19th International

Molecular Med TRI-CON 2012

Moscone North Convention Center
San Francisco, CA

February 19-23

Register by January 20, 2012 and SAVE!

Spanning five days this year!

February 19-20

NEW-Symposia

Targeting Cancer Stem Cells

Cloud Computing

Phage and Yeast Display of Difficult Targets

Point-of-Care Diagnostics

Next-Generation Pathology

Pharma-Bio **Partnering Forums**

February 20

Event **Short Courses**

February 21-23

Core **Programs**

- Diagnostics Channel
- Drug Discovery & Development Channel
- Informatics Channel
- Cancer Channel

New This Year!

TRI-CON ALL ACCESS PACKAGE

Includes 1 Symposium OR Partnering Forum, 2 Short Courses, and 1 Core Program.

OVER $1200 IN SAVINGS!

See page 2 for details.

get inspired

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February 19-20

NEW-Symposia

InterContinental San Francisco Hotel

Pharma-Bio Partnering Forums

InterContinental San Francisco Hotel

February 20

Event Short Courses *Page 13*

The Moscone North Convention Center

February 21-23

Core Programs

The Moscone North Convention Center

Diagnostics Channel

Drug Discovery & Development Channel

Informatics Channel

Cancer Channel

Plenary Keynotes

Tuesday February 21

8:00-9:40am
Positive Exposure: Celebrating the Beauty of Genetic Diversity
Rick Guidotti, Director, Positive Exposure

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

Wednesday February 22

10:10-11:00am
Overcoming Adversity When Life Throws Curve Balls
Dave Dravecky, Former Pitcher, San Francisco Giants and Cancer Survivor

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

2:30-3:50pm
Plenary Keynote Panel: Emerging Technologies & Industry Perspectives
As a change-up to our usual keynote program, we're offering a session that will feature a series of presentations on emerging and hot technologies in diagnostics, drug discovery & development, informatics, and oncology. Interactive Q&A discussion with the audience will be included.

Harry Glorikian, Founder & Managing Partner, Scientia Advisors LLC
Jeremy Bridge-Cook, Senior Vice President, Assay Research and Development, Luminex Corporation
Gary Kennedy, Chairman & CEO, Remedy Informatics
Richard Lawn, Ph.D., Executive Director of Translational Medicine, SomaLogic
Jeffrey T. Yap, Ph.D., Assistant Professor of Radiology, Harvard Medical School, Senior Diagnostic Physicist, Dana-Farber Cancer Institute

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New This Year!

TRI-CON ALL ACCESS PACKAGE

Get the best 5-day value!

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

Example of a Suggested ALL ACCESS Package:

Symposium	Event Short Course	Event Dinner Short Course	Core Program
Cloud Computing	Next-Generation Sequencing in the Cloud Era	Ontologies for the Bio-Science Industry	Bioinformatics & Cancerinformatics

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

2012 **Conference-at-a-Glance**

Sunday, February 19

Events at InterContinental Hotel

7:30 am	Registration and Morning Coffee
8:25-5:00 pm	Concurrent Symposia
8:45-6:00 pm	Pharma-Bio Partnering Forums

Monday, February 20

Events at InterContinental Hotel

8:25-12:00 pm	Concurrent Symposia
8:45-6:00 pm	Pharma-Bio Partnering Forums

Events at Moscone Convention Center

12:00 pm	Short Course Registration and Coffee
1:00-4:00 pm	Concurrent Afternoon Short Courses
4:30-7:30 pm	Concurrent Dinner Short Courses

Tuesday, February 21

Events at Moscone Convention Center

7:00 am	Registration
8:00-9:40 am	**Plenary Keynote Session**
9:40-11:00 am	Grand Opening Refreshment Break in the Exhibit Hall
11:00-12:40 pm	**Core Programs**
12:40-1:45 pm	Luncheon Presentations or Lunch on Your Own
1:45-2:15 pm	Dessert in the Exhibit Hall
2:15-4:20 pm	**Core Programs**
4:20-5:20 pm	Reception in the Exhibit Hall
5:20-6:20 pm	Breakout Discussions

Wednesday, February 22

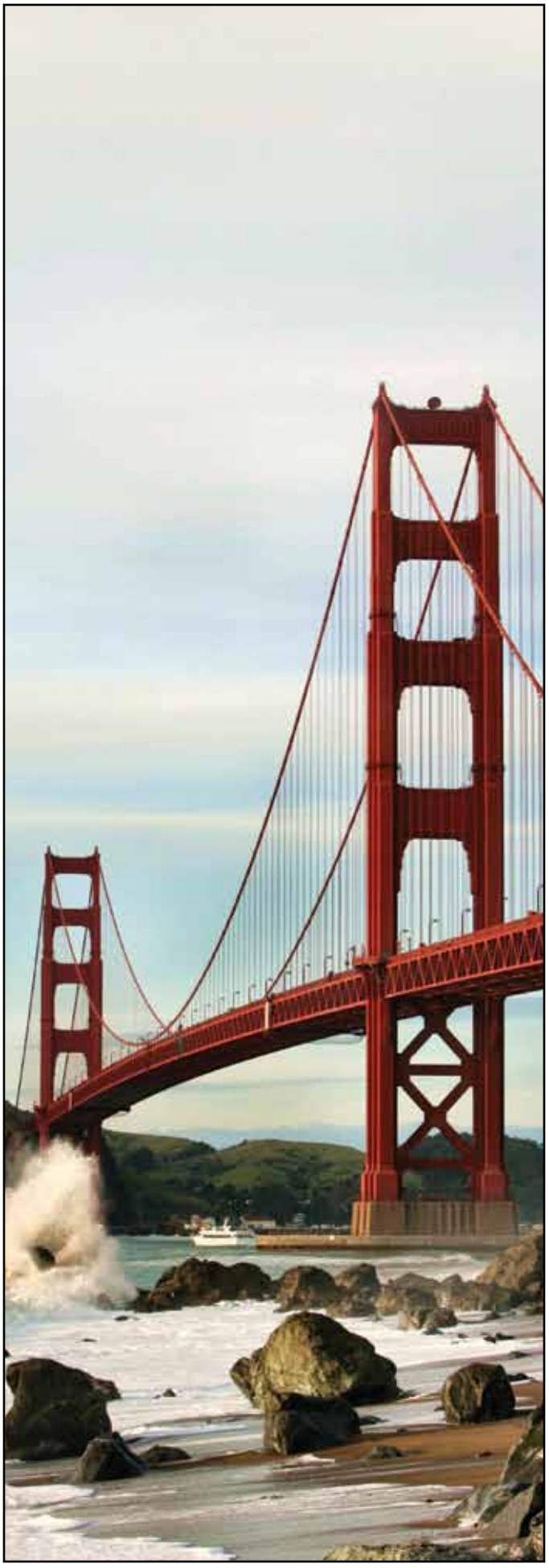
Events at Moscone Convention Center

8:00-10:00 am	**Core Programs**
10:00-11:00 am	**Plenary Keynote Presentation**
11:00-12:00 pm	Refreshment Break in the Exhibit Hall
12:00-1:00 pm	**Core Programs**
1:00-2:00 pm	Luncheon Presentations or Lunch on Your Own
2:00-2:30 pm	Ice Cream Refreshment Break in the Exhibit Hall
2:30-3:50 pm	**Plenary Keynote Panel**
3:50-4:25 pm	Refreshment Break & Poster Awards in the Exhibit Hall
4:25-6:30 pm	**Core Programs**

Thursday, February 23

Events at Moscone Convention Center

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



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BAYBIO

Second Annual

Emerging Targeted Oncology Partnering Forum

February 19-20

PROGRAM ADVISORY BOARD:

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Neela Patel, Ph.D., Director, External Programs, West Coast, Abbott Laboratories
John Stille, Clinical Research Advisor, Chorus, Eli Lilly
Jonathan Usuka, Ph.D., Director, Global Business Partnering, Celgene

SUNDAY, FEBRUARY 19

8:00 am Registration and Morning Coffee

9:15 Chairperson's Remarks

9:25 Criteria for Evaluating Partners for Targeted Small Molecule Therapies Panel Discussion

SMALL MOLECULE THERAPEUTICS

9:55 Identification of Novel Inhibitors of SIK2 Kinase: A Novel Ser/Thr Kinase for Multiple Disease Indications
Hariprasad Vankayalapati, M. Pharm., Ph.D., CSO, Arrien Pharmaceuticals

10:10 COTI-2: A Highly Effective and Selective Allosteric Modulator of AKT/AKT2 Protein Levels and Phospho-Activation for the Treatment of Susceptible Human Cancers
Wayne Danter, M.D., President & CEO, Drug Discovery & Pre-Clinical Development, Critical Outcome Technologies, Inc.

10:25 OCID 4681-S-01: A Novel Orally Available Class-Selective HDAC Inhibitor
Shridhar Narayanan, Executive Vice President, Discovery Biology & Drug Development, Orchid Research Laboratories Ltd.

10:40 Targeting Tumor Hypoxia: Suppression of Tumor Growth and Metastasis with Novel Carbonic Anhydrase IX Inhibitors
Jasbinder Sanghera, Ph.D., President & CEO, MetaSignal Therapeutic, Inc.

10:55 Networking Coffee Break

11:30 Concurrent Anti-Angiogenic and Anti-Metastatic Effects from Novel Recombinant Integrin Agonists
Douglas C. Lane, CEO, Applied Integrin Sciences, Inc.

11:45 From Rockets to Radiosensitizers: Novel Oncology Drugs Sourced from the Aerospace Industry
Jan Scicinski, Ph.D., Vice President, Research and Development, RadioRx, Inc.

12:00 pm Introducing TUSC2/FUS1 Tumor Suppressors to Induce Cancer Cell Apoptosis, as well as Enhancing Cell Signaling and Controlling Inflammation
David G. Nance, Executive Chairman, Genprex, Inc.

12:15 Neurotensin Branched Tumor-Targeting Peptides. Low MW, Modular, Multimeric Anticancer Peptides.
Luisa Bracci, Ph.D., Director & Professor, Research & Development, Setlance Spa

12:30 Networking Lunch, Discussion with Company Presenters

1:45 Chairperson's Remarks

1:50 Panel Discussion: Expectations for Immunotherapies and Monoclonal Antibodies

MONOCLONAL ANTIBODY THERAPY FOR CANCER

2:20 Phase 2 Development of the Monoclonal Antibody TRC105 that Inhibits Angiogenesis by Targeting a Non-VEGF Pathway
Charles Theuer, M.D., CEO, TRACON Pharmaceuticals, Inc.

2:35 Development of APX005, a CD40 Agonist Antibody for the Treatment of Pancreatic and Other Cancers
Yongke Zhang, Director, Pre-clinical Development & Clinical Research, Apexigen, Inc.

2:50 Development of Tanibirumab and DIG-KT: A Leading Pipeline of DIG-Bodies Platform
Jin-San Yoo, Ph.D., CEO, PharmAbcine, Inc.

3:05 Proteolytically Activated Antibodies Have the Potential to Expand Therapeutic Index and Open up New Target Space
Henry Lowman, Ph.D., CSO, Research and Development, CytomX Therapeutics, Inc.

3:20 Networking Refreshment Break

ANTIBODY CONJUGATES AND IMMUNOTHERAPIES

3:45 A Versatile Nanodelivery Platform for Efficient Targeted Delivery of Macromolecular Payloads in Oncology
Matthew Giacalone, Ph.D., Director of Business Development, Vaxiion Therapeutics

4:00 Extracellular Antibody/Drug Conjugates: A New Paradigm for MAb/Drug Conjugates
Stephen Worsley, Chief Business Officer, Centrose LLC

4:15 NEURADIAB - A Novel Targeted Radiolabelled Mab Therapy for Brain Tumors
Michael Zalutsky, Ph.D., Professor, Radiology, Radiation Oncology and Biomedical Engineering, Duke University Medical Center

4:30 Clinical Development of a Novel DNA-Based Immunotherapeutic for Intraperitoneal Treatment of Peritoneally Disseminated Cancers
Khursheed Anwer, Ph.D., President & CSO, Corporate, EGEN, Inc.

4:45 Targeted Synthetic Vaccine Nanoparticles (SVP™): A Potent and Versatile New Class of Cancer Vaccines
Takashi Kei Kishimoto, Ph.D., CSO, Immunology, Selecta Biosciences

5:00 From Promise to Products: Clinical and Regulatory Approaches for Targeted Immunotherapy Development
Mark Ahn, Ph.D., CEO, Galena Biopharma

5:15 Networking Session, Discussion with Company Presenters

6:15 End of Day One

MONDAY, FEBRUARY 20

Emerging Molecular Diagnostics and Emerging Targeted Oncology Partnering Forums (Joint Session)

8:45 Chairperson's Remarks

8:55 Cancer Screening and Diagnosis Panel Discussion

BIOBANKS AND DIAGNOSTICS

9:25 Private Public Partnership Developing Biomarkers for Cancer Prognostics under a $30 Million Grant with Access to 15 Million Biological Samples Associated with Cradle to Grave Electronic Medical Records
Gitte Pedersen, CEO, Genomic Expression, Inc.

9:40 Advancing Cancer Biomarker Development for Early Diagnosis and Screening Using Abcodia's unique Prospective Serum Biobank
Julie Barnes, Ph.D., CEO, Abcodia

9:55 OncoScore: The New Paradigm in Molecular Diagnostics
Francois Ferre, Ph.D., CEO, AltheaDx, Inc.

10:10 BronchoGen: Breakthrough Gene Expression Diagnostic for Lung Cancer
Michael Webb, M.B.A., CEO, Allegro Diagnostics

10:25 A Bioinformatics-Derived Gene Signature which Predicts the Time to Distant Metastases in ER+ Breast Cancer
Adam Gouldsworthy, Ph.D., Business Development Manager, CompanDX Ltd.

10:40 Networking Coffee Break

BLOOD-BASED CANCER DIAGNOSTICS

11:00 The Capture, Identification, and Interrogation of Circulating Tumor Cells
Lyle Arnold, Ph.D., Senior Vice President & CEO, Research and Development, Biocept, Inc.

11:15 Nano-Velcro for Highly Efficient Enrichment of Capture of Circulating Tumor Cell
Mitch Garcia, Ph.D., CTO, CytoScale Diagnostics LLC

11:30 IVDiagnostics' Novel Companion Diagnostic for Pancreatic Cancer Involving Circulating Tumor Cell (CTC) Detection and Profiling
Hui Chen, Ph.D., Research Scientist, IV Diagnostics, Inc.

11:45 Isolation and Analysis of Rare Circulating Cells for Cancer Diagnostics
Klaus Lücke, Ph.D., CEO, GILUPI GmbH

12:00 A Novel Approach for Finding and Characterizing CTCs
David Nelson, Ph.D., President & CEO, Epic Sciences, Inc.

12:15 The Clinical Utlility of Exosomes for Biofluid-Based Molecular Diagnostics
Hannah Mamuszka, Vice President, Business Development, Exosome Diagnostics, Inc.

12:30 Networking Lunch, Discussion with Company Presenters

1:45 Chairperson's Remarks

1:50 Panel Discussion: Challenges of Biomarker and Therapeutic Co-Development

CANCER BIOMARKERS

2:20 Oncimmune's Proprietary Platform: The Road to Commercialization & the Future Ahead
John Robertson, M.D., Co-Founder & CSO, Oncimmune

2:35 Enabling Next-Generation, Predictive Diagnostics with the SnapPath™ Live Tumor Testing System
Adam Schayowitz, Director of Business Development, BioMarker Strategies, LLC

2:50 Diagnostic and Therapeutic Approaches Involving Immune Signatures to Aberrant Post-translational Modifications in Oncology
Thayer White, Ph.D., CEO, GlycoZym

3:05 Breakthrough SOMAmer-based Technology for Multiplexed Diagnostic Discovery and Development
Mark Messenbaugh, Director, Corporate Strategy, SomaLogic, Inc.

3:20 Clinical Cancer Genomics Using Targeted Next-Generation Sequencing (NGS)
Matthew Hawryluk, Ph.D., Associate Director, Business Development, Foundation Medicine, Inc.

3:35 Networking Refreshment Break

COMPANION CANCER DIAGNOSTICS

4:00 An Alternative Strategy for Rapid Drug-Biomarker Co-Development, Validation, and Commercialization
Paul Beresford, Ph.D., Vice President, Business Development and Strategic Marketing, Biodesix, Inc.

4:15 Highly Sensitive and Specific Detection of Cancer Mutations using myT™ Primer qPCR
Vladimir Makarov, Ph.D., CSO, Swift Biosciences, Inc.

4:30 Leveraging CTCs into Molecular Analyses Using the IsoFlux System for High Efficiency Rare Cell Access
Michael Schwartz, Program Director, Fluxion Biosciences Inc.

4:45 Biological Target for the Development of a Therapeutic with Companion Diagnostic for Non-Small Cell Lung Carcinoma (NSCLC)
Ginette Serrero, Ph.D., CEO, A&G Pharmaceutical, Inc.

5:00 Networking Session, Discussion with Company Presenters

6:00 End of the Partnering Forums

CHI's Partnering Forums:
FOCUSED and EFFICIENT Collaboration Exploration

CHI's Partnering Forums are designed to bring together a number of promising emerging companies within a focused range of technologies or indications, to present to and discuss potential interest in collaboration with an audience of people from larger, more established companies looking for new early-stage partnering opportunities within that focused area. Each Partnering Forum is designed to increase the efficiency of finding a number of excellent opportunities and having the chance to start discussions to explore potential fit and suitability. The **Emerging Targeted Oncology Partnering Forum** combines novel therapeutics with cancer diagnostics, since increasingly most targeted therapies will need to be combined with biomarkers and companion diagnostics starting early in development. The **Early Stage Molecular Diagnostics Partnering Forum** covers platform technologies, including point-of-care, as well as a range of indications, with a particular emphasis on the second day on cancer diagnostics. The Cancer Diagnostic session is held jointly, and attendees of both events will have access to speakers and attendees for both meetings.

PHARMA-BIO PARTNERING FORUMS
Focusing on the Right Partners

Your networking tool to
PARTNER DIRECT
Successful Partnerships

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 Bio-Pharma 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**

Inaugural

Early Stage Molecular Diagnostics Partnering Forum

February 19-20

PROGRAM ADVISORY BOARD:

Steven Anderson, Ph.D., CSO & Vice President, LabCorp
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Bryan DeChairo, Ph.D., Senior Director & Development Head, Medco Health Solutions
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Mollie Roth, COO, Diaceutics
Premal Shah, Ph.D., Director, Business Development, Genomic Health
Rosanne Welcher, Ph.D., Vice President, Research & Development, DAKO
Emily Winn-Deen, Ph.D., Vice President, Diagnostic Development, Illumina

SUNDAY, FEBRUARY 19

8:00 Registration and Morning Coffee

9:00 Chairperson's Remarks

9:10 Opportunities and Challenges for New Diagnostic Platforms Panel Discussion

PLATFORM SYSTEMS

9:40 Single Sample, Single Slice, Single Prep, Single Well… Multiple Answers
Lilly Kong, DVM, CSO, PrimeraDx, Inc.

9:55 Using LinkSēq™ Technology for HLA Typing, Companion Diagnostics, and Personalized Medicine
Zachary Antovich, President & CEO, Linkage Biosciences, Inc.

10:10 Highly Multiplex PCR/qPCR Detection of Nucleic Acids: MDx Applications
Eugene Spier, Ph.D., Founder, UniTaq Bio

10:25 A Fully Automated, Open Platform for Molecular Differential Diagnoses
Jian Han, Ph.D., President & CEO, Research & Development, iCubate, Inc.

10:40 Enabling Low Cost, Complex Genomic Testing in Routine Medical Care
Bob Terbrueggen, Ph.D., CEO, DxTerity Diagnostics

10:55 Networking Coffee Break

POINT-OF-CARE SOLUTIONS

11:15 Simple, Cost-Effective Molecular Diagnostic Assays Based on Isothermal HDA Technology
Huimin Kong, Ph.D., President & CEO, BioHelix Corp.

11:30 Single-Use Electric Biosensor Chip Embedded Molecular Test for Rapid Quantitative Analysis of Multiple Markers in a Single Sample
Sunnie Kim, CEO, NanoIVD, Inc.

11:45 A Novel, Rapid, Easy-to-Use, and Cost-Effective Point-of-Care Chemiluminescent in vitro Diagnostic Test Platform System for the Detection of Potentially Lethal Pathogens, DNA and Biomarkers
Joel Ivers, CEO, NanoDetection Technology, Inc.

12:00 Multiplexed Biomarker Assays for Near Patient Diagnostics
Michael Lochhead, Vice President, Research & Development, mBio Diagnostics, Inc.

12:15 One Stop Diagnostics
Luc Gervais, Ph.D., Co-Founder, One Stop Diagnostics

12:30 Networking Lunch, Discussion with Company Presenters

1:45 Chairperson's Remarks

1:50 Assessing the Market Potential for Novel Molecular Diagnostics Panel Discussion

DIAGNOSTICS FOR SPECIFIC INDICATIONS

2:20 Molecular Diagnostic Platform for Detection of Neurological Disease
Susan Dana Jones, Ph.D., Vice President, Corporate Development, Gene Solutions, Inc.

2:35 Biomarkers in Psychiatry: How Genetic Testing Can Inform Treatment Decisions
Jay Lombard, Ph.D., CSO, GenoMind LLC

2:50 FibriLyzer: Companion Dx for Anticoagulants and Thrombolytics
Krassen Dimitrov, Ph.D., Founder and CEO, Digital Diagnostics, Pty

3:05 Serum Proteomic Profiles Detect Coronary Artery Disease in Symptomatic Patients Referred for Coronary Angiography
William LaFramboise, Ph.D., Associate Professor, Pathology, University of Pittsburgh and Co-Founder, Prevencio LLC

3:20 Microbiome Signature Discovery
Peter DiLaura, President and CEO, Second Genome, Inc.

3:35 Networking Refreshment Break

INFECTION, PROTEINS AND GENETIC DIAGNOSTICS

4:00 Highly Multiplexed Detection of Pathogens and Antibiotic Resistance Markers for Infectious Diseases
Oliver Schacht, Ph.D., CEO, Curetis AG

4:15 Low-Cost, Point-of-Care Diagnostics for Human Health and Food Safety
Una Ryan, Ph.D., President and CEO, Diagnostics for All

4:30 SISCAPA® Technology for Accurate, Specific, Multiplexed, and Scalable Quantitation of Protein Biomarkers in Drug Development and Clinical Diagnostics
N. Leigh Anderson, Ph.D., Founder & CEO, Siscapa® Assay Technologies, Inc.

4:45 Highly Multiplexed PCR Assays for Routine Diagnostic Next Generation Sequencing.
Dirk Pollet, Ph.D., CEO, Multiplicom N.V.

5:00 How Self Organizing Genomes with Real Time Consent will Disrupt the Molecular Diagnostics Marketplace
Alice Rathjen, Founder & CEO, DNA Guide, Inc.

5:15 Networking Session, Discussion with Company Presenters

6:15 End of Day One

MONDAY, FEBRUARY 20

Shared day with Emerging Targeted Oncology Partnering Forum; please see pages 5 and 6 for details.

Example of a Suggested ALL ACCESS Package:

Partnering Forum Early Stage Molecular Diagnostics → **Event Dinner Short Course** Regulatory Approval of a Therapeutic & Companion Diagnostic → **Core Program** Molecular Diagnostics

Targeting Cancer Stem Cells in Oncology

The Challenge of Drug Development against a Moving Target

SUNDAY, FEBRUARY 19

7:30 am Registration and Morning Coffee

RELEVANCE AND REALITY: THE PROMISE OF CANCER STEM CELLS

8:25 Organizer's Opening Remarks

8:30 Chairperson's Welcoming Remarks
Raymond Winquist, Vice President, Vertex Pharmaceuticals

FEATURED PRESENTATION

8:50 Characterization and Targeting of Human Leukemia Stem Cells
Craig T. Jordan, Ph.D., Professor of Medicine, James P. Wilmot Cancer Center, University of Rochester School of Medicine
We have demonstrated that certain classes of compounds are able to direct target Human leukemia stem cells (LSCs) via a multiparameter mechanism. Data will be presented describing the pathways involved and strategies for therapeutic targeting of human LSCs.

9:20 Translating the Cancer Stem Cell Hypothesis from the Lab to the Clinic
William Matsui, M.D., Associate Professor of Oncology, Division of Hematologic Malignancies, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University
Cancer stem cell targeting approaches are rapidly emerging, but it is unclear how to best evaluate their efficacy in the clinical setting. Translational considerations, including clinical trial design, outcome measures, and biomarker strategies will be discussed.

9:50 Networking Coffee Break with Poster Viewing

10:30 Will Telomerase Inhibitors Target Cancer Stem Cells?
Jerry W. Shay, Ph.D., Professor, Department of Cell Biology, University of Texas Southwestern Medical Center
Do cancer cells with stem cell properties have long or short telomeres? Are cancer cells with stem cell properties mostly quiescent? These critical questions will be discussed in the context of ongoing telomerase inhibitor clinical trials.

11:00 Unraveling Leukemia Stem Cell Survival Mechanisms
Kristen M. Smith, Ph.D., Project Leader, Jamieson Lab, Moores Cancer Center, University of California San Diego
Leukemia stem cells display splice isoform switching which enable them to co-opt stem cell properties and evade therapies targeting proliferating cells. Anti-leukemia stem cell therapy together with splice isoform biomarkers may provide for cancer stem cell detection and eradication of refractory malignancies.

11:30 SMO Independent Blockers of HH Signaling
Sponsored by 4SC
Daniel Vitt, Ph.D., CSO, 4SC AG
Since resistance formation potentially limits therapeutic use of SMO antagonists this presentation will introduce a novel class of small molecules which selectively block hedgehog signaling in a SMO receptor independent way with a special focus on cancer stem cell phenotypes.

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

DEVELOPING *IN VITRO* SCREENING ASSAYS FOR THERAPEUTIC DEVELOPMENT

1:25 Chairperson's Remarks
Raymond Winquist, Vice President, Vertex Pharmaceuticals

1:30 Divergent Roles of the Coactivator Proteins CBP and p300 in Stem Cells and Cancer Stem Cells
Mike Kahn, Ph.D., Professor of Biochemistry and Molecular Biology; Provost's Professor of Medicine and Pharmacy, Eli and Edythe Broad CIRM Center for Regenerative Medicine and Stem Cell Research, University of Southern California
We have demonstrated that a CBP/catenin-mediated transcription cassette is critical for the maintenance of CSCs. The specific CBP/catenin antagonist, PRI-724, is currently in Phase I. It has proven extremely safe and effective as judged by reduction of the biomarker survivin.

