Harris, M.D., Case Comprehensive Cancer Center, Case Western Reserve

3:20 Close of Conference

Oncology Clinical Trials

Continued from page 38.

3:50 Sponsored Presentation
Speaker to be Announced

Sponsored by SomaLogic

4:05 Sponsored Presentation
(Opportunity Available)

4:30 Close of Conference

Clinical and Translational Science

Continued from page 38.

Sponsored by Tessella

10:05 A Day in the Life of a Data Scientist: Improving Translational Informatics
Jamie MacPherson, Ph.D., Consultant, Tessella
Translational informatics integrates and interrogates multiple data assets across different stages in drug development; these assets are diverse in type, scale and quality. To be efficient and effective, translational informatics projects must balance technical innovation and a practical ability to provide interpretable results. Here, we present a novel approach to translational informatics support: embedding 'Data Scientists' within drug-project teams.

10:35 Coffee Break

Molecular Profiling for Patient Selection

11:00 Clonal Analysis and Molecular Profiling for Patient Selection
Michael Barrett, Ph.D., Associate Professor, Clinical Translational Research Division; Unit Head, Oncogenomics Laboratory, TGEN
Cancers frequently arise as a result of an acquired genomic instability and the subsequent evolution of neoplastic cells with variable genomes. Thus the behaviors of distinct clonal populations in each patient's tumor underlie the clinical phenotypes of many cancers.

11:30 Molecular Profiling for Patient Selection: MD Anderson Perspective
Apostolia-Maria Tsimberidou, M.D., Ph.D., Associate Professor, Investigational Cancer Therapeutics, University of Texas MD Anderson Cancer Center

12:00 pm Challenges and Issues in the Clinical Execution of a Biomarker Driven Clinical Trial
Jonathan Cheng, M.D., Director, Oncology Clinical Development, Merck

12:30 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

Clinical Trial Specimens in Cancer Research

1:45 Chairperson's Remarks

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3:50 Close of Conference

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Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations and deliver prospects. Evening will be customized according to sponsor's objectives (i.e. purely social, focus group, reception style, or plated dinner with specific conversation focus).

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San Francisco, CA

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Includes 1 Symposium or Partnering Forum, 2 Short Courses, and 1 Conference Program.	Commercial	Academic, Government, Hospital-affiliated
Advance Registration until January 11, 2013	$3195	$1845
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PARTNERING FORUM (Monday, Feb 11 – Tuesday, Feb 12)

Emerging Molecular Diagnostics	$1450

SYMPOSIA (Monday, Feb 11 – Tuesday, Feb 12)

		$1450		$1025
S1 Targeting Cancer Stem Cells	S2 Genomics in Medicine	S3 Point-of-Care Diagnostics	S4 Quantitative Real-Time PCR	S5 Next Generation Pathology

SHORT COURSES (Tuesday, Feb 12)

1 Short Course	$695	$395
2 Short Courses	$995	$695

Afternoon
SC1 Identification & Characterization of Cancer Stem Cells
SC2 Commercialization Boot Camp: Manual for Success in the Molecular Diagnostics Marketplace
SC3 NGS Data and the Cloud
SC4 Best Practices in Personalized and Translational Medicine
SC5 Latest Advances in Molecular Pathology
SC6 Regulatory Approval of a Therapeutic & Companion Diagnostic: Nuts & Bolts
SC7 PCR Part I: qPCR in Molecular Diagnostics
SC8 Data Visualization
SC9 Methods for Synthesis & Screening of Macrocyclic Compound Libraries

Dinner
SC10 PCR Part II: Digital PCR Applications and Advances
SC11 Sample Prep and Biorepositories for Cancer Research
SC12 Next-Generation Sequencing in Molecular Pathology: Challenges and Applications
SC13 Strategies for Companion Diagnostics Development
SC14 Patient-Derived Cancer Tissue Xenograph Models
SC16 Microfluidics Technology and Market Trends
SC17 Open Cloud & Data Science
SC18 Human Microbiome Research & Modern Molecular Technologies

CONFERENCE PROGRAMS (Wednesday, Feb 13- Friday, Feb 15)

Advance Registration until January 11, 2013	$2145	$1195
Registration after January 11, 2013	$2345	$1245

Diagnostics Channel
P1 Molecular Diagnostics
P2 Personalized Diagnostics
P3 Cancer Molecular Markers
P4 Circulating Tumor Cells
P5 Digital Pathology– NEW
P6 Companion Diagnostics– NEW

Therapeutics Channel
P7 Mastering Medicinal Chemistry Summit
P9 Cancer Biologics
P11 Clinical and Translational Science

Clinical Channel
P10 Oncology Clinical Trials
P11 Clinical and Translational Science
P12 Clinical Sequencing– NEW

Informatics Channel
P13 Bioinformatics
P14 Integrated R&D Informatics & Knowledge Management

Cancer Channel
P3 Cancer Molecular Markers
P4 Circulating Tumor Cells
P15 Predictive Pre-Clinical Models in Oncology – NEW
P10 Oncology Clinical Trials
P9 Cancer Biologics

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