2:00 Development of Novel Small Molecule Anti-Cancer Agents that Selectively Target Cancer Stem Cells
Jonathan Pachter, Ph.D., Vice President & Head, Research, Verastem, Inc.
We have used EMT induction to establish unique CSC assays providing a robust platform for high-throughput screening. Cellular assays used to screen for CSC-selective agents will be described, and data will be presented showing *in vitro* and *in vivo* effects of representative compounds.

EMT & TREATMENT RESISTANCE

2:30 EMT and the Cancer Stem Cell State: A Lens for Treatment Combinations
John D. Haley, Ph.D., Senior Research Director, OSI Pharmaceuticals LLC, a wholly owned subsidiary of Astellas US
Tumor tissues are comprised of heterogeneous collections of cell types and cell states utilizing distinct signaling networks. The role of EMT and cancer stem cells in promoting cellular heterogeneity and drug resistance, guiding the combination of anti-cancer agents is discussed.

3:00 Networking Refreshment Break with Poster Viewing

3:30 Overcoming Cancer Stem Cell Treatment Resistance
Maximilian Diehn, M.D., Ph.D., Assistant Professor, Department of Radiation Oncology, Cancer Institute; Institute for Stem Cell Biology & Regenerative Medicine, Stanford University School of Medicine
Cancer stem cells (CSCs) are often relatively resistant to standard treatments, including chemotherapy and radiotherapy. Multiple CSC resistance mechanisms have been identified and may be tumor type specific. Overcoming CSC resistance is a promising approach for improving clinical outcomes.

ISOLATION & CHARACTERIZATION OF CANCER STEM CELLS

4:00 A New Model Recapitulating Colon Cancer Differentiation Provides Evidence for Intestinal Stem Cell Origin of Cancer Stem Cells
Jennie Mather, Senior Vice President, Stem Cell Technologies, Macrogenics, Inc.
Cancer stem like (CSLC) cell lines were selected in defined medium that formed tumors and metastasized. While some lines were negative for CD44, CD133 and ALCAM; all expressed the ISC associated markers, ALDH1, ASCL2, LGR5, SOX9 and bound anti-SSEA1 antibody.

4:30 Pre-Clinical Development of OMP-18R5: A Novel Wnt Pathway Antagonist with Anti-CSC Activity
Tim Hoey, Senior Vice President, Cancer Biology, Oncomed

5:00 Close of Day

MONDAY, FEBRUARY 20

FROM THERAPEUTIC DISCOVERY TO THE CLINIC

8:25 am Chairperson's Remarks
Robert Hollingsworth, Ph.D., Director, Cancer Biology, MedImmune, Inc.

8:30 Targeting Telomeres and Telomerase in Cancer Stem Cells
Calin O. Marian, MS.c., Ph.D., Assistant Professor, Department of Urology, University of Texas Southwestern Medical Center
Evidence has suggested that the capability for tumor recurrence and metastasis resides in cancer stem cells. Current investigation into the role of telomeres and telomerase in cancer stem cells (C SCs) has lead to viable approaches towards targeting telomerase in CSCs.

9:00 Imetelstat as an Inhibitor of Cancer Stem Cells
Martha Blaney, Pharm.D., Medical Director, Geron
Imetelstat is a novel oligonucleotide and a potent inhibitor of telomerase. Preclinical studies suggest that imetelstat may play a key role in the inhibition of cancer stem cells. Phase II clinical trials are ongoing.

9:30 A Review of Stemline Therapeutics' Clinical Programs
Eric Rowinsky, M.D., CMO & Head, Research & Development, Stemline Therapeutics, Inc.

10:00 Networking Coffee Break with Poster Viewing

EMERGING CANCER STEM CELL THERAPEUTIC PROGRAMS

10:30 Cancer Stem Cell Therapeutics from a Different Perspective: A Bottom-Up View
Norman J. Maitland, Ph.D., Director, Yorkshire Cancer Research Unit and Department of Biology, University of York, UK
There is currently no long-term treatment for prostate cancer. Employing a biology-driven strategy, Pro-Cure Therapeutics has validated novel therapeutic targets, designed to target therapy resistant disease, in proprietary prostate cancer stem cell assays.

10:50 Elimination of Cancer Stem Cells by Using Redirected T Cells
Patrick A. Baeuerle, Ph.D., Professor of Immunology, CSO & Senior Vice President, Micromet, Inc.
Cancer stem cells (CSC) appear resistant to anti-proliferative therapies. Temporarily non-dividing CSC can however be eliminated by T cells redirected with the help of bispecific antibodies that are simultaneously binding to a surface target on CSC, and to T cells.

11:10 Immunologic Strategies to Target Cancer Stem Cells
John S. Yu, M.D., Professor & Vice Chairman, Neurosurgery, Cedars-Sinai Medical Center; Chairman & CSO, ImmunoCellular Therapeutics
Recent observations of the laboratory have demonstrated that cancer stem cells are chemoresistant and may be the major reason for the recurrence of these deadly tumors. Hence we have developed novel immunologic strategies to target cancer stem cells.

11:30 Therapeutic Antibodies Targeting Colon Cancer Stem Cells
Christopher Reyes, Ph.D., CSO, Eclipse Therapeutics, Inc.
Eclipse Therapeutics is dedicated to the discovery and development of therapeutics that target cancer stem cells. This presentation will discuss Eclipse's cancer stem cell therapeutic antibody program and provide insights on the development of effective, functional antibodies targeting cancer stem cells.

11:50 Q&A with Emerging Therapeutic Programs

12:00 pm Close of Symposium

Cloud Computing
Applications and Advances in Life Sciences R&D

SUNDAY, FEBRUARY 19

7:30 am Registration and Morning Coffee

8:25 Chairperson's Opening Remarks

CLOUD COMPUTING OVERVIEW

8:30 The Why, What, How and Future of Cloud
Todd Papaioannou, Ph.D., Entrepreneur-in-Residence, Battery Ventures; Former Vice President, Cloud Architecture, Yahoo! Inc.
Is Cloud Computing just marketing hype? Why build Clouds? How can they benefit your organization? This presentation provides an overview of Cloud computing, the rationale for it as a technology trend, and the implications for the future of Computing and IT.

9:00 Cloud Computing and Big Data: How Both Can Work Together
Jimmy Lin, Ph.D., Professor, College of Information Studies, University of Maryland

9:30 A Platform for Data Science
Deepak Singh, Principal Product Manager, Amazon Web Services
Data intensive science requires new approaches to data management, analysis and sharing. This talk covers distributed systems, "data science", and the potential of a very large scale cloud service, Amazon Web Services, as a platform for data intensive biology.

10:00 Networking Coffee Break with Poster Viewing

ORCHESTRATING THE CLOUD

10:30 Orchestrating the Cloud
Chris Dagdigian, Principal Consultant, Cloud Consulting & HPC Practice, BioTeam, Inc.
This talk will discuss tools for automating the deployment of complex systems into the cloud that maximize efficiency and auditability while reducing operational and systems management burden.

11:00 Big Data Bioinformatics Analytics Using the Hadoop Software Ecosystem
Ronald Taylor, Ph.D., Research Scientist, Pacific Northwest National Laboratory (U.S. Deptartment of Energy, Battelle)
This talk will present an overview of Apache Hadoop and associated open source software projects. The basic concepts behind Hadoop and HBase will be outlined, current usage within the bioinformatics community will be presented (focusing on next-gen sequencing), and future directions will be described.

11:30 Biopharma Case Study: Rewiring Bioinformatics for Cloud Computing to Drive the Re-Foundation of Sequence Analysis Algorithms
Jonas Almeida, Ph.D., Professor, Director, Division Informatics, Pathology, University of Alabama Birmingham
Personalization of medicine and the emergence of the Web 3.0 is pushing bioinformatics workflows to take full advantage of scalable MapReduce programming patterns facilitated by cloud computing. This is the key rewiring of resource usage at the core of cloud based data processing.

LUNCHEON PRESENTATION

12:00 pm The Roadmap to HPC Cloud
Sponsored by Platform Computing an IBM Company
Chris Porter, Product Manager, HPC Cloud, Platform Computing
For organizations challenged by large datasets, application performance and finite budgets, cloud computing presents a new opportunity to squeeze more utility from existing infrastructure. This session outlines best practices for evaluating whether HPC Cloud is a viable option and provides a roadmap for implementation.

CLOUD COMPUTING SECURITY AND GOVERNANCE

1:25 Chairperson's Remarks

1:30 An Expert's Guide through the Identity Landscape
Rich Furr, Head, Global Regulatory Affairs and Chief Compliance Officer, SAFE-BioPharma Association
The presentation will provide an overview of US and EU government and industry-driven identity management initiatives to develop a trusted internet identity capability community, applicable standards, governance models, and approaches to cloud based identity management.

2:00 Research Collaboration in the Cloud: How NCI and Research Partners are Using Interoperable Digital Identities, Digital Signatures, and Cloud Computing to Accelerate Drug Development
Steven Friedman, MHSA, Chief, Clinical Trials Operations and Informatics Branch, Cancer Therapy Evaluation Program, National Cancer Institute
The presentation will describe a recent pilot study involving government (NCI) and industry (Bristol-Myers Squibb, sanofi-aventis) cancer researchers showing that use of interoperable digital identities, digital signatures and cloud computing accelerates initiation of a clinical trial while lowering its costs.

2:30 The Role of a Standard-Based Interoperable Digital Identity in Unlocking the Cloud
Mollie Shields-Uehling, President & CEO, SAFE-BioPharma Association
This presentation will explore the use of a single, universal interoperable digital identity, its role in the NCI-CTEP pilot, and its ability to improve clinical trial management, globally.

3:00 Networking Refreshment Break with Poster Viewing

BIOPHARMA PERSPECTIVES AND SUCCESS STORIES

3:30 Biopharma Case Study: Running HPC Workflows in the Cloud
Jonathan A. Klinginsmith, Senior Systems Analyst, Eli Lilly

4:00 Biopharma Case Study: NGS Cloud Based Analysis
Giles Day, Co-Founder and Managing Director, Distributed Bio, LLC

4:30 Applying Biomedical Semantics in the Cloud: Current Weather and Forecasts
Jim McCusker, Tetherless World Constellation, Rensselaer Polytechnic Institute; Krauthammer Lab, Yale School of Medicine

5:00 Close of Day

MONDAY, FEBRUARY 20

BIOPHARMA PERSPECTIVES AND SUCCESS STORIES

8:25 am Chairperson's Remarks

8:30 Biopharma Case Study: BioGPS and mygene.info: Consuming and Providing Cloud Computing Resources
Andrew Su, Ph.D., Associate Professor, Molecular & Experimental Medicine, Scripps Research Institute
Cloud computing is an increasingly common commodity in the development and hosting of computational biology tools. This presentation will describe two cloud-based bioinformatics resources focused on understanding gene function.

9:00 Biopharma Case Study: Using Galaxy on the Cloud to Perform Large-Scale Data Analyses
James Taylor, Ph.D., Assistant Professor, Biology/Computer Science, Emory University

9:30 Biopharma Case Study: Designing Effective Clinical Trials using Cloud-Based Simulations
Vincent Fusaro, Ph.D., Laboratory for Personalized Medicine, Center for Biomedical Informatics, Harvard Medical School
Randomized clinical trials are unsustainable in the era of personalized medicine due to the exponential number of combinations necessary for evaluating personalized treatment options. We will discuss a computational method to predict the outcomes and guide planning and design of a clinical trial.

10:00 Networking Coffee Break with Poster Viewing

10:30 Utility Supercomputing for Molecular Modeling and NGS
Sponsored by CYCLE COMPUTING
Jason Stowe, CEO, Cycle Computing
We'll discuss real use cases for 30000-processor high performance computing costing $1279/hr to answer questions in molecular modeling, protein binding, and next-gen sequencing. There was a time when certain scientific questions wouldn't even have been considered - too few compute resources, too much time to complete. Now important scientific questions can be securely answered in hours or days with 30000-core CycleCloud clusters, and this talk will show you how.

11:00 Biopharma Case Study: Proteomics in the Cloud
Speaker to be Announced

CLOSING KEYNOTE PRESENTATION

11:30 All Your Datum Belong are Belong to Us [sic]
Jason J. Hoyt, Ph.D., Chief Scientist & VP Research and Development, Mendeley
How, why and what of data aggregators in the cloud, not in the future, but today. In particular, this talk will take a look at value-added services, such as adding structure to otherwise unconnected data, that aggregators can provide.

12:00 pm Close of Symposium

Phage and Yeast Display of Difficult Targets
New Tools and Strategies

SUNDAY, FEBRUARY 19

7:30 am Registration and Morning Coffee

8:25 Chairperson's Opening Remarks

INTRODUCTORY SESSION

8:30 Phage and Yeast Display Libraries and Screening
Andrew M. Bradbury, M.B. B.S., Ph.D., Staff Scientist, Biosciences, Los Alamos National Laboratory
James D. Marks, M.D., Ph.D., Professor, Anesthesia & Pharmaceutical Chemistry, University of California, San Francisco; Chief of Anesthesia and Vice Chairman, Anesthesia & Perioperative Care, San Francisco General Hospital
The session will bring scientists up to speed on the latest tools available for display technologies and is tailored for both the novice and those with experience in display technologies. The session will provide an overview not exclusive to membrane proteins, including phage display and construction of phage-displayed peptide, scFv and Fab libraries, yeast display and construction of yeast-displayed scFv and Fab libraries, selection and screening technologies that are compatible with phage and yeast-display libraries.

10:00 Networking Coffee Break with Poster Viewing

10:30 Phage and Yeast Display Libraries and Screening (Continued)
Andrew M. Bradbury, M.B. B.S., Ph.D., Staff Scientist, Biosciences, Los Alamos National Laboratory
James D. Marks, M.D., Ph.D., Professor, Anesthesia & Pharmaceutical Chemistry, University of California, San Francisco; Chief of Anesthesia and Vice Chairman, Anesthesia & Perioperative Care, San Francisco General Hospital

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

DISPLAYING ANTIBODIES AGAINST MEMBRANE PROTEINS: Identifying Hot Spots for Binding

1:25 Chairperson's Remarks

KEYNOTE PRESENTATION

1:30 Expressing Membrane Proteins in Yeast and Other Eukaryotic Cells
Robert M. Stroud, Ph.D., Professor, Biochemistry & Biophysics, University of California, San Francisco
This presentation addresses the key issues that need to be addressed to obtain pure, functional, homogeneous, stable membrane proteins as well as lessons and methods that are advancing this key area of membrane biology in the service of human health.

2:00 Selection of Internalizing Phage Antibodies Using Tumor Cells and Yeast Displayed Tumor Antigens
James D. Marks, M.D., Ph.D., Professor, Anesthesia & Pharmaceutical Chemistry, University of California, San Francisco; Chief of Anesthesia and Vice Chairman, Anesthesia & Perioperative Care, San Francisco General Hospital
We show that such antibodies to specific tumor antigens can be generated by first selecting phage antibody libraries on a tumor cell line expressing the target antigen followed by selection on yeast displaying the same antigen on their surface. Advantages and specific examples will be covered.

2:30 Filamentous Phage Display Vectors for Different Protein Classes
Andrew M. Bradbury, M.B. B.S., Ph.D., Staff Scientist, Biosciences, Los Alamos National Laboratory

3:00 Networking Refreshment Break with Poster Viewing

3:30 Adapting Yeast Antibody Display for Membrane Protein Targets
Eric V. Shusta, Ph.D., Associate Professor, Chemical & Biological Engineering, University of Wisconsin, Madison
Membrane proteins are challenging to work with in terms of antibody selection, engineering, and antigen identification as a result of their insolubility in aqueous solutions. We have therefore developed a platform for antibody engineering using either whole cells or cell lysates as antigen sources.

4:00 Antibodies against GPCR Dimers as Tools for Exploring Tissue Distribution, Regulation and Mapping Functional Domains of Receptor Heteromers
Lakshmi A. Devi, Ph.D., Professor, Pharmacology & Biological Chemistry, Mount Sinai School of Medicine

Mounting evidence suggests that GPCRs form dimers and dimerization is necessary for receptor maturation, signaling and trafficking. Using GPCR heterodimer-selective antibodies we have begun to characterize tissue localization, regulation and heteromer-specific function as well as to map their functional domains.

4:30 Cell-Free Expression of Polytopic Membrane Proteins for Drug Research
Frank Bernhard, Ph.D., Lab Leader, Institute of Biophysical Chemistry, Goethe University Frankfurt
This presentation demonstrates the systematic development of expression protocols for the cell-free production of high quality membrane proteins in preparative scales. The quality of the cell-free expressed proteins is demonstrated by a number of functional and structural approaches.

5:00 Close of Day

MONDAY, FEBRUARY 20

DISPLAY OF MEMBRANE PROTEINS

8:25 am Chairperson's Remarks

8:30 Expanding Phage Display to Include Membrane Proteins
Gregory A. Weiss, Ph.D., Professor, Departments of Chemistry, Molecular Biology & Biochemistry, University of California, Irvine
This talk will describe the scope and limitations of the phage display of membrane proteins with examples of plasma, nuclear, peripheral, single and multipass membrane proteins for binding and re-engineering studies.

9:00 Regio-Specific Synthetic Affinity Binders as Chaperones for Membrane Structure and Probes of Function
Anthony Kossiakoff, Ph.D., Otho S. A. Professor and Chair, Department of Biochemistry and Molecular Biology, Knapp Center for Biomedical Discovery, University of Chicago
Regio-specific synthetic affinity binders (sABs) are generated using competitive phage display selection strategies to capture and stabilize different functional forms of integral membrane proteins. These sABs are based on Fab scaffolds and are effective crystallization chaperones and functional probes.

9:30 Structural Investigation of GPCR Transmembrane Signaling by Use of Nanobodies
Jan Steyaert, Ph.D., Group Leader, Structural Biology Brussels, Vrije Universiteit Brussels
Last year, we generated Nanobodies that selectively recognize an active state of the human β2 adrenergic receptor. One of these nanobodies was used to obtain the high-resolution crystal structure of this complex, providing the first view of transmembrane signaling by a GPCR3.

10:00 Networking Coffee Break with Poster Viewing

10:30 Using Yeast as a Host – Its Limitations and Advantages for Biophysical and Structural Studies of Membrane Protein
Anne S. Robinson, Ph.D., Professor, Chemical Engineering, University of Delaware
I will highlight our studies of G-protein coupled receptors, in which we try to understand how the proteins form and insert into the membrane of *S. cerevisiae*. We also use a variety of techniques to characterize the proteins in membrane-mimetic environments.

11:00 Baculovirus Particles as a Source of Mammalian Integral Membrane Proteins for Phage Display Applications
Isidro Hotzel, Ph.D., Scientist, Antibody Engineering, Genentech, Inc.
A major impediment to the application of phage display technology to mammalian multispan targets is the difficulty in generating and purifying these proteins. We describe the use of baculovirus particles as a source of multispan proteins for phage display applications.

11:30 Generation of Fully Human Antagonistic Antibodies against GPCR Targets
Sergej Kiprijanov, Ph.D., Vice President, Research & Pre-Clinical Development, R&D, Affitech AS
Using antibody phage display and Cell-Based Antibody Selection (CBAS™) technology, we generated a panel of antagonistic antibodies against GPCR targets involved in cancer progression and inflammation. Data showing applicability of the GPCR targeting antibodies for treatment of cancer, inflammatory and autoimmune diseases will be presented.

12:00 pm Close of Symposium

Point-of-Care Diagnostics
Taking Molecular Diagnostics to the Market

SUNDAY, FEBRUARY 19

7:30 am Registration and Morning Coffee

8:25 Chairperson's Opening Remarks

INTRODUCTORY SESSION

8:30 Business Models for Pharma in Point-of-Care and Molecular Diagnostics
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.

10:00 Networking Coffee Break with Poster Viewing

10:30 Business Models for Pharma in Point-of-Care and Molecular Diagnostics (Continued)
Keith F. Batchelder, M.D., CEO, Genomic Healthcare Strategies
Peter S. Miller, COO, Genomic Healthcare Strategies

11:00 Commentary and Industry Perspective Discussion
John McDonough, CEO, T2 Systems
Timothy T. Stenzel, M.D., Ph.D., CSO, Quidel

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

POINT-OF-CARE OPPORTUNITIES AND APPLICATIONS

1:25 Chairperson's Remarks

FEATURED PRESENTATION

1:30 Universities as Source of Point-of-Care Diagnostics Technology
Lita L. Nelsen, M.B.A., Director, Technology Licensing, Massachusetts Institute of Technology
Research institutions are a fertile source of new ideas and new intellectual property for point-of-care diagnostics, both platforms and tests. This presentation will discuss how to access these resources and how to overcome the barriers to commercialization.

2:00 Molecular Profiling of Cancer with Point-of-Care Tests
Marek Malecki, M.D., Ph.D., Associate Professor of Genetics, Genomics, and Gene Therapy; Director, Biotechnology Program, Western University of Health Sciences

2:30 To Be Announced

3:00 Networking Refreshment Break with Poster Viewing

INNOVATIVE POINT-OF-CARE DEVICES

3:30 Smart Phone Optical Diagnostics
J. Matt Dubach, Bioengineering, Northeastern University
Novel fluorescent sensors provide an optical signal that corresponds to analyte target. A smart phone can be easily adapted to make fluorescent measurements and provide *in vivo* or *in vitro* concentrations measurements of targeted molecules.

3:45 Novel Electronic Assay Platform for Multiplexed Genomicand Proteomic Analysis
Hyowon Lee, Ph.D., Senior Biomedical Engineer, Technical Operations, NanoIVD, Inc.
Nanotechnology-enabled electronic assay platforms can be well-suited for point-of-care test (POCT) application. The test system is miniaturized and can be made simple to use for early disease detection testing, post therapy monitoring, and genetic and proteomic profiling of clinical samples.

4:00 Sample to Answer System for Point-of-Care Molecular Diagnostics
Michael J. Heller, Ph.D., Professor, Bioengineering and Nanoengineering, University of California, San Diego
A unique dielectrophoretic device has been developed for the isolation of cancer biomarkers (cfc-DNA), bacteria and virus from blood and other samples. Direct detection can be carried out on the device providing "seamless" sample to answer point-of-care diagnostics.

4:15 Using Ubiquitous Personal Glucose Meters for Portable Quantitative Detection of a Broad Range of Non-Glucose Targets
Yi Lu, Jay and Ann Schenck Professor, Chemistry, University of Illinois, Urbana-Champaign
This presentation demonstrates a novel method of using pocket-sized personal glucose meters (PGMs) to detect many targets beyond glucose, ranging from recreational drugs such as cocaine to important biological cofactors, and from disease markers such as interferon-gamma of tuberculosis to toxic metal ions.

4:30 Integrative Innovation: Bringing together Payers, Providers, and Innovators
Halle Tecco, Founder & CEO, RockHealth

4:45 Q&A with Speakers

5:00 Close of Day

MONDAY, FEBRUARY 20

8:25 am Chairperson's Remarks

8:30 PANEL DISCUSSION: Investing in Point-of-Care Diagnostics
Moderator: Peter S. Miller, COO, Genomic Healthcare Strategies
Panelists:
Stacy A. Feld, J.D., Director, Physics Ventures
Mickey Urdea, Ph.D., Chairman & CEO, Tethys Bioscience, Inc.

9:30 Networking Coffee Break with Poster Viewing

10:00 PANEL DISCUSSION: Diagnostic Benefit Manager – Progress to Date
Moderator: Keith F. Batchelder, M.D., CEO, Genomic Healthcare Strategies
Panelists:
Felix W. Frueh, Ph.D., President, Medco Research Institute, Medco Health Solutions, Inc.
Edward Wassman, M.D., Chief Genomics Officer, Generation Health

11:00 PANEL DISCUSSION: Point-of-Care CEO – How Molecular Diagnostics Fit with their Instruments
Moderator: John McDonough, CEO, T2 Systems
Panelists:
John L. Bishop, CEO, Cepheid
John McDonough, CEO, T2 Systems
Timothy T. Stenzel, M.D., Ph.D., CSO, Quidel

12:00 pm Close of Symposium

Next-Generation Pathology
Integrating Tools and Solutions for Tissue Analysis

SUNDAY, FEBRUARY 19

7:30 am Registration and Morning Coffee

8:25 Chairperson's Opening Remarks

MOLECULAR PATHOLOGY: THE FUTURE IS NOW

KEYNOTE PRESENTATION

8:30 Talk Title to be Announced
Carlos Cordon-Cardo, M.D., Ph.D., Irene Heinz Given and John LaPorte Given Professor and Chairman, Department of Pathology, Professor, Department of Genetics and Genomic Sciences, The Mount Sinai School of Medicine; Professor and Director, Department of Pathology, The Mount Sinai Hospital

9:00 Development of Next-Generation Sequencing as a Clinical Test and Requirements for Laboratory Standards
Nazneen Aziz, Ph.D., Director, Molecular Medicine, Transformation Program Office, College of American Pathologists
CAP has convened a group of experts who are using next-generation sequencing to actively develop standards around many metrics of the analytical and bioinformatics workflow. In this presentation, a summary will be provided on some of the workflow points where standards are critical.

9:30 Clinical Interpretation of Next-Generation Sequencing Tests: A Whole New World
Wayne W. Grody, M.D., Ph.D., Professor, Divisions of Medical Genetics and Molecular Pathology, Departments of Pathology & Lab. Medicine, Pediatrics, and Human Genetics, Director, Diagnostic Molecular Pathology Laboratory, University of California, Los Angelas School of Medicine
Application of NGS at the clinical level represents a true paradigm shift that will require new standards for appropriate test ordering, informed consent, actionable interpretation, access to patented sequences of the genome, and revelation of "off-target" results. This presentation will explore these factors based on precedents from the single-gene experience in molecular diagnostics.

10:00 Networking Coffee Break with Poster Viewing

10:30 Molecular is Nifty…Experiences Trying to Keep it Thrifty?
Jeffrey A. Kant, M.D., Ph.D., Director, Division of Molecular Diagnostics, University of Pittsburgh Medical Center Health System
Although molecular-based assays offer many benefits, as laboratory testing goes they are relatively expensive and may provide uncertain reimbursement. Appreciable savings can be realized by doing some molecular testing in-house and by active involvement with sendout assays.

11:00 Opportunities and Challenges of Molecular Diagnostics and Personalized Cancer Therapy
Dongfeng (Dan) Tan, M.D., Full Professor, Pathology and Laboratory Medicine, MD Anderson Cancer Center
The presentation outlines principles of molecular diagnostics and personalized cancer therapy, updates new developments in drug discovery by using molecular profiling tests including next-generation sequencing, and discusses the challenges and opportunities in the ever-evolving field.

11:30 Transformative Systems Pathology: Moving Omics to Clinics
Michael Roehrl, M.D., Assistant Professor, Pathology and Laboratory Medicine, Boston Medical Center
We will discuss proteomic cancer biomarker discovery, cancer exome sequencing, and joint data interpretation of next-gen sequencing with proteomics. We will demonstrate that ultra-rapid tissue biobanking is critically important for faithful physiome preservation in next-gen diagnostics.

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

PATHOLOGY IN DRUG DISCOVERY AND DEVELOPMENT

1:25 Chairperson's Remarks

1:30 Bringing Biobanks to Life: Rapid and Highly Efficient Generation of Cell Lines from Pathology Specimens
Richard Schlegel, M.D., Ph.D., Professor and Chair, Pathology, Georgetown University Medical School
We describe a general method for rapidly expanding normal and malignant epithelial cells derived from diverse anatomic sites and mammalian species. Many primary cells can now be expanded and passaged indefinitely without transfection of exogenous viral or cellular genes.

2:00 Next-Generation Pre-Clinical Xenograft Models
Yuzhuo Wang, Ph.D., Associate Professor, Urologic Science, University of British Columbia
We have developed a routine procedure for successfully grafting and serially transplanting primary human cancer tissues into immuno-deficient SCID mice. More significantly, such "next-generation" xenograft models have been effectively applied in a number of translational research areas.

2:30 Translational Pathology Research: The Quest for Predictive BioMarkers
Suzanne K. Coberly, M.D., FCAP, Pathologist Director, Amgen
With the growth of biomarkers to predict patient response to therapeutics, particularly in oncology, the role of human pathologists have also grown. Classic diagnostic pathology combines with molecular techniques in drug development to match appropriate patient populations to new therapeutics.

3:00 Networking Refreshment Break with Poster Viewing

QUANTITATIVE TISSUE-BASED MOLECULAR ASSAYS

3:30 Quantification and Standardization of *in situ* Measurement of Biomolecules in Formalin Fixed Paraffin Embedded Tissue
David L. Rimm, M.D., Ph.D., Professor of Pathology; Director, Medical Studies; Director, Pathology Tissue Services, Yale School of Medicine
In situ analysis maintains spatial information which is often critical in understanding biological processes. This talk will describe recent developments that allow accurate, reproducible, standardized and quantitative *in situ* measurements of protein, mRNA and microRNA.

4:00 Power of the Taqman Protein Assay (TPA) for Quantitative Protein Determination in Pathological Samples
Leendert Looijenga, Professor & Head, Laboratory Experimental Patho-Oncology, Pathology, Erasmus Medical Center
Taqman Protein Assay was developed to be informative to quantitatively determine the amount of protein in small samples, derived from either fresh, frozen, or FFPE material. This method allows sensitive and specific investigation of protein content in pathological samples, including diagnostic and prognostic.

4:30 PANEL DISCUSSION: Molecular Pathology as the Driving Force for Precision Medicine
Moderator: Richard Levenson, M.D., Brighton Consulting Group

5:00 Close of Day

INTEGRATING TECHNIQUES AND APPLICATIONS

8:25 am Chairperson's Remarks

8:30 Multiplexing in Pathology: How Far Can We Go?
Richard Levenson, M.D., Brighton Consulting Group
Conventional tissue-based immunohistochemistry and immunofluorescence are limited in the number of targets they can demonstrate in the same cell or section. However, some questions need higher levels of multiplexing, especially in limited samples. New methods promise some compelling solutions.

9:00 Exome Sequencing for Candidate Gene Discovery in Inherited Disorders
Karl V. Voelkerding, M.D., Professor of Pathology, University of Utah; Medical Director, Genomics and Bioinformatics, ARUP Laboratories

9:30 Biomarker Discovery by NexGen Sequencing of Immune Repertoire
Jian Han, M.D., Ph.D., Faculty Investigator, R10K, HudsonAlpha Institute for Biotechnology
We developed mPCR (multiplex PCR) method to amplify immune repertoire inclusively and semi-quantitatively for direct sequencing. We have initiated a large scale repertoire sequencing project called R10K (R10K.org) to sequence 10,000 samples representing 100 diseases.

10:00 Networking Coffee Break with Poster Viewing

DIGITAL PATHOLOGY

10:30 Leveraging the Power of Digital Pathology in Translational Research
Mark Lloyd, M.S., Staff Scientist, Analytic Microscopy, H. Lee Moffitt Cancer Center
Marilyn Bui, M.D., Ph.D., Associate Professor and Director, Anatomic Pathology and Analytic Microscopy, H. Lee Moffitt Cancer Center
The future of pathology requires increasing levels of quantification. Using a multidisciplinary approach to address complex image analysis tasks informed by highly specialized pathologists is necessary to ensure optimal results.

11:00 Automated Feature Classification and Image-Based Feature Search in Whole Slide Image Data Sets
Ulysses G.J. Balis, M.D., Associate Professor and Director, Division of Pathology Informatics, University of Michigan
The recent availability of digital whole slide imaging data sets creates possibilities whereby libraries of histological imagery can be curated and queried for information based on morphology. This presentation explores recent advances in algorithmic technology such as SIVQ, that enables searching of WSI subject matter.

11:30 High Resolution Pathology for Personalized Medicine Using Automated Image Analysis Algorithms
Raj Bandaru, Associate Director, Informatics and Statistics Operations, Oncology Translational Laboratories, Novartis Pharmaceuticals
This talk will focus on how to handle and analyze large volumes of data and the challenges involved by showing data from a breast tumor epidemiology study where we generated multichannel biomarker data at subcellular localization levels from archival tumor biopsies.

12:00 pm Close of Symposium

Event Short Courses

1:00-4:00

February 20

SC1 Identification, Characterization and Targeting of Cancer Stem Cells

A session that examines new tools and new targets, treatment strategies, cancer stem cell lines in drug discovery and development, new therapeutic agents that reduce tumor initiating cell frequency, and defining a cancer stem cell hierarchy for effective targeting.

Robert Hollingsworth, Ph.D., Director, Cancer Biology, MedImmune, Inc.
Norman J. Maitland, Ph.D., Director, Yorkshire Cancer Research Unit and Department of Biology, University of York, UK
Jennie P. Mather, Ph.D., Senior Vice President, Stem Cell Research, Macrogenics, Inc.
Timothy Hoey, Ph.D., Senior Vice President, Cancer Biology, OncoMed Pharmaceuticals, Inc.
Albert J. Wong, M.D., Professor, Cancer Biology and Neurosurgery, Stanford University Medical Center

SC2 Roadmap for Accelerating Commercialization of Molecular Diagnostics

Sponsored by ogt

This short course is focused on development of molecular diagnostics as they make their way from biomarker discovery and initial proof of clinical performance through to commercial launch, partnership delivery and market development.

William Cook, M.B.A., Principal, Strategy and Business Development, Clinical Diagnostics, WECA
Patrick F. Terry, Principal, Pricing & Market Access Practice, Scientia Advisors
Rina Wolf, Vice President, Commercialization Strategies, Consulting & Industry Affairs, Xifen

SC3 Understanding EMT: Mechanisms and Metastasis to MET

This course will provide a framework of the underlying molecular mechanisms of EMT while addressing stem cells, and cancer progression, cMET and their activity as anti-metastasis agents, and the Mesenchymal-Epethelial Transition (MET) as an essential process for tumor re-initiation, colonization, and metastasis.

Sendurai A. Mani, Ph.D., Assistant Professor, Department of Molecular Pathology; Co-Director, Metastasis Research Center, MD Anderson Cancer Center
George Vande Woude, Ph.D., Director & Distinguished Scientific Investigator, Van Andel Institute
Fredika M. Robertson, Ph.D., Professor, Department of Experimental Therapeutics, Center for Targeted Therapy, Translational Therapeutics Laboratory, Morgan Welch Inflammatory Breast Cancer Research Program and Clinic, MD Anderson Cancer Center

SC4 Network Pharmacology

Sponsored by e-Therapeutics Ltd

This course will describe several real applications, with case studies, of the principles of biological networks, chemical promiscuity, and network pharmacology that have generated compounds, for example in cancer therapy and antibiotics, with potent efficacy and acceptable safety profiles.

Malcolm Young, Ph.D., CEO, e-Therapeutics
Jake Chen, Ph.D., Associate Professor, Informatics, Indiana University

SC5 Next-Generation Sequencing in the Cloud Era

The nature of infrastructure cloud platforms makes them perfect for tools designed to automatically provision, configure and deploy systems, servers, clusters and complex scientific pipelines to support sequencing analysis. Data movement, application scaling, security and emerging patterns in cloud architectures will be explored.

Adam Kraut, Scientific Consultant, BioTeam, Inc.
Jacob Glanville, Principal Scientist, Rinat Laboratories, Pfizer

SC6 Marketing and Sales: Science Training 101

This course examines basic biology and genetics concepts for life sciences marketing and sales professionals. Topics covered include: cell structure, inheritance and replication, gene expression and epigenetics, current and next-gen sequencing technologies and their impact on discovery and therapy, and personalized medicine.

SC7 Latest Advances in Molecular Pathology, Part I (Basic)

This course is designed to educate practicing pathologists on the current molecular diagnostics technologies. The course is created in collaboration with Cambridge Healthtech Institute and the College of American Pathologists.

Karl Voelkerding, M.D., Associate Professor, Pathology, University of Utah; Medical Director, Advanced Technology and Bioinformatics, ARUP Laboratories
Iris Schrijver, M.D., Associate Professor of Pathology and (by courtesy) Pediatrics, Stanford University School of Medicine Pathology
Michael Roehrl, M.D., Assistant Professor of Pathology and Laboratory Medicine, Pathology and Laboratory Medicine, Boston Medical Center

SC8 Best Practices in Translational Informatics

This course will explore real world solutions currently in place in pharma, research institutions, and academia. We will discuss tools for enabling better and faster clinical research and informatics solutions that link data from the clinic with cutting edge research.

Kevin Davies, Ph.D., Editor-in-Chief, Bio-IT World
Joshua Snyder, Novartis Institutes for BioMedical Research
Sean Ekins, Collaborative Drug Discovery
Sanjay Joshi, Solutions Architect, Life Sciences, Isilon Systems

SC9 Pharmacology and Drug Discovery in the Allosteric World

High-throughput screening is changing the type of molecules found. This course will familiarize researchers with the tools needed to exploit this area of new drug discovery through discussion of allosteric molecules, detection of allosterism, and quantifying allosterism for lead optimization.

Terry Kenakin, Ph.D., Professor, Department of Pharmacology, University of North Carolina

Event Dinner Short Courses

4:30-7:30

February 20

SC10 Digital PCR Applications and Advances

Digital PCR is poised to make a significant impact in the diagnostics field. This course will address the differences between digital PCR and other PCR techniques, copy number variation, detection of gene expression at the single molecule level and mutation detection.

Jason H. Bielas, Ph.D., Assistant Member, Molecular Diagnostics Program, Fred Hutchinson Cancer Research Center (FHCRC); Affiliate Assistant Professorship, Department of Pathology, University of Washington
Ben Ho Park, M.D., Ph.D., Associate Professor, Oncology, Breast Cancer Research Program; Associate Director, Hematology/Oncology Fellowship Training Program, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
Carl Lars Hansen, Ph.D., Assistant Professor, Center for High-Throughput Biology, Department of Physics and Astronomy, University of British Columbia

SC11 CTCs from Bench to Bed: Streamlining from Research to Clinical Practice

Sponsored by ACD

This course will focus on validation of CTC research data for clinical practice, correlations between CTCs, diagnosis and responses to therapy.

Marek Malecki, M.D., Ph.D., Associate Professor of Genetics, Genomics, and Gene Therapy; Director, Biotechnology Program, Western University of Health Sciences
Patrizia Paterlini Brechot, M.D., Ph.D., Professor of Cell Biology/Oncology, University Paris Descartes, Director of INSERM, Unit 807 and CSO, Rarecells
Stuart Lindsay, Ph.D., Professor, Physics and Chemistry Director, Center for Single Molecule Biophysics, Arizona State University
Nan Su, Ph.D., Senior Scientist and Group Leader, Advanced Cell Diagnostics, Inc.
Patrick Morris, Ph.D., Associate, Intellectual Property, Perkins Coie

SC12 First-in-Human Study and Risk Mitigation Strategy for Biologics

This course will review the basic concepts and study designs for early drug development including Phase I First-in-Human (FIH) Single Ascending Dose (SAD), Food Effect (EF), Multiple Ascending Dose (MAD) and Phase IIa Proof-of-Concept studies, biologic FIH starting dose estimation from No Observed Adverse, Effect Level (NOAEL) to Minimum Anticipated Biological Effect level (MABEL) approach.

Sean Zhang, M.D., Medical Director, Discovery Medicine and Clinical Pharmacology, Bristol-Myers Squibb
Dale E. Johnson, Pharm.D., Ph.D., President & CEO, Emiliem, Inc.

SC13 Scientists: Business Training 101

This course examines basic business concepts and terminology for scientists. Topics covered include: finance, marketing, positioning and selling your business, presenting persuasively to venture capitalists, and reaching your target audience with 21st century communications. The course will feature interactive discussions and video presentations.

Ellen Martin, Partner, Kureczka/Martin Associates
Joan Kureczka, Partner, Kureczka/Martin Associates

SC14 Adaptive Oncology Clinical Trials

Sponsored by AptivSolutions

Most advanced adaptive designs have been developed for the oncology clinical trials. This course will review these designs with specific focus on continual reassessment methods, seamless Phase I/II designs, Bayesian response adaptive designs, seamless Phase II/III designs and population enrichment designs.

Vlad Dragalin, Senior Vice President, Innovation Center, Aptiv Solutions

SC15 Latest Advances in Molecular Pathology, Part II (Advanced)

This course is designed to educate practicing pathologists on advanced and future applications of molecular diagnostics technologies. The course is created in collaboration with Cambridge Healthtech Institute and the College of American Pathologists.

Wayne Grody, M.D., Ph.D., Professor, Departments of Pathology & Laboratory Medicine, Pediatrics, and Human Genetics, University of California Los Angeles School of Medicine
Nazneen Aziz, Ph.D., Director, Molecular Medicine, College of American Pathologists
Jeffrey A. Kant, M.D., Ph.D., Director, Division of Molecular Diagnostics, University of Pittsburgh Medical Center Health System

SC16 Ontologies for the Bio-Science Industry: Development & Use

There is a growing trend in the life sciences to move away from traditional terminology-based ontologies. Ontological Realism strives to develop ontologies that are more stable and able to support automated reasoning using a semantics more powerful than semantic web languages.

Werner Ceusters, M.D., Professor, Department of Psychiatry; Director, Ontology Research Group, NYS Center of Excellence in Bioinformatics & Life Sciences

SC17 Mastering Physicochemical Properties-Based Analysis to Deliver Improved Drug Candidates

This interactive workshop will enable participants to learn the keys to mastering an integrated approach to improve medicinal chemistry lead optimization that yields high quality clinical candidates. Multiple real-life case studies will be used to illustrate the effectiveness of this approach.

Martin P. Edwards, Vice President, Discovery Chemistry, Pfizer San Diego

SC18 Regulatory Approval of a Therapeutic & Companion Diagnostic: Nuts & Bolts

Overview of the requirements and processes for coordinated NDA/PMA or BLA/PMA submissions leading to simultaneous approvals of a therapeutic and companion diagnostic; from working with CDER, CBER and CDRH to labeling considerations, as well as an overview of the evolving Rx/Dx regulatory landscape.

Nancy Gerber, Associate Director, Regulatory Affairs, Genentech
Erling Thor Donnelly, Ph.D., R.A.C., Director, Worldwide Regulatory Strategy, Pfizer, Inc.
Pamela L. Swatkowski, Director, Regulatory Affairs, Abbott Molecular, Inc.

Example of a Suggested ALL ACCESS Package:

Symposium Targeting Cancer Stem Cells in Oncology → **Event Short Course** Identification, Characterization and Targeting of Cancer Stem Cells → **Event Dinner Short Course** First-in-Human Study and Risk Mitigation Strategy for Biologics → **Core Program** Cancer Biologics

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.

TUESDAY, FEBRUARY 21

7:00 am Registration

PLENARY KEYNOTE SESSION

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

IMPROVING PATIENT OUTCOMES: INTEGRATED GENE MUTATION, EXPRESSION & METHYLATION

11:00 Chairperson's Opening Remarks
Alan Carter, President, MDx Consulting

KEYNOTE PRESENTATION

11:10 The Science behind Wide-Scale Adoption of Genomic Analysis in the Clinic
Nicholas J. Schork, Ph.D., Director, Biostatistics and Bioinformatics, The Scripps Translational Science Institute; Professor, Molecular and Experimental Medicine, The Scripps Research Institute
This talk will focus on items that have yet to be refined in routine implementation of genomic analysis in clinical care. It will discuss annotating genomic alterations of relevance to patients, matching patient genomic profiles to therapeutic profiles, and monitoring patients objectively.

11:40 DNA Methylation Profiling Defines Clinically Relevant Biological Subsets of Non-Small Cell Lung Cancer
David S. Shames, Ph.D., Scientist, Development Oncology Diagnostics, Genentech, Inc.
This presentation will discuss the discovery and development of DNA methylation biomarkers that are predictive of sensitivity to molecularly targeted agents such as erlotinib. I will also talk about promising new technology platforms that may be useful in the discovery of new biomarkers.

12:10 pm Methylation-Based Biomarkers for Predictive and Prognostic Use
Wim van Criekinge, Vice President, Science & Technology, MDx Health
MDxHealth's proprietary Methylation-Specific PCR (MSP) platform identifies DNA methylation-based oncology biomarkers for theranostic applications. A comprehensive epigenome-wide profiling pipeline has been established and will be discussed.

12:40 Luncheon Presentation I
Multiplexing FFPE Samples in Your Lab and Achieving Meaningful Results
Sponsored by htg Molecular
BJ Kerns, Senior Vice President, HTG Molecular
Learn how qNPA technology produces significant data from FFPE tissue with no extraction. Successfully quantitating multiple genes in a single well from FFPE differentiates qNPA technology from traditional gene expression methods.

1:10 Luncheon Presentation II
Miniaturized Biomarker Assays in Complex Biological Samples for Drug Discovery and Clinical Trials
Sponsored by nanoINK Nano BioDiscovery
Haris Jamil, Ph.D., Vice President, Research, NanoInk, Inc.

1:45 Dessert in the Exhibit Hall with Poster Viewing

2:15 Chairperson's Remarks

2:20 Integrated Molecular Testing and the Critical Need to Engage Physicians
William G. Loudon, M.D., Ph.D., Assistant Professor, Neurosurgery, University of California Irvine; Section Chief, Neurosurgery, Children's Hospital of Orange County

2:50 A New Paradigm for Advancing Personalized Medicine: The Contract Diagnostics Organization
Sponsored by ResearchDX Your Companion in Diagnostics
Philip D. Cotter, Ph.D., F.A.C.M.G., Co-Founder, ResearchDx, LLC.

3:05 Wrap Up/Debate: Is Integration Realistic?
- No clear regulatory trajectory for such tests and considerable uncertainty
- Cost issues associated with a thorough (prospective) validation
- Availability of suitable tumor tissue

3:35 Biochip Array Technology – A Rapid Multiplex Solution for Mutation Profiling, SNP Genotyping and Pathogen Detection
Sponsored by RANDOX
Scott McKeown, Ph.D., R&D Consultant, Randox Laboratories
Biochip Array Technology is a class-leading multiplex platform, which in combination with a proprietary multiplex PCR amplification process is capable of simultaneous detection of up to 22 mutations, SNPs or pathogen biorecognition elements, with applications developed for oncology (KRAS/BRAF/PIK3CA mutation profiling), cardiovascular disease (risk SNP array) pharmacogenomics and infectious diseases (including sexually transmitted infections and respiratory pathogens). Data from clinical validation studies for a number of these arrays will be presented.

3:50 Integrated Biomarker Discovery: Multi-Method Approach to Enable Early Biomarker Success
Sponsored by ogt
Graham Speight, Ph.D., Head of Genomic Biomarkers, Oxford Gene Technology
How high throughput biomarker discovery can enable rich datasets for rapid proof of concept, analysis and validation.

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

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

6:20 Close of Day

WEDNESDAY, FEBRUARY 22

REGULATION OF LDTs: THREE POINTS OF VIEW

7:55 am Chairperson's Remarks
Harry Glorikian, Managing Partner, Scientia Advisors

8:00 FDA Oversight of Laboratory Developed Tests (LDTs): Where Are We? Where Are We Going?
Elizabeth Mansfield, Ph.D., Director, Personalized Medicine, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), Center for Devices and Radiological Health (CDRH)
This presentation will provide an update regarding FDA oversight of Laboratory Developed Tests (LDTs), discuss publication of a draft guidance document related to Investigational Use/Research Use products, and discuss regulatory issues associated with next-generation sequencing technologies.

8:30 Is There, and Should There Be, a Role for RUO and IUO Labeled Products in LDTs?
Stephen P. Day, Ph.D., Director, Medical Affairs, Hologic, Inc.
This presentation will provide an overview of what recently released draft guidance on RUO and IUO products may mean to clinical laboratories and manufacturers and how it may impact LDTs.

9:00 Regulation of LDTs: The Laboratory's Perspective
Peter M. Kazon, General Counsel, American Clinical Laboratory Association
This presentation examines past actions of FDA regarding LDTs, and will focus on particular concerns that FDA regulation could pose for laboratories, from both a legal and practical standpoint. It will also focus on the other regulatory scheme that affects laboratories, namely CLIA.

9:30 Rigorous Design and Validation of a Molecular Laboratory Developed Test
Sponsored by Asuragen
Carol Berry, Sr. Vice President, Services Division, Asuragen Inc.
This presentation will feature a case study on the design, development, and validation of a molecular LDT, including steps necessary to achieve medical adoption.

10:00 Transition to Plenary Keynote

PLENARY KEYNOTE

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

GLOBAL OPPORTUNITIES FOR MOLECULAR DIAGNOSTICS

11:55 Chairperson's Remarks
Kenneth Bahk, Ph.D., Lurie Investments

12:00 pm Non-Instrumented and Fully Integrated Molecular Diagnostic Solutions for the Developing World
Timothy T. Stenzel, M.D., Ph.D., CSO, Quidel
Quidel is collaborating with BioHelix to develop isothermal amplification tests utilizing lateral flow for detection. In collaboration with Northwestern University, Quidel is developing a low-cost fully integrated molecular diagnostics platform using novel Immiscible Phase Nucleic Acid Purification technology.

12:20 China: Market Opportunity and Characteristics
Min Cui, Ph.D., Principal, Bay City Capital

12:40 Applying Molecular Diagnostic Tests in High Burden Developing Countries (HBDC)
Russel K. Enns, Ph.D., Senior Vice President, Chief Regulatory Officer, Cepheid
A simple to operate, totally automated molecular diagnostic test platform being used for detection of Mycobacterium tuberculosis and multi-drug resistant tuberculosis in HBDC will be described. Insights and experiences with this testing platform and the challenges of this environment will be discussed.

1:00 Luncheon Presentation I

Sponsored by myraqa ENLIGHTENED COMPLIANCE

Proving Value as a Companion Diagnostics Partner
Mya Thomae, CEO, Myraqa, Inc.
What does it take to show a therapeutics firm that you're ready for a companion diagnostics partnership? We'll look at pharma needs and expectations with an eye toward helping MDx firms demostrate readiness for a CoDx regulatory application.

1:30 Luncheon Presentation II

Sponsored by Luminex

Changing the Management of Global Infectious Diseases Using Novel Molecular Diagnostic Tools
Jeremy Bridge-Cook, Senior Vice President of Assay Research and Development, Luminex Corporation
The recent expansion of molecular diagnostics testing is beginning to change how global infectious disease epidemics and outbreaks are detected and tracked. In the advent of an increasingly globalized world, Luminex will discuss how ID assays developed for "modern healthcare" systems are being ported to the developing world and how this may be one sustainable model that will see innovative molecular testing solutions reaching those in highest need. Additionally a different perspective on 'personalized medicine' will be discussed when multiplexed molecular testing identify infectious agents that would normally go undetected.

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

PLENARY KEYNOTE PANEL

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

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

THE SUPPORT OF COMPANION DIAGNOSTICS THROUGH CENTRAL LABORATORY TESTING

4:25 Chairperson's Remarks
Brian T. Edmonds, Ph.D., Research Advisor, Global External Research & Development, Lilly Corporate Center

Sponsored by Quest Diagnostics

4:30 Key Considerations: Biomarkers as Potential Companion Diagnostics
Terry Robins, Ph.D, Director of Biomarker R&D, Quest Diagnostics Clinical Trials
This will cover, gaining insight in developing an optimal biomarker strategy for a drug development program, understanding key issues and considerations in developing a biomarker strategy that can bridge to potential companion diagnostics development and understanding the strategic partnerships needed to enable biomarker to companion diagnostic development.

5:00 The Use of Molecular Diagnostics to Guide Drug Development and Patient Tailoring
Andrew Schade, M.D., Ph.D., Senior Director, Clinical Diagnostics Laboratory, Eli Lilly & Co.
The increasing interest in targeting specific molecular pathophysiology is changing the way therapeutic agents are developed. This talk will provide perspective of patient tailoring/companion diagnostics from the drug development standpoint.

5:30 PANEL DISCUSSION: Are Complex Genetic Tests Fulfilling Their Promise?
This session will review and discuss the status of genetic testing's ability to inform and improve clinical care in the present and in the future from multiple perspectives, including academia, industry, and clinical care.
Moderator: Edward Abrahams, President, Personalized Medicine
Panelists:
Iris Schrijver, M.D., Director, Molecular Pathology Laboratory Stanford University Medical Center, Lucile Packard Children's Hospital; Associate Professor of Pathology and (by courtesy) Pediatrics, Stanford University School of Medicine; and President, American Association of Molecular Pathology
John J. Sninsky, Ph.D., Vice President, Discovery Research, Celera Diagnostics
Kathy Behrens Wilsey, Ph.D., Board Member, KEW Group

6:30 Close of Day

THURSDAY, FEBRUARY 23

COMMERCIALIZATION OF DRUGS AND COMPANION DIAGNOSTICS

8:30 am Chairperson's Remarks
Thomas F. Soriano, President and CEO, DOCRO, Inc.

8:35 Talk Title to be Announced
Elizabeth Mansfield, Ph.D., Director, Personalized Medicine, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), Center for Devices and Radiological Health (CDRH)

9:05 IDE Requirements for Companion Diagnostic Studies: Case Studies to Identify Best Practice
Sam Rua, Senior Director, Regulatory Affairs, Ventana Medical Systems

9:35 Companion Diagnostics: Challenging Dx and Rx Business Models
Joseph V. Ferrara, President, Global Consulting, Boston Healthcare Associates, Inc.
How will a personalized medicine paradigm change pharmaceutical and diagnostics companies' innovation and commercialization approaches? This presentation will review strategic considerations, case studies, and success factors for value capture in Dx/Rx.

Sponsored by Abbott Molecular

10:05 Best Practices in Companion Diagnostics Collaborations
Pamela Swatkowski, Director, Regulatory Affairs, Abbott Molecular
This talk will address partnering from discovery to commercialization, managing expectations and achieving a true partnership, and present learning from a 2011 U.S. IVD launch.

Sponsored by PMI RESEARCH & DEVELOPMENT

10:20 Verification of Systems Biology Research in the Age of Collaborative-Competition
Marja Talikka, PhD, Philip Morris International

10:35 Coffee Break

11:00 Business Models and Value Capture in the Co-Development of Drugs and Diagnostics
Peter Collins, Ph.D., Vice President & Head, Diagnostics, GlaxoSmithKline Biologicals
This talk will consider the critical issues that must be addressed by both parties when embarking upon co-development programs. There will also be discussion of the issue of value capture and risk sharing approaches.

11:30 Capturing the Value of Diagnostic Innovation
William Welch, Senior Vice President, Diagnostics, Sequenom, Inc.
In a CAP/CLIA clinical laboratory operation, development of clinical diagnostics often takes five or more years. This discussion addresses commercializing novel molecular diagnostics during a time of change in regulatory, coding and reimbursement policies.

12:00 pm PANEL DISCUSSION WITH MORNING SPEAKERS: Clarifying Myths and Misconceptions of Companion Diagnostics (or: "I thought you said...")

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

1:50 PANEL DISCUSSION: Transforming Translational Tools: The Commercialization of Novel Diagnostics from Life Science Technologies

Moderator: Kristin Ciriello Pothier, Partner, Health Advances, LLC
Panelists: Nancy Krunic, Ph.D., Vice President, Molecular Diagnostics, Luminex
Austin Tanney, Ph.D., Scientific Liaison Manager, Almac
Pamela Swatkowski, Director, Regulatory Affairs, Abbott Molecular

The evolution of true translational and transformative technologies such as molecular diagnostics, next generation sequencing, digital pathology, and mass spectrometry into the clinical markets from their original life science markets is occurring rapidly, but not without major commercialization challenges for life science companies as they develop their strategies for a very different clinical market. This session will share the experiences of the panelists and the moderator on robust commercialization strategies of these technologies in the clinical market, share the experiences of the panelists on the most poignant successes and failures, detail how to build global market analysis around the true potential and overall strategy and tactics, and explore opportunities for the future both from a company perspective and an investor perspective.

3:20 Close of Conference

Third Annual

Personalized Diagnostics

Impacting Clinical Medicine

February 21-23

TUESDAY, FEBRUARY 21

7:00 am Registration

PLENARY KEYNOTE SESSION

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

NGS FOR THE CLINICAL SETTING

11:00 Chairperson's Opening Remarks

Rong Mao, M.D., FACMG, Medical Director, Molecular Genetics and Genomics, ARUP Laboratories; Assistant Professor, Pathology, University of Utah School of Medicine

11:10 Molecular Diagnosis of Mitochondrial Disorders by Next-Generation Sequencing

Rong Mao, M.D., FACMG, Medical Director, Molecular Genetics and Genomics, ARUP Laboratories; Assistant Professor, Pathology, University of Utah School of Medicine

Mitochondrial diseases are a group of disorders affecting organ systems that have high energy requirements and are dependent on aerobic metabolism. Next-generation sequencing offers the possibility of maximum sequencing of the mitochondrial genome and the nuclear genes.

11:40 Diagnostic Application of Next-Generation Sequencing Using Aortopathy Panel as an Example

Pinar Bayrak-Toydemir, M.D., Ph.D., Medical Director, Molecular Genetics and Genomics, ARUP Laboratories; Assistant Professor, Pathology, University of Utah School of Medicine

This presentation will focus on the development, validation and implementation of an NGS-based gene panel for aortopathies, which includes Marfan syndrome and Marfan-like syndromes. In particular, I will focus on comparison of different enrichment methods.

12:10 pm How to Translate Next-Generation Sequencing Data into Clinically Useful Information

Fuad Gwadry, Bioinformatics Consultant, Sequenom Center for Molecular Medicine

One of the main challenges facing the implementation of next-generation sequencing in clinical practice is the bioinformatic data analysis. This talk will illustrate bioinformatic strategies used to identify the novel variants that may be clinically relevant.

12:40 Perfecting Medicine: Sequence Driven Individualized Care

Sponsored by life technologies

Paul R. Billings, M.D., Ph.D., Chief Medical Officer, Life Technologies

"4P" medicine has been proposed. Really the goal is "1P Medicine"--"p"erfecting the diagnosis and management of illness and the maintenance of health. Rapid progress has been made in delivering reliable, accurate genomic sequencing to translational and clinical research settings. Novel protocols are making the benefits of research medicine more accessible. In this talk, I will review Life Technologies initiatives, product developments and trial results that place us in a key role in fostering truly individualized care.

1:45 Dessert in the Exhibit Hall with Poster Viewing

CELLULAR ASSAYS FOR PERSONALIZED ASSESSMENT OF DISEASE AND THERAPY

2:15 Chairperson's Remarks

Rakesh Sindhi, M.D., FACS, Co-Director, Pediatric Transplantation, University of Pittsburgh

2:20 Analytic and Regulatory Considerations for Cellular Biomarkers (of Disease and Therapy)

Brandon W. Higgs, Ph.D., Senior Scientist, Translational Sciences, MedImmune

This talk discusses best practices for biomarker development, and misconceptions regarding use of biomarkers to measure disease activity, treatment response, or biological processes. Topics will include hypothesis-driven versus best predictor approaches and the evaluation of robustness. Molecular and cellular examples will be presented.

2:50 Impacting Disease Mechanisms with Target Saturation

Robert M. Townsend, Ph.D., Director, Clinical Biomarkers, Bristol-Myers Squibb

Flow cytometry-based studies evaluating the saturation of CD80 and CD86 by belatacept on antigen presenting cells have enhanced our understanding of this new drug's mechanism of action and informed the dose rationale.

3:20 Cellular Assays Linking Disease with Mechanisms

Rakesh Sindhi, M.D., FACS, Co-Director, Pediatric Transplantation, University of Pittsburgh

Cellular assays localize molecular mechanisms of disease to effector cells, thus allowing a visual and measurable link to disease and severity. Clinical and drug development uses as prognostic/companion diagnostic/surrogate endpoint will be illustrated for transplantation as a prototypical immunological disease.

3:50 Enabling Smart Consumable Devices for Biosciences & IVD - Cost Drivers and Technologies

Sponsored by Sony DADC

Jessica Melin, Ph.D., M.B.A., Senior Manager, Business Development & Sales North America, Sony DADC, BioSciences

Providing high quality consumable devices at application compliant cost is critical for diagnostic platforms. Such devices increasingly demand mass manufactured polymer microstructures. This talk discusses the important interplay between device mass manufacturability, cost drivers, and detection principles.

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

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

6:20 Close of Day

WEDNESDAY, FEBRUARY 22

7:55 am Chairperson's Remarks

8:00 KEYNOTE PANEL DISCUSSION:

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

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

Featured Guests:

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

Matthew W. Gilmour, Ph.D., Director, Bacteriology and Enteric Diseases Division, National Microbiology Laboratory

Public Health Agency of Canada, Winnipeg, MB, Canada

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

9:15 Discovering and Developing Biomarkers from FFPE Tissue into Clinical Application

Sponsored by ALMAC

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

9:30 Solving the Sequencing Challenges - The Road to Personal Diagnostics

Sponsored by genia

Stefan Roever, CEO & Founder, Genia Technologies

10:00 Transition to Plenary Keynote

PLENARY KEYNOTE

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

11:45 PANEL DISCUSSION: Regulatory Updates – Three Key Areas

Moderator: Andrew C. Fish, Executive Director, AdvaMedDx

Panelists:

Robert Di Tullio, Vice President, Global Regulatory and Clinical Affairs, Alere

Krista Hessler Carver, Esq., Associate, Covington & Burling, LLP

Sam Chawla, Executive Director, Global Healthcare Group, UBS Investment Bank

Phillip S. Bernard, M.D. Medical Director, Molecular Pathology, University of Utah

1:00 pm Luncheon Presentation I:

Sponsored by MSD Meso Scale Discovery

Multiplex Protein Biomarkers from Discovery to Personalized Diagnostics

Pankaj Oberoi, Ph.D. , Director, Scientific Services and Director, Research and Development, Meso Scale Discovery

Scientists appreciate the importance of protein biomarkers in drug development and therapeutic management. We will explore the challenges associated with the increasing demand for reliable, meaningful biomarker panels and how these demands can be met using MSD's multiplexed, quantitative immunoassays.

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

PLENARY KEYNOTE PANEL

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

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

BIG TRENDS IN MOLECULAR DIAGNOSTICS

4:25 Chairperson's Remarks

Thomas Li, Ph.D., Senior Director, Technology Management, Chief Technology Office, Roche Diagnostics, Pleasanton

4:30 Applications of Digital Amplification Technologies to Personalized Diagnostics

Laurence Tisi, Ph.D., Acting CEO, Lumora Ltd.

Digital amplification technologies can improve both the ability to detect and quantify nucleic acids. The technique offers a new dimension to rapid and accurate profiling of disease states or susceptibilities. The challenge is to make the technique accessible for clinical molecular diagnostics.

5:00 POCT for Molecular Diagnostics

Frederick Kiechle, M.D., Chairman of Pathology, Memorial Healthcare System

The development of a POC molecular device which is portable, handheld, time to result at 30 minutes or less, and cost per test at $25.00 or less will require the miniaturization of all 3 steps in a molecular test using microfluidics and small volumes.

5:30 CPT Coding for Molecular Pathology, a Year of Transition

Mark S. Synovec, M.D., President, Topeka Pathology Group, P.A.

This presentation will review AMA-CPT's past two years work as it pertains to molecular pathology services, including a review of the two-tier coding system, the future of the current molecular diagnostic "stacking" codes, and future consideration for analyses not fitting into the two-tiered construct.

6:00 Diagnostic Sequencing

David Dimmock, M.D., Assistant Professor, Pediatrics, Medical College of Wisconsin

This presentation will discuss our current implementation of clinical whole genome sequencing in a children's hospital. It will consider potential pathways to wider deployment of this technology in the diagnosis of rare disease.

6:30 Close of Day

THURSDAY, FEBRUARY 23

ENABLING CLINICAL GRADE NGS/WGS

8:30 am Chairperson's Remarks

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

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

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

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

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

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

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

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

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

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

10:05 Sponsored Presentation *(Opportunity Available)*

10:20 Coffee Break

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

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

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

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

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

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

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

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

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

12:30 Luncheon Presentation

Sponsored by GenomeQuest

Interactive Roundtables on Clinical NGS Led by BIDMC/GenomeQuest Experts

Join us for lunch to further the discussion on Enabling Clinical Grade NGS/WGS. Each luncheon table will be moderated by one of the morning's distinguished speakers. After a brief introduction, join the first table of your choice for 20 minutes then move to a second table for 20 minutes. Plan to take part to delve into the discussion in more detail with the experts and learn how to plan and implement NGS in the clinical setting. See website for details.

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

1:45 Chairperson's Remarks

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

1:50 QA of Tumor Tissue Samples for Molecular Analyses

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

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

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

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

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

2:50 Presentation to be Announced

3:20 Close of Conference

Sixth Annual

Cancer Molecular Markers

Improving Patient Outcomes

February 21-23

TUESDAY, FEBRUARY 21

7:00 am Registration

PLENARY KEYNOTE SESSION

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

IMPROVING PATIENT OUTCOMES: INTEGRATED GENE MUTATION, EXPRESSION & METHYLATION

11:00 Chairperson's Opening Remarks
Alan Carter, President, MDx Consulting

KEYNOTE PRESENTATION

11:10 The Science behind Wide-Scale Adoption of Genomic Analysis in the Clinic
Nicholas J. Schork, Ph.D., Director, Biostatistics and Bioinformatics, The Scripps Translational Science Institute; Professor, Molecular and Experimental Medicine, The Scripps Research Institute
This talk will focus on items that have yet to be refined in routine implementation of genomic analysis in clinical care. It will discuss annotating genomic alterations of relevance to patients, matching patient genomic profiles to therapeutic profiles, and monitoring patients objectively.

11:40 DNA Methylation Profiling Defines Clinically Relevant Biological Subsets of Non-Small Cell Lung Cancer
David S. Shames, Ph.D., Scientist, Development Oncology Diagnostics, Genentech, Inc.
This presentation will discuss the discovery and development of DNA methylation biomarkers that are predictive of sensitivity to molecularly targeted agents such as erlotinib. I will also talk about promising new technology platforms that may be useful in the discovery of new biomarkers.

12:10 pm Methylation-Based Biomarkers for Predictive and Prognostic Use
Wim van Criekinge, Vice President, Science & Technology, MDx Health
MDxHealth's proprietary Methylation-Specific PCR (MSP) platform identifies DNA methylation-based oncology biomarkers for theranostic applications. A comprehensive epigenome-wide profiling pipeline has been established and will be discussed.

12:40 Luncheon Presentation I
Multiplexing FFPE Samples in Your Lab and Achieving Meaningful Results
Sponsored by htg Molecular
BJ Kerns, Senior Vice President, HTG Molecular
Learn how qNPA technology produces significant data from FFPE tissue with no extraction. Successfully quantitating multiple genes in a single well from FFPE differentiates qNPA technology from traditional gene expression methods.

1:10 Luncheon Presentation II
Miniaturized Biomarker Assays in Complex Biological Samples for Drug Discovery and Clinical Trials
Sponsored by nanoINK Nano BioDiscovery
Haris Jamil, Ph.D., Vice President, Research, NanoInk, Inc.

1:45 Dessert in the Exhibit Hall with Poster Viewing

2:15 Chairperson's Remarks

2:20 Integrated Molecular Testing and the Critical Need to Engage Physicians
William G. Loudon, M.D., Ph.D., Assistant Professor, Neurosurgery, University of California Irvine; Section Chief, Neurosurgery, Children's Hospital of Orange County

2:50 A New Paradigm for Advancing Personalized Medicine: The Contract Diagnostics Organization
Sponsored by ResearchDx Your Companion in Diagnostics
Philip D. Cotter, Ph.D., F.A.C.M.G., Co-Founder, ResearchDx, LLC.

3:05 Wrap Up/Debate: Is Integration Realistic?
- No clear regulatory trajectory for such tests and considerable uncertainty
- Cost issues associated with a thorough (prospective) validation
- Availability of suitable tumor tissue

3:35 Biochip Array Technology – A Rapid Multiplex Solution for Mutation Profiling, SNP Genotyping and Pathogen Detection
Sponsored by RANDOX
Scott McKeown, Ph.D., R&D Consultant, Randox Laboratories
Biochip Array Technology is a class-leading multiplex platform, which in combination with a proprietary multiplex PCR amplification process is capable of simultaneous detection of up to 22 mutations, SNPs or pathogen biorecognition elements, with applications developed for oncology (KRAS/BRAF/PIK3CA mutation profiling), cardiovascular disease (risk SNP array) pharmacogenomics and infectious diseases (including sexually transmitted infections and respiratory pathogens). Data from clinical validation studies for a number of these arrays will be presented.

3:50 Integrated Biomarker Discovery: Multi-Method Approach to Enable Early Biomarker Success
Sponsored by ogt
Graham Speight, Ph.D., Head of Genomic Biomarkers, Oxford Gene Technology
How high throughput biomarker discovery can enable rich datasets for rapid proof of concept, analysis and validation.

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

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

6:20 Close of Day

WEDNESDAY, FEBRUARY 22

7:55 am Chairperson's Remarks

8:00 PANEL DISCUSSION: How Have Biomarkers Been Applied in Clinical Development?
Moderator: Prakash Purohit, Ph.D., Associate Director, Scientific Affairs, IPSEN Biomeasure, Inc.
Panelists:
Dominic G. Spinella, Ph.D., Head, Translational and Molecular Medicine, Pfizer
James Watters, Ph.D., Head, Applied Genomics, Sanofi Oncology
Suso Platero, Ph.D., Director, Oncology Biomarkers, Centocor, Ortho Biotech Oncology R&D, a unit of J&J PRD, LLC
Panelists will discuss how to much more efficiently turn biomarker assays into diagnostics. What challenges are there? What strategies are best for future use of biomarkers for clinical development? Case examples will be used.

9:30 From Bench to Clinic: Quantitatively Assessing Cancer Targets and Biomarkers for Targeted Therapies
Sponsored by Theranostics Health
Corinne Ramos, Ph.D., Executive Director, Clinical Research, Theranostics Health
Theranostics Health utilizes Laser Capture Microdissection and highly sensitive, quantitative protein microarrays to accurately measure the presence and phosphoactivation status of the target and its downstream signaling pathway elements in tumor or diseased cells at the site of drug action.

9:45 Sponsored Presentation *(Opportunity Available)*

10:00 Transition to Plenary Keynote

PLENARY KEYNOTE

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

12:00 pm KEYNOTE PANEL DISCUSSION:

Rapid NGS for Public Health Preparedness & Clinical Microbiology: Bioinformatics, Legal, and Social Issues
Moderator: Dag Harmsen, M.D., Professor & Head, Research, Peridontology, University Münster
Featured Guests:
João André Carriço, Auxiliary Researcher, Microbiology Institute, Faculty of Medicine, University of Lisbon

Matthew W. Gilmour, Ph.D., Director, Bacteriology and Enteric Diseases Division, National Microbiology Laboratory
Public Health Agency of Canada, Winnipeg, MB, Canada
Gary Procop, M.D., Chairman, Clinical Pathology, Cleveland Clinic

Sponsored by MSD Meso Scale Discovery

1:00 pm Luncheon Presentation I: Multiplex Protein Biomarkers from Discovery to Personalized Diagnostics
Pankaj Oberoi, Ph.D. , Director, Scientific Services and Director, Research and Development, Meso Scale Discovery
Scientists appreciate the importance of protein biomarkers in drug development and therapeutic management. We will explore the challenges associated with the increasing demand for reliable, meaningful biomarker panels and how these demands can be met using MSD's multiplexed, quantitative immunoassays.

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

PLENARY KEYNOTE PANEL

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

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

NOVEL TECHNOLOGIES SESSION

4:25 Chairperson's Remarks
Avraham Rasooly, Ph.D., Program Director, Cancer Diagnosis Program, National Cancer Institute

4:30 Nano-Velcro Technology to Improve Capture of Circulating Cancer Cells
Hsian-Rong Tseng, Ph.D., Associate Professor, Department of Molecular and Medical Pharmacology, Crump Institute for Molecular Imaging, Institute for Molecular Medicine, University of California, Los Angeles; California NanoSystems Institute
This presentation will introduce a circulating tumor cell (CTC) enrichment/identification technology that allows isolation of viable (preservative-free) CTCs, enabling their functional and molecular analyses in sequence.

5:00 Laser-Cavitation Based Isolation of Circulating Cancer Cells
John F. Zhong, Ph.D., Assistant Professor, Pathology; Director, Bioinformatics, Gene Therapy Laboratories, University of Southern California School of Medicine
We have developed a laser-cavitation based system to isolate and manipulate single-cells for molecular characterization. With this system, we investigate the expression level of various cancer genes at the single-cell level.

5:30 Detection and Isolation of Circulating Melanoma Cells Using Photoacoustic Flowmetry
John A. Viator, Ph.D., Associate Professor, Biological Engineering and Dermatology, University of Missouri
Photoacoustic flowmetry, similar to flow cytometry, is suited to detect melanoma cells in blood. Using photoacoustics and microfluidic principles, we detect and capture circulating melanoma cells in human blood samples to diagnose metastatic disease.

6:00 Microfluidic Biochips for the Label-Free Detection, Isolation & Retrieval of Circulating Tumor Cells
Chwee Teck Lim, Ph.D., Principal Investigator, Mechanobiology Institute; Faculty Fellow, Singapore-MIT Alliance for Research & Technology (SMART); Professor, Division of Bioengineering & Department of Mechanical Engineering, National University of Singapore
We have devised a separation method in a microfluidic biochip based on knowledge that CTCs are larger and stiffer than blood cells. Physical cell traps placed in the blood flow path block CTCs while deformable blood constituents are removed. Viable unlabeled CTCs are then collected by flow reversal.

6:30 Close of Day

THURSDAY, FEBRUARY 23

ENABLING CLINICAL GRADE NGS/WGS

8:30 am Chairperson's Remarks
German Pihan, M.D., Director, Hematopathology Lab, Department of Pathology, Beth Israel Deaconess Medical Center and Harvard Medical School

8:35 Realizing the Promise of Personalized Medicine: Use of High-Throughput Genome Sequencing in Everyday Clinical Laboratory Diagnostics
Jeffrey E. Saffitz, M.D., Mallinckrodt Professor & Head, Department Pathology, Beth Israel Deaconess Medical Center
Advances in next-generation sequencing technology will soon make it practical and affordable to perform whole genome analysis on patients. This talk will briefly describe steps required to bring high-throughput genome sequencing into everyday clinical laboratory diagnostics.

9:05 Are Clinical Genomes Already Becoming Semi-Routine for Patient Care?
Mark S. Boguski, Ph.D., Associate Professor, Center for Biomedical Informatics, Harvard Medical School
This presentation will elucidate issues relating to workforce needs and requirements, legal and regulatory aspects of "laboratory developed tests," and insurance reimbursement for "multi-analyte" diagnostics.

9:35 WGA, Efficacy, Accuracy, and Application in Best Practice Care
Peter J. Tonellato, Ph.D., Visiting Professor & Senior Research Scientist Pathology, BIDMC & Center for Biomedical Informatics, Harvard Medical School
This presentation will discuss the approach taken at Harvard Medical School and Beth Israel Deaconess Medical Center to develop a genomic processing and clinical variant annotation pipeline to aid in clinical decision making.

10:05 Sponsored Presentation *(Opportunity Available)*

10:20 Coffee Break

11:00 Navigating Uncharted Seas: Ethical Issues in Clinical Genomics
Lauren C. Briere, M.S., Licensed Genetic Counselor, Division of Genetics, Department of OB/GYN, Beth Israel Deaconess Medical Center
This talk will cover issues including informed consent, pre- and post-test counseling, result reporting, long-term follow-up, and data rights and explore possible frameworks to address them.

11:30 Clinically Actionable Genomic Information Database: Bridging the Gap between Genomics and the Clinic
Dennis P. Wall, Director & Assistant Professor, Computational Biology Initiative, Harvard Medical School
This talk describes our efforts to formalize the definition of clinical actionability through the construction of infrastructure and procedures for the annotation of whole-genomic data. It describes how this is being used to generate medical impact reports for decision support in cancer prognosis and treatment.

12:00 pm From Data to Information to Knowledge: Whole Genome MUD GUI for Clinicians
German Pihan, M.D., Director, Hematopathology Lab, Department of Pathology, Beth Israel Deaconess Medical Center and Harvard Medical School
This presentation will offer a blueprint for the curation, analysis, mining, interpretation and visualization of complex digital WGS data to generate readily available clinically actionable information, effectively enabling the looming revolution in personalized medicine.

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

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

1:45 Chairperson's Remarks
David Neil Hayes, M.D., M.P.H., Associate Professor, Clinical Research, Hematology/Oncology, University of North Carolina, Chapel Hill

1:50 QA of Tumor Tissue Samples for Molecular Analyses
David Eberhard, Research Associate Professor, Comprehensive Cancer Center and Research Associate Professor, Pathology & Lab Medicine, University of North Carolina, Chapel Hill
High-quality clinical practice and high-quality research depend on rigorous sample QA. Sample parameters that must be considered include Diagnosis, Description, Composition, Quantity and Quality.

2:20 Providing Comprehensive, Clinical-Grade Molecular Profiles for FFPE Tumor Samples
Maureen Cronin, Ph.D., Senior Vice President, Research and Product Development, Foundation Medicine, Inc.
Massively parallel sequencing technologies enable a new class of molecular diagnostic for oncology patients. Performing high sensitivity, high specificity sequencing on small amounts of FFPE tumor allows comprehensive assessment of clinically useful genomic markers, fully informing therapeutic treatment planning.

2:50 Presentation to be Announced

3:20 Close of Conference

Second Annual

Circulating Tumor Cells

Expediting Clinical Use

February 21-23

TUESDAY, FEBRUARY 21

7:00 am Registration

PLENARY KEYNOTE SESSION

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

CTCs IN THE CLINIC

11:00 Chairperson's Opening Remarks
Massimo Cristofanilli, M.D., F.A.C.P., Professor and Chairman

KEYNOTE PRESENTATIONS

11:10 The Prognostic and Predictive Value of Enumeration and Molecular Characterization
Massimo Cristofanilli, M.D., F.A.C.P., Professor and Chairman, Department of Medical Oncology, G. Morris Dorrance Jr. Endowed Chair in Medical Oncology, Fox Chase Cancer Center
This presentation will review the clinical value of enumeration, introduce the most recent advancements in defining the molecular phenotype of CTCs, integrate this information for the prognosis and monitoring of response to therapy, and introduce their utility in pharmacodynamic monitoring.

11:40 Circulating Tumor Cells as Potential Biomarker for Metastatic Prostate Cancer Clinical Trials for Predicting Benefit and Monitoring Patients
Howard Scher, M.D., Chief, Genitourinary Oncology Service, Memorial Sloan-Kettering Cancer Center

12:10 pm Clinical Significance of Circulating Tumor Cells in Breast Cancer
Minetta C. Liu, M.D., Associate Professor, Medical and Oncology, Lombardi Comprehensive Cancer Center, Georgetown University Hospital
Prospective clinical trials demonstrate that the enumeration of circulating tumor cells (CTCs) has clinical utility when used in conjunction with radiographic imaging and clinical evaluations in the setting of metastatic breast cancer.

12:40 Molecular Analysis of Circulating Tumor Cells Using the IsoFlux System
Sponsored by FLUXION
Carolyn Conant, Ph.D., Senior Scientist, Fluxion Biosciences
We discuss required attributes of CTC samples for downstream molecular diagnostics. The IsoFlux System is a novel platform that provides access to CTCs with high recovery, high purity, and low liquid volume. Clinical and analytical data will be shown that identifies sensitivity limits for genetic analyses using PCR and FISH approaches.

12:55 A Microfluidic System for the Selection of Circulating Tumor Cells that Utilizes both Affinity and Size Capture Technologies
Sponsored by ON-Q-ITY
Denis A. Smirnov, Director, On-Q-ity Inc.
Detection of rare circulating tumor cells (CTC) from blood promises to be valuable for diagnosis, prognosis and treatment of cancer patients. Current techniques, based solely on antibody affinity capture, are compromised by low capture efficiencies, presumably due to limited cell surface antigen expression. We will describe a novel CTC platform combining affinity capture with size filtration capture (C5 CTC chip). Utility of this system for enumeration and characterization of circulating cells will also be described.

1:10 Luncheon Presentation *(Sponsorship Opp Avail)* **or Lunch on Own**
1:45 Dessert in the Exhibit Hall with Poster Viewing

NOVEL APPROACHES FOR CTC ANALYSIS

2:15 Chairperson's Remarks
Steven A. Soper, Ph.D., University of North Carolina, Chapel Hill

2:20 Collection, Manipulation and Molecular Profiling of Circulating Tumor Cells (CTCs) Using Microfluidics
Steven A. Soper, Ph.D., William H. Pryor Emeritus Professor, Biomedical Engineering and Chemistry; Director, Center for Biomodular System, University of North Carolina, Chapel Hill; and WCU Scholar, UNIST, S. Korea
This presentation will discuss a polymer-based modular microfluidic system that can recover CTCs from whole blood, release the CTCs and then manipulate the CTCs into a containment reservoir using electrokinetics which can then be imaged for enumeration and genotyped at the single-cell level.

2:50 Isolation and Genotyping of Circulating Tumor Cells in a Miniaturized System
Chengxun Liu, Ph.D., Senior Researcher, Functional Nanosystems Group, imec
This system integrates immunomagnetic isolation and genotyping for CTCs. The cell isolation module counts cells using a microelectronic sensor. Twenty specific genetic markers were reversely transcripted, amplified by multiplex ligation probe amplification and electrochemically detected in an automated miniaturized system.

3:20 Multi-Orifice Flow Fractionation (MOFF) for the Isolation and Characterization of Circulating Tumor Cells
Hyo-Il Jung, Ph.D. (Cantab), Associate Professor, School of Mechanical Engineering, Yonsei University
This talk will present a new microfluidic method for isolating circulating tumor cells (CTCs) through the combined use of inertial lift forces and turbulent secondary flows generated in a topographically patterned microchannel (MOFF, multi-orifice flow fractionation).

3:50 A Workflow for Single-Cell Resolution, Automated, Image-Based Sorting of Pure Circulating Tumor Cells and their Comprehensive Molecular Characterization
Nicolò Manaresi, Ph.D., CTO, Silicon Biosystems S.p.A.

4:05 CTCscope: A Novel Platform for Detection and Characteri-zation of CTCs using Multiplex RNA *in situ* Hybridization
Sponsored by ACD ADVANCED CELL DIAGNOSTICS, INC
Yuling Luo, Ph.D., Advanced Cell Diagnostics, Inc.

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

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

WEDNESDAY, FEBRUARY 22

CLINICAL USE OF CTCs

7:55 am Chairperson's Remarks
Richard Cote, M.D., FRCPath, Professor and Chairman

KEYNOTE PRESENTATION

8:00 Circulating and Disseminating Tumor Cells in Cancer Care
Stefanie Jeffrey, M.D., Chief, Surgical Oncology Research, Stanford University
Applications for CTCs and DTCs in cancer management will be discussed, including different analytic approaches and strategies for personalized therapy.

8:30 CTC in the Neoadjuvant Setting: Why Do We Need More Information than Tumor PCR?
Jean-Yves Pierga, M.D., Medical Oncology, Institute Curie, Paris
Few studies have shown no correlation between pCR and CTC detection. CTC detection could be a valuable tool to predict relapse even in complete responders. Monitoring CTCs after tumor removal could be a surrogate marker for evaluating adjuvant treatment efficacy.

9:00 Novel Nanotechnology Approaches to Circulating Tumor Cell Capture and Characterization
Richard Cote, M.D., FRCPath, Professor and Chair, Department of Pathology; Director, University of Miami Biomedical Nanoscience Institute, University of Miami Miller School of Medicine
We have precision-engineered a novel parylene-microfilter-based, antigen expression-agnostic, open platform that allows capture, enumeration and characterization of CTCs. This platform enables longitudinal assessment of CTC as 'liquid biopsy' and can serve as a companion diagnostic through study of CTCs in pre-clinical models.

9:30 Capture and Detection of CK+ and CK- CTCs for Subsequent Molecular Analysis Using the OncoCEE™ Platform
Sponsored by BIOCEPT LABORATORIES
Farideh Bischoff, Ph.D., Vice President, Translational R&D, Biocept

10:00 Transition to Plenary Keynote

PLENARY KEYNOTE

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

11:00 Refreshment Break in the Exhibit Hall with Poster Viewing
Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

12:00 pm Circulating Tumor Cells (CTCs) with EMT

Phenotype for Predicting Breast Cancer Progression
Sendurai A. Mani, Ph.D., Assistant Professor, Molecular Pathology, MD Anderson Cancer Center
CTCs detected using the expression of EpCAM are proven prognostic markers in cancer patients. Evidence demonstrates that EMT plays a critical role in promoting metastasis and that carcinoma cells loose expression of EpCAM during EMT. Clinical association of CTCs with and without EMT property will be discussed.
12:30 Molecular Characterization of CTCs: Expression of EMT Markers in CTCs of Breast Cancer Patients
Evi Lianidou, Ph.D., Professor, Analysis of Circulating Tumor Cells (ACTC) Lab, Department of Chemistry, University of Athens
It has been shown that subsets of CTCs have a putative breast cancer stem-cell phenotype, and express EMT markers. Research on the molecular characterization of CTCs offers an approach to understand the biology of metastasis and resistance to established therapies.

Sponsored by ScreenCell

1:00 Luncheon Presentation I
A Mini-Device for Rapid Isolation by Size and Extensive Characterization of Rare Circulating Tumor Cells
Yvon E. Cayre, M.D., D.Sci., Professor, Pierre and Marie Curie University; CSO, ScreenCell
The ScreenCell® is a mini device to isolate circulating tumor cells (CTCs). It was developed, including a removable filter, to provide links allowing full access to a complete menu of analytic tools: cellular studies, cell culture and molecular biology tests.

Sponsored by Rarecells

1:30 Luncheon Presentation II
Clinical Impact of ISET, A Highly Sensitive Diagnostic Method for Isolation and Immuno-Molecular Characterization of CTC
Patrizia Paterlini Brechot, M.D., Ph.D., Professor of Cell Biology/Oncology, University Paris Descartes, Director of INSERM, Unit 807 and CSO, Rarecells
ISET allows the diagnostic identification of CTC and their specific mutation analysis (KRAS, EGFR, HER2, BRAF etc). Its clinical impact has been demonstrated in patients with non metastatic cancers, showing its value in Personalized Medicine and Predictive Oncology.
2:00 Ice Cream Refreshment Break in the Exhibit Hall, Poster Viewing

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

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

NOVEL TECHNOLOGIES SESSION
4:25 Chairperson's Remarks
Avraham Rasooly, Ph.D., Program Director, Cancer Diagnosis Program, National Cancer Institute
4:30 Nano-Velcro Technology to Improve Capture of Circulating Cancer Cells
Hsian-Rong Tseng, Ph.D., Associate Professor, Department of Molecular and Medical Pharmacology, Crump Institute for Molecular Imaging, Institute for Molecular Medicine, University of California, Los Angeles; California NanoSystems Institute
This presentation will introduce a circulating tumor cell (CTC) enrichment/identification technology that allows isolation of viable (preservative-free) CTCs, enabling their functional and molecular analyses in sequence.
5:00 Laser-Cavitation Based Isolation of Circulating Cancer Cells
John F. Zhong, Ph.D., Assistant Professor, Pathology; Director, Bioinformatics, Gene Therapy Laboratories, University of Southern California School of Medicine
We have developed a laser-cavitation based system to isolate and manipulate single-cells for molecular characterization. With this system, we investigate the expression level of various cancer genes at the single-cell level.
5:30 Detection and Isolation of Circulating Melanoma Cells Using Photoacoustic Flowmetry
John A. Viator, Ph.D., Associate Professor, Biological Engineering and Dermatology, University of Missouri
Photoacoustic flowmetry, similar to flow cytometry, is suited to detect melanoma cells in blood. Using photoacoustics and microfluidic principles, we detect and capture circulating melanoma cells in human blood samples to diagnose metastatic disease.
6:00 Microfluidic Biochips for the Label-Free Detection, Isolation & Retrieval of Circulating Tumor Cells
Chwee Teck Lim, Ph.D., Principal Investigator, Mechanobiology Institute; Faculty Fellow, Singapore-MIT Alliance for Research & Technology (SMART); Professor, Division of Bioengineering & Department of Mechanical Engineering, National University of Singapore
We have devised a separation method in a microfluidic biochip based on knowledge that CTCs are larger and stiffer than blood cells. Physical cell traps placed in the blood flow path block CTCs while deformable blood constituents are removed. Viable unlabeled CTCs are then collected by flow reversal.
6:30 Close of Day

THURSDAY, FEBRUARY 23

CLINICAL USE OF CIRCULATING TUMOR CELLS
8:30 am Chairperson's Remarks
Michail Ignatiadis, M.D., Ph.D., Department of Medical Oncology, Jules Bordet Institute, Brussels, Belgium
8:35 Bioengineering and Clinical Applications of Microfluidic Circulating Tumor Cell Chip
Shyamala Maheswaran, Ph.D., Associate Professor, Surgery & Molecular Biology, Harvard Medical School
This presentation will describe the engineering design and clinical validation of the microfluidic CTC-chip.
9:05 Detection of Viable Circulating Tumor Cells (CTC) in Solid Tumors Using the EPISPOT Assay
Catherine Alix-Panabières, Ph.D., Professor Assistant, Laboratory of Rare Human Circulating Cells, Institute of Research in Biotherapy, University Medical Center of Montpellier
We have developed unbiased methods to molecularly profile tumor genomes in highly admixed and complex clinical biopsies in the setting of a clinical trial. The data for each patient are integrated with prior knowledge of tumor signaling pathways in order to advance improved clinical outcomes.
9:35 HER2 Expression on CTCs/DTCs in Breast Cancer: Is there Any Role in Clinical Practice?
Michail Ignatiadis, M.D., Ph.D., Department of Medical Oncology, Jules Bordet Institute, Brussels, Belgium
Results from an international ring study to interrogate inter-reader variability in CTC and HER2-positive CTC detection using the CellSearch technology in early breast cancer will be presented. And update on ongoing trials testing the clinical utility of HER2 expression on CTCs will also be provided.

Sponsored by VERIDEX

10:05 The Development of a Circulating Melanoma Cell Assay
M. Craig Miller, Manager, Clinical Sciences, Veridex, LLC
- Provide an overview of the development and validation of this new Research Use Only assay which utilizes the CellSearch® system for the isolation, enumeration, and characterization of circulating melanoma cells.
- Present a few examples of how this new standardized assay for CMCs may help you in your research and drug development programs for metastatic melanoma.

10:20 Coffee Break

NOVEL TECHNOLOGIES SESSION
10:55 Chairperson's Remarks
Shyamala Maheswaran, Ph.D., Associate Professor, Surgery & Molecular Biology, Harvard Medical School
11:00 Technology "Show 'N Tell" Demonstration in the Foyer
Presenters to be Announced - see website for details
12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

NIH FUNDING OPPORTUNITIES FOR TECHNOLOGY DEVELOPMENT
1:45 Chairperson's Remarks
Avraham Rasooly, Ph.D., Chief, Disparities Research Branch, Center to Reduce Cancer Health Disparities, National Cancer Institute
1:50 Grants Available through SBIR
Xing-Jian Lou, Ph.D, Program Director, SBIR Development Center, National Cancer Institute
2:10 NCI/NIH Funding Opportunities
Avraham Rasooly, Ph.D., Chief, Disparities Research Branch, Center to Reduce Cancer Health Disparities, National Cancer Institute

FUTURE TRENDS IN CTC DIAGNOSTICS
2:25 Chairperson's Remarks
Steven A. Soper, University of North Carolina
Dave Hoon, John Wayne Cancer Institute
2:30 Future Trends in Clinical Development
Dave Hoon, M.Sc., Ph.D., Director, Molecular Oncology, John Wayne Cancer Institute
2:55 Future Trends in Technology Development
Steven A. Soper, Ph.D., William H. Pryor Emeritus Professor, Department of Biomedical Engineering and Chemistry; Director, Center for Biomodular System, University of North Carolina, Chapel Hill; and WCU Scholar, UNIST, S. Korea
3:30 Closing Remarks
3:35 Close of Conference

Inaugural

Genomic Screening and Diagnosis of Human Diseases

How Sequencing Will Change Medicine

February 21-23

TUESDAY, FEBRUARY 21

7:00 am Registration

PLENARY KEYNOTE SESSION

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

OVERVIEW OF GENETIC SCREENING

11:00 Chairperson's Opening Remarks
Stephen Kingsmore, M.B., Ch.B., BAO, D.Sc., FRCPath, Director, Center for Pediatric Genomic Medicine, Children's Mercy Hospital

KEYNOTE PRESENTATION

11:10 Genetic Testing in the Genomic Era: The Emerging Sea Change in the Genetic Testing Landscape
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
The development of high resolution genomic analysis will catalyze wide scale change in genetic testing. This will require innovations in clinical and laboratory practice, regulation, intellectual property management, health care reimbursement, and many other areas both in healthcare and in society.

11:40 Genetic Screening: Evolving Science, Evolving Ethics
John Lantos, Director, Bioethics Center, Children's Mercy Hospital
Recent changes in screening technology, goals of screening programs, and public understanding of genetics lead to a shifting bioethical paradigm where there is less need for cautionary public policies and more room for informed parental decisions.

12:10 pm Research Advances in Translational Genomics and Health Outcomes
Robert C. Green, M.D., MPH, Associate Director for Research, Partners Center for Personalized Genetic Medicine; Division of Genetics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School
Drawing upon experimental studies in genetic risk disclosure and evidence from the study of direct-to-consumer genetic testing services, this presentation will summarize current research and look forward to the integration of whole genome sequencing in the practice of medicine.

12:40-1:40 LUNCHEON PRESENTATIONS

Sponsored by COVANCE

High-Throughput DMET Profiling for Drug Development
Mark Parrish, Sr. Manager, Assay Development, Covance Genomics Laboratory
An important aspect of personalized medicine is understanding how genotypic factors influence drug metabolism. To this end, the Covance Genomics Laboratory has implemented and validated the Affymetrix DMET Plus assay in a CLIA regulated environment for use in clinical trials. This talk will describe how CGL implemented the DMET Plus assay to produce high throughput and high quality data.

Sponsored by Affymetrix

Moving Pharmacogenetics from the Laboratory to the Clinic
William Douglas Figg Sr., Pharm. D., M.B.A., Head of the Clinical Pharmacology Program and Molecular Pharmacology Section, National Cancer Institute, National Institutes of Health
The field of pharmacogenetics is rapidly expanding though we are still in the early stages of characterizing how genetics affects pharmacotherapy and applying that information in the clinic. In the face of accumulating evidence, the NIH Clinical Center has instituted pharmacogenetics-based approaches.

1:45 Dessert in the Exhibit Hall with Poster Viewing

NON-INVASIVE TESTING

2:15 Chairperson's Remarks
Charles Cantor, Ph.D., CSO, Sequenom, Inc.

2:20 Non-Invasive Personalized Genomics
Charles Cantor, Ph.D., CSO, Sequenom, Inc.
Second generation DNA sequencing and DNA mass spectrometry provide synergistic ways of analyzing nucleic acids in patient samples. Examples include non-invasive prenatal diagnostics by plasma analysis and detection of somatic oncogene mutations in plasma. A pilot study will be described.

2:50 Epigenetics, Developmental Plasticity and Human Disease
Sir Peter Gluckman, KNZM FRSNZ FMedSci FRS, University Distinguished Professor, Centre for Human Evolution, Adaptation and Disease, Liggins Institute, University of Auckland
Increasing evidence shows that the processes of developmental plasticity operating through epigenetic mechanisms changes risk of developing disease with an environmental/lifestyle component. This has major implications for developing new targets for therapy and prevention and for the predication of disease risk.

3:20 Adventures in Personal Genomics and Whole Omics Profiling
Michael Snyder, Ph.D., Professor & Chair, Genetics, Cardiovascular Medicine, Stanford University School of Medicine
Genomic medicine will require the integrated analysis of genomic information and omics information. Our study relates personal genomic information to global functional omics activity for physiological and medical interpretation of healthy and disease states.

3:50 Sponsored Presentations *(Opportunities Available)*

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

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

6:20 Close of Day

WEDNESDAY, FEBRUARY 22

DISCOVERY OF RARE AND COMMON DISEASE GENES

7:55 am Chairperson's Remarks
Madhuri Hegde, Ph.D., Associate Professor, Senior Director, Emory Genetics Laboratory, Department of Human Genetics, Emory University School of Medicine

KEYNOTE PRESENTATION

8:00 Regulation of Clinical Sequencing Programs
Steven Spielberg, Ph.D., Deputy Commissioner, FDA

8:30 New Technologies in Genetic Prenatal Diagnosis
Sherri J. Bale, Ph.D., F.A.C.M.G., President and Clinical Director, GeneDx, Inc.
I will discuss the use of next-generation sequencing platforms for the prenatal diagnosis of the Noonan Syndrome spectrum and of skeletal dysplasias, the use of prenatal arrays for detection of disease-associated copy number abnormalities, and methods for the identification of mutations in genes for rare diseases in the prenatal setting.

9:00 Ensuring Quality of Genetic Tests for Rare Disorders: A Proficiency Testing Program for Sequence-Based Tests
Carolyn Sue Richards, Ph.D., FACMG, Professor, Molecular & Medical Genetics; Director, Clinical Molecular Genetics, Oregon Health Science University
This talk describes a new methods-based proficiency testing (PT) program for clinical laboratories that sequence genes involved in rare disorders. The outcomes of the first several cycles of the sequence interpretation survey, future plans for this survey, as well as the next-generation sequencing survey will be discussed.

9:30 Sponsored Presentations *(Opportunities Available)*

10:00 Transition to Plenary Keynote

PLENARY KEYNOTE

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

DISCOVERY OF RARE AND COMMON DISEASE GENES CONTINUED

12:00 pm Carrier Detection Using Digital PCR and Resequencing Array

Madhuri Hegde, Ph.D., Associate Professor, Senior Director, Emory Genetics Laboratory, Department of Human Genetics, Emory University School of Medicine

Identification of carriers for genetic diseases is important to give reproductive options to couples. The design, implementation and clinical testing data using digital PCR and resequencing array for 500 mutations associated with recessive diseases will be presented.

12:30 Next-Generation Clinical Sequencing in a Children's Hospital

Stephen Kingsmore, M.B., Ch.B., BAO, D.Sc., FRCPath, Director, Center for Pediatric Genomic Medicine, Children's Mercy Hospital

Next-generation clinical sequencing promises to transform children's healthcare since inherited illnesses account for much of the disease burden. I will discuss the first year of integration of genomic medicine for Mendelian diseases at Children's Mercy Hospital.

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

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

PLENARY KEYNOTE PANEL

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

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

DIAGNOSTIC TESTING

4:25 Chairperson's Remarks

Donna Maglott, National Library of Medicine, NCBI

4:30 ClinVar: Improved Representation of Medically Important Variation at NIH's National Center for Biotechnology Information (NCBI)

Donna Maglott, National Library of Medicine, NCBI

ClinVar is structured to capture information about human variation along with the supporting clinical and experimental evidence necessary enable interpretation. Our work with the testing community and the status of ClinVar will be reviewed.

5:00 Direct to Consumer Genetic Testing for Predisposition Risk Assessment of Common Diseases

Nazneen Aziz, Ph.D., Director, Molecular Medicine, Transformation Program Office, College of American Pathologists

This presentation will cover recent and relevant concepts behind the research, development and interest in Direct-to-Consumer (DTC) genetic tests for common complex diseases.

5:30 PANEL DISCUSSION: Are Complex Genetic Tests Fulfilling Their Promise?

This session will review and discuss the status of genetic testing's ability to inform and improve clinical care in the present and in the future from multiple perspectives, including academia, industry, and clinical care.

Moderator: Edward Abrahams, President, Personalized Medicine
Panelists:
Iris Schrijver, M.D., Director, Molecular Pathology Laboratory Stanford University Medical Center, Lucile Packard Children's Hospital; Associate Professor of Pathology and (by courtesy) Pediatrics, Stanford University School of Medicine; and President, American Association of Molecular Pathology
John J. Sninsky, Ph.D., Vice President, Discovery Research, Celera Diagnostics
Kathy Behrens Wilsey, Ph.D., Board Member, KEW Group

6:30 Close of Day

THURSDAY, FEBRUARY 23

8:30 am Chairperson's Remarks

Richard Cotton, AM Ph.D., D.Sc., Convenor and Scientific Director, Human Variome Project; Director, Human Variome Project International Limited; Director, Genomic Disorders Research Centre

8:35 Strategies of Collecting Variation Data Worldwide

Richard Cotton, AM Ph.D., D.Sc., Convenor and Scientific Director, Human Variome Project; Director, Human Variome Project International Limited; Director, Genomic Disorders Research Centre

This presentation will cover the Human Variome Project's facilitation of the creation of regional and international databases that can be easily accessed by clinicians and diagnostic labs to greatly improve our ability to accurately diagnose and treat patients with genetic disorders.

9:05 Design and Clinical Validation of a Next-Generation Sequencing-Based Assay for Detecting Somatic Mutations in Clinically Actionable Cancer Genes in a CLIA/CAP Certified Laboratory

Shashikant Kulkarni, Ph.D., Head, Clinical Genomics & Medical Director, Cytogenomics and Molecular Pathology, Pathology, Pediatrics and Genetics, Washington University School of Medicine

To circumvent the limitations of current methods for mutation detection in clinical setting, we have designed and clinically validated an NGS based assay for comprehensive mutation analysis of multiple cancer genes in a single assay.

9:35 Returning Research Results from Next-Generation Sequencing and Analysis to Patients with Idiopathic Disorders

Gholson Lyon, M.D., Ph.D., Research Scientist, Children's Hospital of Philadelphia; Adjunct Assistant Professor, NYU, Pediatrics, CHOP

We describe here our efforts in both a simple X-linked, infantile lethal Mendelian disorder, which we have named Ogden Syndrome, and in a complex neuropsychiatric disorder, namely attention deficit hyperactivity disorder (ADHD).

10:05 Sponsored Presentation *(Opportunity Available)*

10:20 Coffee Break

USING EXOMES AS PART OF CLINICAL WORKUP

11:00 Charcot-Marie-Tooth Disease from Copy Number Variation to Whole Genome Sequencing

James R. Lupski, M.D., Ph.D., D.Sc. (hon), FAAP, FACMG, FAAAS, Cullen Professor and Vice Chairman, Molecular and Human Genetics; Professor, Pediatrics, Baylor College of Medicine; Board Certified Pediatrician, Clinical Geneticist, and Clinical Molecular Geneticist; American Editor, Neurogenetics

To what extent are *de novo* DNA rearrangements in the human genome responsible for sporadic human traits? How many human Mendelian and complex traits are due to structural changes and/or gene CNV? What are the molecular mechanisms for human genomic rearrangements? The answers to these questions will be addressed.

11:30 Multiplex Mutation Screening and Other Assay Technologies in Support of a Personalized Cancer Medicine Registry

Christopher L. Corless, M.D., Ph.D., Professor, Pathology & CMO, Knight Diagnostic Laboratories, Oregon Health & Science University

This presentation will focus on the opportunities and challenges of introducing new multiplexed and next-gen sequencing technologies into clinical laboratories.

12:00 pm Genetic Tests and the Potential Regulatory Framework

Speaker to be Announced, FDA (invited)

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

1:45 Chairperson's Remarks

1:50 Clinical Applications of Next-Generation Sequencing

Thomas Scholl, Ph.D., Vice President, Genzyme Genetics

Clinical diagnostics stand to benefit from the introduction of next-generation sequencing methods. New tests that address unmet needs and improvements are enabled by this technology. The prospects for next-generation sequencing in the clinical reference laboratory setting will be discussed from these perspectives.

2:20 Presentation to be Announced

2:50 Q&A with Speakers

3:20 Close of Conference

Ninth Annual

Mastering Medicinal Chemistry Summit

Success Stories in Applied Medicinal Chemistry

February 21-23

TUESDAY, FEBRUARY 21

7:00 am Registration

PLENARY KEYNOTE SESSION

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

11:00 Chairperson's Opening Remarks

Matt Wessel, Senior Principal Scientist, Seurat Applications Support, Schrodinger

KEYNOTE PRESENTATION

11:10 Getting Pharma R&D Back on Target – Open Innovation in Epigenetics

Mark Bunnage, Ph.D., Head, Medicinal Chemistry, Sandwich Laboratories, Pfizer

IMPROVING DRUG CANDIDATES BY USING PHYSICOCHEMICAL PROPERTY ANALYSIS

11:40 Integration of SBDD & Physicochemical Properties-Based Analysis and Design Approaches to Drive Multiparameter Optimization to Deliver Improved Drug Candidates

Martin P. Edwards, Vice President, Discovery Chemistry, Pfizer San Diego

Analyzing multiple lead series physicochemical properties - data relationships yields knowledge critical for designing for improved potency, selectivity and ADMET. Strategies using this knowledge, strengthened with key insights from protein-ligand structures, have delivered high quality clinical candidates.

12:10 pm Next-Generation Glucokinase Activators: Property-Based Design of AZD1656

Darren McKerrecher, Associate Director, Medicinal Chemistry & Project Leader, Cardiovascular & Gastrointestinal Innovative Medicines Unit, AstraZeneca

We identified and overcame a testicular toxicological liability in a series of acidic glucokinase activators and used property-based design to yield a series of neutral compounds with good solubility, permeability and hERG selectivity, culminating in the identification of PhII clinical candidate AZD1656.

Sponsored by SARmont

12:40 Case Studies of Successful Drug Design

Randy Weiss, President and CEO, SARmont

We will present case studies of successful drug design that were conceived by Dr. John Talley, co-inventor of Celebrex. Dr. Talley leads SARmont's drug design team. We will also provide examples of ongoing drug design projects with clients that optimize the likelihood of identifying a high quality IND drug candidate.

12:55 Enjoy Lunch on Your Own

1:45 Dessert in the Exhibit Hall with Poster Viewing

2:15 Chairperson's Remarks

Walter Huber, Ph.D., Distinguished Scientist & Group Leader, Discovery Technologies, F.Hoffmann - La Roche Ltd.

2:20 Mapping Your Drug Discovery Efforts in Chemico-Biological Space: AtlasCBS

Celerino Abad-Zapatero, Ph.D., Professor, Center for Pharmaceutical Biotechnology, Department of Medicinal Chemistry and Pharmacognosy, University of Illinois, Chicago

Ligand Efficiency Indices (LEIs) are becoming more accepted in medicinal chemistry to relate the potency of compounds to their physico-chemical properties. The concept and application of LEIs to map, guide and optimize drug-discovery efforts will be illustrated with examples.

FRAGMENT-INSPIRED MEDICINAL CHEMISTRY

2:50 Knowledge Generated by Fragment Screening to Inspire Chemistry

Walter Huber, Ph.D., Distinguished Scientist & Group Leader, Discovery Technologies, F.Hoffmann - La Roche Ltd.

Fragment screening methods have evolved for generation of ligand binding information. The impact ranges from a drugability assessment of binding sites and targets to the use of a fragment moiety from screening to market as exemplified with Zelboraf, the first fragment derived FDA-approved drug molecule.

3:20 Efficiency Driven Drug Discovery: Application of Fragment and Structure-Based Methods

Siegfried H. Reich, Ph.D., Fragment-Based Drug Discovery, Translational Sciences and Technologies (TST), Lilly Biotech Center

An approach focused on ligand efficiency combined with enabling supporting technologies (SBDD, NMR, SPR) can help identify optimal starting points for design, that can start and remain in good physicochemical space, resulting in candidate molecules which have a greater likelihood of clinical success.

3:50 Fragment-to-Lead Using Fragment Molecular Orbital QM Calculations

Sponsored by evotec

Richard Law, Group Leader, Computational Chemistry, Evotec (UK) Ltd.

FMO is one of multiple computational chemistry techniques that play a vital role in devising routes for structure-guided medicinal chemistry. FMO can help prioritize fragment hits for expansion, perform virtual fragment expansion and guide subsequent rounds of fragment-to-lead drug design.

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

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

6:20 Close of Day

WEDNESDAY, FEBRUARY 22

7:55 am Chairperson's Remarks

Nicholas A. Meanwell, Ph.D., Executive Director, Medicinal Chemistry, Bristol-Myers Squibb Research & Development

KEYNOTE PRESENTATION

8:00 Hepatitis C Virus NS5A Replication Complex Inhibitors

Nicholas A. Meanwell, Ph.D., Executive Director, Medicinal Chemistry, Bristol-Myers Squibb Research & Development

This presentation will provide an overview of the discovery and development of the hepatitis C virus (HCV) NS5A replication complex inhibitor BMS-790052, a first-in-class therapeutic for the treatment of HCV.

NOVEL STRATEGIES & APPLICATIONS IN MEDICINAL CHEMISTRY

8:30 Antibody-Drug-Conjugates (ADCs) for the Treatment of Cancer

John A. Flygare, Ph.D., Senior Scientist, Discovery Chemistry, Genentech, Inc.

Successful Antibody-Drug-Conjugates (ADCs) require assembling the correct combination of antibody, linker , and cytotoxic drug. This presentation will review successful applications of this technology and discuss future directions of the linkers and cytotoxic drugs used in this approach.

9:00 Accessing New Chemical Space through Flow-Enabled "Forbidden" Chemistries

Neal Sach, Ph.D., Senior Principal Scientist, Oncology Medicinal Chemistry, Pfizer

A flow technology is presented with the capability to run and analyze 100-300 reactions per day. The application of this technology in accessing new chemical space in drug discovery is presented, with examples of chemistries, traditionally considered 'forbidden' in batch, exemplified.

9:30 Drug Design and Development by Molecular Interaction Fields

Sponsored by Intelligent Pharma

Jascha Blobel, Ph.D., Product Manager, Intelligent Pharma

Molecular interaction fields are the key property of a molecule in binding to different receptors in the cell. Thanks to the constantly growing information about molecules and their associated functions in biological systems, Intelligent Pharma will present the use of comparing molecules on basis of their interaction fields to predict the functions of new and unknown molecules.

10:00 Transition to Plenary Keynote

PLENARY KEYNOTE

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

12:00 pm Using Chemical Biology to Increase Biochemical Understanding that Enables Therapeutic Intervention

Lyn H. Jones, Ph.D., FRSC, Senior Director & Head, Chemical Biology and Orphan & Genetics Diseases, WorldWide Medicinal Chemistry, Pfizer

The pharmaceutical industry is plagued by a low return on its investment in research and development. Successful applications of chemical biology in the drug discovery setting will be presented to illustrate a new paradigm for medicinal chemistry design at the interface with biology.

12:30 Chemical Proteomics: Applications to Compound Profiling and Target Discovery
Robert W. Johnson, Ph.D., Senior Group Leader, Structural Chemistry - Advanced Technology, Abbott Laboratories

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

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

PLENARY KEYNOTE PANEL

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

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

HOT TARGETS TO WATCH: ALLOSTERIC MODULATORS

4:25 Chairperson's Remarks
Sylvain Célanire, Group Leader, Medicinal Chemistry Section, Addex Pharmaceuticals

KEYNOTE PRESENTATION

4:30 Optimization of Allosteric Modulators of GPCRs for Treatment of CNS Disorders
P. Jeffrey Conn, Ph.D., Lee E. Limbird Professor of Pharmacology; Director, Vanderbilt Center for Neuroscience Drug Discovery, Vanderbilt University Medical Center
Allosteric modulators of GPCRs exhibit multiple modes of efficacy that dramatically impact *in vivo* effects. This new understanding provides important insights to guide medicinal chemistry efforts aimed at developing allosteric modulators that are suitable as drug candidates.

5:00 Allosteric Modulator for a Pain Indication
Michael R. Schrimpf, Ph.D., Senior Chemistry Group Leader, Neurological Urological, Abbott Labs

5:30 A Drug Discovery Journey across Allosteric Modulators of Metabotropic Glutamate Receptors: from Hit to Candidate
Sylvain Célanire, Group Leader, Medicinal Chemistry Section, Addex Pharmaceuticals
Individual members of mGluR family have been difficult to target selectively using conventional approaches. Allosteric modulators offer a strategy for developing highly selective oral small molecule therapeutics that can readily cross blood-brain barrier against these historically undruggable targets. Discovery and characterization of novel allosteric modulators of Class C GPCRs mGluR2, mGluR4 and mGluR5 will be presented, including extensive structure-activity and structure-property relationship studies.

HOT TARGETS IN CANCER: KINASES

6:00 Linsitinib (OSI-906), a Potent and Highly Selective Dual Inhibitor of IGF-1R and IR Currently Undergoing Clinical Testing in a Phase III Clinical Trial in ACC Patients
Mark J. Mulvihill, Ph.D., Director of Chemistry, Oncology, OSI Pharmaceuticals LLC, a subsidiary of Astellas US
Our drug discovery efforts, including structure-based design and empirical medicinal chemistry efforts have resulted in the discovery of OSI-906, a potent, selective and orally available inhibitor of both IGF-1R and IR. In addition to its activity in preclinical models, OSI-906 has recently shown preliminary activity in Adrenocortical carcinoma (ACC) patients and is currently in a Phase III clinical trial in ACC.

6:30 Close of Day

THURSDAY, FEBRUARY 23

HOT TARGETS IN CANCER: KINASES & Hsp90

8:30 am Chairperson's Remarks
Mark Ashwell, Ph.D., Vice President, Medicinal Chemistry, ArQule, Inc.

8:35 Discovery of PI3K Inhibitors Based on the 5,6-dihydrobenzo[f] imidazo[1,2-d][1,4]oxazepine Scaffold with Improved in vivo Anti-Tumor Activity Due to Increased Unbound Drug Exposure
Chudi O. Ndubaku, Ph.D., Scientist, Discovery Chemistry, Genentech, Inc.
We recently discovered novel inhibitors of PI3K based on the benzoxepin chemical structure that are potent, highly selective and have favorable *in vivo* pharmacokinetic profiles. We reveal our structure-guided and physicochemical property-based approach to optimize unbound drug exposure.

9:05 Identification of NVP-BKM120 as a Potent, Selective, Orally Bioavailable Pan Class I PI3K Inhibitor for the Treatment of Cancer
Sabina Pecchi, Ph.D., Senior Investigator I, Global Discovery Chemistry, Oncology & Exploratory Chemistry, Novartis Institutes for Biomedical Research
The PI3K pathway is frequently de-regulated in tumors. This presentation describes the structure guided optimization of a series of 2-morpholino pyrimidines PI3K inhibitors culminating in the discovery of NVP-BKM120, currently undergoing Phase II clinical trials for the treatment of cancer.

9:35 The RAS-MAPK and PI3K-AKT Cascades: Novel Assays for Detection and Quantitation of Key Phospho Proteins- Part II
Sponsored by BIOSCALE
W. Matthew Dickerson, Ph.D., Senior Scientist, BioScale, Inc.
The RAS-MAPK and PI3K-AKT pathways are involved in signaling cascades that control numerous physiological and pathological processes. This study elucidates the selectivity and sensitivity of a novel assay platformfor analysis of phosphoproteins including pAKT, pALK, pERK, pJNK, pp38, pMEK.

10:05 Activation-State Dependent Conformational Differences in Protein Kinases and the role of Hydrophobic Motifs in Inactive Kinases: Lessons Learned in Drug Discovery and Optimization
Mark Ashwell, Ph.D., Vice President, Medicinal Chemistry, ArQule, Inc.
The presentation will describe the utilization of a new understanding of the role of hydrophobic residues within the ATP-binding cleft of inactive protein kinases in order to discover novel inhibitors. Through the application of this knowledge ArQule has established a new paradigm for kinase inhibitor discovery and will present results on its impact in increasing efficiency and effectiveness in discovery and development.

10:20 Coffee Break

11:00 Discovery of NVP-HSP990, A Potent Oral Inhibitor of Hsp90 in Phase I Clinical Trials
Tim Machajewski, Ph.D., Global Discovery Chemistry, Novartis Institutes for BioMedical Research
Hsp90 is a molecular chaperone whose function is essential for activity of tumorigenic signaling molecules. A structure guided optimization of aminodihydroquinazolinone Hsp90 inhibitors culminated in the discovery of NVP-HSP990, undergoing Phase I trials for treatment of cancer.

11:30 Understanding Structure Intricacies of Protein Kinases: The Road to Invention of c-Met/ALK Dual Inhibitor Crizotinib
Jean Cui, Ph.D., Associate Research Fellow, Oncology Medicinal Chemistry, Pfizer Global R&D
A 2-Amino-5-aryl-3-benzyloxypyridine scaffold was created based on the autoinhibitory conformation of c-Met, and optimized to generate Xalkori (Crizotinib, PF-02341066) as a potent and highly selective c-Met/ALK dual inhibitor with good pharmaceutical properties.

HOT TARGETS IN ALLERGY & OBESITY

12:00 pm The Discovery and Development of ARRY-502: A Potent, Selective CRTh2 Antagonist for Allergic Diseases
Larry Burgess, Ph.D., Senior Director, Medicinal Chemistry, Array BioPharma
Drug discovery efforts focused on substituted phenyl acetic acids lead to the identification of ARRY-502, a potent, selective CRTh2 antagonist. Phase I clinical studies have demonstrated it is well tolerated and possesses excellent pharmacokinetics and prolonged pharmacodynamic activity.

12:30 Rapid Drug Discovery at Nimbus and the Role of Seurat
Sponsored by SCHRÖDINGER.
Matt Wessel, Senior Principal Scientist, Seurat Applications Support, Schrodinger

12:45 Enjoy Lunch on Your Own

1:45 Chairperson's Remarks
Larry Burgess, Ph.D., Senior Director, Medicinal Chemistry, Array BioPharma

1:50 The Discovery of MK-7725, a Potent and Selective Bombesin Receptor Subtype-3 (BRS-3) Agonist for the Treatment of Obesity
Harry Chobanian, Ph.D., Research Fellow, Discovery Chemistry, Merck Research Labs
The BRS-3 receptor is an orphan GPCR expressed primarily in the hypothalamus region of the brain and has been implicated to regulate food intake and metabolic rate. This presentation outlines the effort that led to the discovery of MK-7725 for the treatment of obesity.

HOT TARGETS IN CNS

2:20 Selective JNK Inhibitors for the Prevention of Neurodegeneration
Simeon Bowers, Ph.D., Staff Scientist, Medicinal Chemistry, Elan Pharmaceuticals
The development of a series of selective JNK inhibitors is described. Optimization of the HTS hit led to single digit nanomolar compounds with improved pharmacokinetic properties and greater CNS exposures.

2:50 Inhibiting Caspases in New and Unexpected Ways
Brian Hearn, Ph.D., Medicinal Chemistry, Small Molecule Discovery Center, University of California, San Francisco
Caspase-6 plays a key role in the neurodegeneration associated with Huntington's disease. Our efforts to identify new caspase-6 inhibitors led to the discovery of non-covalent and non-ionic compounds that demonstrate substrate-dependent inhibition. This presentation will focus on lead optimization and mechanism of action studies.

3:20 Close of Conference

Eighth Annual

Translational Science

Translating Pre-Clinical & Clinical Knowledge to Success

February 21-23

TUESDAY, FEBRUARY 21

7:00 am Registration

PLENARY KEYNOTE SESSION

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

TRANSLATIONAL IMAGING

11:00 Chairperson's Opening Remarks
Theresa LaVallee, Ph.D., Director, Research & Development, MedImmune

11:10 Impact and Translational Opportunities of Pre-Clinical Imaging in Biomarker Discovery and Drug Development
Paul McCracken, Ph.D., Director, Imaging, Eisai Research Institute
Review of pre-clinical imaging modalities - applications of SPECT, PET, MRI, and CT, including integration with and utilization of molecular biomarkers to drive imaging development, selected neuroscience and oncology discovery imaging examples, and translational opportunities.

11:40 Integrating Imaging in Early Drug Development: Lessons Learned from the VEGFR TKI Experience
Glenn Liu, M.D., Associate Professor, Medicine, Carbone Cancer Center, Wisconsin Institute for Medical Research, University of Wisconsin
Anatomic imaging is commonly used to assess treatment efficacy in late-phase cancer clinical trials; however, this assumes that the therapy will result in anatomic tumor shrinkage (cytotoxic) and predict survival. Advanced quantitative functional imaging methods can be used to assess early treatment response.

12:10 pm Translational Imaging for De-risking Pharmaceutical Pipelines
Anthony M Giamis, Ph.D., Head, Radiochemistry/Radiopharmaceutical Sciences, Translational Sciences-Advanced Technology, Abbott

12:40 Luncheon Presentation

Sponsored by Molecular Imaging

Use and Validation of Image Based Biomarkers of Drug Response: a CRO Perspective
Patrick McConville, Ph.D., Chief Scientific Officer/COO, Molecular Imaging, Inc.
An overview of the use of multiple preclinical imaging modalities for image-based biomarker assessment of disease progression and drug response will be provided. Special attention will be given to biomarker validation, and examples using probe facilitated imaging will be discussed.

12:55 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

1:45 Dessert in the Exhibit Hall with Poster Viewing

2:15 Chairperson's Remarks
Theresa LaVallee, Ph.D., Director, Research & Development, MedImmune

KEYNOTE PRESENTATIONS

2:20 PET Imaging as a Quantitative Biomarker in CNS Drug Development: Illustration by Examples
Yiyun Henry Huang, Ph.D., Associate Professor, Co-Director, PET Center, Department of Diagnostic Radiology, Yale University
Results from these PET imaging studies for novel CNS therapeutic agents have been shown to be critically important to inform the go/no-go decision in drug development.

2:50 Use of Biomarkers and Translational Science to Improve and Accelerate Oncology Drug Development
J. Carl Barrett, Ph.D., Vice President, Translational Medicine, AstraZeneca

3:50 The JAX Cancer Consortium: Changing the Course of Clinical Advancement

Sponsored by The Jackson Laboratory

Brandy Wilkinson, Ph.D., In Vivo Study Director, The Jackson Laboratory-West
The JAX Cancer Consortium has established a publically available patient derived xenograft (PDX) resource. This presentation will highlight the diverse library of solid and liquid PDX models available to further drug discovery programs.

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

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

6:20 Close of Day

WEDNESDAY, FEBRUARY 22

7:55 am Chairperson's Remarks
Kate Skaare, Conference Producer, Cambridge Healthtech Institute

8:00 PANEL DISCUSSION: How Have Biomarkers Been Applied in Clinical Development?
Moderator: Prakash Purohit, Ph.D., Associate Director, Scientific Affairs, IPSEN Biomeasure, Inc.
Panelists:
Dominic G. Spinella, Ph.D., Head, Translational and Molecular Medicine, Pfizer
James Watters, Ph.D., Head, Applied Genomics, Sanofi Oncology
Suso Platero, Ph.D., Director, Oncology Biomarkers, Centocor, Ortho Biotech Oncology Research & Development, a unit of J&J PRD, LLC
Panelists will discuss how to much more efficiently turn biomarker assays into diagnostics. What challenges are there? What strategies are best for future use of biomarkers for clinical development? Case examples will be used.

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

Sponsored by Theranostics Health

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

9:45 Sponsored Presentation *(Opportunity Available)*

10:00 Transition to Plenary Keynote

PLENARY KEYNOTE

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

TRANSLATIONAL BIOMARKERS

Chairperson: Suso Platero, Ph.D., Director, Oncology Biomarkers, Centocor, Ortho Biotech Oncology Research & Development, a unit of J&J PRD, LLC

12:00 pm Biomarkers: How to Find them and Apply Them in Clinical Trials
Suso Platero, Ph.D., Director, Oncology Biomarkers, Centocor, Ortho Biotech Oncology Research & Development, a unit of J&J PRD, LLC

12:30 Back to Biomarker Basics for Drug Development
Terry Walker, Ph.D., Director, Translational Immunology, Immunology & Autoimmunity Research Unit, Pfizer
The presentation will provide case study illustrations of simple biomarker challenges: Right drug target for the disease? Does the drug hit the target? Does the drug modify disease activity?

1:00 Luncheon Presentation I

Sponsored by DEFINIENS Understanding Images

Image Miner for Biomarker Development & Data Quality Control
Thomas Haberichter, Definiens

There is a growing need for automated and integrated software solutions that can enable scientists to make more informed decisions on scientific programs. Definiens offers a comprehensive end to end solution for Biomarker Development and Data Quality Control. Definiens is the first to market to offer a wholly integrated solution that combines state of the art Image Analysis software "Tissue Studio" with new innovation "Image Miner" an integrated Imaging miner software package. Image Miner enables scientists to extract meaningful image base classifiers, correlate them to patient and sample outcome data, and identify which characteristics are best suited for comparing cohorts in a given study.

1:30 Luncheon Presentation II

SOMAmers Enable High Throughput Screening for Protein Biomarkers and Diagnostics

Sponsored by SomaLogic

Stephen A. Williams, M.D,. Ph.D., CMO, SomaLogic

A synergistic combination of attributes: >1000 proteins measured simultaneously with ELISA-like performance, sample volumes of a few microliters, increasingly high throughput (currently >30,000 samples/yr.), and the same reagents useable for discovery and commercialization. This has enabled an unprecedented productivity breakthrough in mechanistic, diagnostic and prognostic biomarkers.

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

PLENARY KEYNOTE PANEL

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

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

4:25 Chairperson's Remarks

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

4:30 Molecular Profiling of Breast Cancer Trial Sets to Unravel Driving Oncogenic Hubs and Parallel Pathways

Brian Leyland-Jones, M.D., Ph.D., Director, Winship Cancer Institute, Emory University

We are applying complementary molecular profiling methods to tumor bank specimens from several international clinical trials that include all of the major breast cancer subtypes and established a large panel of *in vitro* cell lines and several xenograft models.

5:00 Biomarker Discovery and Validation: What is Missing

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

Efforts to establish biomarker discovery in the pre-clinical stage have been limited by insufficient pre-clinical models. Approaches utilizing novel pre-clinical models that enable early pre-clinical biomarker identification and validation.

KEYNOTE PRESENTATION

5:30 Cancer Pharmacology in Translational Medicine

Z. Alex Cao, Ph.D., Associate Director, Oncology Translational Research, Novartis Oncology Translational Medicine

Oncology Translational Research at Novartis has extensive activities in cancer cell biology, genomics, pharmacology, pathology and informatics. Translational Pharmacology is uniquely positioned to bridge such efforts and drive the clinical development of novel anti-cancer agents.

6:00 Close of Day

THURSDAY, FEBRUARY 23

CENTERS OF EXCELLENCE: ACADEMICS IN TRANSLATIONAL RESEARCH

8:30 am Chairperson's Remarks

Patricia McDonald, Ph.D., Associate Scientific Director, Translational Research, The Scripps Research Institute

8:35 Translational Research at Scripps Florida

Patrick Griffin, Ph.D., Director, Translational Research, The Scripps Research Institute

Discussion focused on the Scripps National Screening Center, as well as the successful collaborations in translational research with pharmaceutical partners; examples from Eli Lilly and Pfizer.

9:05 Translating Innovation into Personalized Medicine: A Centralized Approach for Fostering Research and Engaging Physicians in a Large National Community Hospital Network

Jeffrey M. Otto, Ph.D., M.B.A., National Director, Catholic Health Initiative's Center for Translational Research

Research partnerships leverage the CTR's CLIA MDx laboratory, biospecimen procurement / repository, healthcare data analytics, and research capabilities to develop improved tools for physicians in the community hospital setting.

9:35 Driving Innovation with Forward and Reverse Translation in the Academic Setting

Virginia Burns, Ph.D., Associate Director, Technology Resources, Duke Translational Medicine Institute, Duke University

10:05 Plasma-Based Biomarkers in the Preclinical and Clinical Development of Novel Human Immunomodulators

Sponsored by MYRIAD RBM

Robert Hershberg, MD, Ph.D., President and Chief Medical Officer, VentiRx Pharmaceuticals

Certain immunomodulators target molecules that show marked differences between species. The HumanMAP v1.6 panel of biomarkers (Myriad RBM) provided a link between non-human primates and human clinical development of VTX-2337—a novel small molecule targeting Toll-like receptor 8 (TLR8).

10:20 Coffee Break

11:00 T-Cell Immunotherapy at UPenn: An Integrated Academic Translational Model for Success

Michael Kalos, Ph.D., Director, Translational and Correlative Studies Laboratory, University of Pennsylvania School of Medicine

We will discuss infrastructure elements whose implementation has been crucial for the successful establishment of the T-cell Immunotherapy program, and discuss specific examples of the successful translation of novel therapies from the bench to the bedside. **11:30 Collaboration in Translational Science: Leveraging the Best of Both Worlds**

Moderator: Patricia McDonald, Ph.D., Associate Scientific Director, Translational Research, The Scripps Research Institute

Open discussion focused on the academic-industry collaboration, identification of niche expertise within an academic organization, cultural differences of pharma and academic and how to work within changing timelines/resources/personnel. Audience participation is encouraged.

12:00 pm Enjoy Lunch on Your Own

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

INFORMATICS FOR TRANSLATIONAL SCIENCE

1:45 Chairperson's Remarks

Rong Chen, Ph.D., Scientist, Bioinformatics, Pediatrics & Systems Medicine, Stanford University

1:50 Talk Title to be Announced

Rong Chen, Ph.D., Scientist, Bioinformatics, Pediatrics & Systems Medicine, Stanford University

2:20 Building a Translational Informatics Infrastructure Organically

Shoibal Datta, Ph.D., Associate Director, R&D Information Technology, Therapeutic Areas & Translational Medicine, Biogen Idec, Inc.

Translational data sets by their very nature involve the need to meaningfully integrate data from multiple traditional silos within R&D, each with complex and heterogeneous data representations. Biogen Idec's experience will be shared and a case study will be presented.

2:50 Translational Informatics in Personalized Medicine

Eric D. Perakslis, Ph.D., former Vice President, Research & Development IT, Johnson & Johnson Pharmaceuticals Research and Development

There are significant opportunities for informatics to drive progress towards wide use and utility of personalized medicine by exploitation of multi-modal biomarkers, pre-competitive data sharing and a balance between high-content data and rich phenotypic data.

3:20 Close of Conference

Inaugural

De-Risking Drug Discovery

Strategies & Technologies for Targets & Molecules

February 21-23

TUESDAY, FEBRUARY 21

7:00 am Registration

PLENARY KEYNOTE SESSION

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

DE-RISKING: SAFETY ASSESSMENT TARGETS

11:00 Chairperson's Opening Remarks

Michael Forstner, M.Sc., Ph.D., Integrated Safety Risk Manager, PDS, Roche

KEYNOTE PRESENTATION

11:10 Detoxifying the Early Portfolio

David E. Watson, Ph.D., Research Advisor, Eli Lilly & Co.

11:40 Reducing Attrition: Combining Predictive *in silico* and *in vitro* Safety Assays to Guide Design Chemistry

Thomas Schroeter, Ph.D., Senior Principal Scientist, Compound Safety Prediction, Pfizer

The greatest challenge facing the pharmaceutical industry today is developing more effective decision making tools and strategies to reduce the attrition rate of novel compounds during candidate selection and clinical development.

12:10 pm Integrated Safety Management Planning as a Tool for Proactive Risk Minimization

Michael Forstner, M.Sc., Ph.D., Integrated Safety Risk Manager, PDS, Roche

Safety risk management of new drugs should commence before entry into humans and be maintained in a comprehensive way throughout development. By a combination of risk analysis and RM methods with an integrated approach to the detection/evaluation of safety issues, it is possible to identify important risks.

12:40 LUNCHEON PRESENTATION:

Sponsored by ELSEVIER

Overcoming 'Rubbish In: Rubbish Out': Effectively Supporting Target Identification & Validation Using Target Insights, a New Product from Elsevier

Jabe Wilson, MBA, Ph.D., Senior Product Development Manager, Elsevier (Pharma & Biotech Group)

In target identification/validation the fundamental questions are how is a target identified, and the hypothesis developed using the scientific literature? Reducing time & money investments in literature searching to get to a go-no go decision is crucial. Target Insights from Elsevier is a new online decision support tool for biologists dealing with these issues.

1:45 Dessert in the Exhibit Hall with Poster Viewing

2:15 Chairperson's Remarks

Gary Gintant, Ph.D., Research Fellow, Integrative Pharmacology, Chair, Abbott QT/Proarrhythmia Working Group, Abbott Laboratories

2:20 Safety as a Component of Target Selection

Anne Ryan, D.V.M., Ph.D., Diplomate ACVP, Executive Director, Drug Safety Research and Development, Pfizer, Inc.

Understanding the biology and safety of a proposed target; Understanding Target Expression and Tissue Distribution; Developing a Risk Management strategy early target de-risking studies.

2:50 Early *in vitro* Safety Screening: Impact in Drug Discovery

Speaker TBA

3:20 Pearls (and Perils) of Staged Empirical Pre-Clinical Cardiovascular De-Risking Strategies

Gary Gintant, Ph.D., Research Fellow, Integrative Pharmacology, Chair, Abbott QT/Proarrhythmia Working Group, Abbott Laboratories

Detection of compounds early and later during drug discovery can reduce later stage compound attrition. This talk will focus on strategies and examples of "frontloading" safety pharmacology studies for cardiovascular liabilities, a prominent source of continuing concern in drug development.

3:50 Using Mechanism of Action to Predict Safety Signals and Understand Sub-Populations

Sponsored by Biovista

Aris Persidis, Ph.D., President, Biovista

Mechanism of action (MoA) can be used to predict potential system-driven safety signals. it can also guide the selection of the right sub-populations in clinical trial design. Examples of inclusion/exclusion criteria will be given.

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

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

6:20 Close of Day

WEDNESDAY, FEBRUARY 22

NETWORK PHARMACOLOGY

7:55 am Chairperson's Remarks

Jake Chen, Ph.D., Associate Professor, Informatics, Indiana University

8:00 Network Polypharmacology in Systems Lead Finding

Jeremy Jenkins, Ph.D., Senior Investigator I, DMP, Quantitative Biology, Chemical Biology Informatics, Novartis Institutes for BioMedical Research

Protein interactomics data provides the basis for network maps that can represent theoretical targets in phenotypic assays. Protein interaction networks as an organizing principle for discovering chemical leads - both alone and in combination - will be presented.

8:30 Translating Systems Biology to Systems Pharmacology: Integrating *in vitro* Systems Biology and Disease-PKPD Modeling to Advance the Discovery of Antibody Therapeutics

John Burke, Ph.D., Senior Principal Scientist, Head, Systems Biology and Pre-Clinical PKPD Modeling, Translational Research, Boehringer Ingelheim Pharmaceuticals

First principals Systems Biology modeling and analysis elucidated seemingly contradictory *in vitro* data via model prediction. The model was then translated into the mechanistic disease-PKPD Systems Pharmacology paradigm to predict optimal therapeutic parameters. As a result, the lead was identified.

9:00 Computational Approaches in Studying Network Pharmacology

Philip E. Bourne PhD, Professor, Pharmacology, University of California, San Diego; Associate Director, RCSB Protein Data Bank; Co-Founder & Editor-in-Chief, PLoS Computational Biology

Recent success in using computational network pharmacology to explain unusual outcomes, both positive and negative, that are seen experimentally and/or clinically. Examples will be given, including Nelfinavir. Our approach combines cheminformatics, structural bioinformatics and systems biology.

KEYNOTE PRESENTATION

9:30 De-Risking Drug Discovery Using Network Pharmacology

Sponsored by e-Therapeutics Ltd

Malcolm Young, Ph.D., CEO, e-Therapeutics

Statistical analysis of current attrition rates shows that preclinical and early clinical stage data do not predict efficacy, safety and deliverability in human patients nearly well enough. Further, and more accurate, ways to de-risk candidates before expensive clinical trials are urgently required.

10:00 Transition to Plenary Keynote

PLENARY KEYNOTE

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

12:00 pm Modeling Drug Efficacy Using Network Pharmacology

Jake Chen, Ph.D., Associate Professor, Informatics, Indiana University

This will describe how the study of drugs, molecules, and drug-target can benefit predictive modeling of drug effects and evaluations of their efficacy. This opens up new opportunities for future drug development; this new exciting field can revolutionize future drug development.

12:30 EXPERT PANEL: Implementing Network Pharmacology in Current Pharma Strategies: Unveiling & Championing Existing Resources
Moderator:
Jeremy Jenkins, Ph.D., Senior Investigator I, DMP, Quantitative Biology, Chemical Biology Informatics, Novartis Institutes for BioMedical Research
Panelists:
John Burke, Ph.D., Senior Principal Scientist, Head, Systems Biology and Pre-Clinical PKPD Modeling, Translational Research, Boehringer Ingelheim Pharmaceuticals
Jake Chen, Ph.D., Associate Professor, Informatics, Indiana University
Malcolm Young, Ph.D., CEO, e-Therapeutics
Philip E. Bourne Ph.D, Professor, Pharmacology, University of California, San Diego; Associate Director, RCSB Protein Data Bank; Co-Founder & Editor-in-Chief, PLoS Computational Biology

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

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

PLENARY KEYNOTE PANEL

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

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

4:25 Chairperson's Remarks
Kate Skaare, Conference Producer, Cambridge Healthtech Institute

4:30 PANEL DISCUSSION: Creating Safety Endpoints as a Milestone within Pharmaceutical Discovery & Development
Ernie Bush, Ph.D., Vice President, Collaborative Projects, The Drug Safety Executive Council
- Establishing safety assessment endpoints throughout the pipeline
- Why "one fits all" does not work
- Pre-clinical vs. clinical endpoints

KEYNOTE PRESENTATION

5:30 Target Validation of B-Lymphocyte Stimulator and Development of Belimumab—A Case Study
William W. Freimuth, M.D., Ph.D., Vice-President of Clinical Research Immunology, Rheumatology and Infectious Diseases, Human Genome Sciences, Inc.
B-Lymphocyte Stimulator (BLyS) is a member of the TNF ligand super family responsible for the survival of antibody producing B-cells. Its experimental overexpression is associated with an autoimmune phenotype, and its increase in the blood of patients with systemic lupus erythematosus (SLE).

6:30 Close of Day

THURSDAY, FEBRUARY 23

DRUG REPOSITIONING

8:30 am Chairperson's Remarks
Aris Persidis, Ph.D., President, Biovista

8:35 Systematic Drug Repositioning: Maximizing the Value of Drugs for Patients
Mark Hurle, Ph.D., Senior Scientific Investigator, Computational Biology, Molecular Discovery & Development, GlaxoSmithKline
Typically drugs have been repositioned following serendipitous observations. Now, however, there are a number of computational methods that can evaluate and suggest new indications. Dr. Agarwal will discuss some of these that are based on text-mining literature, genetics, expression signatures and pathways.

9:05 Drug Repositioning: IP & Patent Information Every Scientist Needs
Kevin L. McLaren, Ph.D., Esq., Barnes & Thornburg LLP
The requirements for obtaining patent protection, including the new 2011 laws, with an emphasis on the patentability of repositioned drugs; a summary of important court cases where repositioned drug patents have been litigated, discussing both successful challenges and failed attempts.

9:35 Extended Profiling and Identification of Novel Indication Opportunities Using Knowledge Management Analytics
Natalia Novac, M.Sc., Ph.D., Scientist, Research & Development Knowledge Management, Operational Excellence, Merck Serono
In the times of the constantly rising attrition rates in pharma industry, repositioning is a solution for pipeline de-risking via rapid re-loading of the compounds back into the pipeline. Knowledge accumulated in the public and proprietary domains allows early analysis of compounds' indication profile leading to the better compound positioning and ensuring maximum exploration of existing opportunities. My talk will be focused on the knowledge management technologies and methodologies that enable systematic analysis of pipeline compounds and generation of viable hypotheses continuously supporting the pharma value chain.

10:05 Sponsored Presentation *(Opportunity Available)*

10:20 Coffee Break

11:15 Selected Poster Presentation
Huijun Wang, Ph.D., Senior Scientist, Pfizer

PRE-CLINICAL DE-RISKING STRATEGIES: TARGETS AND COMPOUNDS

11:25 Chairperson's Remarks
Liang Schweizer, Bristol-Myers Squibb

11:30 Driving Right Targets and Right Molecules to Clinic Development by Selectively Integrating Advanced Technology Platforms
Liang Schweizer, Bristol-Myers Squibb and Mechanistic Biochemistry, Bristol-Myers Squibb
Several case studies will be discussed to demonstrate how to selectively integrate advanced technology platforms to deliver diverse modalities for target validation and strengthen *in vitro* pharmacology packages for drug candidate selection.

12:00 pm Academia Drives Innovative Target Discovery
Rathnam Chaguturu, Ph.D., Director, High-Throughput Screening Laboratories, University of Kansas; Editor-in-Chief, Combinatorial Chemistry and High-Throughput Screening
The process of target validation from the protein level to the cellular level and eventually in small animal models is at its best in academia, but academia could benefit immensely by adapting pharmaceutical industry's best practices to ensure that the biological targets are therapeutically relevant and chemically tractable.

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

1:45 Chairperson's Remarks
Liang Schweizer, Bristol-Myers Squibb

1:50 Facilitating Early Stage Projects
Lawrence R. McGee, Ph.D., Scientific Director, Medicinal Chemistry, Amgen South San Francisco
Small molecule drug candidates often closely resemble the initial hit. Improved hit characterization may increase the chance for success. A data-driven approach that facilitates entrepreneurial discovery teams through the hit and lead identification process will be discussed.

2:20 Combination Drug Profiling Strategies to De-Risk Drug Development and Improve Clinical Translation
Glenn Short, Ph.D., Director, Discovery Sciences, Zalicus
Performing combination profiling studies early in the drug discovery process, the observance of synergy will lend insight into which drug combinations are most appropriate for a given patient subpopulation and potentially de-risk critical decisions in trial design that improve the odds of clinical success.

2:50 *In vitro* Safety Profiling during Lead Optimization to Reduce Safety Attrition
Murray Brown, Ph.D., Manager, Data Interpretation and Business Process, Screening and Compound Profiling, GlaxoSmithKline
Efforts are underway across the industry to improve the quality of drug candidates by developing molecules with better physiochemical properties (e.g. MWt, clogP) and by assaying molecules in screening assays that are predictive of drug toxicity in animal or human studies. We show GSK's integrated approach.

3:20 Close of Conference

TUESDAY, FEBRUARY 21

7:00 am Registration

PLENARY KEYNOTE SESSION

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

CANCER CLINICAL TRIALS IN THE ERA OF PERSONALIZED MEDICINE

11:00 Chairperson's Opening Remarks

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

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

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

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

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

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

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

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

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

1:45 Dessert in the Exhibit Hall with Poster Viewing

INDUSTRY-ACADEMIA COLLABORATION

2:15 Chairperson's Remarks

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

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

Laurence H. Baker, D.O., Professor of Medicine and Pharmacology, University of Michigan Medical School; Group Chair, Southwest Oncology Group (SWOG)

SWOG is engaged in studies designed to improve our abilities to diagnose, treat and prevent cancer. Our clinical trials are performed by 4,000 physicians at over 500 sites. In this presentation we will highlight the methodology of the collaboration as well as describe some obstacles to success.

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

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

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

NOVEL SURROGATE ENDPOINTS

3:20 Laboratory and Clinical Endpoints in Cancer Immunotherapy

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

Cancer immunotherapies such as cellular therapies and immune modulators have been recognized to provide clinical benefit, and have received marketing approval in the United States. Nonetheless, well accepted clinical surrogates may not provide effective guidance toward the development of other immunotherapies, or extending the use of the currently approved therapies. The laboratory and clinical endpoints recognized as critical to demonstrating effectiveness will be addressed, along with discussion of their role in informing the development of novel agents.

3:50 CTCs as a Liquid Biopsy

Marielena Mata, Ph.D., Principal Research Scientist, Oncology Biomarkers, Johnson & Johnson

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

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

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

6:20 Close of Day

WEDNESDAY, FEBRUARY 22

CASE STUDIES OF LED-TO-APPROVAL CLINICAL TRIALS

Xalkori Case Study

7:55 am Chairperson's Remarks

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

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

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

Fully integrating a diagnostic test into crizotinib pivotal trials, leading to a simultaneous submission of a drug-diagnostics combination, presented many challenges as well as opportunities in the development of crizotinib for treatment of NSCLC patients.

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

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

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

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

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

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

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

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

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

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

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

10:00 Transition to Plenary Keynote

PLENARY KEYNOTE

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

Adcetris Case Study

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

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

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

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

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

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

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

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

PLENARY KEYNOTE PANEL

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

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

Zelboraf Case Study

4:25 Chairperson's Remarks

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

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

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

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

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

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

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

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

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

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

6:00 PANEL DISCUSSION: Lessons Learned from Case Studies

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

6:30 Close of Day

THURSDAY, FEBRUARY 23

BIOMARKER-DRIVEN CLINICAL TRIALS

8:30 am Chairperson's Remarks

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

KEYNOTE PRESENTATION

8:35 The Story of MetMAb Discovery and Development

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

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

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

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

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

Apostolia-Maria Tsimberidou, M.D., Ph.D., Associate Professor, Department of Investigational Cancer Therapeutics, University of Texas, MD Anderson Cancer Center

Tumor molecular profiling for identification of molecular aberrations and use of matched targeted therapy is associated with superior rates of response, time to treatment failure and survival compared to the standard approach in patients with advanced cancer.

10:05 Sponsored Presentation *(Opportunity Available)*

10:20 Coffee Break

11:00 Testing the Predictive Value of a Genomic Assay

William Barlow, Ph.D., Senior Biostatistician, Cancer Research & Biostatistics Research; Professor, Department of Biostatistics, University of Washington

Prediction refers to the ability of a marker to choose the best treatment for a patient. We illustrate how to test a continuous marker in a clinical trial and how to design a trial to test a marker's predictive value.

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

Ravi A. Madan, M.D., Assistant Clinical Investigator, Laboratory of Tumor Immunology and Biology & Medical Oncology Branch, National Cancer Institute

Modern immunotherapies such as therapeutic cancer vaccines are mechanistically different from standard cytotoxic agents, and thus require special considerations for population selection and clinical trial design. Appropriate trial endpoints for monotherapy may be different from studies which employ immune-based combinations.

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

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

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

12:30 Lunch on your Own

1:45 Chairperson's Remarks

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

Jared Lunceford, Senior Biometrician, Merck Research Laboratories

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

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

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

3:20 Close of Conference

Fourth Annual

Integrated R&D Informatics & Knowledge Management

Leveraging Data from Disparate Sources to Create Value

February 21-23

TUESDAY, FEBRUARY 21

7:00 am Registration

PLENARY KEYNOTE SESSION

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

11:00 Chairperson's Opening Remarks

KEYNOTE SESSION (Part I)

11:10 New Frontiers for Research: Integrating the Virtual R&D Lab

Ingrid E. Akerblom, Ph.D., Executive Director, Discovery & Pre-Clinical IT, Merck Research Laboratories

Research and Development models continue to evolve as pharma companies embrace expanding global markets, new sources of information both public and private, and drug modalities such as Biologics. Integrated Informatics remains a core capability for decision-making in this complex landscape.

11:40 Breaking through the Walls of Traditional Pharma to Access & Generate Information and Enable Innovation

Daniel H. Robertson, Ph.D., Senior Director, LRL IT Research, Eli Lilly & Co.

As available information increases, the pharmaceutical industry can no longer expect all relevant information necessary to drive innovation to be generated or stored internally and in the right context. New methodologies must be explored to gain the insights pharma needs.

12:10 pm The Novartis Data Federation Initiative

Arturo J. Morales, Ph.D., Global Leader, Novartis Data Federation Initiative, Novartis Institutes for BioMedical Research, Inc.

NDFI aims to seamlessly integrate all data, information and knowledge generated within and outside NIBR, such that formal publications are unnecessary, and global team meetings are enabled with on-line, collaborative applications and where geographical and time-zone boundaries are nullified.

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

Sponsored by BioFortis

Steve Chen, Director of Marketing, BioFortis, Inc.

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

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

Sponsored by revelytix emergent analytics spry agile analytics

Todd Jones, Sr. Information Architect, Spry

Mike Lang Jr., VP, Director of Ontology Engineering Services, Revelytix

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

1:45 Dessert in the Exhibit Hall with Poster Viewing

INTEGRATION OF BIOMARKER, CLINICAL AND PERSONALIZED MEDICINE DATA

2:15 Chairperson's Remarks

Carol Hill, Duke Clinical Research Institute

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

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

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

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

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

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

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

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

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

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

Sponsored by REMEDY INFORMATICS

Gary Kennedy, Chairman & CEO, Remedy Informatics

4:05 Breaking the Mold: Whole Genome Sequencing as a Diagnostic Assay

Sponsored by Complete genomics

Jill Hagenkord, MD Chief Medical Officer, Complete Genomics

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

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

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

6:20 Close of Day

WEDNESDAY, FEBRUARY 22

7:55 am Chairperson's Remarks: Martin Leach, Broad Institute

KEYNOTE SESSION (Part II)

8:00 Surfing the Petabyte Waves - IT Partnering for Informatics and Computational Biology at the Broad Institute of MIT & Harvard

Martin Leach, Ph.D., CIO, Broad Institute

In this presentation you will learn how IT works with research at the Broad Institute to support our network of scientists and how we are leveraging innovative technologies in support of next generation sequencing and genomics research.

8:30 Disease and Translational Informatics: From Bioinformatics Playground to Critical Path

Juergen Hammer, Ph.D., M.B.A, Pharma Research & Early Development Informatics; Center Head, Global Head Disease and Translational Informatics, Roche Pharmaceuticals

9:00 New Approaches for Better Decisions

Anastasia M. Khoury Christianson, Ph.D., Senior Director, R&D Information, AstraZeneca Pharmaceuticals

Evidence-based decisions in R&D require the availability of the right data, tools, processes and skills coming together at the right time. This presentation will describe new approaches to old questions and how to leverage disparate components to create valuable knowledge.

9:30 Changing the Landscape of Laboratory Informatics Systems to Enhance the Innovation Lifecycle

Sponsored by accelrys

Robert Brown, Ph.D., Sr. Director of Life Sciences Marketing, Accelrys

Dominic John, Ph.D., Director of Marketing, Accelrys

Optimizing the innovation lifecycle from early discovery through delivery to manufacturing is a critically important process for the success of research and

development organizations. However, today the R&D stakeholders driving innovation are likely to be communicating across time zones and continents rather than across a laboratory bench. And increasingly, project participants no longer all work under the same corporate umbrella but across a network of CROs and collaborators. To be successful, organizations need an end-to-end, unified enterprise-level informatics platform for innovation lifecycle management—one that can facilitate the data integration, process automation, collaboration and information sharing required – but are instead often faced with an existing in-house informatics landscape of fractured, disparate applications that must be held together by an IT organization under increasing cost and time constraints. In this talk we will present an Accelrys solution that directly addresses the new challenges for informatics systems in integrated innovation lifecycle management and externalization – the need for low cost solutions that allow secure collaboration across global, heterogeneous research teams that can be very easily and rapidly deployed to meet the dynamic nature of those teams. We will discuss how the solution allows organizations to realize significant productivity enhancements in their ability to orchestrate, document and manage their innovation lifecycle.

10:00 Transition to Plenary Keynote

PLENARY KEYNOTE

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

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

ONTOLOGIES

12:00 pm BioAssay Ontology Facilitates Standardization, Integration and Meta-Analysis of Massive High-Throughput Screening (HTS) Datasets

Stephan Schürer, Ph.D., Center for Computational Science and Department of Molecular and Cellular Pharmacology, Miller School of Medicine, University of Miami

We have developed BAO to enable the classification of HTS assays and data into categories related to format, design, technology, target, and endpoints. BAO facilitates HTS meta-analysis. HTS results are made available via a novel Semantic Web software application BAOSearch.

INTEGRATING & ACCESSING NON-STANDARD PUBLIC DATA TO DRIVE R&D

12:30 Social Media Analytics for Health Informatics

Christopher C. Yang, Associate Professor, College of Information Science and Technology, Drexel University

Social media captures health consumer opinions and provides a new channel of health intervention. Social media analytics techniques on how to discover knowledge and patterns are introduced. Opportunities of harnessing this knowledge for health intervention will also be discussed.

1:00 LUNCHEON PRESENTATION I: Science at the Bench and the Bedside: Less of a Tightrope, More of a Super Highway

Paul Denny Gouldson, Ph.D., Vice President, Translational Medicine, IDBS

Bench to Bedside R&D has become an information science. Increasingly diverse and distributed research and clinical communities are wrestling with higher volumes of highly context rich data. All researchers in scientific, pre-clinical, clinical and 'real-world' domains expect - and should have - real-time access to scientifically aware, context-rich secured information, delivered in an integrated way to mobile and tethered platforms

1:30 LUNCHEON PRESENTATION II: Topological Data Analysis: A Novel Approach for the Analysis of Large and Complex Data Sets

Pek Yee Lum, Vice President, Ayasdi Inc.

The amount of data today is tremendous and coupled with complexity, it almost impossible for current tools to manage. This presentation will introduce you to a novel data analysis platform that uses Topological Data Analysis to address these challenges.

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

PLENARY KEYNOTE PANEL

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

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

4:25 Chairperson's Remarks: Sandor Szalma, J&J Pharmaceutical R&D

4:30 Mining Social Media Data for Actionable Knowledge

Huan Liu, Professor, Computer Science and Engineering, School of Computing, Informatics, and Decision Systems Engineering, Arizona State University

Social media differs from conventional data in many ways. Novel mining algorithms are introduced with case studies to show the intricacies of social media data, and discuss how one can use it to gain useful information and study human behavior.

5:00 Social Media as Source for New Insights for Medicinal Products

Sandor Szalma, Head, External Innovation, Research & Development IT, J&J Pharmaceutical Research & Development, LLC

The vast amount of data generated in web-based and social media presents an opportunity and challenge for regulators and health care enterprises. The data mining of this media is complicated by multiple factors, and thus poses a special challenge.

5:30 An Integrated Information Platform Serving Research, Development, and Commercial Needs

Paul Caron, Senior Research Fellow, eR&D; Head, Knowledge Management & Competitive Intelligence, Vertex Pharmaceuticals

An overview of a system will be presented that integrates scientific and competitive information in a way that both provides real-time updates and the ability to drill into the underlying background data. The presentation will span from philosophy to logistics to user experience.

6:00 Integrating Drug Discovery Informatics and Computational Chemistry for Project Teams

Jeff Blaney, Director, Computational Chemistry & Cheminformatics, Genentech

6:30 Close of Day

THURSDAY, FEBRUARY 23

INTEGRATING & ACCESSING NON-STANDARD PUBLIC DATA TO DRIVE R&D (continued)

8:30 am Chairperson's Remarks: Michael S. Lajiness, Eli Lilly

8:35 Panel DISCUSSION: Efficient Distributed Drug Discovery

Moderator: Barry Bunin, Ph.D., CEO & Board Member, Management, Collaborative Drug Discovery

Eugenio L. de Hostos, Ph.D., M.B.A., Director, Research & Pre-Clinical Development, OneWorld Health

Daniel A. Erlanson, Ph.D., Carmot Therapeutics, Inc.

- How has your drug discovery process become more efficient?
- What new approaches (technology, process, collaboration) have provided you with the most leverage & why?
- Share an inspiring collaborative drug discovery case study

9:05 Integrating and Exploiting Public Information in Support of Internal Projects

Michael S. Lajiness, Ph.D., Principal Scientist, Structural & Computational Sciences, Eli Lilly

Historically, large pharma has relied on internal data to develop new drugs. However, with the availability of extensive public data sources, there is a wealth of information that can be of value. This talk will highlight work at Lilly to integrate and exploit such information.

9:35 ChemLink: Linked Data Access to Compound Information

Eric Gifford, Ph.D., Associate Research Fellow, Computational Sciences Center of Emphasis, Pfizer

ChemLink is a web-based application that provides compound information from internal and external data sources. It searches multiple databases and returns results in predefined knowledge areas. Summary views of data, links to original data sources and analysis tools are provided.

10:05 Q&A with Morning Speakers

10:20 Coffee Break

WORKFLOW PROJECT

11:00 Opportunities and Challenges in Compound Management Workflow System

Louisa Lo, Associate Director, NIBR IT, Novartis

In this talk, we will present a case study of our partnership with the Compound Management group, a legacy request fulfillment systems replacement project. We will shed light on the workflow landscape, dilemmas, and opportunities during this software-hardware product life cycle.

MEETING THE INFORMATICS NEEDS TO SUPPORT BIOLOGICS DEVELOPMENT

11:30 Biologics Information Workflow – Where Does ELN Play a Role?

Michael Elliott, Founder, CEO & Chief Analyst, Atrium Research & Consulting, LLC.

Investment in biologics R&D is accelerating at a torrent pace, often without regard to effective data management. This presentation will discuss ELN's role and how the technology fits into a comprehensive biologics informatics architecture.

11:50 A Path for Integrating Small and Large Molecule Informatics
Robert H. Gruninger, Ph.D., Program Manager, Informatics CoE, Janssen Research & Development, LLC.
Integrating Small Molecule and Biologics research gives a better understanding of targets and pathways. The ABCD platform at Johnson and Johnson provides a decade of small molecule screening and powerful data analysis, and has been extended to handle large molecules.

12:10 The Evolution of Informatics for Biologics: a Transition from Basic Research to Drug Dvelopment
Beth Basham, Ph.D., Account Manager, Biologics Discovery; IT Site Lead, Merck
Merck's biologics discovery research center is the former DNAX Research Institute. As this site transitions from a traditional biotech to an integrated biologics drug development unit, the information management systems are also evolving to support that new mission.

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

INFORMATICS FOR TRANSLATIONAL SCIENCE

1:45 Chairperson's Remarks
Rong Chen, Ph.D., Scientist, Bioinformatics, Pediatrics & Systems Medicine, Stanford University

1:50 Talk Title to be Announced
Rong Chen, Ph.D., Scientist, Bioinformatics, Pediatrics & Systems Medicine, Stanford University

2:20 Building a Translational Informatics Infrastructure Organically
Shoibal Datta, Ph.D., Associate Director, R&D Information Technology, Therapeutic Areas & Translational Medicine, Biogen Idec, Inc.
Translational data sets by their very nature involve the need to meaningfully integrate data from multiple traditional silos within R&D, each with complex and heterogeneous data representations. Biogen Idec's experience will be shared and a case study will be presented.

2:50 Translational Informatics in Personalized Medicine
Speaker to be Announced

3:20 Close of Conference

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Example of a Suggested ALL ACCESS Package:

Symposium	Event Short Course	Event Dinner Short Course	Core Program
Network Generation Pathology	Network Pharmacology	Adaptive Oncology Clinical Trials	Translational Science

Inaugural

Bioinformatics & Cancerinformatics

Turning the Data Deluge into Meaningful Biological Knowledge

February 21-23

TUESDAY, FEBRUARY 21

7:00 am Registration

PLENARY KEYNOTE SESSION

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

DATA STORAGE, MANAGEMENT AND INTEGRATION STRATEGIES

11:00 Chairperson's Opening Remarks
Kevin Davies, Ph.D., Editor-in-Chief, Bio-IT

KEYNOTE PRESENTATION

11:10 NCI caBIG®: Enabling Collaborative Research
Ken Buetow, Ph.D., Associate Director, Bioinformatics and Information Technology, National Cancer Institute
The National Cancer Institute (NCI) through its caBIG® program has prototyped a standards-based interoperable infrastructure to manage, annotate, and analyze biomedical research data. These community-generated and supported open-source capabilities enable collaborative research among all constituents of the biomedical research ecosystem.

11:40 Biomedical Text Towards Building Multi-Faceted Nutrigenomics Networks
Hui Yang, Ph.D., Assistant Professor, Computer Science, Center for Computing for Life Sciences, San Francisco State University
Advances in bio-technology and life sciences are leading to an ever-increasing volume of published research data, predominantly in unstructured text. To uncover the underlying knowledge base hidden in such data, text mining techniques have been utilized. Past and current efforts in this area have been largely focusing on recognizing gene and protein names, and identifying binary relationships among genes or proteins. In this talk, I will present an information extraction system currently under development at San Francisco State University. This system analyzes scientific publications in an emerging discipline--Nutritional Genomics, a discipline that studies the interactions amongst genes, foods and diseases--aiming to automatically construct nutritional genomics (or nutrigenomics) networks that capture the aforementioned interactions. We are especially interested in the health benefits of foods and their nutrients and their impact over different diseases. We expect such networks will benefit both health *professionals and the general public.*

12:10 pm Oncology Pharmacogenomics Data Integration and Beyond: Right Information and Smart Information
Lihua Yu, Ph.D., Director of Bioinformatics, H3 Biomedicine, Inc.
AstraZeneca's cancer pharmacogenomics data integration systems manage multi-dimensional data from compound profiling to cell line and in vivo model molecular profiling. Learn the system's key functionalities, its application to drug discovery and translational science projects, and how crowd intelligence is changing its information delivery.

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Sponsored by Revelytix Spry

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Sponsored by REMEDY INFORMATICS

Gary Kennedy, Chairman & CEO, Remedy Informatics

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Sponsored by Complete genomics

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

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5:20 Breakout Discussions in the Exhibit Hall

6:20 Close of Day

WEDNESDAY, FEBRUARY 22

DATA MODELING AND COMPUTATIONAL INTEGRATIVE TOOLS

7:55 am Chairperson's Remarks
Michael Liebman, Ph.D., Managing Director, Strategic Medicine, Inc.

8:00 Mastering Complexity of Biosystems without Math and Computing Background
Corrado Priami, Ph.D., President & CEO, The Microsoft Research - University of Trento Centre for Computational and Systems Biology (CoSBi)
This talk presents a new bioinformatics approach that speeds up modeling and analysis of complex biological systems. A natural iHuman-computer interaction interface allows biologists with no math or computing background to master modeling and simulation to infer new knowledge and design better experiments.

8:30 Personalized Medicine: Moving from Correlation to Causality in Breast Cancer
Michael Liebman, Ph.D., Managing Director, Strategic Medicine, Inc.
Sabrina Molinaro, Ph.D., Institute for Clinical Physiology, National Research Council, Italy
We have developed a fundamental model of the disease process for breast cancer, from pre-disease through early detection, treatment and outcome, and apply a multi-scalar approach across the risk assessment-enhanced diagnosis-therapeutic decision axis and will present the modeling methodologies.

9:00 Using Public Molecular Measurements to Drive Discovery of Biomarkers and Therapeutics
Rong Chen, Ph.D., Bioinformatics Specialist, Butte Lab, Systems Medicine, Pediatrics, Stanford University School of Medicine
This presentation will describe how computational integrative tools can be used to convert more than 15 billion points of molecular, clinical, and epidemiological data measured by researchers and clinicians over the past decade into novel diagnostics, therapeutics, and insights into disease.

Sponsored by INGENUITY SYSTEMS

9:30 Prediction of Downstream Effects and Transcription Factor Activation of Breast Cancer Cell Lines Using IPA (Ingenuity Pathway Analysis)
Stuart Tugendreich, Ph.D., Product Management Director, Ingenuity Systems
The epithelial to mesenchymal transition (EMT) that normal cells undergo during development is partially mirrored among different breast cancers and cell lines. IPA's new Downstream Effects Analysis, Transcription Factor Analysis tool, and Human Isoform Viewer are used to explore the molecular differences between breast cancer-derived cell lines using RNA-Seq data.

10:00 Transition to Plenary Keynote

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

GENOMICS AND INTEGRATING MULTIPLE –OMIC DATA TYPES

12:00 pm Chairperson
Sabrina Molinaro, Ph.D., Institute for Clinical Physiology, National Research Council, Italy

12:30 Integrative Network Biology Provides Novel Predictors of Human Disease
Rod Nibbe, Ph.D., Senior Scientist & Director of Product Development, NEO Proteomics, Inc.
Network biology approaches are described that integrate multiple -omic data types to identify parsimonious candidate markers in cancer and Alzheimer's. Network based markers are powerful features for classification and can identify new drug target candidates.

Sponsored by ELSEVIER

1:00 Luncheon Presentation

Using a Bioinformatics Approach to Gain a Better Understanding of the Unique Molecular Features of Non-squamous Cell Lung Cancer (NSCLC)
Kevin Bobofchak, Ph.D., Pathway Studio Product Manager, Elsevier
Elsevier will present a use-case in which Pathway Studio was used to analyze clinical samples of NSCLC subtypes working towards novel therapy development. Pathway Studio incorporates analytical algorithms and powerful MedScan technology that builds knowledgebases to support scientific research.

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

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

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

GENE EXPRESSION & DATA ANALYSIS

4:25 Chairperson's Remarks

4:30 Detection of Lung Cancer Molecular Subtypes by Gene Expression Arrays, Protein Immunohistochemistry and PCR from Paraffin Based Assays
David Neil Hayes, M.D., M.P.H., Assistant Professor, Clinical Research, Hematology/Oncology, University of North Carolina, Chapel Hill
Gene expression profiling has revealed reproducible subtypes of lung cancer not detectable by routine clinical diagnostic methods. We investigate the nature of the tumor subtypes in terms of clinical relevance and biologic underpinnings such as associated mutations and potential cell of origin.

5:00 Recovering Upstream Regulatory Pathways and Predicting Side Effects from Gene Expression Signatures
Avi Ma'ayan, Ph.D., Assistant Professor, Pharmacology & Systems Therapeutics, Mount Sinai School of Medicine
This talk discusses analysis of gene expression signatures from individual patient tissues to uniquely identify upstream transcription factors, protein complexes, and protein kinases, as well as a method to predict new indications and side effects for approved and experimental drugs from gene expression signatures.

5:30 Comparing Two Microarray Covariance Matrices Based on a Novel Conjugate Bayes Factor
James Zhou, Ph.D., Director, Statistical Operations, Clinical Development, Social & Scientific Systems, Inc.
A novel conjugate Bayes factor is developed to assess the equality of two multivariate normal covariance matrices in microarray gene expression data analysis. We illustrate this test and implement it using prior parameters estimated empirically from a large collection of gene sets.

6:00 Web Portal for Integrated Analysis of Radiation Responsive Cancer Gene Expression Profiles
Uma Shankavaram, Ph.D., Staff Scientist, National Cancer Institute & NIH
This presentation will describe a web portal called MAQuery we have created that would house cancer related microarray expression data focusing primarily on radiation oncology data. Attendees will learn how MAQuery will help in the search for genes with particular expression profiles in cancers.

6:30 Close of Day

THURSDAY, FEBRUARY 23

TRANSLATING BIOMARKER DRIVEN CANCER TREATMENTS INTO PRACTICE

8:30 Chairperson's Remarks
Jay M. Tenenbaum, Ph.D., Founder and Chairman, Cancer Commons

8:35 The Road to Personalized Medicine is Paved with Data and Information
John Quackenbush, Ph.D., Professor, Biostatistics and Computational Biology, Cancer Biology Center for Cancer, Dana-Farber Cancer Institute
This presentation will explore the elements necessary to successfully develop an integrated program using genomics and medical data, together with other sources of information, to arrive at robust biomarkers that can be reliably used in a clinical setting.

9:05 Cancer Commons – A Rapid Learning Community for Cancer
Jay M. Tenenbaum Ph.D., Founder and Chairman, Cancer Commons
Cancer Commons is creating an open science community where knowledge is rapidly shared among patients, physicians, and researchers. Our vision is for every patient to be treated with molecularly tailored therapies using the best and most up-to-date knowledge, and to continually update that knowledge based on each patient's response.

9:35 Clinical Information Systems for Genome Directed Cancer Treatment
Mia Levy, M.D., Ph.D., Assistant Professor, Biomedical Informatics & Medicine, Vanderbilt University; Cancer Clinical Informatics Officer, Vanderbilt Ingram Cancer Ctr.
We describe the clinical information systems that support our genome directed cancer treatment. This includes integrating tumor gene mutation testing results into the electronic health record and decision support genome directed cancer treatment including standard of care and clinical trials.

Sponsored by NEXTBIO

10:05 Integrative Biology Approaches for Genome Interpretation in the Age of Personalized Medicine
Ilya Kupershmidt, Co-founder and Vice President, Products, NextBio, Inc.
Changing paradigms in translational research and genomic medicine require novel data analysis approaches and infrastructure linking genomic research to actionable insights for personalized medicine. NextBio's patient-centric platform integrates the world's genomic data with clinical information to enable translational research and clinical initiatives. Intuitive reports leverage this content for biomarker and target discovery, clinical trial optimization and patient stratification, and informing clinical decisions.

10:20 Coffee Break

11:00 How to Translate Next-Generation Sequencing Data into Clinically Useful Information
Fuad Gwadry, Bioinformatics Consultant, Sequenom Center for Molecular Medicine
One of the main challenges facing the implementation of next-generation sequencing in clinical practice is the bioinformatic data analysis. This talk will illustrate bioinformatic strategies used to identify the novel variants that may be clinically relevant.

11:30 Oral Chemotherapy Translation - Why a Web Based Data Repository is Essential for Pharmacist Use of Oral Anticancer Treatments
Tibor van Rooij, Ph.D. Candidate, Faculty of Pharmacy and Pharmaceutical Sciences, University of Alberta
Increasingly chemotherapeutic options are available in oral form and it is expected this trend will continue. The use of uninformed oral chemotherapy can result in misunderstandings, preventable toxicities, or inadequate therapy. We created a practical and targeted e-reference for healthcare use.

12:00 Skinomics – Part I
Miroslav Blumenberg, Ph.D., Associate Professor, Dermatology and Biochemistry, NYU Langone Medical Center
'SKINOMICS' is a field of Bioinformatics specifically applied to Dermatology and Skin Biology. It's primed to enter individualized medicine. Because of its accessibility, skin has been among the first organs analyzed using DNA microarrays. Melanomas, carcinomas, psoriasis, wound healing, etc. have been intensely investigated.

12:30 Enjoy Lunch on Your Own

1:45 Chairperson's Remarks
Jay M. Tenenbaum, Ph.D., Founder and Chairman, Cancer Commons

1:50 Skin-based Genomic Biomarkers for Disease Detection – Part II
William Wachsman, M.D., Ph.D. Associate Professor, Medicine, Hematology-Oncology, University of California, San Diego, School of Medicine
The skin is an underutilized source of biomarkers. This presentation will discuss proof-of-concept studies, the development of a clinical test for melanoma detection, and other uses of Epidermal Genetic Information Retrieval (EGIRTM), for genomic-based assays of dermatologic and systemic disease.

2:20 Pharmaceutical Information Solutions in Oncology
Jonathan Usuka, Ph.D., M.B.A., Director, Research & Development, Celgene Corporation

BIOINFORMATICS IN THE CLOUD

2:50 Bioinformatics in the Cloud: An Affordable Alternative
Giles Day, Co-founder and Managing Director, Distributed Bio, LLC

3:20 Close of Conference

Third Annual

Cancer Biologics

Conjugates, Multi-Specifics, Translational Studies and Novel Approaches

February 21-23

TUESDAY, FEBRUARY 21

7:00 am Registration

PLENARY KEYNOTE SESSION

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

DEVELOPMENTS WITH ANTIBODY-DRUG CONJUGATES

11:00 Chairperson's Opening Remarks
Ho Sung Cho, Ph.D., CTO, Ambrx, Inc.

11:10 Antibody-Drug Conjugates: An Emerging Modality for the Targeted Therapy of Liquid and Solid Tumors
Puja Sapra, Ph.D., Director, Bioconjugates, Oncology Research Unit, Pfizer Biotherapeutics
This presentation will provide an update of Pfizer's ADC programs. Phase II/III data of CMC-544, an anti-CD22 calicheamicin conjugate will be discussed. Additionally, pre-clinical data of an ADC targeting the oncofetal antigen 5T4, expressed on tumor initiating cells in solid tumors, will be described.

11:40 Experiences with Finding a Good Target for ADC Drug Development
Andy Simmons, Ph.D., Principal Scientist, Preclinical Research, Takeda San Francisco, Inc.
Recent data will be highlighted that expands our understanding of the antigen, antibody, and ADC properties required for potent *in vitro* and *in vivo* cytotoxicity.

12:10 pm Proteomics for the Discovery of Novel Oncology Antigen Targets and the Subsequent Development of Antibody-Drug Conjugates
Jon Terrett, Ph.D., CSO, Oxford Biotherapeutics, Inc.
Clinical trials of ADCs are finally producing proof-of-concept with some spectacular results in Oncology. Proteomics is perfectly poised to deliver novel targets for ADC development as detection of cancer specific membrane proteins leads directly to ADC targetable antigens.

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

1:45 Dessert in the Exhibit Hall with Poster Viewing

DEVELOPMENTS WITH ANTIBODY-DRUG CONJUGATES

2:15 Chairperson's Remarks
Jon Terrett, Ph.D., CSO, Oxford Biotherapeutics, Inc.

2:20 Optimizing the Performance of Antibody Drug Conjugates with an Expanded Genetic Code
Ho Sung Cho, Ph.D., CTO, Ambrx, Inc.
The site of conjugation has a significant impact on the plasma stability of cathepsin-cleavable linkers. Site-specific conjugation preserves target binding and minimizes off-target binding. Ambrx ADCs have PK similar to the naked wt-mAb resulting in improved efficacy and Therapeutic Index.

2:50 Advancements in ADC Technologies Using Potent Auristatin Conjugates
Svetlana Doronina, Ph.D., Senior Principal Scientist, Chemistry, Seattle Genetics, Inc.
We have developed antibody-drug conjugates of antitumor mAbs attached to highly potent auristatin antimitotic agents. These contain optimized drugs and linkers and preserve mAb activity. These have been applied to several tumor targets and used in advanced clinical trials.

LIGAND-RECEPTOR INTERACTIONS

3:20 Engineered Receptor Tyrosine Kinase Domains for Treatment of Metastatic Cancers
Jennifer Cochran, Ph.D., Assistant Professor, Bioengineering, Stanford University
We used a soluble receptor as a decoy to inhibit the biological activity of a ligand involved in ovarian cancer metastasis. Yeast surface display was used to engineer variants that bound ligand with 20-fold higher affinity over wild-type receptor. The engineered receptor exhibited a remarkable ability to inhibit ovarian cancer metastasis in several pre-clinical models in contrast to the wild-type receptor which was only marginally effective.

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

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

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

6:20 Close of Day

WEDNESDAY, FEBRUARY 22

TRANSLATIONAL STUDIES FOR PROGRESSION TO CLINICAL

7:55 am Chairperson's Remarks
Ezio Bonvini, M.D., Senior Vice President, Research, MacroGenics, Inc.

8:00 Translational Research Strategies Used to Guide the Development of Elotuzumab, an Anti-CS1 Monoclonal Antibody, for the Treatment of Multiple Myeloma
Gary Starling, Ph.D., Director, GPRD Discovery, Oncology Biologics, Abbott Biotherapeutics Corp.
The enhanced activity of a combination of elotuzumab with lenalidomide in pre-clinical studies as compared to either agent alone has translated to promising clinical activity in Multiple Myeloma.

8:30 Translational Studies for Progression of ADCs from Discovery to Clinical
Robert Lutz, Ph.D., Vice President, Translational Research & Development, ImmunoGen, Inc.
Our growing pre-clinical and clinical experience with antibody-maytansinoid conjugates is leading to an enhanced understanding of how to develop new ADCs for the treatment of cancer with respect to improving efficacy and safety.

9:00 Good Translations: Making the Most of Non-Clinical Data for Clinical Decision-Making
Jay Tibbitts, D.V.M., Ph.D., Senior Scientist, Group Leader, Pharmacokinetics and Pharmacodynamics, Genentech, Inc.
Optimizing the design and use of non-clinical studies can reduce the uncertainty and increase the success of clinical trials. This talk will explore the use of relevant models, biomarkers, and PKPD to improve translations and, ultimately, allow better decision-making.

9:30 Sponsored Presentations *(Opportunities Available)*

10:00 Transition to Plenary Keynote

PLENARY KEYNOTE

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

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

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

MATCHING THE TECHNOLOGY TO THE TARGET & BIOMARKERS FOR PATIENT SELECTION

11:55 Chairperson's Remarks
Gary Starling, Ph.D., Director, GPRD Discovery, Oncology Biologics, Abbott Biotherapeutics Corp.

12:00 pm The Use of Different Antibody Platforms for Cancer Drug Development
Robert Hollingsworth, Ph.D., Director, Cancer Biology, MedImmune, LLC
Various antibody-based therapeutic technologies are now available. A key to successful development of such drugs is using the right technology for specific targets. MedImmune's experience using different technologies to develop novel cancer antibody therapeutics will be described.

12:30 Mechanisms of Trastuzumab Resistance and Development of Biomarkers
Wen Jin Wu, M.D., Ph.D., Principal Investigator, Division of Monoclonal Antibodies, FDA
Despite initial successes and encouraging results, development of monoclonal antibody-based therapies face several challenges. Among them are the selection of patients most likely to benefit from clinical trials and lack of understanding of mechanisms of resistance to monoclonal antibody-based therapies.

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

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

PLENARY KEYNOTE PANEL

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

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

ENHANCED EFFECTOR FUNCTION AND PKPD

4:25 Chairperson's Remarks
Norman J. Maitland, Ph.D., Director, Yorkshire Cancer Research Unit and Department of Biology, University of York, UK

4:30 New Generation of Targeted Therapeutics: Empowering Therapeutic Monoclonal Antibodies with Cytokine Payloads for Cancers
Iqbal S. Grewal, Ph.D., D.Sc., FRCPath, CSO, ImmunGene, Inc.
We use a novel technology to empower therapeutic antibodies with a biologic payload by recombinantly fusing them with cytotoxic cytokines. This results in highly potent therapeutic antibodies to selectively target tumor cells while reducing the systemic toxicity of the cytokines.

5:00 Non-Clinical Development of Fc-Domain Optimized Monoclonal Antibodies with Increased Effector Functions
Ezio Bonvini, M.D., Senior Vice President, Research, MacroGenics, Inc.
Cancer immunotherapeutic mAbs can be enhanced via Fc domain engineering for increased Fc receptor-mediated function. Challenges and solutions in the assessment of Fc-engineered mAbs in animal efficacy models, pharmacology and toxicology will be presented and discussed.

5:30 Pre-Clinical Developments with a Novel Peptide/Antibody Scaffold with Enhanced PKPD
Gary Woodnutt, Ph.D., Executive Director, Biology, CovX Research, LLC
Peptides have potential advantages as therapeutics but size and metabolism have reduced their impact for clinical usage. Scaffold approaches reduce these issues. This talk describes hurdles that have been overcome in the development of these agents for oncology indications.

6:00 Anti-Angiogenic Activity of ALM201, a Targeted Non-Toxic Microtubule Disrupting Agent
Iain James, Ph.D., Vice President, Biology, Almac Discovery Ltd.
ALM201 is a 23 residue peptide that is not cytotoxic and is internalized by endothelial cells through interaction with CD44. Once inside, it binds to tubulin, causing disruption of microtubules, leading to inhibition of migration and prevention of angiogenesis.

6:30 Close of Day

THURSDAY, FEBRUARY 23

ADVANCES WITH MULTI-SPECIFIC PRODUCTS

8:30 am Chairperson's Remarks

8:35 Treatment of Relapsed/Refractory ALL with Bispecific BiTE Antibody Blinatumomab
Patrick A. Baeuerle, Ph.D., CSO, Senior Vice President, Research & Development, Micromet, Inc.
CD19/CD3-bispecific antibody blinatumomab has shown outstanding single-agent activity in treating patients with relapsed or refractory NHL or ALL. BiTE antibodies in pivotal and early stage development emerge as biologicals that can optimally engage T-cells for redirected lysis of cancer cells.

9:05 Technological Background and Proof-of-Concept Studies of DuoBody™, Novel Bispecific Antibody Platform
Janine Schuurman, Ph.D., Director, Strategic Research, Genmab B.V.
The DuoBody™ platform generates highly efficient bispecific antibodies by a controlled Fab-arm exchange process. These bispecific antibodies retain the biochemical structure of regular human IgG, have Fc-mediated effector functions and regular IgG1 pharmacokinetics.

9:35 IMCgp100: a Bi-Specific TCR Anti-CD3 Fusion for the Treatment of Malignant Melanoma
Bent Jakobsen, Ph.D., CSO, Immunocore Ltd.
ImmTACs are soluble, high affinity T-cell receptors fused to an anti-CD3 scFv domain for re-directed T-cell killing of tumors with the ability to target HLA presented epitopes. A melanoma specific ImmTAC, IMCgp100, is undergoing clinical testing in the UK and the US.

10:05 Sponsored Presentation *(Opportunity Available)*

10:20 Coffee Break

COMBINATION THERAPIES

11:00 Elotuzumab, a Humanized Antibody to CS1 for the Treatment of Relapsed/Refractory Multiple Myeloma: Phase 2 Study Results
Anil Singhal, Ph.D., Site Clinical Development Head, Global Pharmaceutical Research & Development, Abbott Biotherapeutics Corp.
While there is significant recent progress in the treatment of multiple myeloma, additional therapies are needed for this incurable disease. Elotuzumab in combination with lenalidomide/dexamethasone shows very high response in the relapse/refractory disease.

11:30 Advantages of Sym004: A Synergistic Antibody Mixture Targeting EGFR
Michael Kragh, Ph.D., Director, Antibody Pharmacology, Symphogen A/S
This presentation will highlight the advantages of recombinant antibody mixtures compared to monoclonal antibody therapy. Sym004, Symphogen's most advanced anti-cancer project, will be used as an example to describe the process from initial idea to clinical trials in patients.

12:00 pm Anti-HGF Antibody Ficlatuzumab: Translational Oncology from Target Selection to Phase 2
Murray Robinson, Ph.D., Senior Vice President, Translational Medicine, AVEO Pharmaceuticals, Inc.
We developed and utilized a unique tumor model platform to discover and develop ficlatuzumab, a potent inhibitor of HGF/Met signaling. Ficlatuzumab exhibits complex interacting effects with the EGFR pathway which led to a phase 2 combination with gefitinib in NSCLC.

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

IMMUNOTHERAPY AND ADOPTIVE T-CELL THERAPY

1:45 Chairperson's Remarks
Iqbal S. Grewal, Ph.D., D.Sc., FRCPath, CSO, ImmunGene, Inc.

1:50 Affinity Enhanced T-Cell Receptors for Adoptive T-Cell Therapy
Gwendolyn Binder-Scholl, Ph.D., Vice President, US Operations, Adaptimmune, LLC
Autologous T-cells genetically engineered with affinity-enhanced TCRs overcome the limitation of poor tumor recognition and elimination, and are undergoing evaluation in clinical trials for Mage-A3- and NY-ESO-1-expressing cancers.

2:20 PD-1/PD-L1 Blockade
Alan Korman, Ph.D., Vice President, Discovery Research, Bristol-Myers Squibb
We have developed human antibodies targeting Programmed Death-1 (PD-1) and its ligand PD-L1, a negative regulatory pathway that controls T-cell function. The activity of this pathway in murine models, non-human primates, and in-human clinical trials will be described.

2:50 Vaccination with Patient-Specific Tumor-Derived Antigen in First Remission Improves Disease-Free Survival in Follicular Lymphoma
Carlos F. Santos, Ph.D., Senior Vice President, Clinical Development & Regulatory Affairs, Cancer Biologics, Biovest International, Inc.
Vaccination with patient-specific hybridoma-derived idiotype vaccine after chemotherapy-induced CR/ CRu may prolong disease-free survival in patients with follicular lymphoma. Vaccine isotype may affect clinical outcome and explain differing results between this and other controlled Id-vaccine trials.

3:20 Close of Conference

Hotel Information

Primary Conference Venue

The Moscone North Convention Center

747 Howard Street, San Francisco, CA 94103 • www.moscone.com

Symposia, Partnering Forums & Host Hotel

InterContinental San Francisco Hotel

888 Howard Street

San Francisco, CA 94103

Discounted Group Rate: $215 s/d*

Discounted Room Rate Cut Off Date: January 19, 2012

(T) 415-616-6500

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

Additional Recommended Hotel

Marriott San Francisco Hotel

55 Fourth Street

San Francisco, CA 94103

Discounted Group Rate: $229 s/d

Discounted Room Rate Cutoff Date: January 25, 2012

Reservations 888-575-8934

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

- Topic-specific poster sessions
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At the Moscone North Convention Center - February 21-22, 2012

- Your poster will be available to over 3,000 delegates
- Posters will be on display for two full days in the exhibit hall
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** One poster discount per registration.*

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

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(Program-specific)

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

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Exhibit Information

Exhibiting allows your company to differentiate your products, services or technology from competitors, and demonstrate your commitment to this science. Over 125 exhibiting companies will display their latest products and solutions to 3,000 conference delegates.

How will CHI ensure that all delegates visit the exhibit hall?

- Dedicated exhibit hall hours during key session breaks with refreshments served
- Renowned keynote speakers drawing high-level attendees
- Opening night cocktail reception held in exhibit hall
- Scientific posters on display and awards presented in exhibit hall
- Judging of Poster Award inside the exhibit hall
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Molecular Medicine TRI-CON 2012

As an exhibitor, you have the opportunity to display your new product literature within the pavilion at no additional cost. Plus, CHI will promote the New Product Pavilion through email, conference website, press releases, and on-site with signage and program guide. Ask us about an upgrade!

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February 19-23, 2012
San Francisco, CA

The Moscone North Convention Center & InterContinental San Francisco Hotel

Regular Pricing – A La Carte Options

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

Afternoon
SC1 Identification, Characterization and Targeting of Cancer Stem Cells
SC2 Roadmap for Accelerating Commercialization of Molecular Diagnostics
SC3 Understanding EMT: Mechanisms and Metastasis to MET
SC4 Network Pharmacology
SC5 Next-Generation Sequencing in the Cloud Era
SC6 Marketing and Sales: Science Training 101
SC7 Latest Advances in Molecular Pathology, Part I (Basic)
SC8 Best Practices in Translational Informatics
SC9 Pharmacology and Drug Discovery in the Allosteric World

Dinner
SC10 Digital PCR Applications and Advances
SC11 CTCs from Bench to Bed: Streamlining from Research to Clinical Practice
SC12 First-in-Human Study and Risk Mitigation Strategy for Biologics
SC13 Scientists: Business Training 101
SC14 Adaptive Oncology Clinical Trials
SC15 Latest Advances in Molecular Pathology, Part II (Advanced)
SC16 Ontologies for the Bio-Science Industry: Development & Use
SC17 Mastering Physicochemical Properties-Based Analysis to Deliver Improved Drug Candidates
SC18 Regulatory Approval of a Therapeutic & Companion Diagnostic: Nuts & Bolts

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